

Evidence for models of diagnostic service provision in the community: literature mapping exercise and focused rapid reviews

*Duncan Chambers, Andrew Booth, Susan K Baxter, Maxine Johnson,
Katherine C Dickinson and Elizabeth C Goyder*



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Abstract

Evidence for models of diagnostic service provision in the community: literature mapping exercise and focused rapid reviews

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Background: Current NHS policy favours the expansion of diagnostic testing services in community and primary care settings.

Objectives: Our objectives were to identify current models of community diagnostic services in the UK and internationally and to assess the evidence for quality, safety and clinical effectiveness of such services. We were also interested in whether or not there is any evidence to support a broader range of diagnostic tests being provided in the community.

Review methods: We performed an initial broad literature mapping exercise to assess the quantity and nature of the published research evidence. The results were used to inform selection of three areas for investigation in more detail. We chose to perform focused reviews on logistics of diagnostic modalities in primary care (because the relevant issues differ widely between different types of test); diagnostic ultrasound (a key diagnostic technology affected by developments in equipment); and a diagnostic pathway (assessment of breathlessness) typically delivered wholly or partly in primary care/community settings. Databases and other sources searched, and search dates, were decided individually for each review. Quantitative and qualitative systematic reviews and primary studies of any design were eligible for inclusion.

Results: We identified seven main models of service that are delivered in primary care/community settings and in most cases with the possible involvement of community/primary care staff. Not all of these models are relevant to all types of diagnostic test. Overall, the evidence base for community- and primary care-based diagnostic services was limited, with very few controlled studies comparing different models of service. We found evidence from different settings that these services can reduce referrals to secondary care and allow more patients to be managed in primary care, but the quality of the research was generally poor. Evidence on the quality (including diagnostic accuracy and appropriateness of test ordering) and safety of such services was mixed.

Conclusions: In the absence of clear evidence of superior clinical effectiveness and cost-effectiveness, the expansion of community-based services appears to be driven by other factors. These include policies to encourage moving services out of hospitals; the promise of reduced waiting times for diagnosis; the availability of a wider range of suitable tests and/or cheaper, more user-friendly equipment; and the ability of commercial providers to bid for NHS contracts. However, service development also faces a number of barriers, including issues related to staffing, training, governance and quality control.

Limitations: We have not attempted to cover all types of diagnostic technology in equal depth. Time and staff resources constrained our ability to carry out review processes in duplicate. Research in this field is limited by the difficulty of obtaining, from publicly available sources, up-to-date information about what models of service are commissioned, where and from which providers.

Future work: There is a need for research to compare the outcomes of different service models using robust study designs. Comparisons of 'true' community-based services with secondary care-based open-access services and rapid access clinics would be particularly valuable. There are specific needs for economic evaluations and for studies that incorporate effects on the wider health system. There appears to be no easy way of identifying what services are being commissioned from whom and keeping up with local evaluations of new services, suggesting a need to improve the availability of information in this area.

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List of abbreviations

2D	two-dimensional	FEV	forced expiratory volume
AF	atrial fibrillation	FVC	forced vital capacity
AOM	acute otitis media	GI	gastrointestinal
BAAP	British Association of Audiological Physicians	GMC	General Medical Council
BNP	B-type natriuretic peptide	GP	general practitioner
BP	blood pressure	GPwSI	general practitioner with a special interest
BSCMR	British Society for Cardiovascular Magnetic Resonance	HbA _{1c}	glycated haemoglobin
BSE	British Society of Echocardiography	HCP	health-care professional
BSG	British Society for Gastroenterology	HTA	health technology assessment
CCG	Clinical Commissioning Group	INR	international normalised ratio
CDSR	Cochrane Database of Systematic Reviews	ISAS	Imaging Services Accreditation Standard
CENTRAL	Cochrane Central Register of Controlled Trials	ISO	International Standards Organisation
CI	confidence interval	IT	information technology
CINAHL	Cumulative Index to Nursing and Allied Health Literature	JAG	Joint Advisory Group on Gastroenterology
COPD	chronic obstructive pulmonary disease	LVSD	left ventricular systolic dysfunction
COSHH	Control of Substances Hazardous to Health	MaDOx	Monitoring and Diagnosis in Oxford
CPD	continuing professional development	MeSH	medical subject heading
CRP	C-reactive protein	MHRA	Medicines and Healthcare products Regulatory Agency
CT	computed tomography	MRI	magnetic resonance imaging
DARE	Database of Abstracts of Reviews of Effects	NHS EED	NHS Economic Evaluation Database
DEC	Diagnostic Evidence Co-operative	NICE	National Institute for Health and Care Excellence
DNA	deoxyribonucleic acid	NIHR	National Institute for Health Research
DRS	diabetic retinopathy screening	NT-proBNP	N-terminal pro B-type natriuretic peptide
ECG	electrocardiogram	OME	otitis media with effusion
ENT	ear, nose and throat	PCT	primary care trust

LIST OF ABBREVIATIONS

POC	point of care	SCoR	Society of Radiographers
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses	STEPPED-UP	Skills, Training, Equipment, Premises, Public perspectives, Economics, Drivers, User perspective and Primary–secondary interface
QUADAS	Quality Assessment of Diagnostic Accuracy Studies	STEP-UP	Skills, Training, Equipment, Premises, User perspective and Primary–secondary interface
RCGP	Royal College of General Practitioners	VAT	value-added tax
RCR	Royal College of Radiologists		
RCT	randomised controlled trial		

Plain English summary

Many diagnostic tests can be done in hospitals or in other places such as general practitioners' surgeries or health centres (often referred to as 'community settings' because they tend to be located nearer to where patients live). We carried out a number of literature reviews to assess whether or not providing services outside hospitals has benefits for patients or the NHS. We started by carrying out a broad search to map the quantity of published research and the types of tests and health conditions studied. We then looked at three specific areas in more detail. These were practical aspects of providing services outside hospitals, ultrasound scanning, and tests used to diagnose the cause of breathing problems.

We found that very few studies have directly compared different ways of organising diagnostic testing. There was some evidence that testing patients in the community can avoid people being referred to hospital and allow them to be treated closer to home. Evidence about the quality and safety of community-based services was unclear. In the absence of clear evidence, decisions about how to provide services may be based on other factors. These include policies to encourage moving services out of hospitals; the availability of a wider range of suitable tests and/or improved equipment; and the ability of commercial providers to bid for NHS contracts. Barriers include issues related to staffing, training and quality control. Further research is needed to compare the outcomes for patients and value for money of community-based and hospital-based diagnostic testing.

Scientific summary

Background

Diagnostic tests and their results are fundamental to clinical decision-making. In the UK NHS, general practitioners (GPs) and other primary care professionals have traditionally had a limited ability to access many such tests directly. Instead, a common model is for GPs to refer patients for blood, tissue or imaging tests at the local hospital, sometimes resulting in waits for appointments and availability of test results. Offering more diagnostic tests in primary care and community settings such as GPs' surgeries and health centres could enable faster and earlier diagnosis of common conditions and avoid unnecessary referrals. Other potential benefits include greater convenience and lower costs for patients and possibly a reduction in numbers of missed appointments. The primary focus of this review is on services rather than individual tests.

Objectives

The review aimed to address the following questions:

- What models of community diagnostic services currently exist (in the UK and internationally)?
- What is the evidence for the quality, safety and clinical effectiveness of different models of diagnostic service provision outside hospital settings?
- Which tests are most commonly provided and is there any evidence for an effect on outcomes?
- Is there any evidence to support a broader range of diagnostic tests being provided in the community? This question was interpreted to refer to:
 - tests that are not currently offered in community settings but which could be appropriate for such use
 - organisational models such as larger diagnostic centres, compared with single-service models.

Methods

We performed an initial broad literature mapping exercise to assess the quantity and nature of the published research evidence. The results of this exercise were used to select three areas for investigation in more detail using focused rapid review methods. The focused reviews covered logistics of diagnostic modalities in primary care, diagnostic ultrasound services and diagnostic pathways for the assessment of breathlessness. Protocols were developed to guide the overall methods and conduct of the project and subsequently for each of the focused reviews.

Mapping exercise

A single database [Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R), searched 1946 to present] was searched for the mapping exercise. The search strategy combined terms around 'primary care' and 'diagnostics', and included both medical subject heading and free-text searches. Methodological search filters were applied to retrieve reviews and comparative studies. Results were limited by date to 2000 to current (December 2014).

Search results were stored in a reference management database (EndNote X7.5, Thomson Reuters, CA, USA) and exported to Microsoft Excel® 2010 (Microsoft Corporation, Redmond, WA, USA) for coding purposes. Records that appeared potentially relevant were coded as far as possible for condition/population studied, intervention/technology, country, setting, type of study (e.g. primary research, systematic review or narrative review) and focus of study (service delivery, test performance or both).

Studies were selected for coding that mentioned any kind of test (diagnostic or screening, including questionnaires or similar) where it appeared that a substantive component of the testing, diagnosis, analysis and interpretation took place in a primary care or similar setting. We tried to exclude studies from settings in which the findings would clearly not be relevant to service delivery in the UK NHS (e.g. tropical diseases in low-income countries). Coding was based on title and abstract (when available) only.

The findings were synthesised narratively by condition and technology. For studies judged to be most relevant to service delivery issues, key details were extracted and tabulated.

Logistics of diagnostic modalities in primary care

A framework entitled STEP-UP (Skills, Training, Equipment, Premises, User perspective and Primary–secondary interface) was developed and used to examine 13 primary care diagnostic topics [audiology, cardiac services, diabetic services, endoscopy, genetic testing, laboratory tests, magnetic resonance imaging, point-of-care (POC) testing, radiology/X-ray, respiratory tests and ultrasound]. We used a systematic mapping approach, standardised across all 13 topics, to identify, map and present findings from key items from the literature. Sensitive searches were conducted using PubMed Clinical Queries and Special Queries and The Cochrane Library. Additional sources, including The King’s Fund Centre Library database, were searched for UK evidence. Dates covered were 2000 to September 2015. A process of examination of full text and follow-up of references was employed to populate the STEP-UP framework for each topic.

Diagnostic ultrasound services

The review aimed to address the following question: what is known about the implications of different ways of providing diagnostic ultrasound services in community or primary care settings? This was defined to include implications for both NHS organisations (e.g. related to provision of staff, premises, training and equipment, costs and cost-effectiveness) and patients (e.g. related to changes in management/pathways, acceptability to patients, accuracy of diagnosis and longer-term clinical outcomes).

We searched five bibliographic databases from 1995 to February 2015. Citation and grey literature searches were also conducted. Studies were included if they recruited people requiring diagnostic ultrasound for any condition and evaluated or described a service provided in a primary care or community setting by primary care/community staff. Open-access services provided to GPs by a hospital using its premises, equipment and staff were treated as a comparator intervention. ‘Outreach’ services using hospital-based staff to deliver services in community settings were also considered to be relevant comparators.

Selection of studies for inclusion (scanning of titles/abstracts and full-text publications) was initially carried out by one reviewer. Uncertainties were resolved by discussion and consensus among the review team. Included studies were classified on the basis of quality and relevance as level 1, level 2 or level 3; these classifications were used to guide data extraction and quality assessment.

Patient-related and service-related issues (as defined above) were used as a framework for a narrative synthesis. Evidence was grouped by type of service model and, when appropriate, by indications/patient groups covered.

Diagnostic pathways for the assessment of breathlessness

The study aimed to address the following research questions:

- What service models and pathways for breathlessness diagnostics delivered in primary care or community settings currently exist in the UK and internationally?
- What evidence is there for the quality, safety, feasibility, acceptability, clinical effectiveness and cost-effectiveness of such models and pathways?
- What are the barriers to and facilitators of developing and implementing such service models and pathways?

A comprehensive search of 10 key bibliographic databases was performed in July 2015. Results were limited by date to 2000 to current. Studies were included if they evaluated or described service models or pathways designed to be initiated in primary care or the community in order to make a differential diagnosis from a presenting symptom of breathlessness. This could include specific diagnostic technologies such as spirometry, although the effectiveness of such technologies was not assessed. Services delivered in secondary care settings were relevant comparators. Studies which evaluated the effectiveness of new services or changes to the referral pathway were given the coding 'intervention studies'. Papers that reported the views or perceptions of staff or patients were coded as 'views studies'. Intervention and views studies were assessed for quality using appropriate tools and synthesised separately using narrative synthesis methods. We used a conceptual modelling method to integrate findings from examination of the intervention and views literature. This was intended to provide an evidence-based overview of elements of the referral pathway that were reported in the identified literature.

Results

Mapping exercise

The searches identified 2644 records, of which 309 were identified by the review filter. Overall, we coded 302 records (11.4%) as meeting the inclusion criteria for the mapping exercise. Comparatively few studies (eight reviews and 20 comparative studies) focused on different models of providing diagnostic services. Most studies focused on test performance (e.g. diagnostic accuracy in a primary care population/setting). Examination of the identified papers supported the need for further focused reviews to synthesise the research evidence in more detail and identify any implications for practice and research.

We decided to examine a particular diagnostic technology in some depth. Ultrasound was chosen because of its wide clinical application, because there was no existing review covering this technology and because of the importance of recent developments in ultrasound equipment. The mapping exercise also gave an indication of the widely differing logistic and service delivery implications of introducing different diagnostic technologies in primary care/community settings and the review team proposed to explore the relevant evidence base using a structured framework. Finally, a major theme of the identified papers was to examine diagnostic tests in the context of patient management pathways and decision-making processes rather than in isolation. This finding led us to examine the evidence base around a selected primary care diagnostic pathway (symptom-based pathways for patients presenting with breathlessness) and its individual components.

It was already clear from this mapping exercise that the published evidence does not include an adequate description or evaluation of the wide range of service models currently being commissioned (or that might feasibly be commissioned) for diagnostic services in the NHS.

Logistics of diagnostic modalities in primary care

A total of 673 items were identified for inclusion across the 13 topics. *Table a* summarises the findings using the STEP-UP framework. For example, implementation of endoscopy services faces difficulties around human resources (skilled staff), premises, equipment and negative views from patients. By contrast, ultrasound appears relatively easy to implement, although the availability of skilled staff was, again, a potential barrier. Overall, information on logistic considerations was scattered, uneven and incomplete. There was more relevant evidence for newer technologies, and training and skills requirements were well specified for technologies supported by a specialist professional group (e.g. endoscopy). We found little direct evidence for equipment requirements, implementation issues and the impact on the primary–secondary care interface. The process of locating relevant information in lengthy documents was methodologically challenging.

Diagnostic ultrasound services

We included 37 studies, of which only three were classified as level 1 studies (comparative empirical studies or descriptions of UK-based service models). The best evidence from the UK was over 10 years old.

TABLE a Summary table for logistics of primary care/community diagnostics

Topic area	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	User perspective		Primary–secondary interface
					Clinician	Patient	
Audiology	○	○	○	○	⊕	⊕	○
Pneumatic otoscopy	○	⊕	⊕	∅	○	∅	∅
Tympanometry	⊕	⊕	⊕	∅	○	⊕	○
Cardiac services	○	⊕	⊕	∅	⊕	⊕	⊕
BNP	⊕	⊕	⊕	∅	⊕	⊕	○
ECG	⊕	⊕	⊕	∅	⊕	⊕	⊕
Echocardiography	○	○	⊕	⊕	⊕	⊕	○
Diabetic services	⊕	⊕	⊕	∅	⊕	⊕	⊕
Endoscopy	⊗	○	⊗	⊗	∅	⊗	○
Genetic testing	⊗	○	⊕	∅	○	⊕	○
Magnetic resonance imaging	○	○	⊗	⊗	∅	∅	○
POC testing	○	○	⊕	∅	○	⊕	○
C-reactive protein	⊕	⊕	⊕	∅	⊕	⊕	○
Radiology/X-ray	○	⊕	○	○	⊕	⊕	○
Respiratory tests	⊕	⊕	⊕	∅	⊕	⊕	○
Pulse oximetry	⊕	⊕	⊕	∅	⊕	⊕	○
Spirometry	○	⊕	⊕	⊕	⊕	○	⊕
Ultrasound	○	⊕	⊕	⊕	⊕	⊕	⊕

∅, insufficient evidence; ⊗, high degree of implementation difficulty; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty; BNP, B-type natriuretic peptide; ECG, electrocardiogram.

The few studies that reported clinical effectiveness outcomes were mostly of poor methodological quality. Two studies indicated that community ultrasound can guide patient management and potentially reduce unnecessary referrals, at least for some indications/settings. One of these studies evaluated ultrasound scanning by GPs in a Scottish rural practice and the other evaluated a community open-access echocardiography service for diagnosing heart failure in the Netherlands. A further study from Australia highlighted problems with poor reliability and quality of scans performed in community settings. Major areas of uncertainty included the cost-effectiveness of community-based services, the training requirements for health professionals delivering such services, and whether or not perceptions of ultrasound scanning as a role for secondary care may represent a barrier to service development.

Diagnostic pathways for the assessment of breathlessness

Thirty-six studies were included in the review of interventions in the pathway for patients presenting with breathlessness. We found few studies using higher-quality comparative designs, although we identified evidence relating to a range of different interventions, and a body of work that was carried out in the UK. Eighteen papers were included in the review of views and perceptions of staff or patients.

Limited evidence from intervention studies, mainly using less robust study designs, indicates that the provision of services in the community (seven studies from the UK or Ireland), POC testing (three studies)

and open-access testing (seven studies) may have a positive impact on the diagnostic pathway for breathlessness in terms of appropriate referral to specialists and in terms of a reduction in misdiagnosis. Qualitative and cross-sectional studies highlight a complex interplay of patient, practitioner and organisational factors influencing the diagnostic pathway for breathlessness. Practitioners in primary care vary in their attitude towards the use of diagnostic technology based on accessibility, motivation, confidence, skills and knowledge. Although there is the suggestion that there should be improved access to diagnostic tools with regular training and financial incentives, the literature emphasises that use of technologies such as spirometry must be carried out to high standards, and that training may not necessarily lead to these standards being achieved.

Conclusions

The mapping exercise and focused reviews identified at least seven main models of service that are delivered in primary care/community settings and, in most cases, with the possible involvement of community/primary care staff. These models are:

1. community diagnostic centre (offering multiple diagnostic services or specialising in a single test); possibly non-NHS provider
2. community outreach from secondary care
3. GP with a special interest (offering test in addition to normal GP services)
4. specialist nurse or advanced nurse practitioner [dedicated to test (e.g. spirometry) or condition (e.g. diabetes)]
5. mobile service delivered at GP surgery or other community setting (possibly by non-NHS provider)
6. shared services within a primary care consortium (e.g. GP federation)
7. teleradiology (interpretation/advice from secondary care).

Overall, the evidence base for community and primary care-based diagnostic services is limited, with very few controlled studies comparing different models of service. There is evidence from different settings that community-based services can reduce referrals to secondary care and allow more patients to be managed in primary care. Evidence on quality (including diagnostic accuracy and appropriateness of test ordering) and safety of such services is mixed.

Implications for health care

In the absence of clear evidence of superior clinical effectiveness and cost-effectiveness, the expansion of community-based services has been driven by other factors. These include government policies to encourage moving services out of hospitals; the promise of reduced waiting times for diagnosis and potentially treatment; the availability of a wider range of suitable tests and/or cheaper, more user-friendly equipment (e.g. handheld ultrasound scanners); and the ability of commercial providers to bid for NHS contracts, potentially offering new and more flexible models of service. However, service development also faces a number of barriers, including issues related to staffing, training, governance and quality control. Perceptions and attitudes of health professionals and patients are particularly influential in the absence of clear evidence-based conclusions. Drivers and barriers vary according to the diagnostic technology involved and other contextual factors.

Implications for research

There is a need for studies to compare the outcomes of different service models using robust study designs. Comparisons of 'true' community-based services (using community staff for test administration, interpretation and decisions about treatment/referral/further testing) with secondary care-based open-access services and rapid-access clinics would be particularly valuable. There are specific needs for economic evaluations and for studies that incorporate the effects of diagnostic decision-making in the community on the wider health system.

Research into logistic and practical factors that can affect decision-making around diagnostic service provision could be based around a specific technology or focus on the needs of a particular condition or management pathway. For example, specific recommendations on research around training for community ultrasound have recently been provided by the National Institute for Health Research Oxford Diagnostic Evidence Co-operative.

The STEP-UP framework presented here, or its extended version (STEPPED-UP, also incorporating Public perspectives, Economics and Drivers), could be used as a framework for planning programmes of research and evaluation that reflect the complex range of factors that may influence decision-making in this area.

The difficulty we encountered in identifying what services are being commissioned and keeping up with local evaluations suggests that there may be a need to improve the availability of information in this area to decision-makers, researchers and the public. Preliminary research could be undertaken to establish whether or not this is a true gap in the information resources available and whether or not NHS decision-makers would find such information helpful.

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Chapter 1 Background

This rapid review was undertaken to address a topic suggested by Professor Erika Denton, National Clinical Director for Diagnostics at NHS England, and identified as a priority by the Department of Health Research and Development Committee. The purpose of the evidence synthesis is to assess the evidence base for diagnostic services provided outside hospital settings, for example in the community or in general practice. The findings will be expected to provide actionable messages for the NHS and/or identify priorities for further research.

Diagnostic tests and their results are fundamental to clinical decision-making. In the UK NHS, general practitioners (GPs) and other primary care professionals have traditionally had a limited ability to access such tests directly. Instead, a common model is for GPs to refer patients for blood, tissue or imaging tests at the local hospital, sometimes resulting in waits for appointments and availability of test results. Offering more diagnostic tests in the community could enable faster and earlier diagnosis of common conditions and avoid unnecessary referrals. Other potential benefits include greater convenience and lower costs for patients and possibly a reduction in numbers of missed appointments. The Health and Social Care Information Centre has reported that in the year to March 2014, over 4.3 million patients accounted for 6.8 million missed outpatient appointments, at an estimated cost of £108 per appointment.¹

Diagnostic tests cover the whole range of clinical conditions, and this review, although not aiming at exhaustive coverage, will include those tests and conditions most relevant to primary care and community settings. A potentially important distinction is between tests (e.g. most types of imaging) that require specialist equipment and/or staff to administer and those that can be administered by any health professional or the patient him- or herself in any setting or at home. Following a preliminary mapping of the literature and further discussion with stakeholders, it was decided to focus primarily on the first group of tests in view of the broader implications for the NHS of any changes to the way these services are delivered, for example in relation to staff training, workforce composition and requirements for equipment and suitable premises in which to perform the tests.

Greater availability of diagnostic testing in primary care is supported by both policy and technological drivers. Current NHS policy supports initiatives aimed at early diagnosis of long-term conditions with an emphasis on management in the community as far as possible. The remainder of this introduction briefly discusses the technological, economic and social factors relevant to the provision of diagnostic services in primary care and community settings.

Technology

Technological drivers are based on a range of advances whose effect is to increase the speed, size and range of devices suitable for primary care that can provide accurate measurements of a wide range of biochemical, microbiological and haematological parameters.² Glucometers have transformed the speed and ease of obtaining accurate blood glucose levels, and urine dipsticks have removed the need for microscopy in many patients.² Electronics increase the portability and ease of use, and reduce the cost, of electrocardiograms (ECGs), ultrasound, spirometry and pulse oximetry. Mobile magnetic resonance imaging (MRI) is more easily accommodated on GP premises. Partially stimulated by direct-to-consumer demand, an array of point-of-care (POC) tests, either in the marketplace or in the developmental pipeline, offers the potential to transform cardiac services, diabetic services and genetic testing. Devices such as endoscopes are easier and safer to use.

Diagnostic services that could, in future, be delivered closer to home include blood tests, audiology, plain film X-rays, ultrasound, 70% of pathology (non-slide-based, non-specialist work), echocardiology,

endoscopy, colposcopy, international normalised ratio (INR) testing, 24-hour ECG monitoring, exercise ECG testing, ambulatory blood pressure (BP) monitoring, nerve conduction studies, *Helicobacter pylori* tests and lung function tests.³ A polyclinic-type diagnostic service in Whitstable already offers digital X-ray, ultrasound, echocardiography, upper endoscopy and mobile MRI.⁴

Equipment requirements for general practice are not generally well documented. Our desk-based research identified a chapter on Equipment and Premises in General Practice in the *Oxford Textbook of Primary Medical Care*.⁵ The Royal Australian College of General Practice maintains accreditation standards around practice equipment in the Royal Australian College of General Practice *Standards for General Practice (4th Edition)*.⁶ Otherwise, requirements for equipment are defined by professional associations with little recognition of which should be housed within primary care. Surveys of equipment in general practice are fairly uncommon. A 2010 survey of equipment among GPs in Ireland found that 83% of practices had an ECG machine, 80% had a 24-hour BP monitor and 64% had a spirometer.⁷ It is unclear how such figures might map to a UK context, given that prevalence may relate to both investment and rurality. However, a survey in a UK cardiac network found that 85% had 12-lead ECG machines, close to the corresponding figure in the Irish study, and 91% used these on a weekly or more frequent basis. GP and practice characteristics are influential, while 'learning-by-using' also affects the adoption of medical equipment in a general practice setting.⁸

Access to imaging and other tests remains relatively restricted. To ensure smoother patient pathways and speedier diagnoses, GPs need increased access to imaging, equivalent to that available to hospital doctors, on the basis of the clinical needs of patients. With improved access to imaging, the Chief Scientific Officer promoted an initiative to improve access to so-called 'physiological measurements'.³ General practitioners with a special interest (GPwSIs) can perform diagnostic procedures, including endoscopy, in primary care settings. However, an expanded role may compromise the essential roles and function of general practice and has implications for service capacity, facilities and trained staff. Although championing a drive to improve services and diagnostics in the community, those working in primary care are keen that it is not seen merely as a 'conduit' to deliver secondary care-type services – the extra services must be integrated in a model that enshrines the values, philosophy and strategic function of general practice.³

Economics

Increases in test utilisation are driven by guidelines to screen more patients and monitor them more frequently.⁹ Diagnostic services, traditionally provided and housed in acute hospitals, have struggled to cope with demand.¹⁰ Increased demand often leads to increased delays and longer waiting lists. Diagnostic departments have sought to redesign their services with a market focus. However, they find it difficult to match the pace and scale of demand.

Efforts have been made to identify those diagnostic tests that offer the best clinical and economic value for primary care. A 'Horizon Scanning' approach, funded by the National Institute for Health Research (NIHR), has produced a series of structured assessment reports to examine the research evidence, including technical accuracy, clinical utility and cost-effectiveness.¹¹ Pressures are increasing to perform more tests, more rapidly, reducing referrals, keeping patients informed and reducing the risk of diagnostic errors. Reductions in health service funding demand that improved performance is balanced with improved cost-effectiveness.² Such an approach, although technically invaluable, stops short of concerns around service redesign. Material concerns (including the test platform, equipment, reagents and supplies) must extend to cover health professionals, their roles, their relations and the sociocultural context in which testing occurs. More operational research is required into health system requirements and the impact of technologies on diagnostic accuracy, retesting and diagnostic delays.¹² Factors associated with reconfiguration in the health system relate to skills, training, cost, equipment, premises, and referral linkages between primary and secondary care.

Social factors

Primary care physicians need to be empowered to redesign diagnostic services. For them to do this requires that perceived barriers and facilitators within current diagnostic services be identified and then overcome. A 2013 review of qualitative studies revealed that primary care clinicians believed that POC testing improved diagnostic certainty, targeting of treatment, self-management of chronic conditions and clinician–patient communication and relationships.¹³ At the same time, clinicians expressed concerns about test accuracy, over-reliance on tests, undermining of clinical skills, cost and limited usefulness. Additional factors include diagnostic uncertainty, patient anxiety and litigation, among others.²

Tests that are developed do not necessarily mirror what GPs and other practice staff (e.g. practice nurses, district nurses and midwives) actually want.² The diagnostic test industry does not always consider which tests GPs would use most often, and which tests to prioritise for research and development.²

The primary focus of this review is on services rather than individual tests. For example, one model of service is a community diagnostic centre offering a range of tests such as radiography, ultrasound, spirometry and electrocardiography, as described by Hollins *et al.*¹⁴ Other models include mobile services providing a specific imaging technology such as MRI, and condition-specific services for conditions such as suspected respiratory disease. In assessing the evidence, it is important to take account of the specific needs of tests to be administered in primary care/community settings (both clinical criteria and practical requirements such as premises, equipment and workforce training).

Chapter 2 Review methods

The review aimed to address the following questions:

- What models of community diagnostic services currently exist (in the UK and internationally)?
- What is the evidence for quality, safety and clinical effectiveness of different models of diagnostic service provision outside hospital settings?
- Which tests are most commonly provided and is there any evidence for an effect on outcomes?
- Is there any evidence to support a broader range of diagnostic tests being provided in the community? This question was interpreted to refer to:
 - tests that are not currently offered in community settings but which could be appropriate for such use
 - organisational models, such as larger diagnostic centres, compared with single-service models.

Protocols were developed to guide the overall methods and conduct of the review and subsequently for each of the focused reviews reported in *Chapters 4–6*. Copies of these documents are available on the project website.¹⁵

We performed the review in two stages. We carried out an initial mapping exercise to assess the quantity and nature of the available research evidence. Full details of the mapping exercise are presented in *Chapter 3*. The results of this exercise, together with discussions involving the review team, our funders and clinical experts, were then used to identify areas to focus on in more detail, as follows.

- Logistics of diagnostic modalities in primary care (see *Chapter 4*): this review reflects the finding from the mapping exercise of a variety of different diagnostic technologies with different implications arising from being located in primary care. It was agreed that it would be helpful to characterise key technologies (e.g. radiology, audiology, POC testing) against a common set of logistic and service delivery considerations. This review was undertaken as a framework map and synthesis.
- Diagnostic ultrasound services (see *Chapter 5*): a more detailed focused review of ultrasound services was also performed. The mapping exercise revealed some evidence on provision of these services and ultrasound is used in diagnosing a wide range of conditions. In addition to seeking comparative evidence around different service models, this review focused on issues around equipment (small portable scanners, including handheld devices, are available) and training.
- Primary care-led diagnostic pathway (see *Chapter 6*): this review covered the differential diagnosis of breathlessness and examined issues related to decision-making and the availability of multiple tests in primary care/community settings.

Protocols were developed for each of these focused reviews before further searching was started. Full details of review methods are reported in the relevant chapters. The findings are reported separately, but overall implications for service delivery and organisation are considered in the overall discussion section (see *Chapter 7*).

Chapter 3 Literature mapping exercise

Introduction

The objective of this initial phase of the review was to map and broadly describe the published literature on diagnostic testing services in community and primary care settings, particularly that relevant to the UK NHS and similar health-care systems. We intended to use the results of this mapping exercise to guide decisions about further focused review work. As a mapping review seeks to characterise a large body of literature by quantity and study characteristics, we did not perform formal data extraction or quality assessment. As the aim was to acquire a broadly representative, not exhaustive, sample, we did not perform any grey literature or citation searches at this stage and restricted the search to one bibliographic database.

For the purposes of this mapping exercise, we applied broad inclusion criteria and in particular did not seek to exclude studies of tests and programmes that were described as 'screening' rather than 'diagnostic'. The terminology related to diagnostic and screening tests is not always clear or consistently applied in the literature and we therefore adopted an inclusive approach to scanning and coding the references identified by the literature search.

Methods

A single database [Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R), 1946 to present] was searched for the mapping exercise. The search strategy combined terms around 'primary care' and 'diagnostics', and included both medical subject heading (MeSH) and free-text searches. In addition, methodological search filters were applied to retrieve two different study types:

1. reviews (including non-systematic reviews)
2. comparative studies.

Results were further limited by date to 2000 to current (December 2014) to enable us to map a reasonable range of literature without including older studies of limited relevance to current practice. The full search strategies and further details of the search filters are provided in *Appendix 1*.

Search results were stored in a reference management database (EndNote X7.5, Thomson Reuters, CA, USA) and exported to Microsoft Excel® 2010 (Microsoft Corporation, Redmond, WA, USA) for coding purposes. Records that appeared potentially relevant were coded as far as possible for condition/population studied, intervention/technology, country, setting, type of study (e.g. primary research, systematic review or narrative review) and focus of study (service delivery, test performance or both). Studies were selected for coding that mentioned any kind of test (diagnostic or screening, including questionnaires or similar) when it appeared that a substantive component of the testing, diagnosis, analysis and interpretation took place in a primary care or similar setting. We tried to exclude studies from settings in which the findings would clearly not be relevant to service delivery in the UK NHS (e.g. tropical diseases in low-income countries). Coding was based on title and abstract (where available) only. A coding scheme covering the major conditions and technologies expected to be found in the literature was developed by one of the authors (DC). Studies dealing with multiple conditions and/or technologies were coded as such so that each study had only one condition and one technology code. A code of 'unclear' was also available for any studies in which the specific condition or technology could not be identified from the available information.

The findings were synthesised narratively by condition and technology. For studies judged to be most relevant to service delivery issues, key details were extracted and tabulated.

Results

The searches identified 2644 records, of which 309 were identified by the review filter. Overall, we coded 302 records (11.4%) as meeting the inclusion criteria for the mapping exercise. This total includes 30 records included after discussion of 46 queries on inclusion between the authors involved (AB and DC).

Summary of findings

Comparatively few studies (eight reviews and 20 comparative studies) focused on different models of providing diagnostic services. Two of the most relevant studies were those by Pallan *et al.*¹⁶ and Voutilainen and Kunnamo.¹⁷ We are aware that other studies of this type, not included in the search results, would be picked up by a search of additional data sources (including grey literature). Most studies focused on test performance (e.g. diagnostic accuracy in a primary care population/setting). More details and examples of these types of service-focused studies are listed below.

The largest number of studies (10 reviews and 23 comparative studies) looked at diagnosis of mental health conditions, followed by cancer, cardiac disease, acute infections, dementia and chronic obstructive pulmonary disease (COPD)/respiratory disease (*Table 1*). Other conditions formed a large miscellaneous

TABLE 1 Number of records coded for different health conditions by study type

Population/condition	Review filter	Comparative study filter	Total
Mental health	10	23	33
Cancer	9	22	31
Heart disease	2	26	28
Acute infection	4	20	24
Dementia	6	10	16
Multiple conditions (using the same diagnostic technology or technologies)	3	12	15
Diabetes		14	14
COPD	1	12	13
Neurological conditions	2	6	8
HIV		5	5
Other STI (syphilis 1; unclear 4)		5	5
Chlamydia	2	1	3
Asthma/allergy		3	3
Liver disease	2		2
IBS/IBD	2		2
Renal disease		1	1
Other	12	87	99
Total	55	247	302

HIV, human immunodeficiency virus; IBD, inflammatory bowel disease, IBS, irritable bowel syndrome; STI, sexually transmitted infection.

group but included studies of primary care diagnosis of *Helicobacter pylori* infection, other gastrointestinal (GI) conditions and low-back pain. Many studies examined multiple technologies, questionnaires/scales or POC tests (Table 2). A sizeable group of studies (26 comparative studies) examined test behaviour in primary care, that is, health professional and patient attitudes and behaviours towards diagnostic testing and interventions aimed at influencing these. Studies of COPD mainly evaluated use of spirometry in primary care settings and addressed some issues relevant to service delivery.

Reviews

The search using the review filter identified 309 records, of which 55 (18%) were coded as potentially relevant; of these, 37 appeared to be systematic or non-systematic reviews and the remainder were other types of study retrieved because of the sensitivity of the filter.

Of all coded reviews, eight were classified as focusing mainly on service (service delivery, organisation, staffing, patient experience/outcomes, etc.);¹⁸⁻²⁵ 16 were classified as focusing mainly on both service and test performance; and the remaining 31 were mainly concerned with test performance (diagnostic accuracy, etc.). The largest groups of reviews dealt with mental health (10 papers), cancer (nine papers) and dementia (six papers). Twelve reviews covered other conditions including obesity and alcohol abuse. The main types of diagnostic test reported by these reviews were questionnaires and scales (22 reviews) and POC testing (eight reviews), while 19 reviews were coded as covering multiple diagnostic technologies.

Among the reviews focusing on service delivery-related topics (Table 3), the largest group was related to cancer diagnosis and screening.^{21,23,24} Others dealt with various conditions including chronic fatigue syndrome,¹⁹ depression,²⁰ respiratory disease²² and arthritis.²⁵ Five reviews appeared to consider diagnostic tests and technologies in the context of broader patient management pathways.^{19-22,25}

TABLE 2 Number of records coded for different diagnostic technologies by study type

Technology	Review filter	Comparative study filter	Total
Questionnaires/scales	22	49	71
Multiple	19	36	55
Other	3	53	56
POC testing	8	34	42
Test behaviour		26	26
Unclear	1	8	9
Ultrasound ^a		6	6
Imaging		6	6
Endoscopy		6	6
Spirometry		6	6
Natriuretic peptides	2	4	6
ECG		5	5
X-ray		4	4
MRI		2	2
Skin prick		2	2
Total	55	247	302

a Including echocardiography.

TABLE 3 Characteristics of coded 'reviews' (studies identified using the review filter) focused on aspects of service delivery

Reference	Condition	Technology	Service topic
Baricchi <i>et al.</i> 2012 ¹⁸	General	Pathology tests	Test ordering
Bayliss <i>et al.</i> 2014 ¹⁹	Chronic fatigue syndrome	General	Physician behaviour
Bijl <i>et al.</i> 2004 ²⁰	Depression	General	Clinical effectiveness
Mitchell <i>et al.</i> 2008 ²¹	Cancer	General	Diagnostic delay
O'Byrne <i>et al.</i> 2010 ²²	Respiratory disease	General	Referral
O'Malley <i>et al.</i> 2002 ²³	Cancer	Mobile clinics	Population screening
Smith <i>et al.</i> 2014 ²⁴	Cancer	General	Workforce
Villeneuve <i>et al.</i> 2013 ²⁵	Arthritis	General	Referral

Comparative studies

A total of 247 records, identified by the search terms combined with a comparative studies filter, were coded as potentially relevant for at least one type of diagnostic test or technology. It was difficult to assess how many of these were genuine comparative studies based on the limited information available from the title and abstract.

In terms of conditions (see *Table 1*), the largest numbers of comparative studies dealt with mental health conditions ($n = 23$), heart disease ($n = 26$) and cancer ($n = 22$). However, 87 studies related to conditions not covered by our pre-specified list of common diseases. The most commonly studied single technologies (see *Table 2*) were questionnaires/scales ($n = 49$ studies) and POC tests ($n = 34$). A substantial number of studies ($n = 26$) dealt with test behaviour (primarily physicians' attitudes and behaviour around ordering or performing diagnostic tests).

Twenty^{16,17,26-43} of the coded comparative studies were considered to relate to aspects of service delivery and organisation (*Table 4*) and 30 dealt with both service delivery and test performance/accuracy. The remaining coded comparative studies were mainly relevant to aspects of test accuracy in primary care or community settings.

As far as could be judged from the title and abstract, the majority of the comparative studies were focused on specific conditions such as cancer or heart disease and included a range of diagnostic technologies (noted as 'general' in *Table 4*). A few studies covered particular diagnostic tests or technologies, for example genetic testing,⁴² ultrasound¹⁶ and endoscopy.¹⁷ The studies were conducted in a range of different health-care systems, with only three performed in the UK.^{16,36,37}

Only three of the coded studies primarily looked at service models for the delivery of diagnostic tests in primary care or community settings.^{16,17,27} Other studies examined related topics such as clinicians' behaviour and attitudes,^{28,29,32} workforce issues (e.g. whether doctors or other health-care personnel administer the tests),^{35,43} resource use and costs,³⁰ and impact of community diagnostics on decision-making about patient management (e.g. prescribing and referrals to other health professionals).^{31,36,38} One study compared cancer diagnostic delays across different health systems with a key role for primary care.³³

Discussion

Main findings and implications

The search results indicated a substantial body of research on diagnostic testing in primary care and community settings. However, only three primary studies that reviewed or compared different models of

TABLE 4 Characteristics of coded comparative studies focused on aspects of service delivery and organisation

Reference	Condition	Technology	Service topic
Arber <i>et al.</i> 2006 ²⁶	Heart disease	General	Physician behaviour
Ayoub <i>et al.</i> 2009 ²⁷	Osteoporosis	General	Service models
Chan <i>et al.</i> 2005 ²⁸	Attention deficit hyperactivity disorder	General	Physician behaviour
Chey <i>et al.</i> 2005 ²⁹	Gastro-oesophageal reflux disorder	General	Physician behaviour
Hay <i>et al.</i> 2009 ³⁰	Peripheral vascular disease	General imaging	Costs
Madurell <i>et al.</i> 2010 ³¹	Acute infection	Rapid antigen detection	Decision-making
Maserejian <i>et al.</i> 2014 ³²	Musculoskeletal pain	General imaging	Physician behaviour
Murchie <i>et al.</i> 2012 ³³	Cancer	General	Diagnostic delay
Nucci <i>et al.</i> 2004 ³⁴	Diabetes	General	Population screening
Oliveria <i>et al.</i> 2002 ³⁵	Cancer	General	Workforce
Pallan <i>et al.</i> 2005 ¹⁶	General	Ultrasound	Service models
Parkins and Edgar 2011 ³⁶	Glaucoma	General	Referral
Pearson <i>et al.</i> 2006 ³⁷	Respiratory disease	General	General
Pérez-Martínez and Puente-Muñoz 2006 ³⁸	Neurology	General	Referral
Peterson and Peterson 2004 ³⁹	Heart disease	Cardiac catheterisation	Safety
Poon <i>et al.</i> 2004 ⁴⁰	General	General	Test result management
Smeeth <i>et al.</i> 2003 ⁴¹	Visual impairment	General	Clinical effectiveness
Tsianakas <i>et al.</i> 2010 ⁴²	Sickle cell/thalassaemia	Genetic testing	Physician attitudes
Urban <i>et al.</i> 2012 ⁴³	General	General	Workforce
Voutilainen and Kunnamo 2005 ¹⁷	Cancer	Endoscopy	Service models

service were found.^{16,17,27} and there were no reviews in this category. Among either reviews (including all studies identified using the review filter) or primary studies, most papers that were coded as potentially relevant to the topic focused on aspects of test accuracy and performance in primary care/community settings and populations.

The reviews that were more directly relevant to service delivery dealt with a range of conditions and topics (see *Table 3*). A major theme of these papers was to examine diagnostic tests in the context of patient management pathways and decision-making processes rather than in isolation. This finding helped to support the subsequent decision of the review team to propose to examine the evidence base around a selected primary care diagnostic pathway (symptom-based pathways for patients presenting with breathlessness) and its individual components in more depth (see *Chapter 6*).

Studies identified with the help of the comparative studies filter covered a similar range of technologies and conditions to those documented by the reviews. As with the reviews, the focus was mainly on test accuracy rather than on service delivery, although several service-focused papers were identified (see *Table 4*). Many papers dealt with multiple diagnostic technologies for a particular condition or group of conditions.

The findings of the mapping exercise suggested that it would be appropriate to examine a particular diagnostic technology in some depth, as this had not been done by any of the reviews that we identified. Ultrasound was chosen because it is a key diagnostic technology for a wide range of clinical conditions; provision of diagnostic ultrasound in the community has been possible since the 1990s⁴⁴ and recent developments in equipment could potentially change the balance between different models of service;⁴⁵ and improving access to ultrasound to support early diagnosis of cancer (particularly ovarian cancer) is a priority for the NHS.

Another finding from the mapping exercise that seemed to require further analysis was the wide range of diagnostic technologies included and the different implications for providing them in community settings. The requirements for equipment, staff (including training) and premises, and associated costs, differ widely between, for example, in vitro POC tests and MRI. In view of this, we proposed to carry out a further piece of work to identify key logistic and service delivery considerations associated with the introduction and ongoing provision of diagnostic services in community or primary care settings (see *Chapter 4*).

One of the largest groups of studies looked at questionnaires and scales for diagnosis of mental health or neurological conditions. Although important, the delivery of these tests is not influenced by the same range of considerations that affects diagnostic technologies such as endoscopy or spirometry, as there is no requirement for special equipment or premises. Papers on questionnaires and scales were, therefore, excluded from further consideration in the review.

An important negative finding from this mapping exercise is that the published evidence does not include an adequate description or evaluation of the wide range of service models currently being commissioned (or that might feasibly be commissioned) for diagnostic services in the NHS. In particular, services (e.g. mobile laboratories, diagnostic co-operatives and open-access diagnostic services) may be designed to impact on primary care without necessarily being located in a primary care or community setting. This limits our ability to assess the relevance of the evidence found to future commissioning decisions. Even a fully comprehensive mapping review will be of little practical use to decision-makers if the published evidence does not reflect the range of services being commissioned in practice. We proposed to explore this issue further by mapping the range of current NHS diagnostic ultrasound services as part of the focused review of that technology (see *Chapter 5*).

Limitations

This mapping exercise was designed to provide a preliminary scoping assessment of the extent and nature of the research evidence relevant to community diagnostic services. Insights provided by examining and coding the search results are intended to assist the review team in deciding where to concentrate our efforts for the remainder of the project. As such, we did not expect the search to be in any way comprehensive: only one bibliographic database (MEDLINE) was searched and we did not examine other potential sources of references such as grey literature and internet searching. Filters for reviews and comparative studies were used in the searches in an attempt to identify the best available evidence and to optimise use of the time and resources available. However, these filters trade off sensitivity and specificity, and some of the studies retrieved by the review search were not identifiable as systematic or narrative literature reviews.

Papers were coded as potentially relevant if they referred to diagnostic or similar tests performed in primary care or community settings. Coding sought to obtain a broad picture of the literature but meant that many studies coded were peripheral to the main objectives of the project. In particular, we coded numerous studies that evaluated diagnostic scales and questionnaires; subsequent discussion indicated that findings of such studies would not be generalisable to diagnostic technologies with greater resource requirements for, for example, equipment.

The coding of records for inclusion was shared between two researchers, and uncertainties were resolved by discussion with a small sample of records being checked by a second reviewer. Use of simple classification system for health conditions sped up the coding process but meant that a higher than

optimum proportion of records was classified under the heading of 'other conditions'. All coding decisions were based on information available in the record title and abstract, if available, as it was not felt to be justified to obtain full-text papers for a preliminary literature mapping exercise.

Conclusions

The results of the mapping exercise suggest that there is a relatively large body of research on diagnostic testing in primary care/community settings, with 302 papers (11.4% of those identified by the search strategy) being coded as potentially relevant. However, only a few studies evaluated or described models of service, with most focusing on test accuracy in primary care populations. The search used broad search terms and covered only one database, so it was designed to be representative, not comprehensive. The review team has no reason to believe that these results are not broadly representative of the overall body of evidence.

Examination of the identified papers supported the need for further focused reviews to synthesise the research evidence in more depth and identify any implications for practice and research. The review team proposed that they might focus on:

- ultrasound, as a key diagnostic technology affected by recent developments in technology (see *Chapter 5*)
- the widely differing logistic and service delivery implications of introducing different diagnostic technologies in primary care/community settings (see *Chapter 4*)
- diagnostic pathways delivered in primary care, using differential diagnosis of breathlessness as an exemplar of a symptom-driven pathway (see *Chapter 6*).

Based on the results of the mapping exercise, it appeared that at least some evidence would be available to inform each of these areas. Given the diverse nature of these three focused reviews, separate protocols and search strategies were developed for each.

Chapter 4 Logistics of diagnostic modalities in primary care: a framework map and synthesis

Executive summary

Introduction

Recent years have witnessed rapid and significant advances in diagnostic technologies and their supporting technological and communications infrastructures. Numbers of tests performed continue to increase as patients, carers and clinicians seek more accurate and rapid diagnoses and treatment selection.² With such demand comes an imperative to locate testing procedures as close as possible to the point of first presentation by the patient, typically requiring service reconfiguration from acute hospitals to primary care. The reconfiguration of diagnostic services involves multifactorial considerations relating to the workforce, equipment and communication among stakeholders. The synthesis team has devised a framework entitled STEP-UP (Skills, Training, Equipment, Premises, User Perspectives and Primary–secondary interface) as a lens through which to examine 13 primary care diagnostic topics [audiology, cardiac services (including specifically ECG and echocardiography), diabetic services, endoscopy, genetic testing, MRI, POC testing, radiology/X-ray, respiratory tests (including specifically spirometry) and ultrasound]. Topic selection sought to examine a wide variety of logistic and implementation considerations and to model disease-specific, system specific and technology-specific topics. These 13 topics were not intended to be either exhaustive or mutually exclusive.

Methods

A systematic mapping approach, standardised across 13 topics, was used to identify, map and present findings from key items from the literature. As the focus of the mapping was descriptive and interpretive, not analytical, the methodology prioritised identification of systematic reviews, randomised controlled trials (RCTs) and qualitative studies, together with UK-based evidence sources. The objective was to identify factors and considerations determining the uptake and utilisation of diagnostic modalities in a primary and community care setting. Sensitive searches were conducted using PubMed Clinical Queries and PubMed Special Queries and The Cochrane Library (including the Database of Abstracts of Reviews of Effects). Modalities were also searched on PubMed in conjunction with the MeSH term 'Great-Britain', and The King's Fund Centre Library database was searched by modality. The time period covered was from 2000 to September 2015. Coverage of logistic issues such as equipment, skills and training in the titles and abstracts of journal articles was minimal. Therefore, an extensive process of examination of full text and follow-up of references in context was employed to populate the STEP-UP framework for each topic. UK sources such as the NHS Horizon Scanning Centre and the NIHR Diagnostic Evidence Co-operative (DEC), Oxford, were scrutinised. Each topic summary includes an overview map, an examination of the type and nature of the evidence and a brief summary under each of the main headings of the STEP-UP framework. In recognition of the mapping function of the synthesis and its interpretative nature, no attempt was made to assess included items for quality.

Results

A total of 673 items for inclusion was identified across the 13 topics. Information on logistic considerations was diffuse, uneven and incomplete. Coverage of new technologies was relatively strong and, when specialist primary care professional associations exist (e.g. endoscopy), training and skills requirements were well specified. However, little direct evidence exists for equipment requirements, implementation issues and the impact on the primary–secondary care interface. A methodological challenge relates to the intensive search and find process required to identify relevant information submerged within lengthy full-text articles and position statements. The diverse range of considerations identified across the 13 topics illustrates the importance of a multifactorial decision-making process.

Skills

Many modalities require a wide range of contextual and/or technical skills: in administering the test, in interpreting the results and in managing the consequences. Genetic tests, although comparatively easy to administer, make considerable demands on specialist knowledge in interpretation and skills in genetic counselling. Radiology/X-ray and other types of imaging (MRI and ultrasound) require interpretation, possibly necessitating follow-up and expert advice from specialists in secondary care. Such a need may translate into a hybrid model utilising telemedicine technologies. Inadequate administration of tests may require repeat testing, either in the primary care setting or following referral to secondary care. It may also impair effective use of telediagnosis. Generally, three main routes have been identified for addressing the potential skills deficit. For some roles the GPwSI is seen as a route by which to fortify diagnostic expertise within primary care (e.g. endoscopy and genetics). For other scenarios, the extended role of the advanced nurse practitioner, either with a specific diagnostic function (e.g. ultrasound or spirometry) or within a management pathway (e.g. respiratory or diabetic specialist nurses), is emphasised. A third route, although not fully exploited, is to bring in a specialist professional, either on a sessional basis or as an employee of the primary care organisation (e.g. radiology or genetic counselling). Alternative models, not covered by this report, include the use of shared diagnostic services within a primary care consortium, mobile testing services and the use of commercial providers.

Training

Training may be delivered through specialist courses, attachments to acute specialist departments or manufacturers of diagnostic equipment. A particular concern relates to whether or not the number of cases to be seen in a practice justifies a significant investment of time and resources in training (e.g. endoscopy). The opportunity costs for the consultation and other aspects of primary care required by pursuit of specialisation are highlighted in the related GPwSI literature. A tension is identified between the professional interests of associations charged with assuring both the quality of procedures and the existence of their professional group and the need to engage with a wider primary care workforce. For example, data on the safety of endoscopy in acute hospitals were initially viewed as prohibitive to wider primary care involvement. In reality, triaging the complexity of particular cases and specific populations (e.g. children, pregnant women and the elderly), particularly for invasive modalities, may increase the accessibility of primary care diagnostics while preserving specialisation in secondary care.

Equipment

The cost and manageability of technologies is extremely variable across topic areas. Some technologies have benefited from moves towards miniaturisation (e.g. ultrasound) or to more end-user friendly versions of a technology (e.g. flexible sigmoidoscopy). Others have seen a trend towards popularisation, either in the health-care professions generally (e.g. POC testing) or through direct-to-consumer marketing (e.g. genetic tests), from which primary care might potentially benefit. Concerns about safety persist, either from the diagnostic equipment itself (e.g. radiation from radiology/X-ray) or from consumables (e.g. glutaraldehyde) or from ancillary equipment to support administration or analysis of the test results (e.g. electrical equipment). Ancillary equipment requirements are not widely documented (e.g. continuous pulse oximetry is recommended when intravenous sedation is required for endoscopy), while requirements for garments, gloves, goggles and glasses should not be overlooked. For newer technologies, the outputs of the NIHR DEC, Oxford, are useful. However, these outputs focus on narrower health technology assessment (HTA) perspectives of the technology, with correspondingly less attention to health services delivery and organisational issues.

Premises

Diagnostic technologies place particular requirements on the physical location in which a test is administered. In some cases the focus is on the housing and safe administration of the equipment (e.g. endoscopy or radiology). Specialist premises, that is, rooms dedicated to a particular diagnostic modality, are particularly prohibitive in legacy primary care premises. Even when premises are purpose-built, changes in technologies and their associated requirements, and a lack of specifications for an integrated multipurpose approach across technologies, make accommodation problematic. Patient flows (e.g. additional seating and queuing)

need examination at a specific practice level. Requirements are not necessarily technology-driven. For example, audiological requirements for a quiet environment, even for simple hearing tests, may be difficult to accommodate and may particularly be compromised in a multipurpose environment. The requirements of accommodation are sparsely populated in Health Building Guidance, although the document Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ is a very helpful starting point. The number of potential cases seen versus the particular spatial requirements of the technology and its administration becomes particularly important when contemplating specialised, dedicated accommodation.

User perspectives

Generally, across primary care, the delivery of diagnostic modalities locally meets increasing demands for improved access and, by implication, enhanced equity. Patients prefer services that may be reached easily and that will not necessitate extensive time away from their day-to-day responsibilities. Prompt test results and the joining up of diagnosis and treatment are important considerations for patient and primary care provider alike. On the other hand, impaired access may function as a disincentive to inappropriate utilisation and, particularly, overtesting. There is little evidence to inform whether or not improved general practice access to testing increases uptake of tests or whether or not a greater awareness of resource use deters general practice staff from initiating testing. Patients presenting with medically unexplained symptoms may be assuaged with offers of more, and more immediately available, tests. More critically, the appropriateness of testing, rather than utilisation rates per se, becomes a key issue. Finally, given that diagnostic services function as a gateway to subsequent health service use, improved access to diagnosis might potentially defer current bottlenecks to other points in the patient care pathway.

Primary–secondary interface

Although the STEP-UP framework encourages a holistic view of primary care considerations, diagnostic services function in a whole-system health system environment. Ramifications of system change at the primary care first point of call are not fully explored in the evaluation literature. Earlier detection may result in earlier and more effective treatment and, thus, result in overall cost savings. Unintended consequences for patient and provider behaviours require careful examination, especially when resulting in increased utilisation or needless duplication. The impact on uptake of direct-to-consumer products and on commercial diagnostic services or private health care is equally important in a whole-system perspective.

Discussion

The multifactorial nature of decisions on diagnostic services, and indeed on general practice-level change more generally, is emphasised by the STEP-UP framework. Observations are discussed under the modalities themselves and the future research and synthesis agenda.

Candidate modalities

The Synthesis team members were constrained by limited data on current UK practice and uptake of diagnostic services. For long-established technologies (e.g. endoscopy), it is unclear whether the extent of spread has been determined by demand or by logistic considerations such as the limited availability of premises or the costs of equipment. In particular, the implications of a concerted attempt to improve diagnostic provision, involving the introduction of diverse modalities within a relatively intensive period, are unclear. Mechanisms for prioritisation, strategically and in an individual practice, are also complex and unclear. Several commentators observe on the importance of identifying particular barriers and constraints at a micro level, as well as acknowledging the role of guidance from the National Institute for Health and Care Excellence (NICE) or professional associations in driving forward initiatives. The variability of context makes it difficult to translate this mapping review directly into actionable recommendations for primary care. At the same time, the STEP-UP lens offers the possibility of a more holistic and consistent approach to evaluation. Economic evaluation, with its whole-systems perspective, its approach to itemisation of particular components and its functionality for handling multiattribute decisions, appears to afford an opportunity to implement STEP-UP considerations in a more technical, consistent and decision-specific manner.

Methodological considerations

As a conceptual framework, STEP-UP is vulnerable to a mismatch between the logistic information required to complete the map and a research agenda focused on innovations and/or on the evaluation of effectiveness. Position statements and professional standards are typically underpinned by implicit and non-articulated assumptions about the stage of diffusion at which a particular technology finds itself. So, for example, early documents state requirements for setting up an endoscopy unit but the costings are now outdated and the specification is time-bound. Extensive use of the STEP-UP framework across a wide variety of topics reveals its general utility for a consistent approach that highlights similarities and contrasts across very different technologies. As such, STEP-UP offers a viable framework for extending evaluation beyond the current narrow interpretation of HTA towards important considerations of service delivery and organisation. Considered reflection leads us to suggest the possible extension of the STEP-UP framework to include three additional components: Public perspectives, Economics and Drivers (STEPPED-UP).

Although the inclusion of economics in the extended framework is unsurprising, it should be noted that the STEPPED-UP framework introduces this in the context of service delivery and not in the more common, limited application of individual diagnostic technologies.

Conclusion

The evidence map and synthesis (*Table 5*) provides a rapid synoptic view of leading areas of development for primary and community care diagnostics and a potential mechanism for identifying and specifying

TABLE 5 Summary table for logistics of primary care diagnostics

Diagnostic technology	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	User perspective		Primary-secondary interface
					Clinician	Patient	
Audiology	○	○	○	○	⊕	⊕	○
Pneumatic otoscopy	○	⊕	⊕	∅	○	∅	∅
Tympanometry	⊕	⊕	⊕	∅	○	⊕	○
Cardiac services	○	⊕	⊕	∅	⊕	⊕	⊕
BNP	⊕	⊕	⊕	∅	⊕	⊕	○
ECG	⊕	⊕	⊕	∅	⊕	⊕	⊕
Echocardiography	○	○	⊕	⊕	⊕	⊕	○
Diabetic services	⊕	⊕	⊕	∅	⊕	⊕	⊕
Endoscopy	⊗	○	⊗	⊗	∅	⊗	○
Genetic testing	⊗	○	⊕	∅	○	⊕	○
MRI	○	○	⊗	⊗	∅	∅	○
POC testing	○	○	⊕	∅	○	⊕	○
CRP	⊕	⊕	⊕	∅	⊕	⊕	○
Radiology/X-ray	○	⊕	○	○	⊕	⊕	○
Respiratory tests	⊕	⊕	⊕	∅	⊕	⊕	○
Pulse oximetry	⊕	⊕	⊕	∅	⊕	⊕	○
Spirometry	○	⊕	⊕	⊕	⊕	○	⊕
Ultrasound	○	⊕	⊕	⊕	⊕	⊕	⊕

∅, insufficient evidence; ⊗, high degree of implementation difficulty; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty; BNP, B-type natriuretic peptide; CRP, C-reactive protein.

future areas for development (for synthesis, primary research and policy). In particular, the need for whole-system evaluations, economic evaluations and a mechanism for better organising and presenting information on aspects relating to service delivery and organisation, possibly analogous to the NIHR DECs, has been highlighted. Further data on current levels of diagnostic provision in primary care and future priorities are required. Finally, the focus of this synthesis on staff and equipment located in primary care has necessarily constrained the scope of the review and subsequent recommendations. Alternative models, such as consortium approaches, direct access, mobile testing services, outreach initiatives and use of commercial laboratories, require a similarly systematic examination.

Background

Recent years have witnessed increasing momentum towards improved access to diagnostic services for GPs, allied health professionals and other primary and community care staff.^{47,48} Department of Health documents such as *Care Closer to Home*⁴⁹ and *Our NHS Our Future: NHS Next Stage Review – Leading Local Change*⁵⁰ outline a need to achieve change through ‘disruptive innovation’, that is, change involving radical service redesign and an emphasis on devolving key aspects of care pathways from secondary to primary care.⁵¹ Other drivers for increased use of diagnostic services in primary care include rapid and significant advances in test technologies (Technology); increases in numbers of tests performed (Economics) and pressure from patients and carers for more accurate and rapid diagnoses (Social Drivers).² For further discussion of these issues, see *Chapter 1*.

This framework map and synthesis was undertaken within a larger review project looking at provision of diagnostic services in community settings. Initial literature mapping revealed a variety of diagnostic modalities with different implications for being located in primary care (see *Chapter 3*). In addition to examining one modality, diagnostic ultrasound (see *Chapter 5*), in detail, the review team believed that it would be helpful to characterise modalities against a common set of logistic and service delivery considerations. They could then populate these considerations with data relating to existing modalities and the framework could become a template for evidence gathering for potential and future technologies.

Hypotheses tested in the review (review questions)

Review question

What are the logistic and service delivery considerations associated with the introduction and ongoing provision of diagnostic services in community or primary care settings? These should include implications for NHS organisations (e.g. related to provision of staff, premises, training and equipment, costs and cost-effectiveness) and patients (e.g. related to changes in management/pathways, acceptability to patients, accuracy of diagnosis and longer-term clinical outcomes).

Objectives

The objectives of this mapping review are:

- to develop a series of maps of logistic factors (STEP-UP) relating to a pre-agreed list of diagnostic modalities of potential use in primary care
- to populate those maps with evidence from rigorous or relevant studies
- to use the maps to produce an analysis of logistic considerations
- to identify needs for further research and development to inform future research priorities.

Scope

This review covers logistic and service delivery considerations associated with the introduction and ongoing provision of diagnostic services in community or primary care settings. It is not possible to anticipate technologies that are currently being developed and tested in acute hospital settings but that have not been used in primary care. For inclusion, technologies should offer some evidence of trialled and or uptake in a primary care or community care setting. Evidence for effectiveness and cost effectiveness is not the focus of the review, serving only as a backdrop to considerations about logistic and service delivery factors.

The emphasis of this mapping review is in identifying, summarising and digesting existing data sources, not in performing original analyses. The deliverables, therefore, relate to the STEP-UP maps, not to detailed assessments of each individual technology.

Appendix 2 sets out the innovative STEP-UP framework used to guide the review process. This framework allows us to:

1. define the scope of the search strategy
2. define inclusion and exclusion criteria to specify the types of studies to be included in the final report
3. construct summary tables of all included studies to present key information and findings
4. synthesise the evidence from the included studies.

Review methods

The framework map and synthesis did not attempt to identify *all* relevant evidence or to search *exhaustively* for all evidence that meets the inclusion criteria; instead, the search approach sought to identify the key evidence of most relevance to the review question. Evidence identification privileged systematic reviews, quantitative studies (including RCTs), qualitative studies and UK studies. In addition, substantive items such as position statements, standards and guidance and editorials were included. Although the last are understandably viewed with caution in the context of an effectiveness review, they were considered appropriate for this logistic 'map'. The emphasis was on identifying factors considered important, not to authoritatively determine their contribution to test development and implementation.

Protocol development

The protocol for the review was developed iteratively between the School of Health and Related Research, University of Sheffield, and NIHR Health Services and Delivery Research. A copy of the study protocol is available on the study website.¹⁵

Literature searching

An efficient search strategy was devised, in response to an initial scoping search which revealed that information on logistic issues was rarely identifiable in the title and abstracts of journal articles and usually could be retrieved only from full text.

Identification of key systematic reviews

Searches were conducted for systematic reviews on each diagnostic technology on the Centre for Reviews and Dissemination databases, the PubMed Clinical Queries search engine using the Broad (Sensitivity) filter for Diagnosis, and searches of The Cochrane Library and the Turning Research Into Practice database.

Identification of key quantitative studies

Searches were conducted for key clinical studies on each diagnostic technology on the PubMed Clinical Queries search engine using the Broad (Sensitivity) filter for Diagnosis. Searches were also conducted on the Cochrane Trials Register.

Identification of key qualitative studies

Searches were conducted for key qualitative studies on each diagnostic technology on the PubMed Special Queries – Health Services Research search engine using the Broad (Sensitivity) filter for Qualitative Research.

Identification of other substantive evidence

Searches were conducted for other substantive studies on each diagnostic technology on the PubMed Special Queries – Health Services Research search engine using the Broad (Sensitivity) filters for Appropriateness, Costs and Economics. The King's Fund Library was also searched for substantive items.

Identification of UK studies

Studies conducted in the UK were identified in three ways:

1. Geographical terms for 'united kingdom', 'uk', 'britain', 'England', 'Scotland', 'Wales', 'Ireland' were used to retrieve records from the PubMed database.
2. Searches by technology, with no geographical limitations given its UK focus, were conducted on The King's Fund database.
3. Similarly, geographical terms for 'united kingdom', 'uk', 'britain', 'England', 'Scotland', 'Wales', 'Ireland', combined with the technology and words such as 'equipment, logistics, premises, facilities' were used to retrieve items from Google Scholar (Google Inc., Mountain View, CA, USA). By harnessing full-text retrieval, this search added value over the title-and-abstract-based approach listed above.

Retrieved items were sifted against the inclusion/exclusion criteria listed in the following section. A bibliography of key items was compiled for each technology. This bibliography was used to retrieve full texts when available and to perform citation searches. As additional relevant items were retrieved, further citation searches were performed for these in turn until saturation of relevant items was achieved.

Inclusion/exclusion criteria

Population

People requiring diagnostic services for any medical condition (excluded: universal screening and monitoring, including pregnancy). Studies that described screening for selective populations (e.g. by age, gender, ethnic group) or for individuals indicated to be at risk were included provided that the identified factors were either common or concentrated in the UK population. Excluded were psychological and psychiatric conditions (e.g. depression) and neurological conditions (e.g. dementia).

Intervention

Diagnostic services where a complete diagnostic (but not necessarily treatment) pathway was provided in a primary care or community setting by primary care/community staff using any type of equipment. Open-access services provided to GPs by a hospital using its premises, equipment and staff were treated as a comparator intervention. (Studies examining telemedicine that links primary with secondary care were excluded from this review because of extent of dependency on secondary care support. However, such initiatives should be factored into any decisions.)

Comparator

Hospital-based diagnostic services (open access or traditional). 'Outreach' services using hospital-based staff to deliver services in community settings were also relevant comparators.

Outcomes and study designs

The main focus was research studies conducted in any developed world setting that evaluated community diagnostic services against a comparator. Audits, service evaluations, descriptive studies, economic evaluations and qualitative research studies were included if they had been conducted in a UK setting.

Systematic reviews with no geographic limits or where geographic limits include UK settings were also eligible for inclusion. In addition, relevant expert opinion or reports from professional bodies identifying practical issues related to the provision of community diagnostic services were included. Articles focusing on test performance with no examination of subsequent health services outcomes were excluded.

Other limits

Given that this was a mapping review, articles without an abstract were excluded. Studies were to be written in English and published from 2000 onwards.

Studies were included in the framework map and synthesis in accordance with *Table 6*.

Given the focus of the review on models of service, studies that report only on the diagnostic accuracy of modalities have not been included.

Data extraction including development of the data extraction tool

A standardised data extraction form was designed to specify and capture relevant information from the studies on a broad range of factors related to community diagnostics (see *Appendix 2*). A narrative commentary was undertaken to discuss identified aspects of each test technology.

Quality assessment

This mapping review sought to identify logistic factors or themes. Given the interpretive nature of this work it was not considered necessary to undertake formal quality assessment. However, high-quality evidence sources were interrogated in seeking the best possible study designs.

Synthesis

Data were extracted and tabulated. This tabulation was used to inform the narrative synthesis in *Results of the framework map and synthesis*. The innovative STEP-UP framework is used for comparison and analysis (see *Appendix 2*).

TABLE 6 Inclusion and exclusion criteria

Criteria	Inclusion	Exclusion
Population	Adults and/or children presenting in primary care without a previous definitive diagnosis	Community diagnostics for healthy patient groups (i.e. those without an indication related to a chronic health condition). This exclusion covers: <ol style="list-style-type: none"> 1. pregnant women or those planning a pregnancy (unless they also have a chronic health condition such as diabetes) 2. smoking cessation and other health promotion clinics
Intervention	Delivery of one or more services to a small group of patients (typically 8–10 patients) simultaneously. Only studies including the delivery of the intervention by one or more specialist HCPs met the inclusion criteria of the review	Tests carried out as part of national screening programmes do not count as a diagnostic test/procedure for the purposes of this review
Comparator	Other methods of organisation of treatment (with the exception of qualitative research and surveys, only studies with a comparator group are included)	
Outcome	Patient outcomes; health services outcomes; patient and carer satisfaction; resource use	

HCP, health-care professional.

Studies included in the review

Table 7 summarises the results of the review by type of test and study type.

Results of the framework map and synthesis

Audiology

Definition: overall service delivery framework within which audiometry (hearing tests) are used to assess ability to hear different sounds and to determine if there are any problems (adapted from NHS Choices).

This map includes otoacoustic emissions; pneumatic otoscopy; pure tone audiometry; spectral gradient acoustic reflectometry; tympanometry.

This map excludes universal newborn hearing screening.

Contains public sector information licensed under the Open Government Licence v3.0.⁵²

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

The complexity of audiological investigation requires that GPs work with a wide range of staff. Some services for adults are now provided in a primary care setting by GPwSIs in otology. Some staff encounter initial difficulties when using the tympanometer or the pneumatic otoscope. However, a wide range of

TABLE 7 Summary table of studies included in the review (all framework domains)

Diagnostic technology	Systematic reviews	Quantitative	Qualitative	UK	Other	Total ^a
Audiology	6	27	9	14	40	83
Cardiac services	6	14	5	19	18	54
ECG	8	9	3	6	9	29
Echocardiography	4	16	5	5	25	49
Diabetic services	5	10	6	4	13	34
Endoscopy	6	16	5	14	15	43
Genetic testing	2	25	24	16	34	79
MRI	1	11	0	5	11	24
Point of care testing	11	31	5	3	24	60
Radiology/X-ray	0	7	1	8	23	32
Respiratory tests	3	6	2	12	17	39
Spirometry	8	39	5	9	46	111
Ultrasound	2	12	0	12	22	36
Total	62	223	70	127	297	673

^a Items may appear in more than one study type or in multiple domains; therefore, the numbers do not add up to the total.

audiological investigations can be performed by community staff not specialising in audiology. In the UK, good practice guidance and standards and quality audit tools have been developed for audiology services.

STEP-UP summary statement With regard to SKILLS, audiology is attributed a MODERATE degree of implementation difficulty owing to initial difficulties in using the tympanometer or the pneumatic otoscope and ongoing concerns about the appropriateness of diagnosis and its implications for secondary care.

Training

Specialist GPs may be trained in the initial diagnosis and management of hearing and balance disorders, particularly in adults. Practice nurses can support delivery of procedures requiring basic skills such as basic hearing aid trouble-shooting, relaxation training for those with tinnitus and vertigo, and in gentle mobility training for those with vertigo. Skills in tympanometry and pneumatic otoscopy can be acquired through short courses.

STEP-UP summary statement With regard to TRAINING, audiology is attributed a MODERATE degree of implementation difficulty owing to the facility of short courses to increase confidence in use of equipment.

Equipment

Equipment most typically used by a practice would include a tympanometer (*Table 8*) and a pneumatic otoscope (*Table 9*). Audiology requires a wide range of equipment. Requirements may include flexible fibre-optic nasendoscopy, Hopkins rod endoscopy, a soundproof facility, audiometry, tympanometry and microscopy. Over 75% of all patients will require an additional investigation or procedure. With the introduction of portable and handheld equipment, tympanometry has become more feasible for a primary care setting. Future-proofing of audiology equipment requires provision for otoacoustic emissions technology, initially used for newborn hearing screening but with potential in small children and the aged.

STEP-UP summary statement With regard to EQUIPMENT, audiology is attributed a MODERATE degree of implementation difficulty because, beyond basic equipment, many needs for additional equipment will require follow-up in secondary care.

Premises

Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ includes provision for an adult hearing test room and a paediatric hearing test room. Audiological testing must be performed in soundproofed accommodation built to International Standards Organisation (ISO) 8253-1 and ISO 8253-2 standards for acoustic test methods and suitable for children. Despite the growth of purpose-built clinics and the increasing miniaturisation of audiology equipment, the inability of premises to accommodate treatment rooms for audiology services has been a reported obstacle to the relocation of hospital-based provision.

STEP-UP summary statement With regard to PREMISES, audiology is attributed a MODERATE degree of implementation difficulty owing to the specific requirement for a soundproofed room.

User perspective

Generally, GPs found tympanometry and pneumatic otoscopy to be acceptable to carers and children, although some GPs stated that they preferred not to use pneumatic otoscopy as children sometimes found it uncomfortable.⁵⁷ Some GPs thought tympanometry was particularly useful for communicating with carers about ear disease, offering tangible proof to parents of the GP's diagnosis and support of the management plan.⁵⁷ Many GPs were unclear about the significance of negative pressure tympanometry⁵⁷ readings in general practice, which could potentially generate unnecessary GP follow-ups.

General practitioners believed that more training and experience was needed to become confident with pneumatic otoscopy than was needed for tympanometry.⁵⁷ GPs could teach themselves how to perform tympanometry after the relatively brief introduction to the equipment, with the main challenge being

TABLE 8 STEP-UP framework assessment for tympanometry

Description of technology						
Tympanometer: equipment for examining the condition of the middle ear and mobility of the eardrum (tympanic membrane) and the conduction bones by creating variations of air pressure in the ear canal. Tympanometry is an objective test of middle-ear function						
Brief summary of effectiveness/cost-effectiveness in primary care						
Tympanometry has a high sensitivity and specificity in diagnosing middle ear effusion in young children. ⁵³ Use of a tympanogram, over visual inspection of photographs, improved agreement between clinicians and with expert observers. ⁵⁴ In children with AOM, pneumatic otoscopy is the preferred diagnostic method with tympanometry used to confirm the diagnosis and document the duration of effusion ⁵⁵						
Skills						
Tympanograms are 'Type A' (normal), 'Type B' (pathology of the middle ear) and 'Type C' (indicating poor eustachian tube function). Good agreement with experts. ⁵⁶ Many GPs unclear on the significance of negative pressure (Type C). ⁵⁷ GPs expressed preference over pneumatic otoscopy based on ease of use and interpretation. ⁵⁷ Machine self-explanatory and easy to use ⁵⁷						
Training						
Three-hour workshop (Australia) improved GP confidence in tympanometry and pneumatic otoscopy. ^{57,58} Supported by online resource (ePROM). ⁵⁹ GPs required further training. Six-hour tympanometry and otitis media course (Denmark) ⁵³						
Diagnosis changed in 26.4% after tympanometry plus GP training (Denmark) ⁶⁰						
Nurses trained in 2-hour course on tympanometry for AOM. Observed reliable test results in excluding middle ear effusions after AOM ⁶¹						
Equipment						
Need for hygiene. Tympanometer and probe tip should be clean (i.e. free from dust and dirt and compliant with local infection control standards). ⁶² Tympanometers shall meet the performance and calibration requirements of BS EN 60645-5. ⁶² Safe equipment [< 5 years old, regularly maintained and calibrated (checked daily) and appropriate to clinical needs ⁶³]. Some tympanometers are difficult to handle ^{61,64}						
Premises						
Health Building Note 11-01, <i>Facilities for Primary and Community Care Services</i> , ⁴⁶ includes provision for an adult hearing test room and a paediatric hearing test room						
Clinician						
Problems reported by primary health-care staff in understanding the meaning of the displayed figures and using them to quality assure the measurement, deriving a reliable curve, obtaining an airtight sealing and understanding what the curves means for the clinical decision. Other problems include handling the tympanometer and getting children to co-operate. ^{53,61} Results obtained at fewer than half of asymptomatic visits owing to young, unco-operative children, inexperienced nurses, and relative rarity of exclusive test results. ⁶¹ Slow diffusion as technology is difficult to handle and understand. ⁵³ Useful in communicating diagnosis to carers ⁵⁷						
Patient						
No details given, except in unco-operative children ⁶¹						
Primary–secondary interface						
No details given						
Skills	Training	Equipment	Premises	Clinician	Patient	Primary–secondary interface
⊕	⊕	⊕	○	○	⊕	○
○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty; AOM, acute otitis media; ePROM, Enhancing Proficiency in Otitis Media.						

TABLE 9 STEP-UP framework assessment for pneumatic otoscopy

Description of technology						
Pneumatic otoscopy is an examination that allows determination of the mobility of a patient’s tympanic membrane in response to pressure changes. The normal tympanic membrane moves in response to pressure. Immobility may be due to fluid in the middle ear, a perforation or tympanosclerosis, among other reasons						
Brief summary of effectiveness/cost-effectiveness in primary care						
Pneumatic otoscopy improves diagnosis by between 15% and 26%, compared with usual otoscopy. ⁶⁵ Taking into account direct and indirect costs, pneumatic otoscopy is cheaper than tympanometry or acoustic reflectometry. ⁶⁶ Pneumatic otoscopy can be as effective as or better than tympanometry and acoustic reflectometry ⁶⁶						
Skills						
Pneumatic otoscopy was seen as a more difficult technical skill than tympanometry ⁵⁷						
Training						
Skills can be acquired through short courses						
Equipment						
Requires otoscope with pneumatic bulb and speculum tips with rubber rings to create proper seal ⁶⁷						
Premises						
Health Building Note 11-01, <i>Facilities for Primary and Community Care Services</i> , ⁴⁶ includes provision for an adult hearing test room and a paediatric hearing test room						
Clinician						
Most important barrier was uncertainty on whether there was true drum immobility or whether their technique was simply inadequate. ⁵⁷ Some GPs ‘gave up’ on pneumatic otoscopy. ⁵⁷ Teachers identified improved diagnostic accuracy as main facilitator for use and for teaching. ⁶⁸ All physicians reported lack of availability of equipment as main barrier to use. Main barrier to teaching reported by teachers was that they did not use it themselves. Uptake of pneumatic otoscopy in UK general practice is not known ⁶⁸						
Evidence Assessment ⁶⁶ concludes that, for typical clinician, pneumatic otoscopy should be easier than other diagnostic methods, not borne out by qualitative study ⁵⁷						
Patient						
No information available						
Primary–secondary interface						
No information available						
Skills	Training	Equipment	Premises	Clinician	Patient	Primary–secondary interface
○	⊕	⊕	○	○	∅	∅
∅, insufficient evidence; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.						

interpretation of the tympanograms, which required them to refer back to written information they were given during training. Most GPs said that they would choose to continue to use tympanometry.

STEP-UP summary statement With regard to USER PERSPECTIVES, audiology is attributed a LOW degree of implementation difficulty in the light of only minor GP concerns with equipment and the referral pathway and difficulties with investigations involving small children.

Primary–secondary interface

The Good Practice Guide, specifically for adults with tinnitus,⁶⁹ recommends strategies for tinnitus assessment, management and referral at four different levels of the service: primary care, local community-based tinnitus services, specialist hospital-based centres and supra-specialist assessment centres. Patient routes through the system were to be determined by clinical assessment and specific referral criteria, designed with service efficiency and equity of patient care in mind. A systematic review of outreach

services in primary care found a direct counterpoint between the needs of the patient and the needs of the service.⁷⁰ Reported disadvantages concerned administrative costs, accommodation costs and inefficient use of specialists' time. Comparative studies showed that more patients expressed a preference for outreach clinics than for hospital-based clinics, and measures of patient satisfaction and convenience generally were higher for outreach clinics. A self-contained satellite facility within a GP practice sought to enable 5000–7000 people to receive secondary care hearing services in a primary care setting. The project explored the benefits to patients and to the health economy of shifting care closer to home.⁷¹

Traditionally, patients needing a hearing aid would be referred by their GP to the audiology service, with one appointment for assessment and one for fitting. Advances in technology⁷² mean that some patients can be assessed and fitted at the same appointment.

STEP-UP summary statement With regard to the PRIMARY–SECONDARY INTERFACE, audiology is attributed a MODERATE degree of implementation difficulty owing to dependence on secondary services for further investigation and yet the possibility of streamlined hearing aid pathways.

Conclusion

Provision of audiology services in primary care is complex, in that it not only requires a wide variety of equipment and, optimally, an audiology-friendly environment, but also may necessitate access to other diagnostic services, most notably endoscopy or radiology. *Table 10* summarises the overall findings. There is little evidence available to examine the impact of acquisition of audiology-related skills by primary care

TABLE 10 Overall STEP-UP summary map: audiology (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary–secondary interface
Audiology	○	○	○	○	⊕	⊕	○
Systematic reviews	A81		A42, A73				A32, A37, A65
Quantitative studies	A4, A5, A6, A11, A31, A46, A50, A63, A78	A46, A50, A60, A72	A12, A13, A35, A62, A71, A75			A54	A2, A8, A22, A23, A38, A39, A45
Qualitative studies		A68	A1		A1, A15, A29, A80	A80	A15, A29
UK studies	A27, A33		A20, A27	A16, A34	A24	A69	A23, A27, A38, A40, A48, A83
Other significant evidence	A3, A7, A17, A21, A25, A26, A31, A36, A52, A55, A67, A76	A30, A41, A66	A9, A10, A14, A18, A19, A28, A43, A44, A47, A49, A51, A59, A61, A64, A70, A74, A77, A79			A25, A26, A53	A56, A57, A58, A82
Pneumatic otoscopy	○	○	○	○	○	○	∅
Tympanometry	○	⊕	○	○	○	○	∅

∅, insufficient evidence; ⊕, high degree of implementation difficulty; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.

staff. Studies on provision of specialist outreach clinics (i.e. a hospital specialist operating in a primary care environment) offer supplementary data on equipment utilisation and premises. Current models being favoured in primary care audiology involve direct-access referral clinics or provision of services under contract by commercial (or, alternatively, independent) providers.

Cardiac services

Definition: cardiac tests are used to diagnose and treat heart disease, such as heart failure and AF. Some tests are non-invasive; others are more invasive but potentially are more useful for diagnosis of heart disease.

This map includes BNP, blood tests (specifically in the context of heart disease) (see also *Point-of-care testing*), 24-hour ambulatory BP monitoring.

This map excludes chest X-ray (see *Radiology/X-ray*), electrocardiography (see *Electrocardiography*), echocardiography (see *Echocardiography*), telecardiology.

BNP, B-type natriuretic peptide.

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*. The findings are summarised in *Table 11*.

Skills

Based on clinical scenarios, GP experts have concluded that natriuretic peptides testing should be the routine test for suspected heart failure where referral for diagnostic testing is considered appropriate. Abnormal natriuretic peptides testing should be followed up with referral for echocardiography.⁷³ In a survey on barriers to effective management of heart failure, the majority of respondents who diagnosed

TABLE 11 Overall STEP-UP summary map: cardiac services (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary–secondary interface
Cardiac services	○	⊕	⊕	∅	⊕	⊕	○
Systematic reviews			C6, C29, C30, C33, C34				C38
Quantitative studies	C3, C7, C26, C50		C12, C17, C19, C36, C42, C47, C49, C51, C54		C35		
Qualitative studies	C26				C4, C21, C32, C37		
UK studies	C7, C26, C39, C44, C45, C46		C2, C5, C8, C9, C12, C25, C41, C48, C54		C32, C35, C37		C20
Other significant evidence	C15, C40	C18	C1, C10, C11, C13, C14, C16, C22, C23, C24, C27, C43, C49, C53				C31, C52

∅, insufficient evidence; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.

left ventricular systolic dysfunction (LVSD) used ECGs, chest radiography and clinical assessment, the exception being nurses. Around one-quarter of the nurses and half of the GPs were confident about interpreting the results of an ECG, whereas most cardiologists and general physicians were confident.⁷⁴

STEP-UP summary statement With regard to SKILLS, cardiac services is attributed a MODERATE degree of implementation difficulty owing to the range of diagnostic scenarios and investigations.

Training

Education and training in cardiac imaging should meet the present requirements specified by the General Medical Council (GMC) in curricula in cardiology and cardiac radiology, the future demands of revalidation and the requirements of allied professional groups.⁷⁵ The British Society of Echocardiography (BSE) (www.bsecho.org), the British Society for Cardiovascular Magnetic Resonance (BSCMR) (www.bscmr.org) and the British Society for Cardiac Imaging (www.bsci.org.uk) have endorsed voluntary accreditation procedures for their members.

A survey of 170 general practices in one cardiac network suggests that training of staff in use of cardiac equipment is variable.⁷⁶ Training updates were not provided for 12-lead ECG in 20 practices, static BP in 26 practices, ambulatory BP in 21 practices and Holter monitors in 10 practices. Responding practices indicated that staff require additional training in 12-lead ECG ($n = 17$), static BP ($n = 3$), ambulatory BP ($n = 11$) and Holter monitors ($n = 8$).

A new extended GP role in cardiology was developed and piloted to enable GPs to diagnose and manage patients with mild to moderate heart failure or atrial fibrillation (AF) and to use diagnostics effectively in primary care.⁷⁷ Training entailed GPs participating in a four-session short course with ongoing clinical supervision. A mixed-methods evaluation found that participating GPs perceived the extended GP role as a professional development opportunity with the potential to reduce health-care utilisation and costs, through a reduction in referrals, while meeting the patient's wishes for the provision of care closer to home. Patient experience of the new GP service was positive.

STEP-UP summary statement With regard to TRAINING, cardiac services is attributed a LOW degree of implementation difficulty owing to the widespread availability of appropriate training and accreditation, although underutilisation of training in basic cardiac equipment remains a concern.

Equipment

A survey of 170 general practices in one cardiac network suggests that the provision of cardiac equipment, and the training of staff in its use, is variable.⁷⁶ Service contract providers included local hospitals and equipment suppliers, while practice nurses are the group of staff most likely to be responsible for the equipment on a day-to-day basis. Following the purchase and installation of equipment, there is a need for appropriate maintenance and training to ensure optimal use and patient safety. Guidance and standards regarding equipment maintenance and training within primary care premises is difficult to identify,⁷⁶ typically being scattered across a range of stakeholder professional association.

With regard to emerging technologies, *Table 12* offers a specific framework assessment for B-type natriuretic peptide (BNP). Implementation of BNP will incur initial expenses including the purchase or hire of the analyser. Quality control issues relate to equipment and the purchase of limited shelf-life reagent strips. The cost of each BNP test is likely to be higher when relatively small numbers of tests are required, and will reduce with volume.⁸⁰ A key source for an evaluation of the BNP POC testing kit is a 2011 Horizon Scanning report.⁸¹

STEP-UP summary statement With regard to EQUIPMENT, cardiac services is attributed a LOW degree of implementation difficulty owing to developments in POC testing and the increased portability of equipment.

TABLE 12 STEP-UP framework assessment for BNP

Description of technology						
BNP involves taking blood from a patient and testing it, often in a GP surgery						
Brief summary of effectiveness/cost-effectiveness in primary care. BNP is produced from heart muscle cells as a pro-hormone (proBNP) and released into the cardiovascular system in response to ventricular dilatation and pressure overload. The pro-hormone is secreted as BNP and NT-proBNP. POC BNP testing devices measure either BNP or NT-proBNP (the latter has a longer half-life). Different models have been identified and evaluated by the Horizon Scanning report						
A systematic review, ⁷⁸ including 12 studies from primary care, found that BNP and NT-proBNP are useful diagnostic tools to identify patients with heart failure in primary care. Results agree with a 2009 HTA report, using individual patient data meta-analysis, when both BNP and NT-proBNP had high sensitivities for diagnosis of heart failure. ⁷⁹ NICE guidelines on the diagnosis of heart failure recommend using BNPs in place of ECG						
Skills						
Not specified						
Training						
Not specified						
Equipment						
Ten studies used TRIAGE BNP test, one study used the ADVIA-Centaur® BNP Assay and one study used the Abbott AxSYM® BNP Microparticle Enzyme Immunoassay ⁷⁸						
Premises						
No details given						
Clinician						
No details given						
Patient						
No details given						
Primary–secondary interface						
Abnormal natriuretic peptides testing should be followed up with referral for echocardiography						
Skills	Training	Equipment	Premise	Clinician	Patient	Primary–secondary interface
⊕	⊕	⊕	∅	⊕	⊕	○
∅, insufficient evidence; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty; BNP, B-type natriuretic peptide; NT-proBNP, N-terminal pro B-type natriuretic peptide.						

Premises

Most aspects of cardiac services have been accommodated in primary care for many years, typically specified for the ‘near patient testing room’.⁴⁶ The implications of equipment purchases such as ECG or echocardiography are reviewed elsewhere (see *Electrocardiography* and *Echocardiography*). This review was not able to identify information on the implications of providing an increased range of cardiac testing facilities in primary care (i.e. BNP), specifically in relation to implications for the premises.

STEP-UP summary statement With regard to PREMISES, cardiac services is attributed an UNCERTAIN degree of implementation difficulty owing to the lack of information on the facilities required.

User perspective

A study in UK general practice examined management of suspected heart failure.⁸² Some GPs requested a full blood count and urea and electrolytes on all of their patients with suspected heart failure. Very few GPs reported sending a patient for echocardiography to confirm a diagnosis of heart failure. Most GPs mentioned the adequacy of facilities as an obstacle to diagnosing and managing patients with heart failure, specifically lack of access to an echocardiogram. Many GPs mentioned poor access to

echocardiography as a barrier to diagnosing patients with suspected heart failure. Those few GPs and practices who admitted to routinely arranging echocardiograms for patients suspected of having heart failure were also more likely to report treating patients with angiotensin-converting enzyme inhibitors.

STEP-UP summary statement With regard to the USER PERSPECTIVE, cardiac services is attributed a LOW degree of implementation difficulty owing to the non-invasive nature of most cardiac tests. However, the non-availability of echocardiology services remains a significant barrier.

Primary–secondary interface

Open-access services (echocardiography, stress testing, Holter monitoring) may simply provide an investigation or add value by providing interpretation and advice.⁸³ Open-access services may be provided either on hospital premises or in partnership with primary care in a community setting and should be quality assured with appropriate governance arrangements and regular systematic audit. An alternative to a primary care-based approach involves using a local NHS trust laboratory. A NHS Improvement report⁸⁴ concludes that this is often a more cost-effective option, citing a likely correlation between the number of tests and the cost per test. Points to consider are the length of time for the results to be returned, the courier service required to transport the samples to the provider, transport difficulties for patients and the importance of a robust service-level agreement.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, cardiac services is attributed a LOW degree of implementation difficulty owing to existing pathways for the management of heart disease and heart failure.

Conclusion

Benefits of a BNP service include rapid results, convenience for patients, early diagnosis and commencement of treatment. Centralising in one agreed location allows one GP practice to serve several surgeries, allowing results to be available within a few days or even on the same day. Benefits include that it is convenient for the patient, it is cheaper than doing the test in individual surgeries, and results may still be available within an acceptable time span (depending on the agreement). This type of service may involve the transportation of samples from or to the testing centre, and this must be factored into planning.

In some parts of the UK, the introduction of BNP has led to increased numbers of echo tests being performed without an increase in true positives. This means that if the test is used indiscriminately, false-positive results may outnumber true positives. A local agreement may help to decide who should order the test or when access to ordering a BNP test is appropriate. A further consideration when calculating costs is that a percentage of those with positive BNP results will require an echocardiogram. The cost of the BNP test will need to be added to the cost of an echocardiogram. Many studies have identified savings with an increase in the number of appropriate referrals once those testing negative had been set on alternative pathways of care. N-terminal pro B-type natriuretic peptide (NT-proBNP) concentrations increase with age in the normal population. Some areas, through collaboration and agreement have introduced age-related 'cut-off' values when deciding which patients to refer for further investigations.

The NHS Improvement Heart Improvement Network has identified examples in the UK where BNP testing has been used as a means of 'rule-out' for echocardiography.⁸⁰ Some documents include economic information and cost analysis for the projects. NICE guidelines on the initial diagnosis of chronic heart failure and referral for echocardiography recommend use of BNP in combination with clinical assessment.⁸⁵ NICE guidelines recommend measurement of serum natriuretic peptides in patients with suspected heart failure without previous myocardial infarction, and those with previous myocardial infarction should be referred for an urgent echocardiogram.⁸⁵ Although several hospital laboratories carry out BNP testing, few return results within a day. POC BNP testing can considerably reduce turnaround time and could lead to earlier initial treatment, more timely referral and less uncertainty for patients. Using POC BNP levels to quickly rule out heart failure could allow more rapid initiation of investigation of other causes of dyspnoea.

A UK HTA carried out a comprehensive systematic review and meta-analysis of all studies comparing the diagnostic accuracy of BNP testing with clinical examination by cardiologists in heart failure in all settings until 2006.⁷⁹ The review included 20 studies on the accuracy of BNP for the diagnosis of clinically defined heart failure. Four studies took place in primary care, one used the POC test and three used laboratory-based tests. These demonstrated a slightly lower sensitivity (84%) but similar specificity (73%). Eight of 16 studies reporting data on the accuracy of NT-proBNP for the diagnosis of clinically defined heart failure were conducted on samples from patients presenting in primary care (pooled sensitivity of 90%, a specificity of 60%). The HTA report also highlighted that the utility of BNP testing will depend on the pre-test probability of chronic heart failure in the patient.⁷⁹ BNP testing would contribute important diagnostic information, as a negative test would reduce the post-test probability. A US technology assessment gave similar results.⁸⁶

A systematic review and meta-analysis of diagnostic accuracy of BNP testing for heart failure in the emergency department, in which 9 of the 11 studies used the Triage system, showed that the ≤ 100 pg/ml cut-off value used in most studies has a sensitivity of 0.93 and a specificity of 0.66.⁸⁷ Two other systematic reviews that included the same studies achieved similar results.^{88,89} However, most studies on the Triage BNP system were performed in a US emergency setting, so cut-off values for primary care may be different.

Although a study investigating the impact of POC NT-proBNP testing with the Cobas h 232 (Roche Diagnostics Limited, Rotkreuz, Switzerland) has yet to be carried out, feedback on its ease of use has been documented.⁹⁰ In this study, the nurses on duty in the coronary care unit, who operated the device, found it simple to learn and handle.

The Horizon Scanning report observes that most published studies have investigated the use of BNP in an emergency department or hospital setting.⁸¹ It concludes that more studies are required on the diagnostic accuracy of POC BNP tests in primary care.

Electrocardiography

Definition: an ECG is a simple test used to check the heart's rhythm and electrical activity (NHS Choices).

This map includes portable ECGs.

This map excludes N/A.

N/A, not applicable.

Contains public sector information licensed under the Open Government Licence v3.0.⁹¹

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

Wireless ECG equipment is easy to use. The challenge with ECG devices of any type lies in interpretation. A systematic review of ECG interpretation accuracy studies found that both physicians and computer software frequently made errors, compared with expert electrocardiographers; however, there was also frequent disagreement in interpretation between experts.⁹² When interpreting ECG studies, it is important to distinguish the effect of using a simpler ECG from the effect of using a non-expert to interpret the trace. Thus, relatively poor results of single-lead ECGs interpreted by GPs were similar to results obtained for 12-lead ECGs when read by GPs.⁹³ In contrast, two studies found high sensitivity and high specificity when a bipolar thumb ECG was read by a cardiologist and a bipolar ECG was read by an experienced GP, respectively.

STEP-UP summary statement With regard to SKILLS, ECG is attributed a LOW degree of implementation difficulty owing to the fact that a large majority of practices have the equipment, although interpretation is variable.

Training

The interpretation of readings from the ECG is included in standard medical and other health-care professional (HCP) training. NICE guidance⁹⁴ notes that skill can be lost in general practice if it is not used frequently, and commissioners should ensure that training on interpretation is offered, linked to local need (the national training cost is quoted to be £105 per person). Some practices may feel that they are too small to develop expertise in ECG interpretation, which may present opportunities for local practices to work together rather than refer to secondary care. In a survey of cardiac equipment use in a cardiac network, a higher proportion of registered nurses than GPs had received formal training in the use of ECG machines, although the interpretation of ECG recordings is predominantly undertaken by GPs rather than by registered nurses.⁷⁶ Most ECG machines have interpretative software, but combining interpretative software with GP interpretation does not improve the sensitivity of diagnosis significantly. The evidence suggests that GPs can detect AF on ECGs accurately, given the appropriate training.⁹⁵

STEP-UP summary statement With regard to TRAINING, ECG is attributed a LOW degree of implementation difficulty owing to the availability of training provision, although many training needs are not fulfilled.

Equipment

A new ECG machine with installation and initial training costs approximately £2000, including value-added tax (VAT).⁹⁴ Increasingly portable ECG machines have become an attractive option. Handheld ECG devices allow ECG readings to be stored on a portable device for review at a later time. Unlike 12-lead ECGs, which require electrodes to be placed on the patient and connected to the ECG, handheld devices have integral electrodes. The Horizon Scanning report⁹⁶ documents devices that can be used very quickly in primary care for screening or in acutely unwell patients, as well as a monitoring device over a period of time. Two devices could be used for screening for AF in the general population.⁹⁷ One is a finger probe similar to that used in general practice for pulse oximetry; the other is a modified BP monitor as used by patients to monitor their BP at home.⁹⁸⁻¹⁰⁰ The latter could be used either by people monitoring their own BP to self-screen for AF or by primary care professionals to opportunistically screen patients. These devices are able to adjust their sensitivity to optimise their value as screening devices.

The AliveCor Heart Monitor and AliveECG apps (Alive Technologies, Ashmore, QLD, Australia) are, respectively, a pocket-sized ECG recorder and a mobile device application for the analysis and communication of the results.¹⁰¹

STEP-UP summary statement With regard to EQUIPMENT, ECG is attributed a LOW degree of implementation difficulty owing to the availability of a wide range of relatively cheap and acceptably accurate equipment that can be matched to clinical need.

Premises

Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ locates ECG in the 'examination/therapy room' (contains public sector information licensed under the Open Government Licence v3.0). In the remaining literature, little detail is available of the premises in which ECGs, portable or not, are to be stored, cleaned or maintained. This corresponds with the findings from the survey of equipment from a UK cardiac network.⁷⁶

STEP-UP summary statement With regard to PREMISES, ECG is attributed an UNCERTAIN degree of implementation difficulty owing to insufficient detail of storage requirements.

User perspective

The ease of use, convenience and portable nature of ECG devices means that their implementation could see a better rate of patient compliance than that for a Holter monitor in patients who use the device for home recordings.¹⁰²

STEP-UP summary statement With regard to USER PERSPECTIVE, ECG is attributed a LOW degree of implementation difficulty owing to ease of use, particularly of wireless devices.

Primary–secondary interface

Excessive delays for cardiac patients waiting for a hospital appointment led Harrow Primary Care Trust (PCT) to establish a mobile cardiac service delivered in community-based settings: in GP surgeries, in community health-care centres and in patients’ homes.¹⁰³ The service used a portable ECG system to automatically store and analyse recorded ECG data using existing computer hardware. The service has reduced waiting times and improved patient care.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, ECG is attributed a LOW degree of implementation difficulty owing to the already-integrated nature of the diagnostic and management pathway.

Conclusion

The overall STEP-UP summary for ECG is presented in *Table 13*. The increasing portability, ease of use and low prices of ECG equipment has led to almost universal diffusion in NHS primary care; therefore, issues relate to choice of the most appropriate equipment for practice needs, including an optimal mix of static and portable equipment. The reduction in the number of leads in ECG systems makes them easier to use and more acceptable to both patient and clinician. Of particular value is the potential for small ECG devices to replace the 24-hour Holter monitor tests. Organisational issues concerning loans of, and maintenance for, equipment to patients may need to be addressed. Similar concerns will relate to ambulatory BP monitoring.

TABLE 13 Overall STEP-UP summary map: ECG (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary–secondary interface
ECG	⊕	⊕	⊕	∅	⊕	⊕	⊕
Systematic reviews	EC20, EC22, EC24, EC26		EC11, EC12, EC20, EC28				
Quantitative studies	EC18		EC3, EC10, EC17, EC19, EC21, EC27		EC15		EC22
Qualitative studies					EC7, EC9		
UK studies		EC16	EC4, EC8, EC10, EC16				EC14
Other significant evidence	EC6	EC16	EC1, EC3, EC5, EC16, EC24, EC29				EC2

∅, insufficient evidence; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.

Echocardiography

Definition: an echocardiogram is a test that uses sound waves to create pictures of the heart. The picture is more detailed than a standard X-ray image. An echocardiogram does not expose the body to radiation.

This map includes portable and fixed echocardiography.

This map excludes other forms of ultrasound (see *Ultrasound*).

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

Echocardiography is pivotal in the management of heart failure as it can make the diagnosis, determine the aetiology and help plan treatment.¹⁰⁴ Community echocardiography is also indicated for heart murmurs, AF and hypertension.¹⁰⁵ An echocardiography service must be integral to a general local plan for heart failure to avoid isolated open-access echocardiography. A UK study comparing community echocardiography with hospital echocardiography found that community echocardiography gave comparable results with traditional hospital echocardiography for LVSD detection and for significant valvular disease detection.¹⁰⁶

STEP-UP summary statement With regard to SKILLS, echocardiography is attributed a MODERATE degree of implementation difficulty owing to difficulties in diagnosis.

Training

Echocardiography should be performed and reported by operators trained to the standards set by the of BSE, that is, they should hold Accreditation in Adult Transthoracic Echocardiography or Adult Community Echocardiography. The BSE has endorsed voluntary accreditation procedures for their members. BSE accreditation in community echocardiography qualifies a GPwSI in standard echocardiography, being equivalent to the BSE adult accreditation process. The provision of echocardiography services, regardless of their setting, must link with staff training and continuing professional development (CPD), which in turn informs workforce planning. In the UK study comparing community echocardiography with community echocardiography, the community echocardiography was performed by a cardiology trained research fellow.¹⁰⁶ The authors identified a need to assess whether or not other HCPs (e.g. nurses) could be trained to successfully to provide similar accuracy with community echocardiography.

STEP-UP summary statement With regard to TRAINING, echocardiography is attributed a MODERATE degree of implementation difficulty owing to the need for an extended period of certificated training.

Equipment

A standard echocardiogram is required for all patients with suspected heart failure and is the required quality standard for Community Echocardiography.¹⁰⁴ The type of study is mainly determined by the clinical question, but also depends on the level of experience of the operator and the type of machine. Standard machines are usually required for standard and advanced studies. Advances in ultrasound technology have led to the development of smaller echocardiography machines that may be transported more easily to different sites in the community. However, studies have not looked at the performance of these smaller echocardiogram machines in community settings where conditions may be different, for example in terms of suitable couches, lighting and lack of an immediate second opinion.

STEP-UP summary statement With regard to EQUIPMENT, echocardiography is attributed a LOW degree of implementation difficulty owing to the ease of use and portability of acceptable devices.

Premises

Community service settings for echocardiography may include mobile units, community hospitals/ diagnostic centres, primary care polyclinics/primary care centres/super surgeries, GP practice surgeries and other appropriate locations such as walk-in facilities or high-street settings. Although the performance of smaller echocardiogram machines in community settings has been found to be comparable with that of larger machines in an acute setting, the conditions may be different, for example in terms of the non-availability of suitable couches and the presence of suboptimal lighting.¹⁰⁶

STEP-UP summary statement With regard to PREMISES, echocardiography is attributed a LOW degree of implementation difficulty owing to the flexibility of locales and settings in which the technology may be administered.

User perspective

A UK qualitative study reports numerous barriers to use of echocardiography in primary care. These include lack of availability of electrocardiography, chest radiography and echocardiography, and lack of confidence in interpreting results. GPs are keen to have access to echocardiography, and, where access is provided, they use it appropriately.⁸² In another qualitative UK study, cardiologists and nurses were more confident in using and interpreting echocardiography reports than GPs¹⁰⁷ but expressed frustration that patients were not routinely referred for echocardiography testing and about the poor quality of referral information.

STEP-UP summary statement With regard to USER PERSPECTIVE, echocardiography is attributed a LOW degree of implementation difficulty owing to the ease of use and lack of an invasive procedure.

Primary–secondary interface

The organisation of services should be based around a BSE-accredited department but organised as a network, avoiding barriers between community and hospitals. Services should extend between hospital and community bases as part of a continuum of care, irrespective of organisational barriers. The service should complement existing hospital-based provision and be integral to the delivery of heart failure services in a health community. The service should be linked to the hospital-based service for second opinions and clinical back-up and to ensure quality assurance.

The favoured model of care is probably the one-stop heart failure clinic, offering diagnosis and initial treatment while liaising with GPs and nurses.¹⁰⁸ A community echocardiography service must always be considered in the context of the whole patient pathway for those with suspected heart failure. The Rapid Access Heart Failure Clinic locates echocardiography within a heart failure one-stop shop linking secondary care-based staff with primary care staff for ongoing care and tertiary staff for specific specialist advice.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, echocardiography is attributed a MODERATE degree of implementation difficulty owing to the need for secondary care support in training, support and referral.

Conclusion

Echocardiography remains a skill that continues to challenge significant numbers of primary care staff, including GPs. Although the administration of the technology is comparatively easy, the challenge lies in the interpretation of the readings. Some GPs may welcome the opportunity to pass on the responsibility for definitive diagnosis and resultant communication to secondary care. Substantive personal and organisational barriers remain in integrating the use of echocardiography into an integrated pathway that spans both primary and secondary care. The STEP-UP summary for echocardiography is presented in *Table 14*.

TABLE 14 Overall STEP-UP summary map: echocardiography (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary–secondary interface
Echocardiography	○	○	⊕	⊕	⊕	⊕	○
Systematic reviews	EH31, EH34						EH24, EH32
Quantitative studies	EH5, EH21, EH22, EH23, EH33		EH8, EH26, EH28, EH29, EH39, EH45		EH13		EH37, EH41, EH43, EH48
Qualitative studies					EH12, EH16, EH20, EH25, EH37, EH47		
UK studies			EH7, EH35				EH37, EH40, EH41
Other significant evidence	EH3, EH17, EH42, EH44	EH3, EH4	EH6, EH7, EH9, EH10, EH11, EH14, EH18, EH26, EH27, EH30, EH35, EH36, EH38, EH46, EH49			EH1, EH2, EH7, EH15, EH19	

○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.

Diabetic services

Definition: tests to establish the presence of diabetes or to monitor the progress of the condition, especially its sequelae relating to eye and foot consequences.

This map includes HbA_{1c}, diabetic retinopathy tests, diabetic neuropathy tests.

This map excludes POC tests of more general use (see *Point-of-care testing*).

HbA_{1c}, glycated haemoglobin.

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

Diabetes is a complicated, multisystem condition. It typically proves a complex condition to integrate into diagnostic testing. However, general practice, in the UK and elsewhere, has extensive experience in managing the condition in a community setting. It is not a considerable extension to include diabetes testing in a primary care-orientated pathway of care. Dipstick tests for microalbuminuria are convenient, but their accuracy is uncertain. An Oxfordshire study compared results of single dipstick tests and sequences of dipstick and laboratory tests with a clinical testing strategy based on current guidelines to assess the accuracy and estimate costs of testing.¹⁰⁹ Testing strategies involving dipstick and laboratory measurements or dipstick tests had similar accuracy. The costs of using dipstick tests were, overall, lower

than laboratory-based testing. The authors concluded that dipstick testing in this study did not reliably identify diabetes patients with microalbuminuria. Although dipstick testing would decrease testing costs, it could either fail to diagnose most patients with microalbuminuria or increase the numbers of patients retested, depending on the dipstick used.

STEP-UP summary statement With regard to SKILLS, diabetic services are attributed a LOW degree of implementation difficulty owing to the existence of recognised pathways and guidance.

Training

Biochemical tests can be diagnostic and often necessary for monitoring metabolic and endocrine diseases, so it is important for GPs to know which tests are useful in a primary care setting and how to interpret these tests and understand their limitations. A GMC core competency is to understand the use and main limitations of tests commonly used in primary care to investigate and monitor metabolic or endocrine disease, for example fasting blood glucose, glycated haemoglobin (HbA_{1c}), urinalysis for glucose and protein, urine albumin-to-creatinine ratio, near-patient testing for capillary glucose, lipid profile and thyroid function tests, and uric acid tests.¹¹⁰ Blood glucose meters are a good example of POC testing, and central to result quality is high-quality training, robust internal quality control, external quality assurance schemes and effective process management.¹¹¹

STEP-UP summary statement With regard to TRAINING, diabetic services are attributed a LOW degree of implementation difficulty owing to the wide availability of training provision.

Equipment

In patients with existing diabetes, HbA_{1c} monitoring is usually performed every 3–6 months. It typically involves a nurse visit or phlebotomist for venepuncture, with follow-up 1–2 weeks later to discuss results. POC testing could provide more immediate therapeutic decisions and result in fewer patient visits.

Typically, the POC HbA_{1c} device uses a finger-stick drop of blood applied to a reagent cartridge, which is then inserted in a desktop analyser, where the analysis is performed, and HbA_{1c} is reported. A prospective controlled trial comparing POC testing and standard laboratory testing in an urban primary care clinic showed that POC testing availability resulted in more frequent intensification of therapy when baseline HbA_{1c} was $\geq 7.0\%$. HbA_{1c} fell significantly in the POC testing group but not in the standard care group.¹¹²

STEP-UP summary statement With regard to EQUIPMENT, diabetes services are attributed a LOW degree of implementation difficulty owing to the increasing availability of POC tests and other portable equipment.

Premises

Health Building Note 11-01, *Facilities for Primary and Community Care Services*, locates near-patient testing services in the near-patient testing room.⁴⁶ No specific detail was identified relating to the implications of storage and maintenance of increasing numbers of POC tests.

STEP-UP summary statement With regard to PREMISES, diabetic services is attributed an UNCERTAIN degree of implementation difficulty owing to insufficient detail on storage and stock maintenance requirements.

User perspective

Diagnostics for diabetes can include POC testing, screening for diabetic retinopathy and a variety of tests for specific diabetes-associated disorders. A survey by the MaDOx (Monitoring and Diagnosis in Oxford) team found that the majority of UK clinicians would like to use POC devices for HbA_{1c} testing,¹¹³ but the reasons for their low uptake are unclear. In England, routine diabetes care and diabetic retinopathy screening (DRS) are principally managed in primary care, whereas treatment for retinopathy takes place in secondary care. Patients appear to confuse routine retinal photography at optometry practices during eye

examinations with DRS.¹¹⁴ The same study observed differences between patients screened at GP and those screened at optometrist practices, identifying that ease of making an appointment, including its time and navigating home after the mydriasis drops, etc., appeared less problematic at GP practices.

STEP-UP summary statement With regard to USER PERSPECTIVE, diabetic services are attributed a LOW degree of implementation difficulty owing to accepted pathways and standards of care.

Primary–secondary interface

Initiatives to break the reported primary–secondary divide in diabetes care include a West Sussex initiative in which services have been redesigned so that the primary care diabetes specialist nurses are employed by the PCT and work with nurses and GPs in general practice, but are based at the secondary care diabetes centre.¹¹⁵ This model of care has enabled the primary care diabetes specialist nurses to function as part of the wider diabetes team, which encompasses all primary and secondary care clinicians, while not being isolated from their secondary care colleagues.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, diabetic services are attributed a LOW degree of implementation difficulty owing to the existence of integrated pathways across primary–secondary care, notwithstanding the continuing ‘divide’ in some circumstances.

Conclusion

Diabetic services has a long tradition of being delivered as a two-tier service across the primary–secondary interface. The distinction is becoming increasingly blurred, as is the case for cardiac services (as described earlier). In examining these technologies it is most important to first define the optimal management pathway and then decide where to locate the various diagnostic interventions. A key consideration, therefore, is the existence of guidelines that make the basis for intervention, and for specific roles, manifestly clear for both patients and clinicians. *Table 15* presents the STEP-UP summary map for diabetic services.

TABLE 15 Overall STEP-UP summary map: diabetic services (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary–secondary interface
Diabetic services	⊕	⊕	⊕	∅	⊕	⊕	⊕
Systematic reviews			D1, D8, D22, D26, D30				
Quantitative studies	D24		D3, D7, D14, D16, D17, D18, D25			D21	D10
Qualitative studies			D2, D7		D9	D6, D9, D29	
UK studies	D28		D11			D29	D11
Other significant evidence	D12, D19, D23, D32	D27, D31	D13, D15, D20, D33, D34				D4, D5

∅, insufficient evidence; ⊕, low degree of implementation difficulty.

Endoscopy

Definition: an endoscope is a long, thin, flexible tube that has a light source and a video camera at one end. Images of the inside of the body are relayed to a television screen. Endoscopes can be inserted into the body through a natural opening, such as the mouth and down the throat, or through the anus (NHS Choices).

This map includes flexible sigmoidoscopy.

This map excludes colonoscopy.

Contains public sector information licensed under the Open Government Licence v3.0.¹¹⁶

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

Many GPwSIs in gastroenterology will probably have developed skills or expertise in endoscopy during their hospital training. Competent GPs should be able to demonstrate that they have sufficient skills to ensure the safe and effective practice of adult endoscopy. Endoscopy procedures in primary care are typically performed on a selected population of otherwise fit patients, making comparison with secondary care unhelpful and irrelevant. A 2015 systematic review of the safety, competency and cost-effectiveness of nursing staff providing GI endoscopy services, although not examining a primary care context, reported the collective experiences of nurses working in metropolitan areas under the strict supervision and guidance of a specialist gastroenterologist.¹¹⁷ Nurse endoscopists were less cost-effective per procedure at year 1 than services provided by physicians, due largely to the increased need for subsequent endoscopies, specialist follow-up and primary care consultations. However, the studies clustered between 1999 and 2001, making applicability problematic.

STEP-UP summary statement With regard to SKILLS, endoscopy in primary care is attributed a HIGH degree of implementation difficulty owing to the range of skills and competencies required, the risk of serious consequences and the time taken to acquire requisite competencies.

Training

Training for endoscopy is regulated by the Joint Advisory Group on Gastroenterology (JAG). All training must take place at JAG-approved units. Initially, all practitioners have to attend a formal training course (a JAG-compliant course) in that particular procedure. In addition, the GP should have knowledge of the 15 endoscopy workforce competencies that pertain to a primary care setting. In 2002, 96% of GPs performing endoscopy had undergone training in, and continued to work in, a consultant-led endoscopy unit.¹¹⁸ The same survey concluded that simple diagnostic endoscopies could be performed safely in the primary care setting, leaving secondary care units to concentrate on patients requiring sedation, those who are acutely ill and those who require therapeutic procedures.¹¹⁸ Primary Care Society for Gastroenterology guidelines suggest that no unit should offer fewer than 200 cases of any flexible endoscopy per year and the endoscopist should have continuing association with a secondary care unit for a wider exposure to case mix. Although the accreditation of a practitioner as fit to provide endoscopy services is outlined by JAG, providing endoscopy services goes beyond this and requires fulfilment of the formal GPwSI accreditation process. Support for endoscopy in primary care may be achieved through active membership of a professional society, such as the Primary Care Society for Gastroenterology or the British Society of Gastroenterology.

STEP-UP summary statement With regard to TRAINING, endoscopy in primary care is attributed a MODERATE degree of implementation difficulty owing to the availability of courses, the clear definition of

a curriculum, the existence of specialist groups and the variety of training methods available that mitigate, to some degree, the wide range of skills and competencies required.

Equipment

Endoscopy 'incurs significant cost through its high usage rate of consumables coupled with significant capital costs (eg, endoscope systems)'.¹¹⁹ When endoscopy is performed in a setting outside a hospital unit, such as a cottage hospital, diagnostic and treatment centre or GP surgery, the facilities, staffing and equipment should be of the same quality. In 1994, a specification was produced for an endoscopy unit.¹²⁰ This included upper GI endoscopes and a fibre sigmoidoscope, a light source, a procedure trolley, an endoscopy trolley, three suction machines, an automated washing machine and three pulse oximeters. Anaesthetic and resuscitation facilities must be provided on site for the management of sedated patients. Adequate equipment must be available, together with safe facilities for its cleaning and maintenance. Cleaning and decontamination of endoscopes should comply with British Society for Gastroenterology (BSG) and Control of Substances Hazardous to Health (COSHH) guidelines.¹²¹ The BSG has published recommendations in a report on aldehyde disinfection and health in endoscopy units.¹²² Glutaraldehyde is most commonly used for disinfection of flexible GI endoscopes, and it is toxic, an irritant and allergenic.

STEP-UP summary statement With regard to EQUIPMENT, endoscopy in primary care is attributed a HIGH degree of implementation difficulty owing to the capital costs of purchase, the expense of consumables, the precautions required for cleaning and maintenance and the risks associated with glutaraldehyde.

Premises

Requirements for an endoscopy unit, typically based in an acute hospital, are outlined in Health Building Note 52¹²³ and in the *Users Guide to Achieving a JAG Compliant Endoscopy Environment*.¹²⁴ Similarly, guidelines from the World Endoscopy Organization specify design principles for a digestive disease endoscopy unit. Health Building Note 11-01, *Facilities for Primary and Community Care Services*, suggests that 'most invasive procedures and certain procedures using rigid endoscopes can take place in a generic treatment room' (contains public sector information licensed under the Open Government Licence v3.0).⁴⁶ Endoscopy needs to be practised in a purpose-designed area with adequate space and easy accessibility. Instruments, their accessories, monitoring equipment and all the necessary drugs need to be readily to hand. The standards of care in purpose-built, well-equipped primary care premises need not fall noticeably short of those in a general hospital, particularly when staff are well trained and experienced in endoscopy. Endoscopy should be performed in a unit that complies with the JAG guidelines for safe endoscopy. In general practice any endoscopy facility is likely to be used for multiple purposes, but due consideration must be given to the care, storage and security of endoscopy equipment.

STEP-UP summary statement With regard to PREMISES, endoscopy in primary care is attributed a HIGH degree of implementation difficulty owing to the high capital costs of specific accommodation for equipment and the requirements to provide a safe environment for operation of the equipment and for cleaning.

User perspective

Consumer preference is frequently cited as a major driver for a move towards primary care endoscopy services. However, the public is relatively poorly informed of the risks, precautions and the importance of staff training and experience as they contribute to safe endoscopy. Endoscopy procedures should be performed to recognised levels of safety and accuracy, ensuring patient comfort and satisfaction. The lack of severe symptoms, fear of pain, concerns of sedation, comorbidity and competing life demands have been reported by patients as barriers to performing an endoscopic investigation.¹²⁵

In a qualitative study of UK ethnic groups, focus groups were used to explore barriers to the uptake of flexible sigmoidoscopy screening among UK ethnic minority populations. Common barriers across all ethnic groups were anxiety regarding the invasiveness of the test, the bowel preparation and fear of a cancer diagnosis.¹²⁶

STEP-UP summary statement With regard to the USER PERSPECTIVE, endoscopy in primary care is attributed an assessment of UNCERTAIN, given that attitudes of patients and staff to endoscopy in primary care are not well explored.

Primary–secondary interface

Hospital-based endoscopy depends largely on highly trained specialists. These specialists have acquired a wider clinical knowledge of gastroenterology over and above simple endoscopic interpretation. Conflicts of access and perceived vested interest are best resolved by improving communication between GPs, specialists, patient groups, purchasers and provider units. Alternatives to a GP-based community service include greater open access to hospital facilities by GPs and outreach clinics performed by hospital-based consultants in community hospitals or individual/group practices.¹²⁷

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, endoscopy in primary care is attributed a MODERATE degree of implementation difficulty given existing working relationships with secondary care but the need to refer more serious or complex cases to an acute hospital setting.

Conclusion

The potential to offer endoscopy in primary care has been long recognised and it may make an important potential contribution to the disease management pathway. It no longer holds the high level of risk that it was once perceived to have. Developments in more flexible diagnostic tools have helped to make it easier to conduct. It continues to occasion fear among patients, particularly those who are older and female. The physical requirements for the premises, for example for disinfection and storage of the equipment, may be prohibitive in an ordinary-sized general practice. However, these requirements may more easily be accommodated in purpose-built clinics or community hospitals. *Table 16* presents the overall STEP-UP summary map.

TABLE 16 Overall STEP-UP summary map: endoscopy (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary–secondary interface
Endoscopy	⊗	○	⊗	⊗	∅	⊗	○
Systematic reviews	En33, En40		En7, En21, En41				En41
Quantitative studies	En4, En12, En31	En35, En39	En6, En8, En9, En10, En13, En20, En23, En30				En37, En38, En42
Qualitative studies					En22, En34	En3, En28, En34	
UK studies	En4, En16	En15	En8, En9, En10, En13, En14, En20, En23, En30, En32				En27, En32
Other significant evidence	En1	En2, En11, En15, En18	En14, En19, En29, En43	En17, En24, En26			En5, En25, En36

∅, insufficient evidence; ⊗, high degree of implementation difficulty; ○, moderate degree of implementation difficulty.

Genetic testing

Definition: genetic testing is a type of medical test that identifies changes in chromosomes, genes or proteins. The results of a genetic test can confirm or rule out a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder.

This map includes testing for inherited genetic conditions and for genetic risk factors indicating a predisposition to particular conditions, for example cardiac conditions.

This map excludes newborn heel screening.

Definition is public domain information reproduced from US National Library of Medicine: Genetics Home Reference.¹²⁸

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

Skills for genetic testing relate to understanding which patients to test, what tests to order and how to interpret the results of these genetic tests. Importantly, they also require being able to handle the counselling and communication issues associated with testing and the test result.¹²⁹ A Dutch survey¹³⁰ of knowledge of genetics and genetic tests revealed general levels to be poor, with GP knowledge being poorer than that of paediatricians and gynaecologists.

STEP-UP summary statement With regard to SKILLS, genetic testing is attributed a HIGH degree of implementation difficulty owing to inadequate knowledge of genetics, challenges in interpretation and the need for skills in communicating and handling the outcome of the test.

Training

Generally, primary care practitioners receive minimal training in clinical genetics. Various methods are required to support practitioners to develop these genetic skills and knowledge, including changes to the undergraduate curriculum. The empirical evidence of the learning needs of practitioners in relation to genetic testing reveals widespread deficits in knowledge and skills, and low confidence levels. Skills-based training, clinical scenarios and assessment have all been identified as factors that can promote learning.

Primary care providers are interested in learning more about who should receive genetic testing and what tests are available. Educational efforts should build on primary care providers' prior knowledge base, highlight the clinical relevance of genetic medicine to primary care practice and emphasise red flags: cues to alert primary care providers to a potential genetic contribution.¹³¹ Nurses are on the front line and are expected to recognise patterns of disease that may indicate a possible genetic link, educate the family about the implications of a potential genetic susceptibility and refer the family for counselling. Many studies of nurses' knowledge of genetics reveal gaps in professional competence and/or education.¹³² The authors suggested that each nurse should, thus, acquire a minimum basic knowledge of genetics.¹³³

STEP-UP summary statement With regard to TRAINING, genetic testing is attributed a MODERATE degree of implementation difficulty owing to the need to receive significant training and ongoing support in offering genetic services.

Equipment

Genetic testing is expensive and time-consuming, given the sheer scale of the genes that need to be examined. However, the development of direct-to-consumer testing is likely to reduce this financial burden. A systematic review of genetic tests in primary care was published in 1999.¹³⁴ This mapping review

has been unable to find a more recently published review. Specific searching for such a systematic review is recommended before considering whether or not to commission further work.

STEP-UP summary statement With regard to EQUIPMENT, genetic testing is attributed a LOW degree of implementation difficulty owing to increasing numbers of direct-to-consumer POC tests.

Premises

The mapping review was unable to identify any items that specifically described requirements to house genetic testing facilities in general practice or community premises. Health Building Note 11-01, *Facilities for Primary and Community Care Services*, locates near-patient testing services (such as blood and gas) in the 'near-patient testing room' (contains public sector information licensed under the Open Government Licence v3.0).⁴⁶ This Health Building Note does not provide detailed design guidance on specific rooms and spaces. It is unclear what tests should be provided and what the implications are with regard to the management of stock.

STEP-UP summary statement With regard to PREMISES, genetic testing is attributed an UNCERTAIN rating for implementation difficulty owing to the shortage of studies describing how tests might be accommodated. Co-ordinated approaches with regard to storage may relate to POC tests.

User perspective

Concerns are expressed about potential harm from the inappropriate use of genetic testing. It is believed that primary care practitioners are reluctant to adopt responsibility for genetic testing. In a survey of family physicians, respondents felt that genetic tests would be more useful for breast cancer and haemochromatosis than for Alzheimer's disease, heart disease or diabetes. Individuals who believed themselves more familiar with genetic tests were more likely to anticipate that genetic testing would impact significantly on their future practice.¹³⁵

The findings from qualitative studies of patient viewpoints report misunderstandings concerning genetic tests, for example that genetic tests are more predictive than they actually are, and that they are predictive of behaviours for which no markers have in fact yet been discovered.¹³⁶ A qualitative study of genetic testing for risk of coronary heart disease found that the test was acceptable.¹³⁷ The findings from qualitative studies of provider viewpoints report that cost of testing consistently appears as the most frequently cited barrier to genetic testing.¹³⁸⁻¹⁴⁰

STEP-UP summary statement With regard to USER PERSPECTIVES, genetic testing has LOW implementation difficulty for patients and MODERATE difficulty for clinicians, because patients already have access to direct-to-consumer genetic tests but GPs are cautious about the ramifications of interpretation.

Primary–secondary interface

Studies in the UK have evaluated community genetic counsellors acting as outreach workers¹³⁴ from the genetics clinic to liaise with local general practices. Such practitioners are either genetic nurses¹⁴¹ or genetic counsellors, and they can fulfil a dual role of filtering referrals to the geneticist and providing basic genetic information.¹⁴²

Genetic nurse counsellors, specifically in a cancer genetics context, were found to perform not significantly differently from conventional cancer genetic services in two RCTs in Scotland and Wales.¹⁴³ The development of primary care specialists, possibly working in conjunction with community genetic counsellors, has been suggested to offer an intermediate point of referral between general practice and specialist genetic clinics.¹⁴²

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, genetic testing is attributed a MODERATE degree of implementation difficulty owing to a high dependence on secondary care expertise, support and follow-up provision.

Conclusion

Because of the uncertainties around the benefits and harm from genetic testing, the clinical implications of a specific genetic test will require careful evaluation, including information about cost-effectiveness, before widespread adoption is recommended.¹⁴² With thousands of tests being developed it is important to ensure that these are matched to meaningful intervention. Rather than focusing on the organisation and service delivery of specific individual tests, the priority is to organise services that can adapt to emerging technologies, their interpretation and their implications for patient support and counselling. *Table 17* presents the STEP-UP summary map for genetic testing.

Magnetic resonance imaging

Definition: MRI is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body (NHS Choices).

This map includes portable MRI and (exceptionally for this review) commercial service provision.

Contains public sector information licensed under the Open Government Licence v3.0.¹⁴⁴

TABLE 17 Overall STEP-UP summary map: genetic testing (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary-secondary interface
Genetic testing	⊗	○	⊕	∅	○	⊕	○
Systematic reviews		G15	G3				
Quantitative studies	G1, G2, G7, G25, G28, G33, G58, G63, G71	G16, G25, G51, G52, G53	G21		G6, G23, G31, G58, G71	G40, G78	G1, G4, G63
Qualitative studies		G55, G70			G6, G13, G27, G46, G43, G47, G48, G49, G56, G57, G62, G65, G69, G74, G76, G79	G5, G11, G64, G69	G13, G69
UK studies	G30, G67	G22	G60, G73		G23, G47, G48, G54, G59, G66, G75	G71, G75, G78	G71
Other substantive evidence	G7, G8, G9, G14, G35, G67	G12, G17, G18, G19, G26, G37, G38, G45, G61, G72	G4, G24, G29, G32, G34, G39, G42, G44, G50, G77		G34, G35, G36, G41		G10, G20, G34, G68

∅, insufficient evidence; ⊗, high degree of implementation difficulty; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

To provide a MRI service requires that staff undertake sufficient current MRI practice and a sufficient number of examinations to maintain competency in every area of MRI. Staff interpreting the images and providing a clinical report should fulfil the following requirements:¹⁴⁵

- Be a UK-registered radiologist on the GMC Specialist Register undertaking sufficient current clinical practice in that modality. A consultant radiologist must have undertaken planned regular clinical MRI sessions in their current job plan.
- Be a radiographer currently registered with the Health and Care Professions Council and have performed regular sessions of MRI examinations within the last 12 months.
- Have a minimum of 1 year's experience.
- Maintain their CPD in accordance with their professional body guidelines.
- Meet the specification set out in the *National Occupational Standards for Imaging* (RD5: produce MRI images for diagnostic purposes).¹⁴⁵

STEP-UP summary statement With regard to SKILLS, MRI is attributed a MODERATE degree of implementation difficulty owing to its requirements in terms of experience and training.

Training

The BSCMR has endorsed voluntary accreditation procedures for their members. These have no statutory role but are provided to allow both medical and non-medical practitioners to demonstrate a specified level of experience in an appropriate educational environment. In the case of MRI, the BSCMR and the British Society for Cardiac Imaging support the criteria developed by the US-based Society for Cardiovascular Magnetic Resonance and do not separately accredit individuals.

STEP-UP summary statement With regard to TRAINING, MRI is attributed a MODERATE degree of implementation difficulty owing to the ongoing need for professional development and updating.

Equipment

Magnetic resonance imaging has entered common use as part of the standard equipment portfolio over the last 10–15 years. The following are commissioned requirements for MRI equipment that should be met or exceeded: fixed or mobile units shall contain one full-body MRI scanner with a magnetic strength of at least 1.5 Tesla; complies with the *Safety Guidelines for Magnetic Resonance Equipment in Clinical Use*¹⁴⁶ as updated; and is superseded and replaced from time to time.

STEP-UP summary statement With regard to EQUIPMENT, MRI is attributed a HIGH degree of implementation difficulty owing to the prohibitive cost of an installation.

Premises

There is no specific provision for MRI in Health Building Note 11-01, *Facilities for Primary and Community Care Services*.⁴⁶ Commissioners will need to consider mobile or static sites. All facilities, including mobile units, are required to have a minimum of a patient reception and waiting area either on the unit or nearby, access to a toilet and access to appropriate levels of security. We found no specific guidance on housing MRI units in primary care.

STEP-UP summary statement With regard to PREMISES, MRI is attributed a HIGH degree of implementation difficulty owing to the exacting requirements for facilities and supplies.

User perspective

Because MRI equipment is typically housed in secondary care, we were unable to find qualitative research relating to attitudes to MRI specifically in a community setting. Items on perspectives of MRI provided by acute hospitals from GPs and their referred patients would indirectly inform this issue. However, these will require a supplementary search strategy.

STEP-UP summary statement With regard to USER PERSPECTIVE, MRI is attributed an UNCERTAIN degree of implementation difficulty owing to the shortage of published experience on MRI in a primary care context.

Primary–secondary interface

A MRI service needs to work with other providers to offer an integrated service. Key to the successful integration of MRI services is consideration of the management pathway, irrespective of which facilities are located in the primary or secondary sectors of local health service provision. The London NHS Diagnostic Service was established by the InHealth Group in 2007 following competitive tendering.⁵¹ Local PCTs and federated general practice groups utilise the service, which charges for imaging services including ultrasound, plain film and MRI at standard tariff costs. This popular model of service delivery avoids the heavy capital expenditure required for purchasing the MRI equipment.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, MRI is attributed a MODERATE degree of implementation difficulty owing to the dependence on secondary care support facilities and/or commercial providers.

Conclusion

Ultimately, MRI provision did not meet the criteria for this review in terms of services and staff managed in a primary care setting. The most common model was of service provision under contract by an external provider. This sidesteps many of the considerations from the STEP-UP framework, for example training and equipment, except from a commissioner and quality assurance customer perspective (*Table 18*). The implications of offering MRI services have not been explored and represent a potential line of future exploration.

TABLE 18 Overall STEP-UP summary map: MRI (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary–secondary interface
MRI	○	○	⊗	⊗	∅	∅	○
Systematic reviews							M17
Quantitative studies			M2				M5, M6, M8, M9, M12, M18, M20, M22, M23, M24
Qualitative studies							
UK studies			M2				M12, M18, M21, M22
Other significant evidence	M4		M1, M3, M7, M14	M16			M10, M11, M13, M15, M19

∅, insufficient evidence; ⊗, high degree of implementation difficulty; ○, moderate degree of implementation difficulty.

Point-of-care testing

Definition: POC testing is defined as any analytical test performed for an individual by a HCP outside the conventional laboratory setting.¹⁴⁷

This map includes CRP, D-dimer, faecal occult blood, haemoglobin, HbA_{1c}, Infectious disease testing, INR, lipid profiles, nose/throat swab for influenza, platelet count, procalcitonin biomarkers, quantitative β -human chorionic gonadotropin, throat swab for group A streptococci, urine albumin–creatinine ratio, urine leucocytes or nitrite, urine pregnancy test, urine strips and whole-blood lactate.

This map excludes BNP (see *Cardiac services*), blood glucose, HbA_{1c} (see *Diabetic services*), cholesterol screening, pregnancy tests and respiratory POC tests (see *Respiratory tests*).

CRP, C-reactive protein.

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

To practise competently, users of POC testing equipment must have the knowledge and skills for safe and effective practice when working without direct supervision; they must recognise and work within the limits of competence, keeping knowledge and skills up to date, and take part in appropriate learning and practice activities that maintain and develop their competence and performance.¹⁴⁸

Standard operating procedures would include clinical governance, risk management and also implementation of risk reduction strategies. This would be achieved by careful patient selection, internal and external quality control procedures, a regular audit process, and ensuring relevant, complete and accurate documentation of the clinic process.

The internal quality control supplied by the manufacturer should be performed at the start of each clinic, and external quality assurance, provided either by collaboration with a hospital laboratory or through a quality assurance scheme, such as the National External Quality Assessment Service, should be performed regularly.

STEP-UP summary statement With regard to SKILLS, POC tests are attributed a MODERATE degree of implementation difficulty owing to the exacting requirements for quality assurance.

Training

Training of health professionals to manage POC testing should include an understanding of the specific POC device used, setting up and using the device, recording of results and quality assurance materials, health and safety, disposal of sharps, and the COSHH regulations.¹²¹

STEP-UP summary statement With regard to TRAINING, POC tests are attributed a MODERATE degree of implementation difficulty owing to the need to identify which to use, what they mean and how to integrate them into existing clinical practice.

Equipment

As with all in vitro diagnostic equipment, new POC equipment should be thoroughly evaluated prior to clinical implementation to ensure that reliable results are consistently obtained.¹⁴⁹ In the UK, this is performed on a voluntary basis at the manufacturers' discretion by the Medicines and Healthcare products Regulatory Agency (MHRA) of the Department of Health. Calibration should be performed by the

manufacturers, using the same procedure as conventional laboratory systems. Calibration as performed by the manufacturers typically cannot be altered by the operator. New POC coagulometers are currently under evaluation with the MHRA and will have further field evaluations in the primary care setting.¹⁵⁰ A Cochrane review concluded that a POC biomarker to guide antibiotic treatment of acute respiratory infections in primary care can significantly reduce antibiotic use.¹⁵¹

An illustrative STEP-UP framework assessment, for C-reactive protein (CRP), is given in *Table 19*.

STEP-UP summary statement With regard to EQUIPMENT, POC testing is attributed a LOW degree of implementation difficulty owing to the ease of testing and ready availability of equipment and supplies.

Premises

Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ locates near-patient testing services (such as blood and gas) in the 'near-patient testing room' (contains public sector information licensed under the Open Government Licence v3.0). This document does not provide detailed design guidance on specific rooms and spaces and refers to the following for guidance on generic rooms

TABLE 19 STEP-UP framework assessment for CRP

Description of technology						
CRP is a protein in the blood that can quickly be measured from a finger-prick blood sample using a POC test. When CRP is low in acute exacerbations of COPD, patients are unlikely to benefit from antibiotics						
Brief summary of effectiveness/cost-effectiveness in primary care						
Cochrane review concluded that CRP, to guide antibiotic treatment of acute respiratory infections in primary care, can significantly reduce antibiotic use. ¹⁵¹ A major HTA trial (the PACE study) is currently under way and due to report in June 2018 ¹⁵²						
Skills						
No details available – unlikely to be complex – requirement for quality control						
Training						
No details available – unlikely to be complex – requirement for knowledge on interpretation and practical application						
Equipment						
Simple POC test requiring only a finger-prick sample. Also analysis equipment						
Premises						
No evidence for impact on premises						
Clinician						
Interviews with 20 clinicians to gather in-depth feedback on use of the test, will help plan general uptake should the CRP POC test prove worthwhile (PACE study protocol) ¹⁵²						
Patient						
Interviews with 20 patients to gather in-depth feedback on use of the test, which will help plan general uptake should the CRP POC test prove worthwhile (PACE study protocol) ¹⁵²						
Primary–secondary interface						
Implications unclear at present; potential to reduce antibiotic administration						
Skills	Training	Equipment	Premise	Clinician	Patient	Primary–secondary interface
○	○	⊕	∅	⊕	⊕	∅
∅, insufficient evidence; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.						

and spaces: Health Building Note 00-03, *Clinical and Clinical Support Spaces*.¹⁵³ It is unclear what tests should be provided and what the implications are with regard to the management of stock.

STEP-UP summary statement With regard to PREMISES, POC testing is attributed an UNCERTAIN rating for implementation difficulty owing to the shortage of studies describing how tests might be accommodated. Co-ordinating approaches with regard to storage may relate to genetic tests.

User perspective

Paradoxically, the greater the ease with which tests might be severed from existing secondary care domination of supply by primary care services, the correspondingly greater the likelihood of these tests bypassing primary care altogether, by going direct to consumer. GPs with different levels of experience of using diagnostic POC tests had similar perceptions that they would help to reassure patients and lead to more effective targeted treatment without alienating or upsetting patients.¹³ Overall, primary care clinicians believed that POC tests increase diagnostic certainty, help target treatment, educate and empower patients, and improved the relationship between clinicians and patients by enhancing communication and shared decision-making.¹³ Clinicians were also concerned about cost, over-reliance (in that POC tests could undermine clinical skills) and limited usefulness. Some issues are not unique to POC tests, but also apply to laboratory testing in general. In addition to the barriers to POC test use identified here, other reasons for lack of widespread use may include lack of needs assessments of primary health-care clinicians, resulting in discordance between the tests that they want/would use frequently, and those that are produced. A published review¹³ focused on blood POC tests in primary care, so further research is needed to confirm whether or not the issues raised here apply to other types of POC tests.

STEP-UP summary statement With regard to USER PERSPECTIVES, attitudes to POC testing between patients and clinicians differed, resulting in a MODERATE rating for implementation difficulty for clinicians and a LOW rating for implementation difficulty for patients.

Primary–secondary interface

In seeking to reduce variation, some PCTs are commissioning laboratories to provide a satellite service from the central laboratory to primary care sites. Testing in primary care reduces the dependency of primary care clinicians on hospital-based services, many of which are outside their own control.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, POC testing is attributed a MODERATE degree of implementation difficulty, as it may facilitate earlier diagnosis but has a potentially unpredictable effect on demand for secondary care services.

Conclusion

Evidence so far indicates that POC testing systems have great potential for primary care with clear quality-of-life benefits for patients. *Table 20* presents the overall STEP-UP summary map. The implementation of POC testing technologies requires collaboration between manufacturers, pathology laboratories and general practice, as well as adherence to a recognised external quality assurance scheme. Diagnostic technologies need to improve both accuracy and precision.

The increased availability of a test is likely to increase the usage of that test. Increased use may indicate previously unmet need, constitute an inappropriate response or simply reflect a growth in demand. In practices where desktop analysers are introduced, the rate of testing increases, but these extra tests do not inform changes in diagnosis or management.¹⁵⁴ However, such studies often fail to acknowledge the effect of tests in reducing the uncertainty experienced by both doctor and patient.

From the perspective of GPs, likely benefits of introducing POC tests include increased diagnostic certainty, more efficient care and fewer (re)consultations.¹³ Barriers to the implementation of POC tests must be addressed, some by primary care and others elsewhere. The accuracy of POC tests in primary care populations must be addressed by manufacturers. Policy-makers and clinicians should carefully consider the

TABLE 20 Overall STEP-UP summary map: POC testing (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary–secondary interface
POC testing	○	○	⊕	∅	○	⊕	○
Systematic reviews	P23		P2, P10, P17, P22, P37, P38, P39, P44, P52		P26		
Quantitative studies	P7, P11, P18, P31, P32, P40, P45, P60	P48	P3, P5, P15, P19, P24, P27, P30, P31, P33, P40, P41, P45, P51, P58		P12	P9, P29, P45, P53	P18, P47, P60
Qualitative studies					P6, P8, P59	P57, P59	
UK studies	P11		P41			P29	
Other substantive evidence	P20, P56	P4, P28, P36, P55	P1, P4, P14, P16, P21, P25, P30, P34, P35, P42, P43, P46, P49, P50, P52, P54, P56				P13

∅, insufficient evidence; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.

role and impact of POC tests in primary care in relation to GP roles. Against a backdrop of reductions in health service funding, attention must be paid to how POC tests are to be funded.¹³

Radiology/X-ray

Definition: an X-ray is a quick and painless procedure commonly used to produce images of the inside of the body (NHS Choices).

This map includes chest X-ray and partial CT scanning.

This map excludes echocardiography and MRI.

CT, computed tomography. Contains public sector information licensed under the Open Government Licence v3.0.¹⁵⁵

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

Radiology is a well-documented profession with well-developed education, training and curricula. For example, the Royal College of Radiologists (RCR) produces a Specialty Training Curriculum for Clinical Radiology.¹⁵⁶ Training must include the equipment and its intended application. It will also include related topics such as health and safety, radiation protection and control of infection.¹⁵⁷ RCR guidance for clinical radiographers emphasises quality assurance issues. It would be challenging for a small radiological unit based in primary care to achieve the adherence to standards and quality control required by a fully-established radiological department.

STEP-UP summary statement With regard to SKILLS, radiology/X-ray is attributed a MODERATE degree of implementation difficulty due to the need to satisfy the expectations created by the curriculum and quality assurance procedures.

Training

Patients should have timely access to appropriate imaging provided by a service with proven clinical governance structures in place, by appropriately trained staff using appropriately maintained equipment, with underlying compliant '24/7' information technology (IT) support. Comprehensive clinical imaging services in the NHS provide patients, GPs and other referrers and commissioners with direct access to essential core services. The quality of any clinical service can be judged by patient outcomes, patient safety, patient and user experience and efficiency. The RCR and the Society and College of Radiographers (SCoR) have developed the Imaging Services Accreditation Standard (ISAS) and the associated accreditation scheme. Patients, GPs, referrers and commissioners can be assured that ISAS-accredited services are delivering the highest quality of services.

STEP-UP summary statement With regard to TRAINING, radiology/X-ray is attributed a HIGH degree of implementation difficulty owing to extensive and specialist training requirements.

Equipment

One study in primary care reports that patient management by the GP changed in 60% of patients following chest X-ray. Chest X-ray substantially reduced the number of referrals and initiation or change in therapy, and more patients were reassured by their GP. This confirms that chest X-ray is an important diagnostic tool for GPs.¹⁵⁸

STEP-UP summary statement With regard to EQUIPMENT, radiology/X-ray is attributed a LOW degree of implementation difficulty owing to established practices and procedures for using X-ray equipment.

Premises

An imaging cluster will require such facilities as X-ray rooms, image control/reporting rooms and changing rooms. These facilities should be clustered together, alongside other dedicated imaging rooms, where provided.¹⁵⁹ Rooms have to meet the requirements of the Ionising Radiations Regulations 1999,¹⁶⁰ which have much stricter limits than earlier regulations on radiation exposure to the public from man-made sources of radiation.

STEP-UP summary statement With regard to PREMISES, radiology/X-ray is attributed a MODERATE degree of implementation difficulty owing to the need for accommodation with radiation protection and shielding.

User perspective

When ordering radiological tests, clinicians in primary care consider such factors as the potential impact on the clinical outcome for the patient, the probability of significant findings based on the clinical picture and the sensitivity/specificity of the test. Urgent cases in which the report has an impact on the immediate management of the patient need to be reported at the time of examination and to be made available to the referrer. All reports should be communicated electronically via a reporting system that can push both

key images and the report directly into the patient management system. The timeliness of test, and then the result, is thus a key question for patients when they are referred for an imaging test.

STEP-UP summary statement With regard to USER PERSPECTIVES, radiology/X-ray is attributed a LOW degree of implementation difficulty owing to the familiarity of X-ray arrangements.

Primary–secondary interface

The Department of Health has been seeking to facilitate imaging tailored to the needs of primary care, and thus combat a perceived secondary care imaging agenda. When GPs have access to diagnostic testing from primary care and clear referral guidelines, they are likely to use imaging resources as efficiently as hospital doctors. If implemented correctly, improving imaging access should shorten the patient pathway, facilitate better patient care and produce savings across the health-care economy. Traditional providers of NHS clinical imaging based in secondary care hospitals must seek to balance demands from both secondary and primary care for their services. A London-based group explored the effect on patient management of direct access to diagnostic imaging.¹⁶¹ Three core components supported appropriate GP referral guidelines, structured referral forms and clinical triage with telephone feedback to GPs suggesting alternative tests or contraindications to testing. Thirty-two per cent of patients referred for echocardiography were found to have an abnormal report but only 29% of these were referred to secondary care, as the majority were managed in primary care.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, radiology/X-ray is attributed a MODERATE degree of implementation difficulty owing to uncertainties about the new provider arrangements.

Conclusion

Imaging services are facing what has been described as a paradigm shift. Although the increase in competitiveness and a market orientation ultimately holds the prospect of higher standards and expectations, this is being realised on only a small local scale at present. There is considerable uncertainty in this particular area of diagnostic provision (*Table 21* gives a STEP-UP summary), making it very difficult to predict what will happen in the short term.

TABLE 21 Overall STEP-UP summary map (radiology/X-ray) (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary–secondary interface
Radiology/X-ray	○	⊕	○	○	⊕	⊕	○
Systematic reviews							
Quantitative studies	R11, R26, R27		R7, R16, R19, R20				
Qualitative studies						R3	
UK studies		R4, R21	R2, R12	R9			R1, R22, R31
Other substantive evidence	R15, R28, R29	R6, R13, R14, R21, R23	R2, R5, R10, R15, R17, R18, R29, R32		R2		R8, R17, R18, R24, R25, R30

○, insufficient evidence; ⊕, high degree of implementation difficulty; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.

Respiratory tests

Definition: respiratory tests measure how much air is moved in and out of the lungs, how successful the lungs are at getting oxygen into the blood stream and if there are problems in the lungs that can be seen in images of the lungs.

This map includes lung function tests.

This map excludes spirometry (see *Spirometry*) and CRP (see *Point-of-care testing*).

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

A systematic review of 30 primary care studies from across the world¹⁶² evaluated the diagnostic ability of GPs in relation to respiratory diseases, such as acute respiratory infections, tuberculosis, asthma and COPD. In relation to asthma and COPD, studies show either overdiagnosis or underdiagnosis. With increasing affordability and recognition of its clinical applications, there is an increasing interest of the role of the oximeter in primary care. Data concerning the influence of pulse oximetry on patient management and on the extent of oximetry use in the general practice setting are scarce. Several studies identify the role and potential of the oximeter as a screening tool in assessing hypoxia in primary care.^{163–166}

STEP-UP summary statement With regard to SKILLS, respiratory tests are attributed a LOW degree of implementation difficulty owing to the existence of well-established testing technologies.

Training

A draft working document outlines possible roles for a GPwSI, using respiratory medicine as a model. It envisages the role of a GPwSI in respiratory medicine as primarily one of leadership and service development. A modified draft document proposes a hybrid framework that combines a generic Royal College of General Practitioners (RCGP) framework with a respiratory disease-specific framework.¹⁶⁷

STEP-UP summary statement With regard to TRAINING, respiratory tests are attributed a LOW degree of implementation difficulty owing to the ease of use of most equipment.

Equipment

Table 22 offers an illustrative framework assessment for pulse oximeters. Pulse oximeters are increasingly used during endoscopy and other diagnostic procedures, and as part of pulmonary function testing. Data on the role of pulse oximeters in detecting hypoxia in general practice are limited. A minority of GPs reported that they used a pulse oximeter to measure pulse rate or to assess respiratory status.^{2,177}

Pulse oximeters are available, highly portable and increasingly becoming less costly to purchase.¹⁷⁸ If pulse oximeters are being considered for a practice/community setting, it may be worth discussing this with colleagues who use pulse oximeters regularly. The NICE Centre for Evidence Based Purchasing has published an evidence review, market review and buyers' guide for pulse oximeters, providing a list of pulse oximeters with evidence of their accuracy and performance.¹⁷⁹

STEP-UP summary statement With regard to EQUIPMENT, respiratory tests are attributed a LOW degree of implementation difficulty owing to portability, increasingly cheap equipment and ease of use.

TABLE 22 STEP-UP framework assessment for pulse oximeters

Description of technology						
Pulse oximeters give non-invasive estimation of arterial haemoglobin oxygen saturation and are routinely used in primary care, ¹⁶⁸ useful in initial assessment, ongoing monitoring and in both acute and chronic clinical situations. NICE guidelines on the management of COPD ¹⁶⁹ advocate pulse oximetry as screening tool in identifying patients eligible for long-term oxygen therapy						
Brief summary of effectiveness/cost-effectiveness in primary care						
Oximetry offers objective measure of respiratory compromise. It helps in diagnosis and management of several common respiratory diseases in primary care. There is little evidence of its clinical utility in primary care ²						
Skills						
Routine use of pulse oximetry in patients suspected of having community-acquired pneumonia would detect clinically unrecognised hypoxaemia, thereby identifying patients requiring hospitalisation. ^{170,171} British Thoracic Society guideline update (2004) for management of community-acquired pneumonia in adults recommended that pulse oximetry, with appropriate training, should become increasingly available to GPs and others responsible for out-of-hours assessment of patients, for assessment of severity and oxygen requirement for patients with community-acquired pneumonia and other acute respiratory illnesses ¹⁷²						
Training						
Appropriate training is required. No professional guidance is available						
Equipment						
Pulse oximetry available in 3.9% of practices and 37.5% of out-of-hours services (2006). ¹⁷³ Pulse oximeter inaccurate in anaemic patients. Cold or poorly perfused peripheries give false readings, as do poorly positioned or dirty probes. Normal SpO ₂ can occur in patients with abnormal blood pH or CO ₂ levels; arterial or capillary blood gas sampling and analysis are needed. Owing to their small size, user-friendliness and affordable prices, handheld pulse oximeters are available in primary care. ¹⁷⁴ Prices vary from £50 to £300. Sizes vary from small pocket-sized models to bench-top displays						
Premises						
No details given						
Clinician						
Pulse oximetry is underused (only 1.8% of primary care referrals to accident and emergency with acute exacerbation of asthma had documented pulse oximetry) ¹⁷³						
Patient						
No details						
Primary–secondary interface						
The British Thoracic Society guidelines for emergency oxygen use in adult patients state that, in emergency situations, pulse oximetry should be checked in all breathless ^{175,176} and acutely ill patients, and should be regarded as ‘the fifth vital sign’ ¹⁷²						
Skills	Training	Equipment	Premise	Clinician	Patient	Primary–secondary interface
⊕	⊕	⊕	⊕	⊕	⊕	○
○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty; SpO ₂ , blood oxygen saturation.						

Premises

Little detail is available on the implications of respiratory tests for primary care premises. If patients are being assessed in an area with a high level of artificial light (e.g. operating theatre fluorescent lighting), this can falsely reduce the readings.^{180,181}

STEP-UP summary statement With regard to PREMISES, respiratory tests is attributed an UNCERTAIN degree of implementation difficulty owing to lack of detail on storage and stock space requirements.

User perspective

Interviews with family practitioners¹⁷⁴ found that they considered pulse oximetry especially valuable when they were on an out-of-office-hours shift, as a supportive tool to decide whether to send a patient to an emergency department or to refer to a medical specialist. They considered pulse oximetry an adjunct in diagnostic assessment of patients, not a full diagnostic tool by itself.

To reduce the likelihood of inaccurate readings in patients undergoing pulse oximetry, HCPs should always ensure that a patient's nail varnish is removed, if present, that a patient's hand is warmed, if it is cold on presentation, and that the probe is correctly positioned and clean.

STEP-UP summary statement With regard to USER PERSPECTIVES, respiratory tests are attributed a LOW degree of implementation difficulty, as they tend to be well understood and well tolerated.

Primary–secondary interface

Several countries have developed respiratory assessment units to improve the diagnosis of respiratory diseases, such as asthma and COPD, and to overcome problems with misdiagnosis. A community respiratory assessment unit was established in London to optimise diagnosis of respiratory disease by providing focused history-taking, quality-assured spirometry and evidence-based guideline-derived management advice.¹⁸² Based in a secondary care hospital, this was a nurse-led facility, staffed by two specialist respiratory nurses with extensive experience of caring for respiratory diseases in both hospital and the community. A 4-year review found that one-third of suggested diagnoses of COPD by the GP were incorrect, resulting in the inappropriate prescribing of inhaled therapies. The authors identified significant financial, ethical and safety implications and highlighted a need for either diagnostic centres (community respiratory assessment unit) or alternative peripatetic practice-based services operating to quality-controlled standards.

STEP-UP summary statement With regard to the PRIMARY–SECONDARY INTERFACE, respiratory tests are attributed a MODERATE degree of implementation difficulty owing to dependencies on follow-up secondary care diagnosis and treatment.

Conclusion

The overall STEP-UP summary map for respiratory tests is presented in *Table 23*. The evidence base to support pulse oximetry is limited, but there are several areas in which further work may demonstrate benefits from the application of this technology in primary care.¹⁸³ Quantitative studies involving the rate of admission to hospital of acute respiratory illness might evaluate this device further in acute illness scenarios. Further qualitative studies could examine GPs' experiences of the use of portable oximeters. It is conceivable that the oximeter could be used in health promotion, for example in encouraging patients to give up smoking. Although no clinician would base treatment solely on the oximeter's readings, there is some evidence for the usefulness of pulse oximetry in general practice. It is not yet clear whether or not its use has any effect on diagnosis or patient-defined outcomes.

Spirometry

Definition: spirometry is a simple test used to help diagnose and monitor certain lung conditions by measuring how much air someone can breathe out in one forced breath (NHS Choices).

This map includes portable spirometry.

This map excludes other respiratory tests (see *Respiratory tests*).

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TABLE 23 Overall STEP-UP summary map: respiratory tests (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	Clinician perspective	Patient perspective	Primary–secondary interface
Respiratory tests	⊕	⊕	⊕	∅	⊕	⊕	○
Systematic reviews	Re22		Re20, Re31				
Quantitative studies	Re37		Re6, Re14, Re25, Re26, Re36				Re3
Qualitative studies					Re33	Re13	
UK studies	Re15, Re32, Re28, Re39	Re4, Re5, Re10, Re11	Re12, Re27, Re29		Re21		
Other substantive evidence	Re7, Re8, Re16, Re17, Re18, Re30, Re39	Re10	Re1, Re3, Re9, Re19, Re23, Re24, Re34, Re35, Re38				

∅, insufficient evidence; ○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

A study of spirometry carried out by GPs in primary care found that, in 95% of cases, fewer than five trials were required to achieve the highest-quality grade, concluding that spirometries undertaken in general practice are of acceptable quality and reproducible in only 60% of measurements.¹⁸⁵ Although the study involved only small numbers of diagnoses, it was concluded that the practice nurses required more training than they were originally given, again highlighting the importance of high-quality training if spirometry is to be used successfully in primary care. A study conducted with community pharmacists found that 73% of spirometries carried out by pharmacists were of acceptable quality, as judged by lung function experts in an acute setting.¹⁸⁶ Ongoing challenges related to the selection of a suitable spirometric screening test and to maintaining the quality of spirometric tests in primary care. A further study investigating the quality of spirometry in primary care found that > 15% of the tests being sent from primary care to specialists to analyse lacked complete data.¹⁸⁷ The results showed unacceptable quality in the provision of spirometry in primary care for patients with COPD, suggesting that adequate training must be given if spirometry is to be performed appropriately in primary care.

STEP-UP summary statement With regard to SKILLS, spirometry is attributed a MODERATE degree of implementation difficulty owing to the skills required to obtain a valid reading.

Training

Spirometry should be performed only by people who have been trained and assessed to Association for Respiratory Technology & Physiology, or equivalent, standards by recognised training bodies in the performance and interpretation of spirometry. Most COPD training courses include training in spirometry. Spirometry can be performed by any health-care worker who has undergone the appropriate training and who keeps his or her skills up to date.¹⁸⁸ However, a RCT in Australia, in which 26 intervention practices received comprehensive spirometry training and 14 control practices provided usual care, concluded that

training in spirometry did not result in any measurable improvement in the use of spirometry, quality of management of asthma or patient outcomes in primary care.¹⁸⁹

A longitudinal study in Denmark demonstrated that improved education of staff enhanced the use of spirometry in hospital outpatients with COPD, indicating the importance of staff training.¹⁹⁰ Further education has also been shown to increase the use of spirometry by GPs¹⁹¹ and also improve their capacity to diagnose clear-cut pathologies.

STEP-UP summary statement With regard to TRAINING, spirometry is attributed a LOW degree of implementation difficulty owing to the success of short training courses for skills acquisition.

Equipment

In its *Spirometer Users and Buyers Guide*, the National Asthma Council Australia provides a useful list of factors to consider when purchasing a spirometer.¹⁹² Several devices are available on the market, and one study reviewed the technical properties of 10 different spirometers designed for use in general practice.¹⁹³ Spirometers should be regularly cleaned and sterilised, as they may become reservoirs of micro-organisms. In a small study of 16 spirometers in South Australia, microbiological contamination was present in three.¹⁹⁴ The frequency of spirometer disinfection did not match the manufacturers' recommendations, highlighting a need for stricter hygiene measures for spirometer maintenance in general practices. A Dutch study examined 50 desktop spirometers in general practices and found that, on average, they slightly overestimated forced expiratory volume (FEV) and forced vital capacity (FVC) values, with some devices showing substantial deviations.¹⁹⁵ Spirometers, therefore, need to be calibrated yearly and verified before each session.

STEP-UP summary statement With regard to EQUIPMENT, spirometry is attributed a LOW degree of implementation difficulty owing to improvements in ease of use, cost and portability.

Premises

Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ locates spirometry testing services in an 'examination/therapy room' (contains public sector information licensed under the Open Government Licence v3.0). Initial testing could occur in community locations or surgery waiting rooms, but diagnosis should be confirmed in line with recommendations from NICE and the British Thoracic Society.

STEP-UP summary statement With regard to PREMISES, spirometry is attributed a LOW degree of implementation difficulty owing to the facility to apply portable spirometry in a variety of primary care settings.

User perspective

Evidence suggests that spirometry is underutilised and that guidelines that recommend spirometry to confirm airflow obstruction among patients with suspected COPD are not routinely followed.¹⁹⁶ Reported barriers to the use of spirometry include poorly designed and unduly complex spirometers with too many confusing parameters of limited value, lack of availability of spirometers, poor or no teaching in medical schools and the perceived lack of an evidence base demonstrating the value and cost-effectiveness of spirometry. In a UK context only specialist registrars and GPwSIs in undergraduate education spontaneously cited spirometry as a diagnostic tool.¹⁹⁷ GPs stated that they now felt that they had more access to spirometry than in the past and they were highly aware of the value of spirometry, perhaps reflecting its inclusion as a quality marker in the NHS GPs' contract. GPs in the study commented on the need for retraining, confirmed by a further study which showed that only 33% of GPs were confident in interpreting spirometry and 58% were confident in using spirometers.¹⁹⁸ Health-system barriers specific to spirometry use were not identified, suggesting that the availability of spirometry was not a perceived barrier.

STEP-UP summary statement With regard to USER PERSPECTIVES, spirometry is attributed a LOW implementation difficulty for clinicians and a MODERATE difficulty for patients. The equipment is becoming easier to use but may require multiple attempts for a patient to make their technique acceptable.

Primary–secondary interface

The increased availability of spirometers in primary care offers the potential for wider use. Newer spirometers are user-friendly and have the capacity for self-monitoring. With the advent of telemedicine and internet transmission of data, many more patients could have access to a diagnostic screening and/or monitoring.

Konstantikaki *et al.*¹⁹⁹ compared an open spirometry programme with a case-finding programme providing spirometry to high-risk subjects selected by primary care physicians. The proportion of newly diagnosed COPD was 27.9% in the case-finding programme, compared with 8.4% in the open spirometry programme. The average cost for a new diagnosis of COPD was €173 in the open spirometry programme and €102 in the case-finding programme. Thus, a case-finding programme involving primary care physicians was more cost-effective than an open spirometry programme for the identification of new cases of COPD.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, spirometry is attributed a LOW degree of implementation difficulty owing to existing referral pathways for asthma, COPD, etc.

Conclusion

Spirometry equipment has frequently figured in GP practices, alongside other requisite equipment such as ECGs. It is similarly benefiting from the move to miniaturisation, as well as from demand for end-user friendly devices. However, the availability of the technology should not disguise the fact that interpreting spirometry readings, and indeed deciding to use the equipment in the first place, when readily available, remains a significant barrier to the effective utilisation of the technology. The STEP-UP summary for spirometry is presented in *Table 24*.

Ultrasound

Definition: an ultrasound scan, sometimes called a sonogram, is a procedure that uses high-frequency sound waves to create an image of part of the inside of the body (NHS Choices).

This map includes portable and fixed ultrasound.

This map excludes echocardiography (see *Echocardiography*) and neonatal screening for dysplasia of the hip.

Contains public sector information licensed under the Open Government Licence v3.0.²⁰⁰

STEP-UP summary

NB: a full account of the evidence used in compiling this STEP-UP map can be found in *Appendix 3*.

Skills

Imaging must be undertaken by trained and experienced practitioners, and, even then, perfect images may not be obtained in every patient.²⁰¹ Ultrasound images can be saved or printed for reference, but, unlike MRI scans and computed tomograms, performance and interpretation are much more dependent on the skill and experience of the operator. This limits ultrasound's use for the skull, chest and abdomen. Ultrasound has no known long-term side effects, but it has a more limited scope than other imaging methods.

STEP-UP summary statement With regard to SKILLS, ultrasound is attributed a MODERATE degree of implementation difficulty owing to its being very operator dependent.

TABLE 24 Overall STEP-UP summary map: spirometry (for study identifiers see *Appendix 3*)

	HUMAN RESOURCES		LOGISTICS		COMMUNICATIONS AND RELATIONSHIPS	
	Skills	Training	Equipment	Premises	User perspective	Primary–secondary interface
Spirometry	○	⊕	⊕	⊕	⊕	○
Systematic reviews			Sp38, Sp65, Sp79, Sp94, Sp103, Sp106, Sp107		Sp21	
Quantitative studies	Sp1, Sp2, Sp16, Sp19, Sp52, Sp54, Sp55, Sp62, Sp63, Sp87	Sp8, Sp9, Sp15, Sp43, Sp75, Sp87, Sp89, Sp90, Sp92, Sp97	Sp6, Sp14, Sp16, Sp18, Sp27, Sp36, Sp47, Sp49, Sp55, Sp60, Sp61, Sp64, Sp88, Sp100			Sp2, Sp57, Sp59, Sp68, Sp108
Qualitative studies					Sp5, Sp39, Sp50, Sp85	
UK studies	Sp22, Sp31, Sp33, Sp35, Sp54, Sp61, Sp84, Sp110, Sp111	Sp34, Sp109	Sp42, Sp45, Sp46, Sp48, Sp71			Sp58, Sp95, Sp101
Other substantive evidence	Sp3, Sp7, Sp11, Sp20, Sp23, Sp24, Sp25, Sp28, Sp41, Sp67, Sp69, Sp70, Sp74, Sp80, Sp81, Sp90, Sp91, Sp99, Sp102, Sp105	Sp4, Sp12, Sp26, Sp30, Sp43, Sp44, Sp53, Sp76, Sp77, Sp96	Sp10, Sp17, Sp20, Sp29, Sp32, Sp51, Sp72, Sp73, Sp78, Sp82, Sp86, Sp93, Sp98		Sp83, Sp104	Sp40

○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.

Training

The fact that it is safe to carry out, is relatively inexpensive and can be provided in most clinical facilities makes ultrasound one of the most commonly requested examinations in the field of diagnostic imaging. Ultrasound examinations are undertaken by practitioners from a wide range of professional backgrounds and in many different clinical settings. The National Ultrasound Steering Group of the British Medical Ultrasound Society recommended in 2008 that local clinical governance boards be established to oversee the training, supervision and audit of all providers of ultrasound imaging services.²⁰² Many factors affect the quality of ultrasound examinations, including appropriate training, experience, the equipment itself, clinical leadership, audit, general support and having sufficient time to undertake the examination and compile a clinically relevant report. Clear, effective clinical leadership is also essential if the ultrasound service provider is to achieve timely, accurate, clinically relevant reports. Ultrasound practitioners for whom statutory registration is not possible can apply for voluntary registration with the Public Voluntary Register of Sonographers, which is administered by the College of Radiographers.

STEP-UP summary statement With regard to TRAINING, ultrasound is attributed a LOW degree of implementation difficulty owing to the widespread availability of training courses and opportunities.

Equipment

The latest portable machines produce images that are almost the same quality as that of the larger machines; they are easy to use, durable and cost as little as £5000.²⁰¹ Images obtained with a portable ultrasound machine are usually not stored, and a decision on how to act on the scan is made at the time by the clinician doing the scan. The role of the operator is critical, and matching the operator knowledge and competence level to the equipment features is essential, to include the key machine characteristics, how these characteristics match to clinical need, features to be considered when purchasing a machine, and the associated environmental and organisational systems needed to support the efficient use of the machine. Physicians in many medical specialties are thought to be using POC scanning, but the scale on which this is happening is not yet clear; these scans are not systematically recorded in the same way as those performed by imaging experts. In 2002 a cost analysis and an assessment of quality of GP scans, based on a clinical audit and a postal survey of patients' preferences in the Grampian region of Scotland, reported that the unit cost of a scan was higher in the practice than at the hospital.²⁰³ However, when all of the costs of a scanning episode were considered, the total and average costs were lower in the practice because of the avoidance of hospital visits.

STEP-UP summary statement With regard to EQUIPMENT, ultrasound is attributed a LOW degree of implementation difficulty owing to its portability, its ease of use and the absence of radiation risk.

Premises

Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ locates ultrasound services in a generic treatment room. A key consideration is the size of the machine relative to the size of the room in which it is to be used. Other issues to be considered include the scanning couch and operator seating, the display monitor, the room heating and lighting, hygiene, infection and cleanliness, and electrical and IT provision.²⁰⁴

STEP-UP summary statement With regard to PREMISES, ultrasound is attributed a LOW degree of implementation difficulty owing to increasing developments in miniaturisation and portability.

User perspective

A patient preference study for 500 patients from a GP list and 250 consecutive patients scanned at a Grampian general practice found that patients preferred to be scanned at the practice. They were prepared to wait up to an extra 5 days to enact their preference.²⁰³ Patients were prepared to accept a reduction in the accuracy of scanning of up to 3.5% in being able to realise their choice. Patients were not concerned about which member of staff actually carried out the ultrasound scan.

Skills and willingness were not sufficient factors in themselves to prompt rural family practitioners to utilise ultrasound.²⁰⁵ Economic considerations (i.e. equipment cost and remuneration) were seen as more important.²⁰⁵

STEP-UP summary statement With regard to USER PERSPECTIVES, ultrasound is attributed a LOW degree of implementation difficulty owing to it being well accepted among clinicians and well tolerated among patients.

Primary–secondary interface

The number of ultrasound examinations performed by imaging experts has increased on average by 5.2% every year for the past 10 years, according to Department of Health data, and imaging experts are struggling to keep up with the growing demand. With increasing pressure on ultrasound services owing to the number of requests, changing patterns of service delivery and a shortfall in the qualified workforce, there have been concerns that the quality of some ultrasound examinations has been affected.²⁰¹ A 2002 audit of a small series of patients demonstrated that the use of an ultrasound scanner at a Grampian general practice reduced the number of hospital scans, outpatient and inpatient visits, and emergency admissions.²⁰³ Blackpool, Fylde and Wyre Hospitals Foundation Trust extended primary care ultrasound as a NHS improvement initiative.²⁰⁶ Long waiting times for routine ultrasound examination, accompanied by

patients arriving late for appointments due to parking difficulty, and a limited choice for patients in terms of time and location of appointment, required an innovative service response. The trust negotiated the use of a PCT facility, off the main district general hospital site, and acquired a portable ultrasound machine to provide community-based ultrasound. Improvements included 30–40% of routine outpatient work being performed off the main site (more local scanning with better parking), improved patient satisfaction and increased patient choice of scanning venue.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, ultrasound is attributed a LOW degree of implementation difficulty owing to its being comparatively easily implemented in primary care and the likely shifting demand from secondary care.

Conclusion

Ultrasound is one of the fastest growing areas of diagnostic technology application, excluding POC testing. There is substantive concern that this might not be translating into clinical benefit. Ultrasound, notwithstanding its portability and ease of use, carries requirements for quality assurance. These must be monitored and met if the technology is to achieve its potential clinical benefit. Furthermore, there is a need to examine the impact of ultrasound scans on the referral and secondary care pathways. The STEP-UP summary map for ultrasound is presented in *Table 25*.

Discussion

Summary of evidence

A total of 673 items for inclusion was identified across the 13 topics. Information on logistic considerations was diffuse, uneven and incomplete. Coverage of new technologies was relatively strong and, where specialist primary care professional associations exist (e.g. endoscopy), training and skills requirements were well specified. However, little direct evidence exists for equipment requirements, implementation issues and the impact on the primary–secondary care interface. A methodological challenge relates to the intensive search and find process required to identify relevant information submerged within lengthy full-text articles and position statements. The diverse range of considerations identified across the 13 topics illustrates the importance of a multifactorial decision-making process.

TABLE 25 Overall STEP-UP summary map: ultrasound (for study identifiers see *Appendix 3*)

	Human resources		Logistics		Communications and relationships		
	Skills	Training	Equipment	Premises	User perspective	Primary–secondary interface	
Ultrasound	○	○	⊕	⊕	⊕	⊕	○
Systematic reviews			U18, U19				
Quantitative studies	U5, U13, U28		U1, U7, U31		U28, U30		U4, U5, U17, U23
Qualitative studies							
UK studies	U36	U22	U4, U32		U36	U36	U2, U8, U10, U11, U12, U14
Other substantive evidence	U1	U22, U25, U26, U27, U34	U3, U6, U9, U12, U15, U16, U20, U21, U33, U34, U35		U9		U8, U16, U24, U29

○, moderate degree of implementation difficulty; ⊕, low degree of implementation difficulty.

The multifactorial nature of decisions on diagnostic services, and, indeed, on general practice-level change more generally, has been emphasised by the use of the STEP-UP framework. Observations are discussed under the modalities themselves and the future research and synthesis agenda.

Skills

Many modalities require a wide range of contextual, interpretative and/or technical skills: in administering the test, in interpreting the results and in managing the consequences. Genetic tests, although comparatively easy to administer, make considerable demands on specialist knowledge in interpretation and skills in genetic counselling. Radiology/X-ray and other types of imaging (MRI and ultrasound) require interpretation, possibly necessitating follow-up and expert advice from specialists in secondary care. Such needs may translate into a hybrid model utilising telemedicine technologies. The inadequate administration of tests may require repeat testing, either in the primary care setting or following referral to secondary care. It may also impair the effective use of telediagnosis. Three main routes were identified for addressing the potential skills deficit. For some roles, the GPwSI is the route by which to fortify diagnostic expertise within primary care (e.g. endoscopy and genetics). For other scenarios the extended role of the advanced nurse practitioner, either with a specific diagnostic function (e.g. ultrasound or spirometry) or in a management pathway (e.g. respiratory or diabetic specialist nurses), is emphasised. A third route, although not fully exploited, is to bring in a specialist professional, either on a sessional basis or as an employee of the primary care organisation (e.g. radiology or genetic counselling). Alternative models, not covered by this report, include the use of shared diagnostic services within a primary care consortium, mobile testing services and the use of commercial providers.

A survey of equipment in a cardiac network revealed another important role in the practice team, that of the person responsible for the equipment.⁷⁶ Most typically, this is a practice nurse, and so not necessarily the person using the equipment, thus requiring that the equipment is in good working order, remains safe and is supported by the availability of supplies of consumables. The supply of diagnostic equipment and consumables is not well covered in the research literature. In particular, there is a need to accompany the purchase of equipment with maintenance schedules and equipment replacement policies to ensure the effective continued use of equipment, where needed.

Training

Training may be delivered through specialist courses, attachments to acute specialist departments or manufacturers of diagnostic equipment. A particular concern relates to whether or not the number of cases to be seen in a practice justifies a significant investment of time and resources in training (e.g. endoscopy). The opportunity costs for the consultation and other aspects of primary care required by pursuit of specialisation are highlighted in the related GPwSI literature.

A palpable tension exists between the professional interests of associations charged with assuring both the quality of procedures and the existence of their professional group and the need to engage with a wider primary care workforce. For example, historically, data on the safety of endoscopy in acute hospitals were initially viewed as prohibitive to wider primary care involvement. In reality, triaging the complexity of particular cases and specific populations (e.g. children, pregnant women and the elderly), particularly for invasive modalities, may increase the accessibility of primary care diagnostics while preserving specialisation in secondary care.

For modalities such as echocardiography and ultrasound, stepped approaches have been developed whereby the type of equipment and reliability of the test result are commensurate with the criticality of the clinical pathway. However, the need for accreditation can vary across modalities, often being associated not so much with risk as with how mobilised and active the relevant professional associations are.

The survey by Day *et al.*⁷⁶ revealed that little attention is being given to requirements for training, especially in relatively low-cost items of equipment. There is a need to accompany the purchase of equipment with schedules for training so that they can be used to best effect.

Equipment

The cost and manageability of technologies is extremely variable across topic areas. Some technologies have benefited from moves towards miniaturisation (e.g. ultrasound) or to more end-user friendly versions of a technology (e.g. flexible sigmoidoscopy). Others have seen a trend towards popularisation, either in the health-care professions generally (e.g. POC testing) or through direct-to-consumer marketing (e.g. genetic tests), from which primary care might potentially benefit. Concerns about safety persist, either from the diagnostic equipment itself (e.g. radiation from radiology/X-ray) or from consumables (e.g. glutaraldehyde) or from ancillary equipment to support administration or analysis of the test results (e.g. electrical equipment). Ancillary equipment requirements are not widely documented (e.g. continuous pulse oximetry is recommended when intravenous sedation is required for endoscopy), whereas requirements for garments, gloves, goggles and glasses should not be overlooked. For newer technologies, the outputs of the NIHR DEC, Oxford, are useful. However, these focus on narrower HTA perspectives of the technology, with correspondingly less attention given to health services delivery and organisational issues.

Premises

Diagnostic technologies place particular requirements on the physical location in which a test is administered. In some cases the focus is on the facilities and safe administration of the equipment (e.g. endoscopy or radiology). Specialist premises, that is, rooms dedicated to a particular diagnostic modality, are particularly prohibitive on legacy primary care premises. Even where premises are purpose-built, changes in technologies and their associated requirements, and a lack of specifications for an integrated multipurpose approach across technologies, make accommodation problematic. Patient flows (e.g. additional seating and queuing) need examination at a specific practice level. Requirements are not necessarily technology-driven. For example, audiological requirements for a quiet environment, even for simple hearing tests, may be difficult to accommodate and may particularly be compromised in a multipurpose environment. A particular deficiency relates to the facilities to store equipment and consumables. Although this most obviously relates to sizeable items of equipment, it must not be overlooked for the storage of portable devices or in large volumes of consumables, for example POC or genetic test kits.

Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ recognises that 'as technology improves, more direct diagnosis will be undertaken in primary and community care settings' (contains public sector information licensed under the Open Government Licence v3.0). The building note acknowledges that near-patient testing will require bench-top equipment, whereas digital diagnosis will comprise ultrasound scans, resting ECGs and radiography. It suggests that some of these activities may be 'delivered on a timetabled basis' from generic rooms, such as the consulting/examination room equipped to carry out resting ECGs and the treatment room equipped to carry out ultrasound scans and/or resting ECGs. In addition, the near-patient testing room would be used for blood-gas analysis. It suggests that a 'docking station may also be required to accommodate mobile vehicles carrying diagnostic equipment such as MRI, CT [computed tomography] and mammography scanners'. It specifies that the internal route to the docking station should be well planned, passing the main reception desk and waiting area.

Of particular importance is the degree to which developments in the adoption of one technology may facilitate accommodating a similar technology across diagnostic groups, for example ECGs and spirometers, echocardiographs and ultrasound or X-ray and MRI. Developments in POC testing will, thus, probably impact on cardiac and diabetic diagnostic services. Equally unexplored are antagonisms between potential diagnostic technologies in terms of the space they consume or the type of activity that they necessitate. For example, providing for the safe cleaning of endoscopes may impact on the non-availability of the required space for patient examination or care.

User perspectives

Generally, across primary care, the delivery of diagnostic modalities locally meets increasing demands for improved access and, by implication, enhanced equity. Patients prefer services that may be reached easily and that will not necessitate extensive time away from their day-to-day responsibilities. Several qualitative

studies refer to the patient experience of difficulties in parking when attending secondary care for tests. Prompt test results and the joining up of diagnosis and treatment are important considerations for patient and primary care provider alike. On the other hand, impaired access may function as a disincentive to inappropriate utilisation and may control overtesting. There is little evidence to inform whether improved general practice access to testing increases uptake of tests or whether a greater awareness of resource use deters general practice staff from initiating testing. Patients presenting with medically unexplained symptoms may be assuaged with offers of more, and more immediately available, tests. More critically, the appropriateness of testing, rather than utilisation rates per se, becomes a key issue. Finally, given that diagnostic services function as a gateway to subsequent health service use, improved access to diagnosis might potentially defer current bottlenecks to other points in the patient care pathway.

Primary–secondary interface

Whereas the STEP-UP framework encourages a holistic view of primary care considerations, diagnostic services function in a whole-system health system environment. The ramifications of system change at the primary care first point of call are not fully explored in the evaluation literature. Earlier detection may result in earlier and more effective treatment and, thus, in overall cost savings. Unintended consequences for patient and provider behaviours require careful examination, especially when resulting in increased utilisation or needless duplication. The impact on uptake of direct-to-consumer products and on commercial diagnostic services or private health care is equally important in a whole-system perspective.

Candidate modalities

The synthesis team members were constrained by limited data on current UK practice and uptake of diagnostic services. For long-established technologies (e.g. endoscopy) it is unclear whether the extent of spread has been determined by demand or by logistic considerations such as the limited availability of premises or the costs of equipment. In particular, the implications of a concerted attempt to improve diagnostic provision, involving the introduction of diverse modalities within a relatively intensive period, are unclear.

Mechanisms for adoption and prioritisation, strategically and in an individual practice, are also complex and unclear. Several commentators observe on the importance of identifying particular barriers and constraints at a micro level, as well as acknowledging the role of guidance from NICE or professional associations in driving forward initiatives. The variability of context makes it difficult to translate this mapping review directly into actionable recommendations for primary care. At the same time, the STEP-UP lens offers the possibility of a more holistic and consistent approach to evaluation. Economic evaluation, with its whole-systems perspective, its approach to itemisation of particular components and its functionality for handling multiattribute decisions, appears to afford an opportunity to implement STEP-UP considerations in a more technical, consistent and decision-specific manner.

Strengths and limitations of this review

The conduct of this mapping review was challenging. Information to populate the STEP-UP framework was diffuse and required full-text examination of numerous sources. In particular, information on the spatial implications of the technology for the primary care premises was lacking. The principal exception to this was endoscopy, for which a health building note exists.

When examining a technology, it proved problematic to identify what the current uptake of a technology was likely to be. Where prevalence was considered high, for example for ECGs or spirometry, the emphasis of the evidence was on migration to more portable, handheld technologies. Expensive equipment, such as MRI (and, by implication, CT scanning), was becoming more compact and, consequently, less expensive. Consumer demands shaped a corresponding reaction in primary care with regard to POC and genetic testing. A further consequence was to reduce any likely demand to house laboratory facilities in a primary care setting. Other contexts, such as cardiac services and diabetic services, were affected to a partial degree by developments in POC testing. All of these variables made comparability across technologies problematic, particularly in terms of stage of innovation and extent of available information.

A further complication relates to a dilemma concerning technology or service. STEP-UP reports could examine a service as a whole or a specific technology. In fact, some of the services examined in this report, such as cardiac services and audiology services, incorporate specific technology summaries as well as trying to summarise at a service level. This mixed approach proved problematic. It is preferable to either single out a particular technology – to conduct a more extended and holistic technology assessment – but with corresponding difficulty in identifying implications for more system-based considerations such as premises or the primary secondary interface; or conduct a service-based assessment which privileges whole-system considerations but perhaps lacks granularity for skills, training and equipment considerations.

Several workforce planning documents were identified from The King's Fund Library catalogue. These reports, from PricewaterhouseCoopers,^{207,208} may help to inform the workforce requirements (as itemised under the skills and training headings for all modalities), but they are not available online. Time constraints meant that it was not possible to consult these in their physical location.

Methodological limitations of the included studies

As a conceptual framework STEP-UP is vulnerable to a mismatch between the logistic information required to complete the map and a research agenda focused on innovations and/or on the evaluation of effectiveness. Position statements and professional standards are typically underpinned by implicit and non-articulated assumptions about the stage of diffusion at which a particular technology finds itself. So, for example, early documents state requirements for setting up an endoscopy unit but the costings are now outdated and the specification is time-bound. Extensive use of the STEP-UP framework across a wide variety of topics reveals its general utility for a consistent approach that highlights similarities and contrasts across very different technologies.

As such, STEP-UP offers a viable framework for extending evaluation beyond the current narrow interpretation of HTA towards important considerations of service delivery and organisation. Considered reflection leads us to suggest the possible extension of the STEP-UP framework to include three additional components: Public perspectives, Economics and Drivers (STEPPED-UP). Although the inclusion of Economics in the extended framework is unsurprising, the STEPPED-UP framework introduces this in the more relevant context of service delivery and not in the more common, limited application of individual diagnostic technologies. In our experience we also found it useful to separate providers and patients under the User perspective heading, in recognition that some tests may be viewed as attractive by patients but might occasion concern among service providers, or vice versa. A further modification, although not implemented in this report, is to distinguish between skills and training for administration and skills and training for interpretation. Furthermore, communication skills for handling the implications of a positive test may be particularly important for some types of otherwise easily administered testing, most notably genetic tests.

Research implications

Many studies of diagnostic modalities focus almost exclusively on technical accuracy. The MaDOx initiative sought to extend this to include reliability, diagnostic accuracy, impact on outcomes and cost-effectiveness.²⁰⁹ This mapping review has revealed that an even wider breadth of scope is required when seeking to implement these technologies in a primary care environment. Additional considerations relate to the skills and training required by the staff, the physical properties of the equipment and the facilities required for its use and storage of equipment and consumables. Furthermore, there is the impact of the use of the equipment, and any consequential changes in procedures, on those delivering and those receiving the service. Finally, examination of the impact on the primary–secondary interface, in the context of a pathway of care, is considered essential if the diagnostic technologies are to be integrated into overall patient management.

Horizon Scanning reports from the Oxford Horizon Scanning Programme (<http://madox.org/>) exist for many of the diagnostic technologies under review. These offer a useful structure on which to hang this logistics review and they particularly address the domain of Equipment in the STEP-UP model. Horizon Scanning reports sometimes afford passing mention to implementation issues such as quality assurance and training, but this occurs unevenly and incompletely. The coverage of these useful reports might be enhanced by

either (1) extending their structure to include the dimensions addressed by the STEP-UP framework or (2) commissioning a parallel set of research products specifically addressing service delivery and organisation issues, either from the same agency or from a comparable agency with specific expertise in health services management and implementation issues. However, it is to be noted that the last report was dated 2013.

Other diagnostics to explore

It was not possible, for logistic reasons, to perform a STEP-UP map for every candidate technology. Primary exclusions include CT scanning and colonoscopy. In terms of the specific detail, these may be populated from similar sources to the exemplars in this report. In the absence of a detailed assessment, considerations may be informed by the assessments for radiology and MRI (for CT scans) and for endoscopy (for colonoscopy). However, specific technical details and qualitative studies on the patient and clinician views and attitudes towards the technology are required to supplement the overall maps.

Alternative methods of delivery

The specific remit of this mapping review, that is, to look at implications for staff and equipment located in primary or community care, has necessarily excluded some innovative approaches that transect the primary and secondary care divides. Although some of these issues and examples have been included opportunistically in the STEP-UP sections entitled 'primary care interface', we have identified a need to systematically examine models, from the literature or good practice, that include some of the following:

- commercial providers
- diagnosis and treatment centres
- direct access
- mobile laboratories
- outreach clinics
- rapid-access clinics
- telemedicine.

Several of the above options, including direct access, rapid access clinics and telemedicine, are briefly summarised in a report by the Health Services Management Centre.²¹⁰ However, almost a decade has elapsed since this rapid review was conducted. The companion review of NHS experience in the same topic area reported that diagnostics was the least well-populated direction for innovation.²¹¹ This suggests a fruitful area for future examination and review.

Conclusions

Delays or deficiencies in diagnostic services often prove a bottleneck for the patient pathway through treatment. Often the quickest access to tests is achieved by admitting the patient, often unnecessarily, to hospital. Three proposed routes by which to alleviate this bottleneck are (1) to move diagnostic services out of hospital and locate them in primary care, (2) to use independent sector services to increase capacity and (3) to develop POC testing in hospitals. The first of these is the sole emphasis of this report. It may therefore be useful to examine the other options with equal attention, perhaps using the revised version of the STEP-UP framework (see *Discussion*) to facilitate comparability.²¹² Implementation strategies for new diagnostic tests require a structured business plan, including performance management following introduction.²¹³ This approach should seek to involve commissioners, specialists and GPs.

The evidence map and synthesis provides a rapid synoptic view of leading areas of development for primary and community care diagnostics and a potential mechanism for identifying and specifying future areas for development (for synthesis, primary research and policy). In particular, the need for whole-system evaluations, economic evaluations and an improved system for organising and presenting information on aspects relating to service delivery and organisation, possibly analogous to the NIHR DEC, has been highlighted. Further data on current levels of diagnostic provision in primary care and future priorities are

required. Finally, the focus of this synthesis on staff and equipment located in primary care has necessarily constrained the scope of the review and subsequent recommendations. Alternative models, such as consortium approaches, direct access, mobile testing services, outreach initiatives and the use of commercial laboratories, require a similarly systematic examination.

Chapter 5 Focused review: community diagnostic ultrasound services

Introduction

The literature mapping exercise reported in *Chapter 3* revealed a lack of published systematic reviews looking at community provision of specific diagnostic technologies. Diagnostic ultrasound was chosen as a topic for further review based on both the published evidence identified by the mapping exercise, which suggested that there were some relevant published studies,^{16,203} and advice from clinical experts about the need for evidence to guide policy and practice. Following implementation of the Health and Social Care Act 2012,²¹⁴ local Clinical Commissioning Groups (CCGs) have had increased flexibility to commission new models of community services to replace or supplement hospital-based services. The Act also places a duty on CCGs to take account of evidence from research in their decision-making.

Ultrasound appears to be a suitable diagnostic technology for use in primary care and community settings, being relatively inexpensive, safe and non-invasive.²¹⁵ In addition to potential benefits for patients and the health-care system, the main issues that need to be considered in evaluating provision of diagnostic ultrasound in community or primary care settings are equipment, staffing and workload, and training. Training may be required for health professionals newly required to perform ultrasound scans and for GPs to enable them to make optimum use of new service models.

The traditional model of service for non-emergency ultrasound scanning in the UK NHS involved secondary care radiology departments performing the examination following an outpatient appointment for patients referred by GPs. Since the 1990s, many areas have developed direct-access or open-access services, whereby patients referred by GPs are scanned using hospital facilities without being seen by a secondary care specialist. The location of services outside hospital settings has also been possible for many years. This model of service is driven by increasing demand, the relatively low cost of the equipment and improvements including improved imaging quality and the availability of smaller, more portable scanners (including handheld devices).

However, wider access to ultrasound scans may increase the risk of the technology being used inappropriately. There is some evidence that rates of inappropriate requests are high for ultrasound scanning, compared with other types of imaging.^{216,217} In addition to the increased likelihood of excessive imaging and its associated costs, direct access to ultrasound services may lead to additional diagnostic tests and unnecessary treatment.¹⁵⁸ The potential effect on patient anxiety of being referred for a scan is also a factor to consider, although this should be balanced against the reassurance provided by a negative scan result.

In 1990, the RCR released guidelines for radiologic referral²¹⁸ and several subsequent studies showed that the application of these guidelines led to a considerable decrease in inappropriate radiological requests, such as for X-rays.²¹⁹ However, such guidelines require GPs and other primary care staff to be trained appropriately in use of the equipment. This would also be the case for other types of imaging such as ultrasound. Community diagnostic ultrasound services therefore embody a complex decision problem with the potential to impact on the activities of the primary care clinic and, more widely, on referral pathways into secondary care.

Methods

The review aimed to address the following question: what is known about the implications of different ways of providing diagnostic ultrasound services in community or primary care settings? This was defined

to include implications for both NHS organisations (e.g. related to provision of staff, premises, training and equipment, costs and cost-effectiveness) and patients (e.g. related to changes in management/pathways, acceptability to patients, accuracy of diagnosis and longer-term clinical outcomes).

Inclusion/exclusion criteria

Inclusion and exclusion criteria for the review were as follows.

Population

People requiring diagnostic ultrasound for any condition (excluded: population screening and monitoring, including pregnancy). Studies described as screening could be included if the people being screened were identified by having a specific risk factor for a medical condition (rather than through a screening programme offered to all individuals on the basis of age and/or gender) and the identified factors were either common or concentrated (e.g. common in a particular minority ethnic group) in the UK population.

Intervention

Ultrasound provided in a primary care or community setting by primary care/community staff using any type of equipment (including portable ultrasound devices). Open-access services provided to GPs by a hospital using its premises, equipment and staff were treated as a comparator intervention.

Comparator

Hospital-based diagnostic ultrasound services (open access or traditional). 'Outreach' services using hospital-based staff to deliver services in community settings were also considered to be relevant comparators.

Outcomes and study designs

The main focus was research studies in developed countries that evaluate community diagnostic ultrasound services and have a comparator; given the importance of context, we also included evaluative studies without a comparator group [e.g. audits and service evaluations (UK only)] and descriptive studies providing usable information about service delivery in UK settings. Systematic reviews, UK-relevant economic evaluations/cost studies and qualitative research studies were also eligible for inclusion.

In addition, we included relevant expert opinion pieces or reports from professional bodies that identify and/or discuss practical issues related to the provision of community diagnostic ultrasound services (e.g. staffing, training, equipment and premises) in UK settings.²²⁰

Outcomes of interest included patient outcomes (e.g. waiting times, acceptability, changes to diagnosis or management, and any clinical outcomes) and service/process outcomes (e.g. costs/resource use, cost-effectiveness, needs for training, premises and equipment). Resource-use outcomes include any implications for test ordering by GPs.²²¹

Given that the focus of the review was on models of service, studies reporting on the diagnostic accuracy of ultrasound in community settings for particular conditions were not included unless they were considered relevant to the primary–secondary care interface, as defined in the review protocol (e.g. they contained information on referrals or changes to diagnosis or management pathways).

Searching

The following bibliographic databases were searched from 1995 to February 2015:

- MEDLINE via Ovid SP
- EMBASE via Ovid SP
- The Cochrane Library
- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Web of Science.

The start date of 1995 was based on evidence from the initial mapping exercise (see *Chapter 3*) that ultrasound began to appear in UK primary care settings from the mid-1990s.²¹⁵ Search strategies are presented in *Appendix 4*.

Citation searches were performed in Google Scholar for papers citing key studies included in the review: first authors Wordsworth,²⁰³ Everett,²²² van Gorp,²²³ Robinson,²¹⁵ Scholten-Peeters²²⁴ and Pallan.¹⁶

Internet and grey literature

The objective of this part of the review was to identify providers and models of service for diagnostic ultrasound in the UK NHS (primarily England).

The following internet and grey literature searches were performed:

- Internet searches using the Google (Google Inc., Mountain View, CA, USA) search engine (see *Appendix 4* for details)
- OpenGrey (European grey literature database): www.opengrey.eu/
- NIHR DEC, Oxford: www.oxford.dec.nihr.ac.uk/.

The first 100 results from Google searches were examined. Websites of companies providing diagnostic ultrasound services in NHS community settings and of 'NHS community diagnostic centres' (providing diagnostic ultrasound alongside other tests) were searched in more detail to identify any evaluations or fuller descriptions of the services and any information on governance, accreditation and similar issues. These services appeared to meet the criteria for comparator interventions in the protocol and were poorly covered by the published literature.

Study selection

Search results were stored in a reference management database (EndNote X7), where decisions on inclusion/exclusion were recorded. The selection of studies for inclusion (scanning of titles/abstracts and full-text publications) was initially carried out by one reviewer. Uncertainties were resolved by discussion and consensus among the review team.

Included studies were classified on the basis of quality and relevance as level 1, level 2 or level 3, as follows:

- Level 1: comparative studies of community diagnostic ultrasound services from developed countries. This category also includes full publications of non-comparative and descriptive studies from UK settings, UK-relevant economic evaluations/cost studies and qualitative research.
- Level 2: non-comparative empirical studies from non-UK developed country settings that include relevant information about community diagnostic ultrasound services. This category also includes conference abstracts providing limited information on UK services.
- Level 3: non-empirical studies, for example conceptual papers and expert opinion, that include relevant information about community diagnostic ultrasound services.

Data extraction and quality assessment

Included experimental or observational studies (level 1 or 2) were assessed for quality using the following tools:

- case series: Canadian quality appraisal tool for case series²²⁵
- cohort and other non-randomised comparative studies: Downs and Black checklist²²⁶
- cost studies: checklist from Drummond *et al.*²²⁷
- diagnostic studies: QUADAS (Quality Assessment of Diagnostic Accuracy Studies) tool as adapted by the Cochrane Collaboration.²²⁸

Data were extracted from level 1 and 2 studies using forms/tables set up in advance and piloted on a small number of studies. Data extraction and quality assessment were checked by a second reviewer. Any discrepancies were resolved by discussion and consensus, with reference to a third reviewer if

necessary. Basic details were tabulated for included level 3 studies and these were not formally assessed for quality.

Synthesis of evidence

Patient-related and service-related issues (as defined above) were used as a framework for a narrative synthesis. Evidence was grouped by type of service model and where appropriate by indications/patient groups covered. The synthesis aimed to provide an analysis of the quality of evidence and the strength of conclusions which can be drawn from current studies. We also aimed to identify evidence gaps to inform future research.

Results

Systematic review of published literature

A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram for the systematic review is presented in *Figure 1*.

Included studies and characteristics

Three papers met the inclusion criteria for level 1 studies.^{203,222,229} Ten English-language papers,^{16,223,230–237} four papers published in other languages^{238–241} (including one thesis) and three conference abstracts^{242–244} were classified as level 2 studies. Seventeen level 3 studies were also included.^{44,45,205,215,220,224,245–255}

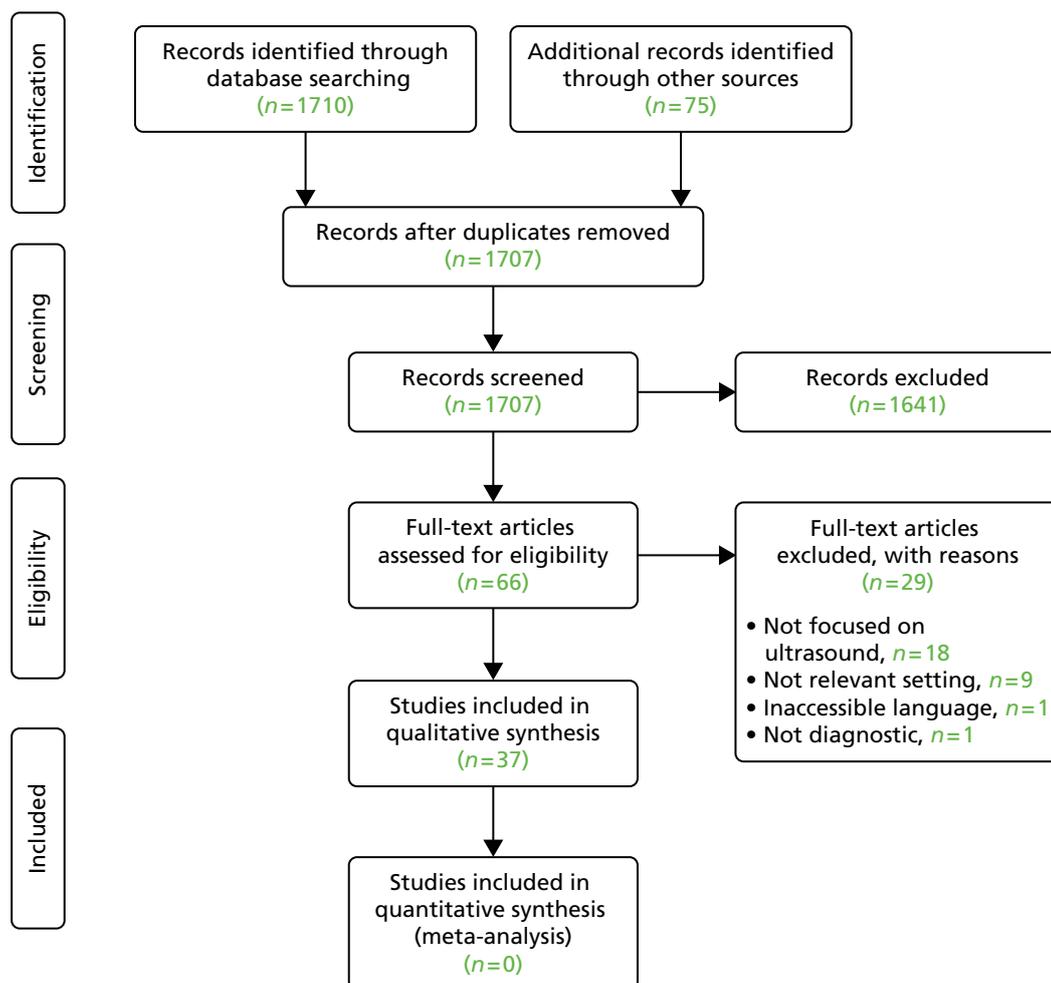


FIGURE 1 The PRISMA flow diagram for Chapter 5.

Full details of the included level 1 and 2 studies can be found in the data extraction tables (see *Appendix 5*) and below. *Appendix 6* summarises the main characteristics and findings of the included level 3 studies.

Quality assessment results

Because of the varied designs of the included studies, a number of different quality assessment tools were used to assess the risk of bias of individual studies. Level 3 studies were not formally assessed for quality. Overall, the quality of the included studies was low. There were no randomised trials included and many studies had no control group. The findings of the quality assessment are discussed in more detail below.

One level 1 study²²⁹ and two level 2 studies with control groups^{16,223} were assessed using the Downs and Black checklist²²⁶ (see *Appendix 7*). The study by Salihefendic *et al.*²²⁹ was of low quality, with many important features missing or not clearly reported. The fact that English was not the first language of the lead author made the study often difficult to understand and interpret. The two level 2 studies clearly described their participants and interventions, and used appropriate methods of analysis, but there was no indication that possible confounding factors were taken into account. The study by van Gurp *et al.*²²³ had no control group; instead, it compared outcomes following referral to a community echocardiography service with what physicians said they would have done in the absence of the service.

Studies classed as case series, including two level 1 studies,^{203,222} were assessed using a checklist developed by the Institute of Health Economics in Alberta, Canada.²²⁵ This tool has considerable similarities with the Downs and Black checklist²²⁶ but was specifically developed to assess studies without a control group. The results (see *Appendix 7*) indicated that the studies had several limitations in addition to those associated with a case series design. For example, both level 1 studies were conducted at one centre and both appeared to have a retrospective design, which increases an already fairly high risk of bias. Other questions were difficult to assess because of reporting limitations.

Two studies^{16,203} that were also among the few to compare different models of service reported elements of costs or cost-effectiveness. In view of the importance of this outcome, the quality of the economic component was assessed using the checklist of Drummond *et al.*²²⁷ A critical abstract from the NHS Economic Evaluation Database (NHS EED) was available for the study by Pallan *et al.*¹⁶ Both studies appeared to adopt a NHS perspective (i.e. wider societal costs and benefits were not included), but this was not stated explicitly. Limitations of the study by Wordsworth and Scott²⁰³ were noted above, particularly the lack of real data for the comparison group, and these should be taken into account when interpreting the economic aspect of the study. The authors reported carrying out a sensitivity analysis to examine the effects of varying the assumptions made, but no details of this were reported. Overall, the findings of this study provide only limited evidence to support the cost-effectiveness of ultrasound scanning by GPs in the surgery.

The main limitations of the Pallan *et al.*¹⁶ study, as noted by the NHS EED commentary, were its retrospective design, its poor reporting of costs and the absence of any sensitivity analysis to explore uncertainty in the findings. These limitations make it difficult to assess the reliability of the authors' conclusions, as discussed further below.

Finally, three diagnostic accuracy studies were assessed using the version of the QUADAS tool adopted by the Cochrane Collaboration (see *Appendix 7*).²²⁸ This tool was chosen because of the ease of application and a level of detail sufficient for the needs of this project, which is not a review of diagnostic accuracy. Although the reporting was not always clear, the quality of the three studies appeared generally moderate to good. The major exception was the study by Grubel,²³¹ in which only a proportion of the patients received a reference standard test, leading to a risk of partial verification bias. The study by Thoomes-de Graaf *et al.*²³⁶ aimed to assess agreement between physiotherapists and radiologists, with the radiologist's diagnosis being treated in effect as a reference standard. There were no major quality issues with this study, although, as with other diagnostic studies in the review, it was not explicitly reported whether or not any unclear or uninterpretable results were recorded.

Summary of included study characteristics

The included studies focused on ultrasound scans for a variety of sites/conditions, cardiac (echocardiography), GI and musculoskeletal being the most common (*Table 26*). Several studies examined general ultrasound services offering scans for a range of conditions, while a group of studies from Finland examined the use of ultrasound for the diagnosis of sinusitis in the primary care setting.

TABLE 26 Mapping of included studies by ultrasound site/condition

Study (authors and year)	Site					
	Heart	GI	Sinus	MSK	Other	General
Level 1						
Everett and Preece 1996 ²²²					✓	
Wordsworth and Scott 2002 ²⁰³						✓
Salihefendic <i>et al.</i> 2009 ²²⁹		✓				
Level 2						
Goldberg <i>et al.</i> 2003 ²³⁰				✓		
Grubel 2011 ²³¹		✓				
Heikkinen <i>et al.</i> 2005 ²³²		✓				
Laine <i>et al.</i> 1998 ²³³			✓			
Landers and Ryan 2014 ²³⁴					✓	
Mäkelä and Leinonen 1996 ²³⁵			✓			
Pallan <i>et al.</i> 2005 ¹⁶						✓
Thoomes-de Graaf 2014 ²³⁶				✓		
van Gorp <i>et al.</i> 2013 ²²³ and van den Brink 2013 ²⁵³	✓					
Varonen <i>et al.</i> 2003 ²³⁷			✓			
Abstracts/Non-English publications						
Blanchet and Thierry 2015 ²³⁸						✓
de la Figuera <i>et al.</i> 2012 ²³⁹	✓					
Esquerra <i>et al.</i> 2012 ²⁴⁰		✓				
Evangelista <i>et al.</i> 2013 ²⁴¹	✓					
Gallagher <i>et al.</i> 2012 ²⁴²	✓					
Hoyer <i>et al.</i> 2007 ²⁴³	✓					
Singh <i>et al.</i> 2009 ²⁴⁴	✓					
Level 3						
Aitken 1999 ⁴⁴						✓
Bono and Campanini 2007 ²⁴⁵						✓
Cardiac Networks Co-ordinating Group 2006 ²²⁰	✓					
Colquhoun <i>et al.</i> 1995 ²⁴⁶	✓					
Doddy 2009 ²⁴⁷						✓
Hölscher <i>et al.</i> 2013 ²⁴⁸					✓	
Hussain <i>et al.</i> 2004 ²⁴⁹					✓	
Mjølstad <i>et al.</i> 2012 ²⁵⁰	✓					

TABLE 26 Mapping of included studies by ultrasound site/condition (*continued*)

Study (authors and year)	Site					
	Heart	GI	Sinus	MSK	Other	General
NIHR DEC Oxford 2014 ⁴⁵						✓
Ottenheijm <i>et al.</i> 2011 ²⁵¹				✓		
Robinson <i>et al.</i> 1997 ²¹⁵						✓
Scholten-Peeters <i>et al.</i> 2014 ²²⁴				✓		
Senior <i>et al.</i> 2003 ²⁵²	✓					
Siu <i>et al.</i> 2013 ²⁰⁵						✓
Vicente-Molinero <i>et al.</i> 2009 ²⁵⁴						✓
Xiao 2003 ²⁵⁵	✓					

MSK, musculoskeletal.

Topics relevant to the review question covered by the included studies are summarised in *Table 27*. The included level 1 and 2 studies were mainly concerned with comparing or describing service models and with workforce and training issues. Level 3 papers also covered these topics but this group also included studies looking at equipment (primarily the role of handheld devices) and attitudes towards community diagnostic ultrasound service, particularly health professionals' attitudes as a barrier (or facilitator) to setting up such services.

Outcomes examined in the included studies were categorised as clinical effectiveness (including diagnostic accuracy and yield), process/system, patient acceptability and costs/resource use (*Table 28*). Most level 1 and 2 studies reported clinical and/or process outcomes, with only two^{16,203} reporting on patient acceptability and costs. Two level 3 studies^{44,247} examined patient acceptability. Some level 3 papers were relatively discursive or conceptual and did not report outcomes per se but are included in the table for ease of comparison.

The following sections examine the included studies in more detail using the topics and outcomes in *Tables 27* and *28* as a framework.

Studies comparing/describing service models

The principal service models for diagnostic ultrasound are listed in *Table 29*. Rapid-access clinics may be hospital based or community based and are relevant only to certain indications, for example suspected heart failure. The other models mentioned could be applied to general diagnostic ultrasound services or services targeted at specific conditions. 'Traditional' access to ultrasound, through referral by a hospital clinician, is not considered in this report, which deals only with community ultrasound.

TABLE 27 Topics covered by included studies

Study (authors and year)	Service models	Equipment	Workforce/training	Barriers/attitudes
Level 1				
Everett and Preece 1996 ²²²	✓			
Wordsworth and Scott 2002 ²⁰³	✓			
Salihfendic <i>et al.</i> 2009 ²²⁹	✓			

continued

TABLE 27 Topics covered by included studies (continued)

Study (authors and year)	Service models	Equipment	Workforce/training	Barriers/attitudes
Level 2				
Goldberg <i>et al.</i> 2003 ²³⁰	✓		✓	
Grubel 2011 ²³¹	✓		✓	
Heikkinen <i>et al.</i> 2005 ²³²	✓			
Laine <i>et al.</i> 1998 ²³³			✓	
Landers and Ryan 2014 ²³⁴	✓		✓	
Mäkelä and Leinonen 1996 ²³⁵			✓	
Pallan <i>et al.</i> 2005 ¹⁶	✓			
Thoomes-de Graaf <i>et al.</i> 2014 ²³⁶			✓	
van Gorp <i>et al.</i> 2013 ²²³ and van den Brink 2013 ²⁵³	✓			
Varonen <i>et al.</i> 2003 ²³⁷			✓	
Abstracts/Non-English publications				
Blanchet and Thierry 2015 ²³⁸				✓
de la Figuera <i>et al.</i> 2012 ²³⁹			✓	
Esquerra <i>et al.</i> 2012 ²⁴⁰			✓	
Evangelista <i>et al.</i> 2013 ²⁴¹			✓	
Gallagher <i>et al.</i> 2012 ²⁴²	✓			
Hoyer <i>et al.</i> 2007 ²⁴³		✓	✓	
Singh <i>et al.</i> 2009 ²⁴⁴	✓			
Level 3				
Aitken 1999 ⁴⁴	✓			✓
Bono and Campanini 2007 ²⁴⁵			✓	
Cardiac Networks Co-ordinating Group 2006 ²²⁰	✓	✓	✓	
Colquhoun <i>et al.</i> 1995 ²⁴⁶	✓			✓
Doddy 2009 ²⁴⁷		✓	✓	
Hölscher <i>et al.</i> 2013 ²⁴⁸		✓		
Hussain <i>et al.</i> 2004 ²⁴⁹			✓	
Mjølstad <i>et al.</i> 2012 ²⁵⁰		✓	✓	
NIHR DEC Oxford 2014 ⁴⁵		✓		
Ottenheim <i>et al.</i> 2011 ²⁵¹				
Robinson <i>et al.</i> 1997 ²¹⁵	✓			✓
Scholten-Peeters <i>et al.</i> 2014 ²²⁴				✓
Senior <i>et al.</i> 2003 ²⁵²		✓		
Siu <i>et al.</i> 2013 ²⁰⁵		✓	✓	✓
Vicente-Molinero <i>et al.</i> 2009 ²⁵⁴	✓			
Xiao 2003 ²⁵⁵		✓		

TABLE 28 Outcomes reported by included studies

Study (authors and year)	Clinical effectiveness	Process/system	Patient acceptability	Costs/resource use
Level 1				
Everett and Preece 1996 ²²²	✓			
Wordsworth and Scott 2002 ²⁰³	✓			
Salihefendic <i>et al.</i> 2009 ²²⁹	✓	✓	✓	✓
Level 2				
Goldberg <i>et al.</i> 2003 ²³⁰	✓			
Grubel 2011 ²³¹	✓			
Heikkinen <i>et al.</i> 2005 ²³²	✓			
Laine <i>et al.</i> 1998 ²³³	✓			
Landers and Ryan 2014 ²³⁴	✓			
Mäkelä and Leinonen 1996 ²³⁵				
Pallan <i>et al.</i> 2005 ¹⁶		✓	✓	✓
Thoomes-de Graaf <i>et al.</i> 2014 ²³⁶	✓			
van Gorp <i>et al.</i> 2013 ²²³ and van den Brink 2013 ²⁵³	✓	✓		
Varonen <i>et al.</i> 2003 ²³⁷	✓			
Abstracts/non-English publications				
Blanchet <i>et al.</i> 2015 ²³⁸		✓		
de la Figuera <i>et al.</i> 2012 ²³⁹	✓	✓		
Esquerra <i>et al.</i> 2012 ²⁴⁰		✓		
Evangelista <i>et al.</i> 2013 ²⁴¹		✓		
Gallagher <i>et al.</i> 2012 ²⁴²	✓			
Hoyer <i>et al.</i> 2007 ²⁴³		✓		
Singh <i>et al.</i> 2009 ²⁴⁴	✓			
Level 3				
Aitken 1999 ⁴⁴			✓	
Bono and Campanini 2007 ²⁴⁵				
Cardiac Networks Co-ordinating Group 2006 ²²⁰				
Colquhoun <i>et al.</i> 1995 ²⁴⁶				
Doddy 2009 ²⁴⁷			✓	
Hölscher <i>et al.</i> 2013 ²⁴⁸	✓			
Hussain <i>et al.</i> 2004 ²⁴⁹				
Mjølstad <i>et al.</i> 2012 ²⁵⁰				
NIHR DEC Oxford 2014 ⁴⁵				
Ottenheim <i>et al.</i> 2011 ²⁵¹	✓			
Robinson <i>et al.</i> 1997 ²¹⁵				

continued

TABLE 28 Outcomes reported by included studies (*continued*)

Study (authors and year)	Clinical effectiveness	Process/system	Patient acceptability	Costs/resource use
Scholten-Peeters <i>et al.</i> 2014 ²²⁴		✓		
Senior <i>et al.</i> 2003 ²⁵²	✓			
Siu <i>et al.</i> 2013 ²⁰⁵		✓		
Vicente-Molinero <i>et al.</i> 2009 ²⁵⁴	✓			
Xiao 2003 ²⁵⁵				

TABLE 29 Main models for diagnostic ultrasound services

Secondary care setting	Community/primary care setting
Secondary care 'traditional' (via consultant referral)	Community diagnostic centre (offering multiple diagnostic services)
Secondary care 'open access'	Community outreach from secondary care
Rapid-access clinic (condition specific)	GP scanning by GP in surgery
	Scanning by radiographer in GP surgery (employed by GP?)
	Mobile service delivered at GP surgery

Studies describing/evaluating service models are those by Everett and Preece,²²² Wordsworth and Scott,²⁰³ Salihefendic *et al.*,²²⁹ Pallan *et al.*¹⁶ (mobile), van Gorp *et al.*²²³ (community open access) and Landers and Ryan²³⁴ (community palliative care) and conference abstracts by Gallagher *et al.*²⁴² and Singh *et al.*²⁴⁴ (echocardiography clinics). Of these, only Salihefendic *et al.*²²⁹ compared primary care services with and without direct ultrasound access. Unfortunately, poor reporting of the methods and results made this study difficult to interpret and greatly limited its usefulness to the review.

The other two included level 1 studies were non-comparative evaluations of services provided in the UK (England²²² and Scotland²⁰³). In both studies, ultrasound scanning was carried out at a GP practice/health centre and primarily by GPs. These studies were performed in the late 1990s to early 2000s, so may not reflect current practice. As discussed below (see *Table 33*), the results of both studies were generally favourable for the community diagnostic ultrasound service model but, given their reported limitations, they must be considered as relatively weak evidence. However, we have not been able to find any more recent and/or rigorous research.

Pallan *et al.*¹⁶ evaluated a community-based mobile service compared with a hospital-based open-access service. The community service was described as an 'independent, radiographer-led service'. It appears likely that this service was delivered by a private sector provider rather than a NHS community organisation; this limits its relevance to the review question as originally defined as the study evaluated two 'comparator' interventions. Given that the grey literature search located numerous examples of services commissioned from private sector providers, Pallan *et al.*'s¹⁶ study clearly addressed an intervention that remains relevant and a comparison for which further research is needed.

The conference abstracts by Gallagher *et al.*²⁴² and Singh *et al.*²⁴⁴ both dealt with the role of echocardiography for heart failure diagnosis in the community. Both abstracts reported limited details of the models of service under study. Singh *et al.*²⁴⁴ may be evaluating a hospital-based service and Gallagher *et al.*²⁴² may be evaluating community outreach, both of which meet the criteria for comparator interventions rather than the main focus of the review. We have not been able to locate full publications for these studies, limiting the conclusions that can be drawn from them.

Finally, Landers and Ryan²³⁴ reported an evaluation of ultrasound in the management of ascites in a community palliative care service. The authors reported that bedside ultrasound allowed scanning and subsequent treatment to be undertaken at home in many cases, which was convenient for the patients and potentially cost saving for the health service. There was an implicit comparison with a model of care based on hospital admission for investigation and treatment, but no comparative data were reported.

Other studies offering insight on service models

Level 3 papers by Robinson *et al.*²¹⁵ and Colquhoun *et al.*²⁴⁶ suggest that the hospital open-access model was widely favoured in the UK in the late 1990s. If there was a general acceptance of this model, this may explain the relative lack of research on alternatives. Interestingly, the 1999 thesis by Aitken⁴⁴ evaluating patient and health professional opinions on community ultrasound services pays little attention to open access as an alternative model of service and concentrates on the implications of transferring a 'conventional' hospital-based service to a community setting.

The results of the internet and grey literature search reported below demonstrate the existence of NHS community diagnostic/primary care centres offering ultrasound and other tests, but we have found no evaluations of these in the published literature.

Equipment

Provision of ultrasound scanning in community settings has been favoured by the development of portable devices, culminating in the availability of handheld or 'pocket' ultrasound. We located two reviews of handheld devices for echocardiography.^{252,255} A third, more up-to-date review examines portable ultrasound devices in other indications, with echocardiography being due for consideration in a separate publication.⁴⁵ Although the use of handheld devices appears well established, this review identifies limitations of the evidence base for outcomes other than diagnostic accuracy and identifies an extensive list of research gaps that we have drawn on in our own research recommendations. The Welsh Cardiac Networks Co-ordinating Group also identified areas of uncertainty around the use of handheld scanners for echocardiography.²²⁰

Three primary studies provided additional evidence on the use of handheld devices in community settings (Table 30).^{205,247,250} The papers by Doddy²⁴⁷ and Mjølstad *et al.*²⁵⁰ provide limited evidence for the effectiveness of handheld scanners in view of their small sample size, lack of a control group²⁴⁷ and reliance on a surrogate outcome measure.²⁵⁰ There is some overlap with the literature on workforce and training as discussed in the following section. The review also included a conceptual paper on equipment for pre-hospital ultrasound in stroke.²⁴⁸ The report by the Welsh Cardiac Networks Co-ordinating Group suggests equipment requirements for echocardiography services.²²⁰

TABLE 30 Level 3 studies reporting details on ultrasound equipment

Study	Indication	Setting	Staff	Details of equipment	Findings relevant to equipment
Doddy 2009 ²⁴⁷	General	Primary care (England)	GPwSI in ultrasound	Handheld systems [SonoSite instruments (FUJIFILM SonoSite Inc.) mentioned, no further details]	Considers handheld systems ideal for use in GP surgery. Mentions initial outlay of £18,000–25,000. Reference to funding of machine/service now out of date
Mjølstad <i>et al.</i> 2012 ²⁵⁰	Echocardiography	Primary care (Norway)	Seven GPs	Portable scanner capable of B-mode and colour flow imaging	Compares handheld with standard echocardiography; findings for septal mitral annular excursion did not differ significantly
Siu <i>et al.</i> 2013 ²⁰⁵	General	Primary care (Canada)	Family physicians	Not applicable	Survey reveals GPs ready to use handheld ultrasound but faced with barriers

Workforce and training issues

Numerous studies examine training for GPs and others to perform ultrasound in the community (see *Table 27*). Further details are provided in *Table 31* for level 2 studies and *Table 32* for level 3 studies. The amount and level of training varies widely across studies, from short courses designed for use of ultrasound in specific indications²⁴³ to comprehensive training programmes designed for clinicians wanting to offer a wide range of ultrasound services.²⁴⁵ The available research looks at training of predominantly GPs to use ultrasound technology (a study on physiotherapists²³⁶ was an exception). No data were available on training or employment of radiographers in community or primary care settings. A general limitation of many of the included studies is that they look only at one or a small number of people being trained.

Echocardiography Full professional training requires at least 2 years of study²²⁰ and developing existing staff has implications for resource use in terms of providing cover/scheduling work.

Two studies^{243,250} looked at short training programmes for GPs to use handheld equipment for echocardiography. In these studies total training time was approximately 4 hours and 8 hours, respectively. In both studies, GPs achieved good levels of accuracy relative to the study's reference standard. However, study authors noted that, given the limitations of current equipment, handheld scanner results cannot be regarded as definitive, so GP scan is not a substitute for full echocardiography by a cardiologist. Further research is needed to assess the role of handheld ultrasound to support decision-making for patients with possible LVSD in primary care.²⁵⁰

General/other indications One study described a full training programme for GPs to operate as ultrasonographers.²⁴⁵ A limitation of this study was that at the time of writing it appeared that no courses had actually taken place, so the study describes a consensus view of a desirable training programme for GPs. [In this respect compare the RCR document *Ultrasound Training Recommendations for Medical and Surgical Specialties*²⁵⁶ (not included in the review because it is not primarily directed at community settings), which recognises three levels of expertise and provides detailed training recommendations for each level by indication.]

Other studies describe individual training experiences of varying intensity.^{231,240,247} In the UK, Doddy²⁴⁷ reported having completed over 100 hours of training, comparable with the amount of teaching in the

TABLE 31 Level 2 studies reporting details of ultrasound training

Study (authors and year)	Indication	Setting	Staff being trained	Type and amount of training	Findings relevant to training
Grubel 2011 ²³¹	Abdominal	Community practice	Gastroenterologist	Daily supervised ultrasound over 6 months; > 1000 scans in total	Specific standards of training required to demonstrate competence in ultrasound have not yet been defined
Hoyer <i>et al.</i> 2007 ²⁴³	Echocardiography	Primary care (training delivered at cardiology centres)	48 GPs	Structured training programme of about 4 hours in use of handheld echocardiography for heart failure diagnosis	After first training session, concordance between GPs and cardiologists for presence of heart failure was 80% at centre 1 and 78% at centre 2. Authors concluded that training allowed previously inexperienced GPs to apply handheld echocardiography for heart failure diagnosis

TABLE 31 Level 2 studies reporting details of ultrasound training (*continued*)

Study (authors and year)	Indication	Setting	Staff being trained	Type and amount of training	Findings relevant to training
Laine <i>et al.</i> 1998 ²³³	Sinus	Primary care centres	12 GPs	GPs at one centre received standard information on the use of the ultrasound machine from the manufacturer; the other centre had used this machine for 6 years	GPs produced a high number of false-positive diagnoses. More education and practice could improve accuracy of diagnosis
Thoomes-de Graaf <i>et al.</i> 2014 ²³⁶	MSK	Primary care	Physiotherapists	Physiotherapists were required to have at least 1 year of experience in diagnostic ultrasound and to have performed at least 100 shoulder ultrasounds after graduating	Physiotherapists with more experience (> 200 ultrasounds) and more training (advanced course) showed greater agreement with radiologists
Varonen <i>et al.</i> 2003 ²³⁷	Sinus	Primary care	35 GPs from nine health centres	GPs received a 1.5-hour small-group tutorial on ultrasound from an experienced specialist. GPs at one health centre had used sinus ultrasound for several years (sensitivity and specificity were calculated on results from this centre)	Authors stated that a short tutorial can improve GPs' accuracy in sinus ultrasound examination
Non-English language					
Esquerria <i>et al.</i> 2012 ²⁴⁰	Abdominal	Hospital radiology department and primary care centre	2 GPs	100 hours of teaching followed by 112 hours based in the hospital radiology department	For the primary diagnosis, GP scans had a sensitivity of 95.5% (95% CI 91.8% to 99.2%) and specificity of 94.3% (95% CI 90.2% to 98.5%). Authors concluded that it is feasible for trained GPs to perform low complexity diagnostic abdominal ultrasound
Evangelista <i>et al.</i> 2013 ²⁴¹	Echocardiography	Primary care centre	1 GP	Basic training recommended for non-cardiologists (no further details reported)	Agreement between GP and cardiologist was good or very good. Authors concluded that pocket echocardiography performed by a GP as an extension of clinical assessment provides an early diagnosis of significant cardiac lesions that may improve therapeutic management of people with hypertension

TABLE 32 Level 3 studies reporting details of ultrasound training

Study (authors and year)	Indication	Setting	Staff being trained	Type and amount of training	Findings relevant to training
Bono and Campanini 2007 ²⁴⁵	General	Italian primary care	GPs	Requirements for certification as GP ultrasonographer: <ul style="list-style-type: none"> • three theoretical courses (≈80 hours) in 2 years • 16 days' practical training • 960 ultrasound examinations • completion of course at Italian Ultrasound Society annual congress 	Programme has been designed to ensure quality of diagnostic ultrasound by GPs
Cardiac Networks Co-ordinating Group 2006 ²²⁰	Echocardiography	NHS in Wales	Cardiac physiologists; echocardiographers; GPs; specialist nurses	4 years for cardiac physiologists, 2 years part-time for others. Training for existing GPs/nurses needs locum cover (GP) or fitting in with other duties (nurse)	A minimum of 2 years is required to train a practitioner to BSE standards
Doddy 2009 ²⁴⁷	General	NHS primary care in England	GP	Over 100 hours of Royal College of Radiology training, including a course on musculoskeletal ultrasound at postgraduate certificate level 1	The choice of training courses for GPs is growing and ranges from a basic general course to specialist applications relevant to primary care
Hussain <i>et al.</i> 2004 ²⁴⁹	Urinary tract symptoms	NHS primary care in England	GP	15 telemedicine sessions in which images from GP scans were transmitted to a university expert	Results show feasibility of teleultrasound in primary care. GP benefited from regular training and supervision and achieved satisfactory competence in scanning prostate, bladder and kidneys
Mjølstad <i>et al.</i> 2012 ²⁵⁰	Echocardiography	Primary care in Norway	7 GPs	8 hours of training from a cardiologist certified in echocardiography	After limited training GPs were able to assess a marker of left ventricular function in 87% of patients using pocket ultrasound. There was no significant difference between GPs' and cardiologists' findings
Siu <i>et al.</i> 2013 ²⁰⁵	General	Primary care	Family physicians	14 out of 18 respondents to a survey had previous training in ultrasonography. Most had received training through a continuing education course	Training issues (confidence, reliability and skill maintenance) were a barrier to physicians using ultrasound in community settings

programme described by Esquerre *et al.*²⁴⁰ Grubel's²³¹ training for GI ultrasound included performing supervised ultrasound daily for 6 months. This training was acquired while working in Germany and the author noted that in the USA it is unusual for GI ultrasound to be performed in community settings.

Two studies in Finland evaluated the use of ultrasound for diagnosis of sinusitis by GPs.^{233,237} In one study, GPs who had received only basic information from the ultrasound machine manufacturer produced a high number of false-positive diagnoses and the authors suggested that more attention to education and training could improve their performance.²³³ In a later study, GPs received 1.5 hours of small group training and high rates of accuracy were received. The authors commented that even a short period of training can improve accuracy.²³⁷ However, it should be noted that the diagnostic accuracy results appear to have come from a centre where the GPs had substantial experience of diagnostic ultrasound, and the findings may not be applicable to less experienced GPs.

The study by Siu *et al.*²⁰⁵ examined attitudes to providing ultrasound in community settings among family physicians in Yukon, Canada. Although training was not the main topic of this study, training-related issues (e.g. confidence and maintenance of skills) were identified as key barriers to doctors offering this type of service.

Attitudes/barriers to community provision

A small number of papers, all classified as level 3 studies, addressed attitudes or barriers to provision as their main focus.^{44,205,215,224,238,246} Studies from the UK/England suggest that most health professionals preferred open access to hospital services rather than facilities based in general practice.^{215,246} This seems to be a key finding, although the most relevant study²¹⁵ (the other source being expert opinion) dates from 1997 and is not high quality, so the findings may not be applicable to current practice. Also in the late 1990s, Aitken's⁴⁴ PhD thesis investigated attitudes to transferring ultrasound services (including monitoring of pregnancy as well as diagnostic ultrasound) to community settings. The research involved focus groups and a questionnaire study with relatively large samples of health professionals ($n = 353$) and patients ($n = 495$). Overall, health professionals regarded ultrasound as a suitable service to be provided in the community and patients would be happy to use such a service. However, given the broad scope of ultrasound services covered by the thesis, the relevance of the findings to specifically diagnostic ultrasound is uncertain. Several potential problems were identified, particularly by hospital-based clinicians. These included issues related to communication, quality control and training. Radiographers were concerned about possible isolation when working in the community.

A more recent paper by a GPwSI in ultrasound also shows some awareness of barriers to ultrasound by GPs.²⁴⁷ Barriers mentioned include access to training and funding for providing the service, although the author believes that these can be overcome. Doddy argues that the perceived benefits to patients are such that all general practices should have access to diagnostic ultrasound for appropriate indications.

Another potential barrier to community ultrasound would arise if secondary care professionals displayed a negative attitude towards this type of service. In the Netherlands, Scholten-Peeters *et al.*²²⁴ found that hospital doctors (radiologists and orthopaedic surgeons) had low confidence in diagnostic musculoskeletal ultrasound performed by physiotherapists or GPs. Scans performed in primary care were often repeated in secondary care, although this was not quantified. It is interesting that the findings of this recent study echo those of Robinson *et al.*²¹⁵ from 1997.

In a non-UK context, respondents to the survey of Siu *et al.*²⁰⁵ identified equipment costs and remuneration as the major barriers to ultrasound in the community, followed by issues related to training. These barriers were evidently considerable, as none of the respondents was currently providing a service in this setting, although most recognised the advantages, had relevant training and were keen to do so.

Siu *et al.*'s²⁰⁵ findings are broadly in line with the results of a qualitative study (involving interviews and focus groups) of French GPs.²³⁸ Again, none of the eight participants was currently providing an ultrasound

service in the community; seven were interested in doing so and five had received training. However, the participants identified numerous barriers: the authors summarised the main themes as lack of experience with ultrasound in general practice; mastering ultrasound scanning techniques; uncertain relevance of ultrasound scanning in general practice; the GPs' own reluctance to use the technique; and possible legal issues.

Clinical effectiveness (includes diagnostic accuracy/yield)

All three level 1 studies reported outcomes related to clinical effectiveness of primary care ultrasound (Table 33).^{203,222,229} Everett and Preece reported that GP ultrasound had a sensitivity of 97% and specificity of 98% for establishing fetal viability in women with bleeding in early pregnancy. The main clinical benefit was that women with a viable fetus could be given a strong reassurance that they were not at high risk of miscarriage. This enabled referral to hospital to be avoided, saving a journey for the patient and the cost of a hospital ultrasound scan for the health service. However, this was not a controlled study and the authors recognised the need for further research to compare different ways of delivering diagnostic ultrasound for women with bleeding in early pregnancy.

The other level 1 UK study reported that having ultrasound scanning available in general practice for abdominal, gynaecological and obstetric problems reduced outpatient referrals, hospital scans and emergency admissions.²⁰³ This study is also limited by the lack of a control group. The results for patients using the GP ultrasound service were compared with a consensus view of how that patient would have been managed had the service not been available.

The only study with a control group that reported any outcomes related to clinical effectiveness of a community ultrasound service was that of Salihefendic *et al.*²²⁹ These authors compared two primary care clinics in Bosnia-Herzegovina, with and without direct access to abdominal diagnostic ultrasound. The usefulness of this study is limited by unclear reporting but the authors stated that abdominal ultrasound was valuable in guiding patient management. It was unclear how the impact on patient management differed between the experimental and control groups.

Eight studies classified as level 2 assessed the diagnostic accuracy of primary care/community ultrasound but in most cases with some attention to wider clinical implications, making it appropriate to discuss them in this section (Table 34).^{230–233,236,237,239} There were contrasting findings across this group of studies, partly explained by differences between different indications. In two studies of musculoskeletal ultrasound, accuracy was found to be poor in community practice in Australia²³⁰ and levels of agreement between community physiotherapists and radiologists were slight to moderate for most shoulder pain diagnoses.²³⁶ These findings cast doubt on the value of community ultrasound for these conditions/settings. A further

TABLE 33 Clinical outcomes from level 1 studies

Study (authors and year)	Application of ultrasound	Main clinical findings
Everett and Preece 1996 ²²²	Obstetric	240 women with bleeding in early pregnancy were scanned. Community ultrasound scanning had a sensitivity of 97% and specificity of 98% for predicting fetal survival to the 20th week of pregnancy. No fetal heart movement was detected in 117 women and all subsequently miscarried
Wordsworth and Scott 2002 ²⁰³	General	131 patients were scanned over 6 months. GP scanning reduced the number of referrals (14.8% vs. 29.9%), emergency hospital admissions (7.8% vs. 13.4%) and hospital scans (0.8% vs. 23.6%)
Salihefendic <i>et al.</i> 2009 ²²⁹	Abdominal	383/1539 patients in the experimental group and 175/1878 in the control group were scanned. Abdominal ultrasound resulted in a change in anticipated patient management in 54% of patients, including a reduction in anticipated referrals to medical specialists

TABLE 34 Clinical outcomes from level 2 studies

Study (authors and year)	Application of ultrasound	Main clinical findings
Goldberg <i>et al.</i> 2003 ²³⁰	Musculoskeletal	The accuracy of diagnostic ultrasound was 0.38, sensitivity was 0.24 and specificity was 0.61. There were 155 false negatives and 51 false positives based on the diagnostic ultrasound reports (out of 336 patients)
Grubel 2011 ²³¹	Abdominal	310 patients underwent ultrasound. Ultrasound findings guided clinical management in two-thirds of patients (exact numbers not reported). A normal ultrasound result was subsequently confirmed in 35 out of 40 patients (88%). Abnormal findings were confirmed in 41 out of 44 patients (93%). Ultrasound missed three (4%) significant clinical lesions but no malignancy was overlooked
Heikkinen <i>et al.</i> 2005 ²³²	Abdominal	Repeated ultrasound examination in people with functional dyspepsia is not recommended and rarely changes the diagnosis
Laine <i>et al.</i> 1998 ²³³	Sinus	Sensitivity of GP ultrasound was 61% and specificity was 53%. For ultrasound combined with clinical examination, sensitivity was 70% and specificity was 37%. Poor accuracy of ultrasound was mainly due to a high number of false-positive diagnoses
Thoomes-de Graaf <i>et al.</i> 2014 ²³⁶	Musculoskeletal	Agreement between physiotherapists and radiologists is borderline substantial for full-thickness tears and slight to moderate for other diagnoses
van Gorp <i>et al.</i> 2013 ²²³	Echocardiography	GPs using a community open-access service reported that they referred fewer patients to a cardiologist than they would have done without the service and managed more patients themselves. In 127 cases (82%), the GP thought that the echocardiogram was beneficial to decision-making
Varonen <i>et al.</i> 2003 ²³⁷	Sinus	With practice and training, primary care physicians can perform sinus ultrasound as accurately as specialists, potentially reducing unnecessary use of antibiotics for patients with acute maxillary sinusitis
de la Figuera <i>et al.</i> 2012 ²³⁹	Echocardiography	Data on 684 patients who underwent echocardiography at four health centres in 2006–7 were analysed. 84% of requests were appropriate and 79.7% showed the presence of disease. Echocardiography results influenced decision making in > 35% of cases: 17.1% were referred to a cardiologist, 10.5% had their treatment changed and 9.6% were referred for additional tests

two studies examined abdominal ultrasound. An investigation of scans performed by a gastroenterologist in a US community setting indicated that the results were useful for guiding clinical management in two-thirds of cases and findings were generally supported by subsequent reference tests.²³¹ However, Heikkinen *et al.*,²³² in a long-term study of patients with functional dyspepsia, reported that repeat ultrasound rarely changes the diagnosis and hence it was not recommended.

Two studies of ultrasound for diagnosis of sinusitis in Finnish primary care identified problems caused by a high rate of false-positive diagnoses²³³ but, given appropriate training, GPs could diagnose as accurately as specialists,²³⁷ with the potential to reduce unnecessary antibiotic use. Two studies of echocardiography were identified. A study of a community-based open-access service in the Netherlands²²³ was accompanied by a critical commentary.²⁵³ The study authors concluded that the open-access service reduced referrals and allowed more patients to be managed in primary care, although again there was no control group and comparison was against what the primary care physician reported they would have done in the absence of the service. The author of the commentary criticised the lack of connection between the open-access service and local hospitals. The commentary also stated that the ultrasound technicians might have had insufficient experience and the cardiologists involved in the study were provided with insufficient information. In conclusion, the commentary author argued that open-access echocardiography may lead to a 'low-budget pseudo-consult[ation] of the cardiologist, whilst the patient thinks he is getting a state-of-the-art treatment'.²⁵³

Overall, these studies indicate that community ultrasound can guide patient management and potentially reduce referrals, at least in some indications/settings. However, the contradictory results and generally poor quality of the studies, particularly the absence of true control groups, make it difficult to draw any firm conclusions.

Conference abstracts by Gallagher *et al.*²⁴² and Singh *et al.*²⁴⁴ are discussed separately, as they deal with different service models for echocardiography (Table 35). Gallagher *et al.*²⁴² studied a community outreach clinic giving GPs access to natriuretic peptide testing followed by echocardiography in the community if required. The main outcome measure in this non-comparative retrospective study was diagnostic yield (see Table 35). The authors concluded that specialist review in the community offers the opportunity for older patients to access specialist care in a timely manner.²⁴² Singh *et al.*²⁴⁴ studied a one-stop diagnostic clinic for heart failure. The setting for this clinic was probably secondary care, although it was run by a primary care physician specialist. As with Gallagher *et al.*,²⁴² the main outcome measure for the study was the diagnostic yield and there was no comparison group. The ability to provide alternative diagnoses for most patients without LVSD was seen as an advantage of the one-stop clinic over open-access echocardiography. Unfortunately, neither study appears to have been published in full, which makes it difficult to evaluate them or place them in the context of the review question.

Four studies classed as level 3 evidence reported issues related to clinical effectiveness, although these were limited. Hölscher's review article assesses the potential use of diagnostic ultrasound in the pre-hospital treatment of people with stroke, but it is described as a concept paper and does not report any hard data.²⁴⁸ Ottenheijm *et al.*²⁵¹ published the protocol for a randomised trial of diagnostic ultrasound-guided therapy in patients with shoulder pain. The primary outcome is patient-perceived recovery at 52 weeks. Full details of the trial had not been published in time for inclusion in the report.

Finally, two review articles should be mentioned for the sake of completeness. Senior *et al.*,²⁵² focusing mainly on accuracy and technical outcomes, compared handheld echocardiography with traditional echocardiography and BNP testing for diagnosis of BNP in the community. A review article in Spanish by Vicente-Moliner *et al.*²⁵⁴ searched a range of sources including INAHTA (International Network of Agencies for Health Technology Assessment), PubMed and websites of scientific societies for the years 1996–2006. This broad-ranging review presented few details of the included studies and was used primarily as a means by which to identify references for possible inclusion in our review.

Overall, the evidence base for clinical effectiveness of community ultrasound is very limited and, in particular, there is a lack of controlled studies comparing different ways of delivering ultrasound services.

Evidence on process/system outcomes (e.g. waiting times)

Only one level 1 study provided evidence on process or health system-related outcomes.²⁰³ The study by Wordsworth and Scott²⁰³ included an evaluation of the quality of GP ultrasound scans by a consultant radiologist. Fifty of 131 scans could not be evaluated, but overall the quality of scans was sufficient to

TABLE 35 Clinical outcomes of level 2 studies reported as abstracts

Study (authors and year)	Application of ultrasound	Main clinical findings
Gallagher <i>et al.</i> 2012 ²⁴²	Echocardiography	GPs were given direct access to natriuretic peptide testing followed by facilitated access to echocardiography in the community. Of 66 patients who completed assessment over 6 months, 37 had echocardiography; 23 were abnormal and 17 were diagnosed with heart failure
Singh <i>et al.</i> 2009 ²⁴⁴	Echocardiography	Of 1008 patients referred to a one-stop diagnostic clinic, 292 (29%) had confirmed LVSD on echocardiography. For the 716 without LVSD, an alternative cause for symptoms was identified in 578 (81%)

allow scanning to continue at the practice, subject to the further training of GPs in specific areas. It was also recommended that one GP, rather than two, should perform ultrasound scans to achieve a sufficient volume of scanning.²⁰³ The authors also noted that 6 of the 131 patients scanned received earlier access to treatment as a result of being scanned at the practice.

Five of the level 2 and 3 studies published in English provided evidence on process/system outcomes. Makela *et al.*²³⁵ reported that, when available, ultrasound was used to diagnose maxillary sinusitis in Finnish primary care in 82–92% of cases. The paper by Pallan *et al.*¹⁶ compared a radiographer-led community diagnostic ultrasound service with a hospital open-access service and found that waiting times for appointments were shorter for the community service (mean 17.44 vs. 44.53 days). Eighteen out of 23 GPs who used both services stated that waiting times influenced their decision about where to refer a patient. Pallan *et al.*¹⁶ also followed the pathways of three pairs of patients referred to secondary care following an abnormal scan. The time interval between initial ultrasound investigation and referral ranged from 1 to 168 days, although the reasons for this were not reported. The authors reported that, overall, there were no systematic differences between the two services.

An important finding from the study by Scholten-Peeters *et al.*²²⁴ was that, according to Dutch orthopaedic surgeons and radiologists, the diagnostic process for people with musculoskeletal problems was rarely focused on the referral diagnosis from primary care. Only 47 (22.1%) respondents stated that it was, compared with 133 (62.4%) answering negatively and 23 (10.8%) not applicable. Combined with the negative opinions of respondents about diagnostic ultrasound performed in primary care, this would suggest that the process of diagnosis may be suboptimal, although it is unclear if the results are likely to be generalisable to the UK setting.

In the Canadian health system, Siu *et al.*²⁰⁵ reported, based on a survey with a 44% response rate, that family physicians were not currently using ultrasound in community office settings. This was attributed in part to the availability of ultrasound technicians locally to perform scans following referral. The authors noted that bedside ultrasonography performed by a physician would most often be focused on a particular clinical question and could be used to inform a decision about referral for further investigation (including ultrasonography).

Process and/or system outcomes reported in van Gorp *et al.*'s²²³ study of community echocardiography in the Netherlands included waiting times and GP adherence to the cardiologist's advice and to Dutch clinical guidelines for heart failure. Waiting time for echocardiography via referral was estimated at 5 weeks, compared with 6 days via the community open-access service. GPs followed specific advice from the cardiologist evaluating the scan in 25 out of 31 cases (81%). In one case the advice was not followed and in five cases the outcome was not known. Adherence to clinical guidelines was considered suboptimal, in that 13 out of 55 patients with suspected heart failure were referred to echocardiography without evidence of an abnormal ECG or BNP result.

A study published as a conference abstract²⁴³ and two studies published in Spanish^{240,241} focused on training GPs for handheld echocardiography^{241,243} or abdominal ultrasound.²⁴⁰ The studies are discussed above, but in terms of health system outcomes, they indicate that training programmes can be delivered successfully at different centres and levels of intensity. By contrast, the barriers to GP ultrasound in the French health system identified by Blanchet and Thierry²³⁸ included uncertainty about various process- or system-related factors, for example impact on length of consultations and relationships with secondary care specialists.

Patient acceptability

The four studies that reported on patient views of ultrasound in the community all reported positive findings.^{16,44,203,247} The studies used different methods to assess patients' views. Wordsworth and Scott carried out a discrete choice experiment which showed that patients strongly preferred scanning at the GP surgery to the hospital alternative. This study was performed in a rural area of Scotland and the hospital was

30 miles from the surgery, so the results may not be generalisable to more urban areas. Patients showed no strong preferences as to who performed the ultrasound scan (e.g. the GP or the radiographer).²⁰³ In the study by Pallan *et al.*,¹⁶ patients (and referring GPs) were asked to rate their satisfaction with a community ultrasound service and a hospital open-access service on a 1–5 scale. Eighty-six per cent of patients rated the community service at 4 or 5 (the highest levels of satisfaction) compared with 76% for the hospital service. GPs were markedly more satisfied with the community service than with the hospital service. This was the only study to compare the views of users of different types of service.

Turning to level 3 evidence, the majority of patients who took part in Aitken's focus groups and surveys indicated that, hypothetically, they were happy to use a community ultrasound service.⁴⁴ Percentages of patients responding positively in the surveys were 76% in a pilot survey and 72% in the main survey. Focus groups identified convenience and improved access as key reasons for preferring community ultrasound. Finally, Doddy states in his opinion article that his patients are 'delighted to be scanned at the surgery', although no evidence is presented to support this.²⁴⁷

Costs/resource use

Two included studies reported on costs or resource use.^{16,203} Wordsworth and Scott performed a cost analysis of GP versus hospital ultrasound scanning. The main finding was that cost per scan was higher for GP scanning (£36.37 vs. £20.32) but the average cost per episode was lower (£148 vs. £183). Pallan *et al.*¹⁶ calculated the cost per abnormality detected for community and hospital ultrasound services and found that the cost was higher for the community service [£107.69, 95% confidence interval (CI) £90.61 to £132.71 vs. £77.35, 95% CI £63.76 to £98.30]. The authors argued that reduced waiting times and high patient and GP satisfaction could justify the higher costs for the community service.

Mapping of current practice (internet search)

Included items and characteristics

Published articles

Two published articles not identified by the database searches^{234,247} were picked up by the internet search and included in the synthesis below. An ongoing systematic review of ultrasound for musculoskeletal disorders in primary care was identified from the PROSPERO systematic reviews register.²⁵⁷ Other online articles were retained as useful background papers. The remaining articles were judged not relevant to the review or added little to the evidence available from the peer-reviewed literature.

Companies providing diagnostic ultrasound services

The searches revealed details of services provided by 22 companies, most of which provided a range of diagnostic (and in some cases clinical) services in addition to ultrasound (see *Appendix 8*). However, one of these appeared to be not mainly focused on ultrasound (InHealth), one was mainly serving hospitals rather than community settings (Independent Vascular Services), and one appeared to be an exclusively private service (The Ultrasound Centre). Details provided by the company websites were highly variable. Commonly reported features include time standards for appointments and report delivery and patient satisfaction ratings. Links to the NHS, including experience of the radiographers and others providing the service and roles of NHS consultants in audit and governance, were emphasised by most of the companies. It appeared that many staff worked part-time for the companies and the remainder of the time for NHS organisations (primarily hospital trusts).

Services were described as being generally commissioned through the 'any qualified provider' system. All services are regulated by the Care Quality Commission (our search found one Care Quality Commission inspection report). All of the services appeared to follow basically the same model of care, namely a mobile service operating through GP surgeries and other community sites and staffed by radiographers (and health-care assistants), with access to consultant radiologists as required.

NHS service specification

The internet search also found a standard NHS specification for non-obstetric ultrasound,²⁵⁸ covering the following indications:

- general abdominal: includes assessment of the aorta, biliary tract, gallbladder, inferior vena cava, kidneys, liver, pancreas, retroperitoneum and spleen
- gynaecological: including transabdominal and transvaginal
- renal/bladder/prostate
- scrotal/testicular
- musculoskeletal
- vascular.

There are various exclusions from the service specification, including scans for suspected cancer, ultrasound-guided procedures and obstetric care, as well as parts of the body not listed above. The NHS service specification also provides for scans to be undertaken in secondary care where this is an integral part of a clear clinical pathway.²⁵⁸

NHS diagnostic centres (or similar names)

Websites were identified for 'diagnostic centres' run by private sector companies in Rotherham (Care UK), Havant (Care UK), Buckinghamshire (Care UK) and Woking (Virgin Care). These centres provide a range of diagnostic tests, including ultrasound. The websites provided little information that could be helpful for evaluation of the service.

Primary care centres

Websites were also identified for 'primary care centres': Bingfield (InHealth), Keyworth (Diagnostic Healthcare), George Street (Diagnostic Healthcare), Duncan Street (Diagnostic Healthcare) and Lordship Lane (InHealth). These differed from the 'diagnostic centres' by being integrated with GP surgeries rather than specialising in diagnostic services, but resembled them in offering ultrasound alongside other diagnostic services. Again, the websites provided limited information.

Service description/specification

Published service specifications for non-obstetric ultrasound from Nottingham City CCG, Milton Keynes CCG, Manchester PCT and Ipswich CCG were identified. All were closely based on the standard NHS service specification described above.²⁵⁸

Summary of findings

Evidence from the internet search results suggests that community-based services run by non-NHS providers with links to the NHS for governance and quality control are feasible and, in some cases, well established. Where reported, levels of patient satisfaction are high. It is possible that the characteristics of patients referred to these services are different from those of patients referred to secondary care services (including 'open access' services); this makes it difficult to compare the two types of service. The limited evidence also suggests that these services support the stated aims of providing patients with services close to home, avoiding unnecessary referrals and allowing more patients to be managed in primary care.

For practical reasons, it was possible to examine only a small proportion of the search results. The results examined were ranked highly for relevance by the search engine but the findings should not be regarded as a comprehensive list of current services. Furthermore, the possibility cannot be ruled out that some of the webpages found relate to services that are no longer operating.

Discussion

Main findings

Service models

To the best of our knowledge this is the first systematic review to examine community and primary care ultrasound from the perspective of service delivery and organisation. We found very little evidence to guide decision-making about models of service for diagnostic ultrasound services. The best evidence from the UK is over 10 years old, with no rigorously designed experimental studies of different service models. Very few studies compare community and secondary care services^{16,203} or even describe UK community-based services.²²² We have found no recent studies from the UK.

Open access for GPs to ultrasound facilities based in secondary care became widely available during the 1990s. Research published in 1997 suggested that this model of care was favoured by GPs and secondary care clinicians.²¹⁵ There was little interest in ultrasound services based in GP surgeries or in training GPs to perform ultrasound. The limited number of studies located meant that we were unable to form a clear picture of the current situation, although we identified one article by an enthusiastic GP who had undertaken training and was offering diagnostic ultrasound services which were popular with his patients.²⁴⁷ Funding structures and training opportunities at the time this article was written did not appear to encourage GPs to take this route and it appears likely that the numbers offering ultrasound in average-size practices would be small.

Lack of research may reflect general satisfaction with the prevalent 'open-access' model. However, increasing pressure to provide services in the community combined with ability to commission services from 'any qualified provider' has favoured the emergence of other models (primarily mobile services operating at community sites and delivered by private providers who may share staff with NHS organisations). We found that such services are widespread in the English NHS, although the extent of this diffusion is difficult to quantify. The only study in our review that evaluated a mobile service found that, compared with a hospital open-access service, waiting times were shorter but costs per abnormality detected were marginally higher.¹⁶ CCGs have also begun commissioning other types of service such as 'community diagnostic centres', primarily from private sector providers. Such centres would offer ultrasound scanning alongside other diagnostic/imaging tests.

Services tend to offer scanning for a standard range of indications for ultrasound as defined by the NHS non-obstetric service specification. Limited evidence suggests that alternative/innovative uses may be possible, for example in community palliative care.²³⁴

Clinical effectiveness

The few studies that reported clinical effectiveness outcomes were mostly of poor methodological quality. Two studies indicated that community ultrasound can guide patient management and potentially reduce unnecessary referrals, at least for some indications/settings.^{203,223} A further study highlighted problems with poor reliability and quality of scans performed in community settings.²³⁰ The contradictory results and generally poor quality of the studies, particularly the absence of true control groups, make it difficult to draw any firm conclusions.

One of the main potential benefits of community diagnostic services is the potential for patients to obtain quicker access to diagnosis, and, if necessary, treatment, than through referral to secondary care. There was limited evidence related to this in studies included in the review. Wordsworth and Scott reported that 6 out of 131 patients in their study 'received earlier access to [surgical] treatment, because their diagnoses had been made earlier as a result of having a scan at the practice'.²⁰³ In the absence of a control group, it was unclear what would have happened to these patients had scanning not been available (e.g. outpatient referral or referral for direct access scan) and so the benefit of GP ultrasound scanning was difficult to quantify. Pallan *et al.*¹⁶ found that waiting times for an appointment were substantially shorter for a

community-based mobile service than for a hospital 'open access' service. However, it was unclear if this translated into improved access to treatment. The authors mapped the pathways of three pairs of patients referred to secondary care after an abnormal scan and reported no systematic differences between the two services.

Cost-effectiveness

Two studies in the review reported on costs of different models of ultrasound services. Wordsworth and Scott reported that cost per scan was higher for GP than hospital scanning but the cost per episode was lower.²⁰³ Pallan *et al.*¹⁶ found that the cost per abnormality detected was higher for a radiographer-led community service than a hospital open-access service. The authors argued that reduced waiting times and high patient and GP satisfaction could justify the higher costs for the community service. The limited quantity and quality of evidence around the cost-effectiveness of community ultrasound services in UK settings is particularly important in view of the recent emergence of new models of service, such as privately operated mobile services and diagnostic centres offering multiple testing services at a single site.

Attitudes

A recent survey of radiologists and orthopaedic surgeons in the Netherlands indicated that they have a low opinion of the quality and appropriateness of ultrasound scanning in primary care, and scans performed in primary care are often repeated after referral to hospital.²²⁴ Many clinicians in this study did not focus on the referral diagnosis from primary care but in effect restarted the diagnostic process from scratch. Lack of confidence by secondary care clinicians in scans performed by their primary care and community colleagues would have considerable implications for resource use and would be a major barrier to the successful implementation of community-based services. We found no evidence on the attitudes of secondary care specialists in the UK. However, the research conducted by Robinson *et al.*²¹⁵ in the 1990s suggested that the delivery of ultrasound was seen as a role for secondary care, despite the then-policy of encouraging primary care and community services.⁴⁴

Training/workforce

The studies included in the review deal with training of GPs and other doctors. Studies are split between those evaluating long periods of intensive training^{220,231,245} and those arguing that short training programmes (hours to days) equip doctors adequately to perform, for example, screening echocardiography using a handheld scanner.^{243,250} The evidence thus suggests that training needs will vary depending on the role of diagnostic ultrasound scanning in the practice of the individual or the service that employs them.

None of the evidence we examined looked at training for health professionals other than doctors, despite the fact that a high proportion of ultrasound scans are delivered by radiographers and/or ultrasonographers. In particular, there was no consideration of the training needs of ultrasonographers working in community settings, how these needs might differ from those of hospital-based staff and how best to deliver training to those working outside hospital structures. Links to secondary care may be important for governance and quality control of a community-based service, as highlighted in the critique of a community echocardiography service in the Netherlands.^{223,253}

Equipment

A major development in the field of ultrasound has been the availability of handheld or 'pocket' devices. These are cheaper and more easily transportable than traditional scanners and as such have facilitated the development of services outside hospital settings. However, a recent report identified many uncertainties around training needs, impact on clinical decision-making and cost-effectiveness.⁴⁵ One study included in the review highlighted that scans performed with handheld devices at the bedside may not be definitive but would have a role in guiding decisions on further investigations, including additional ultrasound scans.²⁰⁵

Strengths and limitations

We aimed to be inclusive in terms of study designs and sought information from a range of other sources in addition to bibliographic databases. The internet search enabled us to identify some useful items of grey literature and articles not indexed by the databases (e.g. articles from non-academic professional periodicals such as the *Health Service Journal*). We were also able to identify a selection of current NHS services and companies offering services to the NHS, and extract relevant data from their websites.

While including evidence from a wide range of study designs, we attempted to assess the quality (risk of bias) of included publications when possible. This involved the use of several different tools and checklists in an attempt to provide the reader with the most appropriate quality assessment for each type of included study. We have also included some reports that we were unable to quality assess, for example conference abstracts, when these provided useful information about models of service. In addition to quality assessment, we categorised evidence into levels based on study design, setting and relevance to the review question. This approach has been used in other systematic reviews²⁵⁹ and is useful when a small subset of core studies is supplemented by studies that meet inclusion criteria but are less useful in addressing the review question (e.g. lower external validity) or address only limited aspects of the question.

The limitations of the evidence base have been discussed above. Possible limitations of the review process include the possibility of omitting relevant studies published before our cut-off date of 1995. We found relevant evidence dating from 1997,²¹⁵ so this possibility cannot be ruled out. However, developments in equipment as well as changes in the organisation of the NHS mean that older literature is decreasingly relevant to the scope of the review, justifying the decision to stop at 1995.

A further possible limitation of the review concerns the selective internet searching. Although the results made a valuable contribution to the review, the websites and pages included represent a snapshot of current services rather than a comprehensive list. Information about the services currently being commissioned in the NHS is contained in many and disparate sources and is constantly changing. The results appear fairly representative but a full picture of the range of services currently available would require a survey of commissioning organisations with intensive follow-up to obtain a reasonable response rate. Such a survey was outside the scope of this project.

Relationship to other research

We are not aware of any other systematic reviews addressing the specific topic of ultrasound services in primary care/community settings, although a protocol for a review of ultrasound imaging for musculoskeletal disorders in primary care was located.²⁵⁷ Based on the details provided, this review appeared to have more of a descriptive/qualitative focus and, as such, its findings will complement our review with its emphasis on issues affecting service delivery. Although not strictly systematic reviews, the Horizon Scanning reports published by the NIHR DEC in Oxford also represent relevant synthesised evidence, and some of the recommendations of the DEC report on portable ultrasound devices⁴⁵ are drawn on below.

Conclusions

The limitations of the evidence base identified by this focused rapid review suggest that there are urgent needs for further data collection and research to guide decision-making in relation to diagnostic ultrasound services.

Implications for health care

We have identified the following implications for health care:

- The evidence suggests uncertainty about the training needs of different staff groups, for example GPs, nurses and radiographers, particularly any specific needs for community-based services. This also applies to needs for the teaching/training of students and GP trainees.⁴⁵

- Further uncertainty surrounds the implications of different models of service for quality control and governance. Relevant standards have been published by the RCR and Society and College of Radiographers.²⁰⁴
- The evidence we were able to locate suggests that the monitoring and evaluation of changes to services at the local level through appropriate audit and data collection is currently limited.

Implications for research

We have identified the following priority suggestions for research.

- Studies to compare different models of ultrasound service, particularly to compare GP-based and hospital-based services with (nurse-led?) 'diagnostic centres'. This could include general diagnostic ultrasound services and/or specific indications, for example echocardiography. Outcomes could include waiting times, access to treatment if required and patient satisfaction. Although randomised studies using a cluster design may be feasible in principle, in practice such research would probably involve an observational study design, for example controlled before-and-after or interrupted time series. The Nuffield Trust has recently published a guide to evaluating new service initiatives using retrospective matched control methods.²⁶⁰ Given access to suitable data, these methods could be valuable for comparing different service models for ultrasound and other diagnostic interventions.
- Research to understand the workforce implications of different models of care as above, including workforce needs, staff training and development, and job satisfaction. This overlaps with the first implication for health care above, but involves research to inform longer-term planning as distinct from short-term service development.
- It would also be valuable to compare patterns of demand for ultrasound scanning, both across areas with different types of service provision and over time within an area. This would be helpful in understanding the extent to which increases in availability of services may create demand that would not otherwise exist, and the implications of this for patient flow within the health system.
- A better understanding is needed of the barriers to and facilitators of the process of developing ultrasound services in primary care/community settings, including both the process of transferring services from secondary care to primary care settings and supporting the growth and development of new service models.
- Rigorous economic evaluation(s) of different models of service using modelling or data collected from clinical studies should be performed to complement the studies mentioned above.
- Integration of information from diagnostic ultrasound with results of other imaging tests and how this feeds into patient management pathways. This could include investigation of the usefulness of POC ultrasound performed by GPs and other trained health professionals.⁴⁵

Chapter 6 Primary care/community-led diagnostic pathways for the assessment of breathlessness

Introduction

Breathlessness (shortness of breath or dyspnoea) is a common symptom associated with a range of acute and chronic conditions, including COPD, asthma, lung cancer, heart failure, AF and obesity. Outcomes for these conditions can be improved with an early diagnosis. In the NHS, diagnostics have traditionally been offered in hospital settings. However, rising demand year on year is contributing to overloading in the secondary care system that impacts on patient pathways, despite relatively recent recommendations to increase the hours of access. The provision of diagnostics in the community or in primary care has the potential to ease flow through the health system as well as increase access to an early diagnosis. However, obtaining a differential diagnosis for a condition such as COPD requires training in the delivery of investigations and increased utilisation of resources and equipment. Therefore, a primary care-led diagnostic service would need to account for implementation costs and benefits accordingly.

International guidelines exist for primary care diagnosis of lung conditions; however, not all breathlessness is associated with a lung condition and not all lung conditions initially present with breathlessness. A number of national and international models of care and pathways currently exist for primary care and/or community diagnosis for symptoms of breathlessness, including rapid-access breathlessness clinics and diagnostic pathways. For example, one aim of providing a rapid-access clinic is to allow multimorbidities to be accounted for in a setting dedicated to breathlessness diagnostics. Another approach is the federated model, which links a network of GP practices to form a collaborative effort in providing diagnostic and follow-up services. However, there is no published consensus about the clinical effectiveness or cost-effectiveness or the acceptability for service users of any particular service model.

The aim of this systematic subreview, within the overall package of work examining services in primary care, was agreed in consultation with NIHR. The purpose was to assess the evidence base for diagnostic services provided outside hospital settings (such as community or general practice) for undiagnosed individuals presenting with symptoms of breathlessness.

Methods

Research questions

The study aimed to address the following research questions:

- What service models and pathways for breathlessness diagnostics delivered in primary care or community settings currently exist in the UK and internationally?
- What evidence is there for the quality, safety, feasibility, acceptability, clinical effectiveness and cost-effectiveness of such models and pathways?
- What are the barriers to, and facilitators of, developing and implementing such service models and pathways?

Inclusion/exclusion criteria

Participants

People with symptoms of breathlessness who have a suspected condition such as COPD or heart failure (*not* people who have a diagnosis and are being monitored/managed in a primary care setting; *not* screening an 'at risk' population for a particular condition).

Intervention

Service models and pathways that are designed to be initiated in primary care or the community in order to make a differential diagnosis from a presenting symptom of breathlessness. This could include specific diagnostic technologies such as spirometry, although the effectiveness of such technologies will not be assessed.

Comparator

Service delivery models or pathways developed to assist diagnosis from breathlessness symptoms and delivered in secondary care settings. This is included comparison of the clinical effectiveness, cost-effectiveness, quality, safety, feasibility and acceptability of the intervention between settings.

Outcomes

Any measure of effect on patient management, outcomes, patient experiences or costs/resource use including training.

Setting

Diagnostics delivered in a primary care or community setting.

Study design

Systematic literature reviews and primary studies of any design that describe or evaluate a pathway of care for breathlessness. These include retrospective/prospective studies and audits as well as experimental, observational and economic evaluations. Qualitative studies that reported service user or staff views about the barriers to, and facilitators of, service development and use of the pathways (received care or decision-making) were eligible for inclusion.

Identification of studies

A comprehensive search of key bibliographic databases was performed in July 2015. The MEDLINE strategy combined terms around 'primary care', 'dyspnoea', 'spirometry' and 'diagnostics', and included both MeSH and free-text searches. Terms were combined using Boolean operators and database-specific syntax. The MEDLINE strategy was subsequently adapted in accordance with the other databases searched as part of the review. Results were limited by date to 2000 to current. The search strategies are provided in *Appendix 9*.

The databases searched were:

- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R), 1946–present
- EMBASE via Ovid, 1974–present
- Cochrane Database of Systematic Reviews via The Cochrane Library, 1996–present
- Cochrane Central Register of Controlled Trials (CENTRAL) via The Cochrane Library, 1898–present
- Database of Abstracts of Reviews of Effects (DARE) via The Cochrane Library, 1946–present
- HTA database via The Cochrane Library, 1989–present
- NHS Economic Evaluation Database (NHS EED) via The Cochrane Library, 1968–present
- CINAHL, 1960–present
- Science Citation Index Expanded (SCI-EXPANDED) via Web of Science, 1900–present
- Conference Proceedings Citation Index- Science (CPCI-S) via Web of Science, 1990–present.

Selection of studies

Citations retrieved via the searching process were uploaded to an EndNote database. This database of study titles and abstracts was independently screened by two reviewers and any queries regarding inclusion were resolved by consulting other team members. Full-text copies of all citations coded as potentially relevant were then retrieved for systematic screening.

Studies that evaluated the effectiveness of new services or changes to the referral pathway were given the coding 'intervention studies'. Papers that reported the views or perceptions of staff or patients were coded as 'views studies'.

Extraction of data and synthesis methods

Studies that met the inclusion criteria following the selection process above were read in detail and data were extracted. Three members of the research team carried out the data extraction. The data extraction and synthesis was carried out separately for the subgroups of intervention and views papers. Following examination of these different forms of evidence, we integrated the findings via use of a conceptual model.

Intervention studies data analysis

The heterogeneity and limited study design of the included work precluded summarising the effectiveness of the interventions via meta-analysis. The effectiveness review findings are therefore reported using narrative synthesis methods, including tabulation of characteristics of the included studies, and examination of outcomes by characteristics such as intervention content and study design. The relationships between studies and outcomes within these typologies are scrutinised.

Views studies

The qualitative and survey data were synthesised using thematic synthesis methods to develop an overview of recurring perceptions of potential obstacles to successful outcomes in the data. This method comprises familiarisation with each paper and coding of the finding sections (which constitute the 'data' for the synthesis) according to key concepts within the findings. Although some data may directly address the research question, sometimes information, such as barriers to and facilitators of implementation, has to be inferred from the findings, as the original study might not have been designed to have the same focus as that of the review question.

Integrating the data

We used a conceptual modelling method to integrate findings from examination of the intervention and views literature. This was intended to provide an evidence-based overview of elements of the referral pathway that were reported in the identified literature.

Quality appraisal strategy

Quality assessment of the higher quality intervention studies was based on the Cochrane criteria for judging risk of bias (The Cochrane Collaboration). This evaluation method classifies studies in terms of sources of potential bias within studies: selection bias, performance bias, attrition bias, detection bias and reporting bias (see *Appendix 10*). The conference abstract papers were not quality assessed, as they provided only limited data; these papers are highlighted in the synthesis. Tools used for the assessment of quality are provided in *Appendix 10*.

The assessment of quality for the qualitative papers was carried out using an eight-item tool adapted from the Critical Appraisal Skills Programme tool for qualitative studies (see *Appendix 10*). The quality scoring for each study is presented in tabular form across each of the eight items.

Results of review of intervention studies

We identified 36 studies that were relevant to our examination of models and pathways for patients presenting with breathlessness in the community.^{105,182,187,195,261–292} These papers evaluated the effectiveness of additions to diagnostic services or technology available to GPs that might be utilised for a patient presenting with breathlessness. Four pairs of papers were linked,^{105,182,195,270,274,278} with the first of each pair reporting earlier findings and the second updating with a more recent set of data. Therefore, there were 28 unique studies across the group of included papers. *Figure 2* provides an overview of the process of inclusion/exclusion, which resulted in the inclusion of 32 intervention studies.

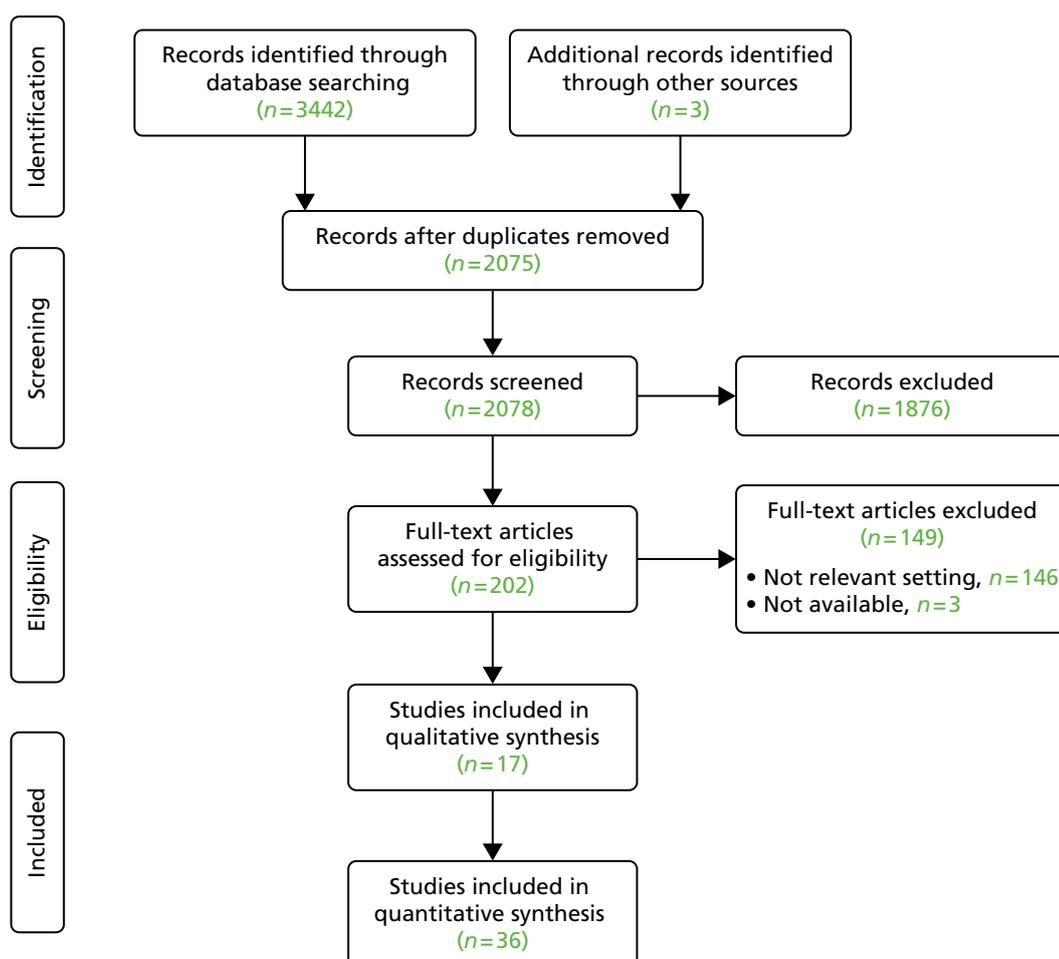


FIGURE 2 The PRISMA flow diagram for Chapter 6.

Type of evidence available

Study design

Table 36 summarises the range of study designs in the included set of papers. As can be seen, we identified six RCTs and one further paper reporting a non-randomised comparator study. We found a sizeable literature retrospectively examining service data or patient data. This was commonly reported via conference presentation abstracts rather than published peer-reviewed journal papers. Although the data contained in these conference publications tended to be limited, we made the decision to include conference abstracts in the review, to provide a more complete indication of where work in this area was being carried out.

Country of origin

Fourteen of the papers originated from the UK; six of these were conference abstracts (Table 37). None of the RCTs originated in the UK, although the non-randomised controlled study²⁶¹ was carried out in the UK (Leicester).

Type of intervention

We developed a typology to categorise interventions described in the literature. We used the term 'interventions' to include both experimental and observational studies when there is an evaluation of change, or potential change, to the pathway for patients with breathlessness in the community. The three main categories of interventions we identified were additional services, additional technology and additional access (Table 38).

TABLE 36 Included papers categorised by study design

Study design	Study (authors and year)
RCT	Burgos 2011 ²⁶⁴ Burri <i>et al.</i> 2012 ²⁶⁵ Lusardi <i>et al.</i> 2006 ²⁷⁹ Masa <i>et al.</i> 2011 ²⁸⁰ Poels <i>et al.</i> 2008 ²⁸⁴ Tomonaga <i>et al.</i> 2011 ²⁸⁸
Non-RCT	Akhtar and Wilson 2005 ²⁶¹
Cohort	Van der Mark <i>et al.</i> 2014 ²⁸⁹
Before and after	Carr <i>et al.</i> 2011 ²⁶⁷ ^a Callister <i>et al.</i> 2011 ²⁶⁶ ^a Schermer <i>et al.</i> 2013 ¹⁹⁵
Retrospective case note/service data analysis ^a	Cawley <i>et al.</i> 2011 ²⁶⁸ Lodewijks-van der Bolt <i>et al.</i> 2007 ²⁷⁸ Starren <i>et al.</i> 2012 ¹⁸² Walker <i>et al.</i> 2006 ²⁹⁰ van Heur <i>et al.</i> 2010 ¹⁰⁵ Wolfenden <i>et al.</i> 2006 ²⁹² ^a Backler <i>et al.</i> 2011 ²⁶² ^a Diar Bakerly and Roberts 2009 ²⁷¹ ^a Harris <i>et al.</i> 2012 ²⁷³ ^a Lau <i>et al.</i> 2014 ²⁷⁷ ^a McNeil <i>et al.</i> 2012 ²⁸¹ ^a Metting <i>et al.</i> 2013 ²⁸² ^a O'Herlihy <i>et al.</i> 2013 ²⁸³ ^a Punwani <i>et al.</i> 2014 ²⁸⁵ ^a Sallaway <i>et al.</i> 2011 ²⁸⁶ ^a Willey <i>et al.</i> 2013 ²⁹¹
Cross-sectional	Chavannes <i>et al.</i> 2004 ²⁶⁹ Hassett <i>et al.</i> 2006 ²⁷⁴ Jones <i>et al.</i> 2005 ²⁷⁵ Thijssing <i>et al.</i> 2014 ²⁸⁷ White <i>et al.</i> 2007 ¹⁸⁷ ^a Denis <i>et al.</i> 2013 ²⁷⁰ ^a Fois <i>et al.</i> 2014 ²⁷² ^a Kaplan and Lerner 2013 ²⁷⁶ Borg <i>et al.</i> 2010 ²⁶³

a Conference abstract.

TABLE 37 Included studies categorised by country

Country	Study (authors and year)
UK	Akhtar and Wilson 2005 ²⁶¹
	Carr <i>et al.</i> 2011 ²⁶⁷
	Hassett <i>et al.</i> 2006 ²⁷⁴
	Jones <i>et al.</i> 2005 ²⁷⁵
	Starren <i>et al.</i> 2012 ¹⁸²
	Walker <i>et al.</i> 2006 ²⁹⁰
	White <i>et al.</i> 2007 ¹⁸⁷
	Wolfenden <i>et al.</i> 2006 ²⁹²
	^a Backler <i>et al.</i> 2011 ²⁶²
	^a Callister <i>et al.</i> 2011 ²⁶⁶
	^a Diar Bakerly and Roberts 2009 ²⁷¹
	^a Harris <i>et al.</i> 2012 ²⁷³
	^a Lau <i>et al.</i> 2014 ²⁷⁷
	^a Punwani <i>et al.</i> 2014 ²⁸⁵
The Netherlands	Chavannes <i>et al.</i> 2004 ²⁶⁹
	Lodewijks-van der Bolt <i>et al.</i> 2007 ²⁷⁸
	Poels <i>et al.</i> 2008 ²⁸⁴
	Thijssing <i>et al.</i> 2014 ²⁸⁷
	van Heur <i>et al.</i> 2010 ¹⁰⁵
	van der Mark <i>et al.</i> 2014 ²⁸⁹
	^a Denis <i>et al.</i> 2013 ²⁷⁰
	^a Metting <i>et al.</i> 2013 ²⁸²
	^a Schermer <i>et al.</i> 2013 ¹⁹⁵
	USA
^a Willey <i>et al.</i> 2013 ²⁹¹	
Canada	Sallaway <i>et al.</i> 2011 ²⁸⁶
	^a Kaplan and Lerner 2013 ²⁷⁶
Spain	Burgos 2011 ²⁶⁴
	Masa <i>et al.</i> 2011 ²⁸⁰
Switzerland	Burri <i>et al.</i> 2012 ²⁶⁵
	Tomonaga <i>et al.</i> 2011 ²⁸⁸
Italy	Lusardi <i>et al.</i> 2006 ²⁷⁹
	^a Fois <i>et al.</i> 2014 ²⁷²
The Republic of Ireland	^a McNeill <i>et al.</i> 2012 ²⁸¹
	^a O'Herlihy <i>et al.</i> 2013 ²⁸³
Australia	Borg <i>et al.</i> 2010 ²⁶³

^a Conference abstract.

TABLE 38 Typology of interventions

Intervention	Study (authors and year)
Additional diagnostic services in the community	
Mobile spirometry unit	Jones <i>et al.</i> 2005 ²⁷⁵
Community respiratory assessment unit	Hassett <i>et al.</i> 2006 ²⁷⁴ Starren <i>et al.</i> 2012 ¹⁸²
Community breathlessness clinic	^a Lau <i>et al.</i> 2014 ²⁷⁷
Community COPD clinic	^a Diar Bakerly and Roberts 2009 ²⁷¹ ^a O'Herlihy <i>et al.</i> 2013 ²⁸³
Community spirometry clinic	^a McNeill <i>et al.</i> 2012 ²⁸¹
Additional diagnostic technology in the GP surgery	
Trained GPs using spirometry	Borg <i>et al.</i> 2010 ²⁶³ Carr <i>et al.</i> 2011 ²⁶⁷ Chavannes <i>et al.</i> 2004 ²⁶⁹ Lusardi <i>et al.</i> 2006 ²⁷⁹ ^a Harris <i>et al.</i> 2012 ²⁷³ ^a Denis <i>et al.</i> 2013 ²⁷⁰ ^a Kaplan and Lerner 2013 ²⁷⁶ ^a Schermer <i>et al.</i> 2013 ¹⁹⁵
Trained practice nurses using spirometry	Akhtar and Wilson, 2005 ²⁶¹ Burgos 2011 ²⁶⁴ (access to a web application)
Additional information accompanying spirometry results	Poels <i>et al.</i> 2006 ²⁸⁴
BNP testing in primary care	Burri <i>et al.</i> 2012 ²⁶⁵
POC testing analyser	Tomonaga <i>et al.</i> 2011 ²⁸⁸
Diagnostic algorithm	van der Mark <i>et al.</i> 2014 ²⁸⁹
Additional access to diagnostic services in secondary care	
Open-access echocardiography service	Lodewijks-van der Bolt <i>et al.</i> 2007 ²⁷⁸ van Heur <i>et al.</i> 2010 ¹⁰⁵
Open-access spirometry clinic	Walker <i>et al.</i> 2006 ²⁹⁰ Wolfenden <i>et al.</i> 2006 ²⁹² ^a Sallaway <i>et al.</i> 2011 ²⁸⁶
Open-access pulmonary function clinic	^a Backler <i>et al.</i> 2011 ²⁶²
Self-referral chest radiography clinic	^a Callister <i>et al.</i> 2011 ²⁶⁶

^a Conference abstract.

Outcomes measured

In the analysis of this set of literature, we focused on outcomes relating to patient pathways and models of service delivery, rather than on clinical outcomes. However, we recognise that there is inevitably some blurring of this distinction as, for example, clinical presentation will impact on the referral pathway.

Table 39 summarises the main range of outcomes that were measured and reported in the identified studies. Included in these categories are specific measures relating to individual tests (such as FVC for

TABLE 39 Outcomes evaluated

Outcome	Study (authors and year)
Accuracy/quality of spirometry testing	Akhtar and Wilson 2005 ²⁶¹
	Borg <i>et al.</i> 2010 ²⁶³
	Burgos 2011 ²⁶⁴
	Carr <i>et al.</i> 2011 ²⁶⁷
	Lusardi <i>et al.</i> 2006 ²⁷⁹
	White <i>et al.</i> 2007 ¹⁸⁷
	Fois <i>et al.</i> 2014 ²⁷²
	Schermer <i>et al.</i> 2013 ¹⁹⁵
	Willey <i>et al.</i> 2013 ²⁹¹
Diagnostic accuracy	Masa <i>et al.</i> 2011 ²⁸⁰
	Poels <i>et al.</i> 2006 ²⁸⁴
	Tomonaga <i>et al.</i> 2011 ²⁸⁸
	van der Mark <i>et al.</i> 2014 ²⁸⁹
	Walker <i>et al.</i> 2006 ²⁹⁰
	van Heur <i>et al.</i> 2010 ¹⁰⁵
	White <i>et al.</i> 2007 ¹⁸⁷
	Backler <i>et al.</i> 2011 ²⁶²
	Metting <i>et al.</i> 2013 ²⁸²
	Burri <i>et al.</i> 2012 ²⁶⁵
	Cawley <i>et al.</i> 2011 ²⁶⁸
Chavannes <i>et al.</i> 2004 ²⁶⁹	
Number of further tests/diagnostic certainty	Hassett <i>et al.</i> 2006 ²⁷⁴
	Lodewijks-van der Bolt <i>et al.</i> 2007 ²⁷⁸
	Starren <i>et al.</i> 2012 ¹⁸²
	Wolfenden <i>et al.</i> 2006 ²⁹²
	Backler <i>et al.</i> 2011 ²⁶²
	Callister <i>et al.</i> 2011 ²⁶⁶
	Diar Bakerly and Roberts 2009 ²⁷¹
	^a Lau <i>et al.</i> 2014 ²⁷⁷
	McNeill <i>et al.</i> 2012 ²⁸¹
	O'Herlihy <i>et al.</i> 2013 ²⁸³
	Punwani <i>et al.</i> 2014 ²⁸⁵
	Sallaway <i>et al.</i> 2011 ²⁸⁶
	Burri <i>et al.</i> 2012 ²⁶⁵
Number of referrals made to specialist service	Carr <i>et al.</i> 2011 ²⁶⁷
	Chavannes <i>et al.</i> 2004 ²⁶⁹
	Hassett <i>et al.</i> 2006 ²⁷⁴
	Starren <i>et al.</i> 2012 ¹⁸²

TABLE 39 Outcomes evaluated (continued)

Outcome	Study (authors and year)
Pattern/type of referrals	Thijssing <i>et al.</i> 2014 ²⁸⁷
	Backler <i>et al.</i> 2011 ²⁶²
	Callister <i>et al.</i> 2011 ²⁶⁶
	Hassett <i>et al.</i> 2006 ²⁷⁴
	Lodewijks-van der Bolt <i>et al.</i> 2007 ²⁷⁸
	Van Heur <i>et al.</i> 2010 ¹⁰⁵
	Wolfenden <i>et al.</i> 2009 ²⁹²
Cost of service/test	Diar Bakerly and Roberts 2009 ²⁷¹
	Harris <i>et al.</i> 2012 ²⁷³
Patient satisfaction	Cawley <i>et al.</i> 2011 ²⁶⁸
	Jones <i>et al.</i> 2005 ²⁷⁵
GP-related outcomes (satisfaction/perceived usefulness/feasibility/confidence)	Hassett <i>et al.</i> 2006 ²⁷⁴
	Thijssing <i>et al.</i> 2014 ²⁸⁷
	White <i>et al.</i> 2007 ¹⁸⁷
GP usage	Backler <i>et al.</i> 2011 ²⁶²
	Kaplan and Lerner 2013 ²⁷⁶
	Hassett <i>et al.</i> 2006 ²⁷⁴
	Jones <i>et al.</i> 2005 ²⁷⁵
	Starren <i>et al.</i> 2012 ¹⁸²
	Thijssing <i>et al.</i> 2014 ²⁸⁷
	Van Heur <i>et al.</i> 2010 ¹⁰⁵
	Diar Bakerly and Roberts 2009 ²⁷¹
	McNeill <i>et al.</i> 2012 ²⁸¹
	Metting <i>et al.</i> 2013 ²⁸²
Punwani <i>et al.</i> 2014 ²⁸⁵ (appropriateness of usage)	
Number of GPs trained	Denis <i>et al.</i> 2013 ²⁷⁰
a Conference abstract.	

spirometry, D-dimer or BNP levels), as will be described in the narrative presentation of the studies. It can be seen from *Table 39* that there was considerable heterogeneity in the outcomes which were considered to represent 'success' when evaluating these initiatives.

Study quality

We assessed the quality of the journal papers to establish those with stronger study designs and less potential for bias. As the included papers included a range of designs, we used appropriate tools for intervention studies, cohort studies and cross-sectional studies (see *Appendix 10*). The quality of the literature was limited by a lack of studies using comparator designs. Of the eight intervention studies, four had issues with potential selection bias and two had issues with potential attrition bias. Many of the cross-sectional studies also had potential issues with selection of the sample.

Analysis of interventions by typology

Additional diagnostic services in the community

Seven papers^{182,271,274,275,277,281,283} examined new services in the community that could be relevant to patients presenting with breathlessness. These services encompassed a mobile spirometry unit,²⁷⁵ a community respiratory assessment unit,^{182,274} a community breathlessness clinic,²⁷⁷ a community COPD clinic^{271,283} and a community spirometry clinic.²⁸¹ The majority of these studies ($n = 5$) reviewed service data, with none using more rigorous designs, and four were in the form of conference abstracts. The quality of this set of papers was, therefore, generally low. Five of the studies were carried out in the UK^{182,271,274,275,277} and two were carried out in Ireland.^{281,283} The three full papers will be outlined first.

The Jones *et al.* study,²⁷⁵ in Plymouth, provided in-service training for staff, and also a mobile spirometry clinic to GPs who were known to own a spirometer. The take-up of staff education was low, with half of the 14 practices that were offered the training accepting. The spirometry results were interpreted by a trained respiratory nurse leading the service and a GP with a respiratory specialist interest. There was a high rate of diagnosis of COPD among the 98 patients who were assessed over a 3-month period, with only six found to have normal lung function. The authors report that the cost of the study was £107 per new patient diagnosed with COPD and that the GPs were satisfied with the service (there are no data regarding this). The paper provides limited evidence regarding pathways or models, as it provides no detail regarding any criteria for patient referral (such as presenting symptoms). It is assumed, rather than documented, that patients might have presented with breathlessness. It describes the service as 'a structured COPD diagnostic and management service', and reports data for diagnosis of COPD only. It is also presumed that the patients diagnosed were seen by the mobile clinic, rather than by the GPs who had received training, as this is not documented.

The Hassett *et al.*²⁷⁴ paper and the Starren *et al.*¹⁸² paper appear to be evaluating the same community respiratory assessment unit in London (although all but one of the authors are different, and this connection is not made in the later paper). The unit was based in a hospital, although it was described as a 'community service', and provided outreach services to practices further from the base. It was staffed by a specialist respiratory nurse for the first 2 years, and was subsequently run by a community respiratory nursing team. The earlier paper focuses on referral rates, reporting that 364 patients were referred in first 12 months of the service. Sixteen GP practices were initially included, with 17 added 6 months later. Analysis of the referral outcomes highlighted that suspected or established diagnoses were often not confirmed. One-quarter of patients referred for suspected or confirmed COPD had no abnormalities detected on assessment, and 34% of those referred for suspected or confirmed asthma had no detectable airway narrowing. The authors report a high take-up of the service among GPs (all but two had used it), and high satisfaction rates among GPs and patients (51% of GPs rated themselves as satisfied and 46% rated themselves as very satisfied with the service; 88% agreed that patients had benefited from the service; and 99% of patients rated their experience as good).

Four years of data from (presumably) the same unit are examined in the Starren *et al.*¹⁸² paper. This article specifically reports that unexplained breathlessness was one of five common reasons for referral to the service (79/1156 referrals). Forty-one of these patients were diagnosed as having a non-respiratory cause of breathlessness, 14 had a restrictive defect, six were diagnosed with COPD, asthma could not be excluded in 17 and for one no explanation for symptoms could be found. The authors echo the finding of the earlier paper in concluding that the unit reduced diagnostic inaccuracy, and suggested that it prevented referrals that might otherwise have been made to specialists. Approximately one-third of COPD diagnoses made in the community were incorrect, with potentially high levels of inappropriate prescribing. However, the study was unable to draw meaningful conclusions regarding asthma referrals.

A further UK study²⁷⁷ assessed the potential clinical utility of a community breathlessness clinic for detecting heart failure and other cardiorespiratory disorders. The clinic offered a 'one-stop testing' service by a tertiary heart failure team. Breathlessness was the presenting symptom in 82% of the 191 patients

assessed over 2 years. A new cardiac diagnosis was made in 17% of patients and a new respiratory diagnosis was made in 10% of patients. The authors highlighted that high levels (38%) of patients were found to have no cardiac or respiratory disease on assessment by the clinic, and thus the service prevented the need for secondary level investigations or review.

Two conference abstracts (one reporting a study in the UK and one reporting a study in Ireland) evaluated community COPD clinics. The first of these²⁷¹ is of limited value to this review, as it reports data from both new patients to the clinic and those transferred from secondary care, and also includes patients with an existing diagnosis of COPD. The authors concluded that community COPD clinics provide easy access to specialist advice. They also found that inappropriate referrals to these clinics did not appear to be a problem (although this may be related to the referral sources and type of patients included). The second abstract (from a team in Ireland)²⁸³ provides limited data, beyond reporting that 50% of patients seen by a COPD satellite clinic were diagnosed with COPD, 25% were diagnosed with asthma and 25% had no significant respiratory problem. The authors concluded that community clinics could provide a time-saving and cost-saving alternative to the traditional hospital-based outpatient clinic model.

The final study in this group (also from the Republic of Ireland²⁸¹) evaluated a community spirometry clinic. Of the 104 patients seen, 82 were tested and 35 were found to have normal spirometry results. The success of the service was reportedly compromised by the underusage of available appointments.

Additional diagnostic technology/information in the general practitioner surgery

The largest subgroup of studies we identified (14 papers) evaluated the provision of technology in GP surgeries (see *Table 38*). All but three^{265,284,288} of these examined the use of spirometry by primary care staff. The papers considered the potential value of spirometry during a consultation, the accuracy of spirometry carried out in primary care, and whether or not training courses could enhance the quality of spirometry. Five of the studies^{261,264,265,279,284} used controlled designs.

An evaluation of the value of spirometry during GP consultations in Italy²⁷⁹ found that there was no significant difference in levels of diagnostic accuracy between GPs who had access to spirometry and those who did not. The study examined GP diagnosis of patients who presented with cough (the majority of patients), dyspnoea, wheezing or chest tightness. There was agreement on diagnosis between GPs and specialists in 78.6% of cases in a group who had been randomised to receive 8 hours of training and had access to spirometry. This compared with 69.2% in the group who had received no training and carried out consultations without spirometry ($p = 0.35$).

Harris *et al.*²⁷³ evaluated the validity of spirometric testing performed in the community, by retrospectively examining records of patients who had been found to have abnormal screening. Although the data are very limited and mainly relate to patients with established COPD diagnosis, it indicates that the majority of patients referred following community testing using spirometry were found to have COPD. The paper therefore provides contrary findings to other studies that indicate poor accuracy of community diagnosis.

The potential value of spirometry for aiding GP decision-making was examined in a study from the Netherlands.²⁶⁹ GPwSIs in spirometry were given 6 hours of training. Case scenarios were used to assess GP decision-making at intervals over the 12-month period following training. The number of diagnoses considered by the GPs reduced over the follow-up period, which the authors described as being due to improved diagnostic skills and less uncertainty. However, the study found that, based on responses to case scenarios, there might be an increase in additional testing and also in referral rates to specialists.

A randomised controlled study examined whether or not additional information accompanying spirometry results was of benefit to GP decision-making.²⁸⁴ The study found that additional information provided by a computerised system had no detectable benefit on the accuracy of diagnosis by GPs. There was no difference in accuracy of diagnosis between the groups who had received additional textual notes regarding the test results, with those who had received only the results (COPD: odds ratio 1.08, 95% CI

0.7 to 1.66; asthma: odds ratio 1.13, 95% CI 0.7 to 1.8; absence of respiratory disease: odds ratio 1.32, 95% CI 0.61 to 2.86).

The only study from the UK²⁶¹ which used a controlled design (non-randomised) evaluated the accuracy of spirometry carried out by practice nurses in Leicester. The work compared the accuracy of practice nurse spirometry with spirometry in a centralised laboratory. The study found that the absolute values of FEV₁, FVC, etc., were lower and hence the COPD would be classified as more severe if measured by nurses than if measured in a specialised laboratory (significant difference in measurement of FEV₁ and FVC; $p < 0.05$), with the potential for overdiagnosis of COPD severity (and, therefore, the potential for over-referral).

A UK-based before-and-after study²⁶⁷ aimed to assess the impact of an educational intervention on the quality of spirometry. The study found a positive impact on assessment quality, and a potential reduction in referrals to specialist services following GP training. Before the intervention, 38% of post-bronchodilator spirometry tests were technically flawed. After the intervention, 2% were flawed. Over the study time period, the proportion of chest clinic referrals following assessment fell from 62% of patients to 32% of patients.

An interactive five-module spirometry training course for GPs and other clinic staff in the Netherlands is described in conference abstracts by Denis *et al.*²⁷⁰ and Schermer *et al.*¹⁹⁵ In the first abstract, the authors recommend that formal training is required for spirometry to be used effectively in primary care by GPs and practice nurses, and that refresher courses are important to maintain skills. The second abstract describes programmes for practice nurses and practice nurses and assistants. The study seems to indicate that structured spirometry training has a limited effect on test quality (for one course, 39.1% of tests were adequate before training and 51.0% were adequate after training: odds ratio 1.60, 95% CI 1.12 to 2.30; for the other course, 45.3% of tests were adequate before training and 44.1% were adequate after training: odds ratio 0.93, 95% CI 0.65 to 1.33).

A paper which supports the limited effect of training on the quality of spirometry comes from Australia.²⁶³ Nurses and physiotherapists in rural health facilities received 14 hours of training. Retrospective review of test quality found that only 37%, 60% and 58% of tests at 5, 7 and 9 months, respectively, had met established criteria. The authors concluded that the course did not provide sufficient skill to perform spirometry to the required quality.

Kaplan and Lerner²⁷⁶ recommend a training programme and tool for interpreting spirometry as increasing GP intention to use spirometry and ability to interpret results. However, there are no data in this abstract to support this recommendation.

A paper from a team from Spain²⁶⁴ indicated the need for not only training but ongoing support in interpretation. This study evaluated the use of spirometry by trained practice nurses who were randomised to have access or no access to a web application. Over a 12-month period, the intervention group presented 71.5% high-quality spirometries and the control group presented 59.5% high-quality tests ($p < 0.001$). The additional web-based support increased the proportion of high-quality spirometry tests carried out (by around 20%), and decreased the percentage of very low-quality spirometries with maintenance of quality over a 1-year period. The application was rated as being acceptable by GPs and useful by nurses.

Three papers evaluated other technologies that may be available in primary care.^{265,288,289} One study evaluated the provision of BNP testing in primary care²⁶⁵ and one examined results following the use of a POC testing analyser in GP practices.²⁸⁸ The final study in this group reported the development and testing of an algorithm which GPs could use to support a diagnosis of asthma.²⁸⁹

Burri *et al.*²⁶⁵ carried out a RCT in Switzerland to evaluate whether or not adding BNP testing in primary care would improve the evaluation and diagnosis of patients with breathlessness. The study found that use

of BNP in primary care improved diagnostic certainty (further diagnostic testing 33% of patients in the BNP group vs. 45% of patients in the control group; $p = 0.02$), and time to initiation of treatment (66% of patients began appropriate treatment on the day of presentation in the intervention group vs. 53% in the control group; $p = 0.02$). There appeared to be little impact on service delivery outcomes with the number of hospitalisations for dyspnoea, number of days in hospital, and number of outpatient visits not significantly different between the groups at 3 or 12 months.

Another Swiss study²⁸⁸ assessed the value of having a three-in-one POC testing analyser (cardiac troponin T, N-terminal pro-brain natriuretic peptide, D-dimer) in primary care. Patients presenting with chest pain or symptoms of dyspnoea were assessed by GPs using conventional diagnosis methods or GPs with the addition of the analyser. In the intervention group the working diagnosis made at first visit was confirmed at second visit in 76% of cases. For the control group the diagnosis was confirmed in 60% of cases ($p = 0.002$). Acute coronary syndromes were correctly ruled out in 92% of patients in the intervention group versus 78% in the control group. The authors concluded that use of the tests improved GP diagnostic accuracy.

An algorithm that could assess the likelihood of developing asthma was described in a cohort study from the Netherlands.²⁸⁹ The Clinical Asthma Prediction Score is calculated on the basis of age, family history, reported symptoms, environmental factors and allergies. The evaluation of the tool found that a score of < 3 had a negative predictive value for asthma of 78.4%. A score of > 7 had a positive predictive value of 74.3%. The authors concluded that the scoring system for pre-school children with symptoms could be a useful decision aid in asthma diagnosis.

Additional access to diagnostic services in secondary care

This group of seven studies can be considered to be on the borderline of meeting our inclusion criteria, as all but one evaluate diagnostic services which were provided in secondary care. However, we have included them in the review as they describe a change to a typical pathway, with GPs referring patients directly for diagnostic testing rather than referring to a specialist. One study in particular reported a significant change to traditional models, by exploring the introduction of patient self-referral for chest radiography.²⁶⁶

The introduction of an open-access echocardiography service in the Netherlands was evaluated in linked papers by Lodewijks-van der Bolt *et al.*²⁷⁸ and Van Heur *et al.*¹⁰⁵ Patients in the study were referred to the open-access service by GPs following examination, and the echocardiogram was carried out without referral to a cardiologist. The study reports that 107 out of 471 patients were referred for dyspnoea. The authors concluded that the service identified around one-quarter of patients with no cardiac abnormality who might otherwise have been referred to a cardiologist (and, therefore, the service prevented referrals). However, there are no data in the paper making this comparison. The second paper adds more recent data and compares the first 250 patients with the last. The study found that fewer referrals for dyspnoea were made in the more recent year (2007) than in 2002. This article reports that the proportion of patients with no cardiac abnormality found on testing increased over the lifetime of the study (32.8% in 2007 vs. 22% in 2002). It is unclear how these data link to referral patterns, as this could indicate a greater prevention of referrals to secondary care, as more patients with no abnormality were seen in the clinic. However, it also could indicate that GPs were referring more patients with less severe symptoms to the service.

Three papers investigated outcomes following introduction of an open-access spirometry clinic. Walker *et al.*²⁹⁰ evaluated a spirometry clinic in London in a 'health suite in the local community'. A respiratory technical officer performed spirometry on the patients (who were smokers or ex-smokers over 40 years with respiratory symptoms) and a consultant respiratory physician reviewed the data to produce a report that was sent back to the referring GP. Of those referred, 39% had no existing diagnosis, 30% had a diagnosis of asthma and 29% had a diagnosis of COPD. Following testing, 128 patients were newly diagnosed with asthma or COPD and 46 patients had their diagnosis changed. The authors concluded that the spirometry clinic increased rates/accuracy of diagnosis and improved treatment.

Another paper reporting a study carried out in London²⁹² evaluates a different service from the one in the Walker *et al.*²⁹⁰ study. This open-access spirometry clinic operated one morning each week in a hospital. GPs could refer with a suspected or actual diagnosis and spirometry was carried out by a consultant respiratory physician. The study found that just over half of referrals with suspected or actual COPD were found to have airway obstruction. Airway obstruction was rarely observed in patients referred for stated or suspected asthma. The authors stated that spirometry is needed to establish correct diagnosis of COPD, and so referrals for suspected or stated COPD were appropriate. However, home peak flow monitoring rather than referral may be more helpful for those with suspected asthma.

A conference abstract reporting an open-access spirometry clinic in Canada²⁸⁶ found, in contrast to the above study, that a significant proportion of referrals to the service yielded abnormal results. There are limited data regarding the setting or operation of the service.

An open-access pulmonary function clinic in the UK²⁶² was reported to have resulted in 72% of patients not being referred to an outpatient chest clinic, with an estimated saving of £1800 to the health service. The sample that this is based on is small (18 referrals) and, as the document is a conference abstract, there are limited data.

Callister *et al.*²⁶⁶ evaluated a UK self-referral radiography clinic, which was provided as part of an awareness campaign to improve the early detection and diagnosis of lung cancer. During the first 7 weeks, 95 patients presented for self-referral chest radiography, of whom three had confirmed lung cancer. There was a 30% increase in the number of GP-ordered chest radiographs, compared with the same period in 2010 (mean 557 (SD 65) per week vs. mean 428 (SD 55), respectively; $p < 0.001$), and a 70% increase in fast-track lung cancer clinic referrals, compared with 2010 as a whole [mean 16.0 (SD 6.0) per week vs. mean 9.4 (SD 3.1), respectively; $p < 0.05$].

Summary of evidence from intervention studies

Seven papers provide evidence that additional services in the community, including mobile clinics and community clinics, can be a useful means of differentiating between patients who have no significant respiratory problems or cardiac disease and may be managed in community services, and those who may need referral to a specialist (see *Table 38*). Around one-third to one-quarter of patients may have no abnormalities detected on assessment. It should be noted that this evidence comes from studies that have less rigorous study designs. However, the findings have high applicability, as they were carried out in either the UK or Ireland.

Fourteen papers provide evidence regarding the use of additional technology in community settings (see *Table 38*). The papers exploring the use of spirometry, by either GPs or other practice staff, provide evidence of limited impact on diagnostic decision-making, and conflicting evidence of impact on referrals. One study suggested a reduction in referrals to a chest clinic and another suggested the potential for increased referrals to specialists. A number of studies raised concerns regarding the quality and accuracy of spirometry testing in the community, with variable outcomes following targeted training. One paper indicated that training, together with web-based support, may improve the quality of spirometry. The quality of evidence in this group of studies is more robust, with five studies using controlled designs (four RCTs).

The three papers^{265,288,289} examining other (non-spirometry) technologies suggested that POC testing can have a positive impact on GP differential diagnosis, diagnostic certainty and time to treatment, although the impact on specialist referral is less clear. A simple algorithm for asthma also may be a useful decision-aid.

Only three^{261,267,273} of the papers in this group examining the use of technologies in primary care were from the UK, although there appear to be no features of the studies, which would suggest that they would not be applicable to the UK health-care context.

Seven studies provide evidence regarding the provision of open-access diagnostic services in secondary care (see *Table 38*). As with the provision of additional services in the community group of papers, there are data supporting a beneficial impact in terms of a reduction in referrals to specialist services. This is associated with high numbers of patients found to have no abnormality in these clinics. There is also an indication in this set of papers that these services could reduce misdiagnosis.

The papers as a group report an uncertain effect on referrals (sometimes rates increased and sometimes they reduced). Referral rates as a measure of intervention effectiveness can be perceived as a crude measure. Patients who would not have been referred may be now appropriately referred as a positive outcome, although, equally, referral may be seen as a negative outcome, as patients might have been referred who would have been better managed in the community.

Results of views review

From the database searches (see *Figure 2*), a total of nine qualitative papers were identified that met the criteria for inclusion. Through scrutiny of the reference lists related to these papers, a further four papers were identified, giving a total of 13 included qualitative papers. However, one of these papers could not be obtained, giving 12 papers reporting 10 studies (see *Table 40*). Six papers relevant to the review question were identified that reported views of staff or patients and used cross-sectional survey methods to collect data (level 3). One of these papers could not be obtained, giving five papers reporting five studies (see *Table 41*). Seventeen papers reporting 15 studies were therefore included in the review of views and perceptions of staff or patients.

Characteristics of included studies

We developed a three-level grading system for the included papers based on relevance to the research question and richness of data. Thus, level 1 papers were those that explored views and experiences, using interview, focus group or observation methods, of diagnosis pathways in general practice where breathlessness was undifferentiated. Level 2 papers use these same qualitative methods, with a focus on a particular condition where breathlessness presents as a typical symptom, for example COPD, asthma, lung cancer or heart failure. Level 3 papers utilise cross-sectional methods to identify aspects of diagnosing breathlessness-related conditions, such as the degree of spirometry use in a population, or the perceived extent of confidence that staff have in using a spirometer or interpreting results.

Consistent with other subsections of this review study, level 1 and level 2 papers have been subjected to quality assessment using a tool aligned with the study design. Level 3 papers have not been formally assessed for quality but are critiqued, where applicable, in the synthesis of findings.

Qualitative studies

Of the 12 qualitative papers, one was considered a level 1 paper, having a focus on undifferentiated dyspnoea. The remaining 11 papers (level 2) focused on a range of conditions for which dyspnoea was the main symptom (e.g. COPD and asthma) or one of a number of potential symptoms (such as lung cancer, heart failure and pulmonary arterial hypertension). *Table 40* provides a summary of the included qualitative papers.

One level 1 study was published in the UK¹⁹⁷ and sampled HCPs, although it was not focused specifically on primary care. Nine level 2 studies reported in 11 papers were published in the UK ($n = 6^{82,293-296,299}$), Australia ($n = 4^{297,300-302}$) and the USA ($n = 1^{198}$). Five papers sampled patient-only populations, four sampled HCPs only and one study reported in two papers sampled a mixed population of HCPs and patients. COPD was the condition of interest in two studies reported in three papers,^{198,300,301} lung cancer in three studies reported in four papers,^{295,296,299} asthma in two studies,^{297,302} heart failure in one study⁸² and pulmonary arterial hypertension in one study²⁹³ (see *Table 42*).

TABLE 40 Characteristics of included qualitative studies

Study (authors and year)	Country	Population and sample size	Condition	Focus of paper	Data collection methods	Data analysis methods
Level 1 papers						
Roberts <i>et al.</i> 2011 ¹⁹⁷	UK	HCPs, medical undergraduates, junior doctors, GPs, specialist registrars	Dyspnoea	Reasons for the underuse of spirometry in diagnosis of breathlessness	Focus groups	Thematic coding
Level 2 papers						
Armstrong <i>et al.</i> 2012 ²⁹³	UK	Patients, 30	Pulmonary arterial hypertension	Patients' experience of the trajectory to receiving diagnosis	Interviews	Thematic analysis
Birt <i>et al.</i> 2014 ²⁹⁴	UK	Patients, 35	Lung cancer (and other conditions)	Factors impacting on pathways prior to referral	Interviews	Framework analysis
Comer <i>et al.</i> 2005 ²⁹⁵	UK	Patients, 22	Lung cancer	Delayed diagnosis	Interviews	Thematic analysis
Comer <i>et al.</i> 2006 ²⁹⁶	UK	Patients, 22	Lung cancer	Reasons for delay in seeking care	Interviews	Constant comparison
Dennis <i>et al.</i> 2010 ²⁹⁷	Australia	HCPs and GPs, 18	Asthma	Difficulties faced by GPs when trying to make a diagnosis	Focus groups	Thematic coding
Goeman <i>et al.</i> 2005 ²⁹⁸	Australia	HCPs and GPs, 49	Asthma	GPs' priorities for achieving optimal outcomes; barriers	Nominal group technique	Thematic coding
Joo <i>et al.</i> 2013 ¹⁹⁸	USA	HCPs and PCPs, 12	COPD	Attitudes and barriers to performing spirometry	Focus groups	Thematic coding
Khunti <i>et al.</i> 2002 ⁸²	UK	HCPs, unsure: 18 practices	Heart failure	Perceived obstacles to diagnosis and management	Interviews	Open coding; constant comparison
Tod <i>et al.</i> 2008 ²⁹⁹	UK	Patients, 20	Lung cancer	Factors in delayed diagnosis	Interviews	Framework analysis
Walters <i>et al.</i> 2005 ³⁰⁰	Australia	Patients, 38; HCPs and GPs, 16	COPD	Barriers to use of spirometry	Interviews and focus groups	Thematic coding
Walters <i>et al.</i> 2008 ³⁰¹ (same study as above)	Australia	Patients, 14; HCPs and GPs, 16	COPD	Attitudes influencing diagnosis	Interviews and focus groups	Thematic coding

Three included studies used focus group methods,^{197,198,297} six used interviews^{82,293–296,299} and two combined these two methods^{300,301} to collect data. A further study³⁰² utilised the nominal group technique to obtain GPs' views about optimising patient outcomes. The analysis of qualitative data was mainly thematic, with two studies using constant comparison methods and two using the framework method. In general, studies that sampled patients were concerned with the illness trajectory, including diagnosis, particularly delay of diagnosis. Those sampling HCPs were interested in barriers to making a diagnosis, including attitudes towards the use of spirometry.

Cross-sectional studies

In five level 3 studies,^{191,303–306} telephone or mailed questionnaires were utilised to explore diagnosis of COPD/asthma and/or the use of spirometry in primary care. Two of these papers^{304,306} had higher applicability, being published in the UK. The remaining three papers were published in Belgium,³⁰³ Italy³⁰⁵ and the USA.¹⁹¹ All were condition specific, focusing on COPD or a combination of COPD and asthma (Table 41).

Quality assessment

Included level 1 and level 2 studies were assessed for quality using an adapted version of the CASP qualitative research checklist, as outlined in the methods section. Ten studies met most of the assessment criteria to a greater or lesser extent (see Appendix 10). The area that was least reported across all studies was the relationship between researchers and participants. Reporting of ethical considerations was mixed, with half of the papers not discussing consent or confidentiality issues. One study was reported in two papers,^{300,301} the latter being a brief summary of the former and presenting less detail generally about the study. Most of the papers presented findings that included rich data, for example quotations, to verify the discussed themes.

However, our research question focused on diagnosis of undifferentiated dyspnoea in primary care rather than condition-specific diagnosis and management. All but one of the papers¹⁹⁷ focused on condition-specific dyspnoea, and one paper sampled hospital staff as well as GPs.¹⁹⁷ This meant that we could not extract all of the data from each paper; rather, we extracted only relevant sections of text. This has resulted in a data set that varies in quantity and relevance.

TABLE 41 Characteristics of included cross-sectional studies

Study (authors and year)	Country	Population and sample size	Condition	Focus of paper	Data collection methods	Response rate
Level 3 papers						
Boffin <i>et al.</i> 2006 ³⁰³	Belgium	GPs, <i>n</i> = 197	COPD/asthma	Use of spirometers by GPs	Telephone questionnaire	81%
Bolton <i>et al.</i> 2005 ³⁰⁴	UK	Practitioners at 227 primary care practices Patients, <i>n</i> = 125	COPD	Spirometry in primary care (availability, training, interpretation of results)	Mailed questionnaire	61.6%
Caramori <i>et al.</i> 2005 ³⁰⁵	Italy	All general practices	COPD	Extent of spirometry use in primary care	Mailed questionnaire	Almost 100% (2474/2475)
Halpin <i>et al.</i> 2007 ³⁰⁶	UK	Total from 2001 and 2005: GPs, <i>n</i> = 85; practice nurses, <i>n</i> = 121	COPD	Confidence of practitioners in diagnosing COPD	Telephone questionnaire	Not reported
Kaminsky <i>et al.</i> 2005 ¹⁹¹	USA	General practices, <i>n</i> = 29	COPD	Use of spirometers to diagnose COPD	Mailed questionnaire	51%

Results of the review

Theoretical framework for presenting the results: model of pathways to treatment

The Andersen Model of Total Patient Delay is a five-stage model describing decisional processes that might lead to delays in eventual treatment.³⁰⁷ Critiques of this model, not least owing to the potentially value laden aspect of 'delay' and the inability of the model to convey the complexity of the diagnostic pathway, have led to the development of a revised framework, the Model of Pathways to Treatment.³⁰⁸ This model does not specify a particular sequence of events in the lead-up to diagnosis and treatment; rather, it allows for a range of ways of entering and timings along the pathway, as well as capturing dynamic movements between stages.³⁰⁹

The initial stages of the Model of Pathways to Treatment are concerned mainly, but not always, with the patient, and include 'detection of bodily changes', which, for the purposes of this review, would include some degree of breathlessness. A patient may decide, for whatever reason, not to consult a HCP at this stage. The model then moves to a position where the patient perceives there is a reason to seek attention from a HCP; in our review this would be in the community, although in reality a patient may well have sought advice elsewhere first.

The first consultation with a HCP is where the bodily change is discussed and advice is sought. At this stage the views and experiences of patients and HCP views are both relevant and there is interaction between the two population groups. Typically, investigations are carried out or requested to rule in or out particular conditions based on HCP knowledge and skills. In our review, we have obtained evidence from studies that explore the diagnostic pathway experiences as well as attitudes to diagnostic procedures in both patients and HCPs in primary care. In particular, we are interested in diagnostic procedures that are new to primary care or the community that would historically have required a referral to a hospital. Spirometry is a procedure that can be carried out in primary care without referral, and some of the included papers address the extent to which this is occurring and barriers to its use.

Differential diagnosis is important so that management can be tailored to specific conditions such as COPD, asthma, lung cancer, heart failure and pulmonary arterial hypertension. We have utilised the Model of Pathway to Treatment³⁰⁸ to organise the data extracted from included views studies, as it allows the diagnostic pathway to be analysed at various stages and from the viewpoint of patients and HCPs. It also affords us an opportunity to critically assess the model and its usefulness in developing pathways of care for a particular presentation.

Views/perceptions of community diagnostic pathways for breathlessness

In this section we present a synthesis of the findings from included qualitative and cross-sectional studies focusing on the views of patients and HCPs about the diagnostic pathway in regard to breathlessness (dyspnoea). As described above, we use the Model of Pathway to Treatment³⁰⁸ as a framework from which to analyse the data and draw out factors that influence the diagnostic process at each stage. As already discussed, only one paper¹⁹⁷ fulfilled the research question in terms of its focus on undifferentiated dyspnoea; therefore, the remaining data will be addressed in the context of different conditions.

Patient appraisal and self-management

Four qualitative studies reported in five included papers^{293-296,299} explored the views and experiences of patients with symptoms of breathlessness alone or with other symptoms. The first stage of the Model of Pathway to Treatment, that is, patient appraisal and self-management, was addressed in these studies and described in a similar way. Typically, the studies report that, far from seeking medical help at the first onset of breathlessness, the symptom was 'contained' and self-managed for a time, partly owing to the insidious nature of dyspnoea which makes it difficult for patients to discern as a change in health status.²⁹⁴⁻²⁹⁶ For those with comorbidities it could be difficult to identify changes in health deemed important enough to trigger help-seeking.²⁹⁴ Symptoms were played down or 'normalised' or attributed to something other than illness, such as smoking behaviour or ageing.²⁹⁴ Patients also reportedly used strategies that delayed

help-seeking, such as avoidance, perseverance or 'covering up' the symptom. Such strategies provided a degree of protection for the patient and family members.²⁹³ Some patients remained stoic or did not want to bother HCPs, remembering a time when seeking medical advice was costly. Anxiety regarding a feared diagnosis was another factor in delayed help-seeking.²⁹⁹ Self-management of symptoms accompanied by the strategies described above were generally the initial coping behaviours and this stage could last for weeks or several months.

Decision to consult health-care professionals and arrange appointments

According to findings from three included qualitative studies with service user participants,^{293,294,299} patients experiencing symptoms of breathlessness eventually made a decision to seek medical advice from their GP according to 'triggers'. Triggers to help-seeking included the symptom becoming severe and/or a decline in the patient's health status.^{293,294} Family and friends were often instrumental in persuading patients to seek help and would even make appointments on their behalf.^{293,294,299} For some patients there was recognition that the symptom was not related to existing conditions or that the symptom was not responding as expected. A few participants were prompted to seek advice following a media campaign, from which they recognised the symptoms as potentially linked to lung cancer.²⁹⁴ A further study that sought the views of GPs identified the need for patient education at this stage to raise awareness of the need to seek help.²⁹⁸

First consultation with health-care professionals

Views of both patients and HCPs were represented at this stage of the model, as it describes interactions and consultations between the patient and the GP about this particular symptom. However, the initial consultation did not necessarily lead to a diagnosis, with patients reporting iterations of ineffective treatments resulting in another period of appraisal and self-management before reconsulting the GP.²⁹⁴ For some patients, a number of doctors were consulted before an accurate diagnosis was offered. Diagnostic uncertainty was more likely to occur in primary care where that actual diagnosis was relatively rare, such as for pulmonary hypertension.²⁹³

It was also reported that some patients had attended their GP practice while experiencing symptoms but had not mentioned them to the GP, or the patient had mentioned them but perceived that the GP had been dismissive.²⁹⁴ For others, a consultation triggered by a different condition led to the identification of a respiratory problem.²⁹⁴ *Tod et al.*²⁹⁹ highlighted the role of families as advocates for patients when they perceived that symptoms were not being investigated.

Diagnosis

Owing to the increased relevance to the review question, this section includes a larger, although still limited, body of evidence from eight qualitative^{82,197,198,293,295-298,300,301} and five cross-sectional^{191,303-306} studies.

The patient pathway from a reported symptom of breathlessness at this point was contingent on the condition being ruled in or out by the GP and on primary care resources, access to diagnostic equipment, medical knowledge and skill in performing and interpreting diagnostic information. Therefore, diagnostic activity is reported to take place variously in the GP practice and as a shared activity between primary and secondary care settings, with referrals to specialists a common feature of the pathway. One study noted that conditions could be labelled differently over time; for example, an initial diagnosis of asthma could change to one of emphysema. HCPs also reported that medical language has altered over time, with 'COPD' being a relatively recent diagnosis.^{300,301}

Referral to a specialist

Referrals to specialists by GPs depended on the medical condition and the investigations required for a diagnostic work-up. For example, echocardiography was reported to assist in identifying cases of heart failure. However, *Khunti et al.*⁸² reported a lack of systematic diagnostic work-up among GPs for this condition, perhaps due to a lack of awareness regarding the usefulness of echocardiogram. Many GPs preferred ECG and referral for an X-ray because it was 'easier to organise' and 'less expensive' than accessing echocardiography, particularly for non-fundholding practices. There was also a reported lack of

trust at the interface between primary and secondary care. Some single-handed GPs referred their patients to a rapid-access cardiology unit at the hospital, whereas others requested access through cardiologists. Lack of time to assess patients for heart failure was cited as another barrier in primary care diagnostics, particularly as the population with suspected heart failure are elderly and can require more time to undress for physical examinations.

For patients with breathlessness and accompanying symptoms suggestive of lung cancer, the process of specialist referral was rapid once the symptom had been recognised by the GP, possibly because of greater awareness of recent UK guidance for cancer symptoms.^{295,296}

Office spirometry

Spirometry was one investigation that could be conducted in the GP office and was particularly associated with the differentiation between a diagnosis of COPD and one of asthma. A number of included studies explored the perceived usefulness of office spirometry from the point of view of the clinicians involved. No included study was identified that looked at patient views and experiences of spirometry in this setting.

In the four qualitative studies exploring GP views about performing spirometry, there were contradictory findings. Joo *et al.*¹⁹⁸ reported that GPs felt confident in diagnosing COPD without the use of spirometry, particularly if risk factors such as smoking were apparent and trialled treatments for COPD appeared to be working. The results from referred spirometry were reported as confusing for GPs, furthering their confidence in using non-spirometric diagnostic strategies. Practical considerations were also reported, such as lack of time to perform spirometry²⁹⁷ and the patient's unwillingness to return for follow-up investigations. Goeman *et al.*²⁹⁸ found that Australian GPs felt uncomfortable about their ability to use spirometers properly and that few practices had access to a spirometer. These findings highlighted a gap between national guidelines and current practice. However, Roberts *et al.*¹⁹⁷ found that GPs regarded spirometry as an essential diagnostic tool, albeit with acknowledgement of the need for training and retraining. This study sampled GPs in the UK who may be incentivised by criteria in the new GMC contract. They also had a special interest in medical education, and, therefore, their perceptions of spirometry use might differ from those of the broader UK GP population.

Five included cross-sectional studies assessed the use and perceived usefulness of spirometers in the diagnosis of COPD and/or asthma. Boffin *et al.*³⁰³ found that although 38% of Flemish GPs had access to a spirometer, 66% had never or almost never used one. One in five GPs was using a spirometer at the time of the study and a similar number had used spirometers but stopped doing so. Seventy per cent were using a peak flow meter, suggesting that GPs recognised the importance of assessing lung function. Reasons for not using spirometers or stopping spirometer use included the time it takes during the consultation, and a lack of knowledge and skill. Eighty-six per cent of GPs responded that training in spirometry ought to be provided. Of users, 71% had attended educational sessions, of which 64% were organised by vendors of spirometers. A study carried out in Italy³⁰⁵ concluded that GPs probably only diagnose the most severe cases of COPD and that 70% of these will have used spirometry. They suggest that this could be improved by offering better educational programmes. Following a workshop that included a presentation and hands-on experience of how to use a spirometer in a US-based study,¹⁹¹ the main reasons given for not carrying out spirometry were reimbursement, time, lack of familiarity with testing and uncertainty with interpretation of results. The authors point towards a lack of awareness or acceptance of the value of lung function testing among primary care practitioners.

By contrast, two studies^{304,306} found that access to spirometers and perceived confidence in diagnosis using a spirometer was higher in the UK. Over 80% of practices in one study³⁰⁴ reported possessing a spirometer and 160 out of 187 of these used it in every case of suspected COPD. However, 44% rarely used a spirometer. Over half of those using spirometry were confident in its use, and these practices used spirometry more than those who reported less confidence. However, only one-third of using practices were confident about interpreting the results. Most spirometry was carried out by a nurse, with only one-third

carried out by a GP. Halpin *et al.*³⁰⁶ reported that practice nurses were less confident (55%) in diagnosing COPD than GPs (80%), although GP confidence had increased from 2001 to 2005, whereas that of practice nurses remained the same at the end of this period. Bolton *et al.*³⁰⁴ concluded that reported misdiagnosis of COPD could benefit from more widespread use of spirometry. More GPs than practice nurses reported feeling confident in differentiating COPD from asthma.

For patients, diagnosis was received with mixed emotions, and the way that the diagnosis was conveyed by HCPs was important; for example, there were reports of a lack of empathy. GPs might have come across some conditions, such as pulmonary hypertension, only rarely, and this might also be the first time that a patient had heard of the condition. Patients often felt ill-informed, returning home to look for information on the internet, with upsetting consequences.²⁹³ Similarly, Khunti *et al.*⁸² found differing views between GPs within practices about diagnosing heart failure, as well as diagnostic confusion about whether a condition was respiratory or cardiac related. In another study, continuing education for GPs to promote better care was a priority for Australian GPs.²⁹⁸

Summary of the views review findings

Differing perspectives, different conditions

This limited body of views and perspectives from a combination of level 1, level 2 and level 3 evidence provides some insight into the way in which patients and HCPs enter and interact in a theoretical pathway from the onset of breathlessness symptoms to diagnosis. Each enters the pathway at a different stage and, rather than a linear progression, there are often iterations of consultation leading to diagnosis. For patients, the psychological barriers to disclosing a symptom such as dyspnoea can lead to delay in diagnosis, as GPs may not have the full patient history at their disposal. As patient history-taking is an initial indication on the care pathway, GPs need to be aware of the potential sensitivities that patients may have regarding disclosure.

Findings from included studies highlight the barriers to developing a single pathway for diagnosis of breathlessness (dyspnoea) symptoms in primary care. The evidence base lacks strength in terms of how practitioners might move forward in this endeavour. It also shows the heterogeneity of conditions that could be diagnosed from a symptom of breathlessness, of both respiratory and cardiac origin, some of which are not covered here owing to a lack of identified relevant publications. Such conditions are also associated with other symptoms, for example cough in lung cancer and wheezing in asthma as well as a range of symptoms and signs, such as oedema, related to heart failure.

Barriers to breathlessness diagnostic pathway in primary care

The evidence synthesis indicates a number of barriers to diagnostics for breathlessness in primary care. The first consideration is that patients might not want to reveal their breathlessness symptoms owing to a perceived lack of importance attributed to the symptoms, fear of receiving a challenging diagnosis or a wish not to be a burden on family, friends or the health service. Although diagnostic pathways are reliant to some extent on patient history, the wishes of patients are of great importance in diagnostic decision-making. Second, patients may not feel satisfied with the consultation and, as a result, may not return for follow-up sessions at the practice. Third, GPs may not identify the symptom as indicative of a relatively rare condition, resulting in delayed or misguided referrals for investigations.

Evidence for attitudes towards diagnostics in primary care suggested that ease of access to certain facilities, such as echocardiography, would increase referrals for patients with suspected heart failure.⁸² Evidence for views about and the extent of use of spirometry in primary care was mixed, with some GPs preferring to prescribe treatments and see how they impacted on the symptom rather than measure lung function.^{198,297} Lack of time during the consultation, lack of access to spirometers and lack of confidence in using spirometers or interpreting the results were reported barriers to spirometry use in primary care.

Integrating the intervention and views data

Figure 3 provides a conceptual model summarising elements of the pathway for patients with breathlessness that are described in the literature. We developed this model from analysis of the interventions and outcomes described in the intervention literature, combined with analysis of the themes emerging from the views studies.

The initial element of the model recognises the influence of patient decision-making in regard to whether or not to seek a consultation with a GP. The views literature highlighted a lack of importance attributed to the symptoms, fear of receiving a challenging diagnosis or a wish not to be a burden on family, friends or the health service, all of which could delay presentation. Following patient presentation, the next phase of the model outlines elements described in the literature that may act as mediating factors (influences) on the selection of various patient management options. These include factors reported in the views literature (such as time available during the consultation and condition type) and elements reported in the intervention studies (such as accuracy of spirometry). The following section of the model details potential GP management options, including direct referral to a specialist service, and the initiatives outlined in the intervention papers. These are potential points for interventions with GPs to be put in place. We have indicated the repeat cycle of patient presentation and GP management described in the qualitative studies by a two-way arrow. The final sections of the model detail the potential outcomes at different levels that were described in the included studies: immediately following an intervention, for patients and GPs, and impacts on the wider system/services.

Discussion

Thirty-six studies were included in the review of interventions in the pathway for patients presenting with breathlessness. Our search of the literature found few studies using higher-quality comparator designs, although we identified evidence relating to a range of different interventions, and a body of work that was carried out in the UK.

Although the limited robustness of the evidence should be fully recognised, the included research suggests that additional services in the community (such as mobile or community clinics) can be a useful means of differentiating between patients who may be managed in community services and those who need referral to a specialist. Similarly, the provision of open-access diagnostic services in secondary care may reduce the referral of patients with no abnormality to specialists and/or may reduce the numbers of patients misdiagnosed. The findings regarding spirometry use in GP surgeries suggest a limited impact on diagnostic decision-making, and conflicting evidence regarding the impact on referrals. This may be linked to the reported limited quality and accuracy of much spirometry carried out in the community. A small number of studies evaluating other technologies, such as POC testing or algorithms, suggest that these may impact on GP differential diagnosis, diagnostic certainty and time to treatment. However, the impact of these technologies on referral rates to specialists is unclear.

The studies as a group provide limited consistency in evidence, and also highlight the challenge of measuring effectiveness. Although a reduction in specialist referrals for some conditions that can be managed in primary care may be advantageous, a reduction in early referrals to specialists for other conditions may have a negative impact on optimal and cost-effective management and outcomes.

Seventeen papers were included in the review of views and perceptions of staff or patients. Findings from these papers were structured within the Models of Pathway to Treatment framework.^{307–309} Eight included views studies were based in the UK, increasing the applicability of findings in these studies to NHS settings. For example, one study that explored diagnosis of heart disease found that there was a perceived lack of access to echocardiography in primary care which influenced the GP decision-making process. Patients were referred for chest radiography instead, as it was easier and less costly.

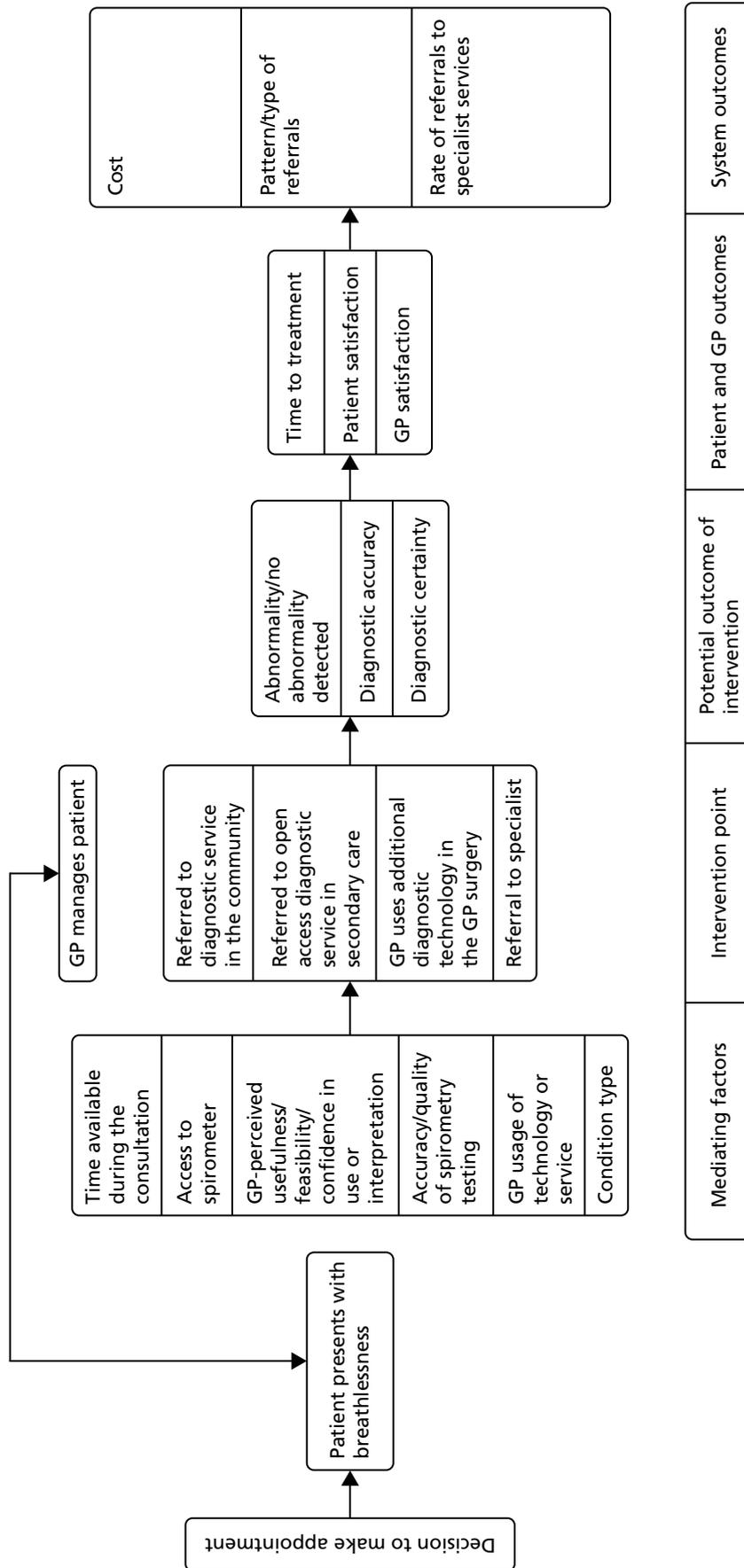


FIGURE 3 Conceptual pathway model.

In this literature, there was acknowledgement of the benefits of spirometry among a group of UK-based GPwSIs in education. Cross-sectional studies also revealed higher levels of access to spirometers and greater confidence in their use in the UK, suggesting differences across international health-care settings. Authors suggested that incentives through quality framework measures as well as regular training might act as motivators to spirometry use. However, spirometry use remains low in the UK, and, although the evidence suggests that UK-based practice nurses are more likely than GPs to perform spirometry, they are less confident in doing so.

Comparison of the findings from the intervention and views studies provides insights into the evidence relating to spirometry in primary care. The intervention studies highlighted the limited impact and accuracy of much spirometry, with the views papers providing potential explanations for this by reporting that some GPs prefer to prescribe treatments rather than test lung function, and limited confidence in testing or interpreting results. Although the views review suggested that training might increase the usage of spirometry in the UK, the intervention studies provide a cautionary note to this, with evidence that training may not increase the quality of testing.

The views data also may provide some insight into the unclear effect on referrals reported in much of the intervention literature. The association made by many of the intervention studies was that high numbers of patients with no abnormality seen in the new services were evidence of a reduction in specialist referrals. An alternative explanation is that GPs use these additional services for patients who might have more borderline/less severe symptoms, and who would not have been referred for specialist assessment. In support of this possibility, views studies reporting attitudes towards diagnostics in primary care suggested that ease of access to certain facilities, such as echocardiogram, would increase referrals for patients with suspected heart failure.

Limitations

Although the review included a reasonable volume of work, the limited quality of the included intervention literature requires the study findings to be treated with caution. The views review found little literature which related to patients with undiagnosed breathlessness, and highlighted the heterogeneity in conditions that could be associated with breathlessness.

Structuring qualitative findings in the Models of Pathway to Treatment framework^{307–309} also highlighted the extended pathway that includes patient decision-making when breathlessness symptoms occur. Delays in presentation, along with practice-related factors, can lead to delayed diagnosis.

Implications for health services

1. There is limited evidence derived from a range of study designs that community clinics, including mobile services, might be useful in providing a way of distinguishing between patients whose respiratory problems might be managed in the community and those who require referral to a specialist.
2. More robust evidence, along with qualitative and cross-sectional views data, suggests that the use of technology such as spirometry for diagnosing breathlessness in primary care is mixed in terms of access to technology, impact on diagnostic decision-making and impact on referrals. There is conflicting evidence regarding whether referrals may increase or decrease as a result of spirometry use in primary care.
3. Quantitative and qualitative evidence suggests that confidence and accuracy in using equipment and interpreting results varies in primary care. A small body of work associates increased confidence in using the technology with having received training, although the evidence is mixed regarding training having a substantial impact on the accuracy of testing.
4. There is a small body of evidence to suggest that POC testing can positively impact on differential diagnosis, diagnostic certainty and time to treatment in primary care.
5. A larger body of quantitative evidence suggests that open access to secondary care diagnostic services can reduce referrals to specialists, as well as reducing the risk of misdiagnosis.

6. Qualitative evidence highlights barriers to carrying out diagnostic procedures in primary care, such as the extended time required during consultations, and also the beliefs and attitudes of providers towards specific diagnostic procedures.
7. The literature highlights the range of conditions to which dyspnoea can be attributed, all of which are characterised by other signs and symptoms as well as psychological and social impact on the patient. This diversity is a barrier to developing a single pathway for breathlessness.

Implications for research

1. The review of available literature highlights a lack of robust evidence in the area of service models for differential diagnosis of breathlessness in primary care, with much of the literature, particularly the qualitative data, focusing on particular conditions rather than patient pathways.
2. The evidence indicates that some interventions may be more worthwhile than others, providing a rationale for further evaluation of these technologies or practices. Examples include mobile and community clinics and open-access clinics in secondary care. As noted for diagnostic ultrasound services in *Chapter 5*, when randomised trials are not feasible, research and evaluation may use a variety of observational study designs making use of routinely available data.²⁶⁰
3. The evidence base was underdeveloped, with a need for more and higher-quality studies in the area. A key area of uncertainty relates to the value of spirometry testing in GPs' surgeries and similar settings. There is a need for research both to clarify the effects of testing on subsequent patient management and to evaluate methods of providing training and support to improve the quality of spirometry in primary care.

Conclusions

Limited evidence from intervention studies indicates that the provision of services in the community, POC testing and open-access testing may have a positive impact on the diagnostic pathway for breathlessness, in terms of appropriate referral to specialists and a reduction in misdiagnosis. Qualitative and cross-sectional studies highlight a complex interplay of patient, practitioner and organisational factors influencing the diagnostic pathway for breathlessness. Patient data highlight an iterative process from symptom onset to diagnosis that may involve a number of consultations. Practitioners in primary care vary in their attitude towards the use of diagnostic technology based on accessibility, motivation, confidence, skills and knowledge. Although there is the suggestion that there should be improved access to diagnostic tools with regular training and financial incentives, the literature emphasises that the use of technologies such as spirometry must be carried out to high standards, and that training may not lead to these standards being achieved.

Chapter 7 Discussion and conclusions

Main findings

Following an initial broad literature mapping exercise, we conducted three separate focused reviews examining the evidence base around community diagnostic services from three different angles: the diverse logistic and practical implications of implementing a wide range of diagnostic technologies; a focus on a specific widely used diagnostic technology (ultrasound); and diagnostic pathways for patients presenting with breathlessness, a symptom associated with a range of possible underlying causes. We have identified at least seven main models of service that are delivered in primary care/community settings and, in most cases, with the possible involvement of community/primary care staff (*Table 42*). Not all of these models are relevant to all types of diagnostic test. The current organisation of the UK NHS means that some types of service can potentially be commissioned from private sector providers, which makes it difficult to generalise about who is involved in providing the service.

In general, there is a lack of evidence comparing different service models directly. The focused review of ultrasound services (see *Chapter 5*) found only two such studies,^{16,229} one of which was difficult to interpret due to language difficulties. Other studies used weaker designs, for example comparing outcomes of screening in the community with hypothetical outcomes in the absence of such a service.^{203,223} The review of breathlessness pathways (see *Chapter 6*) included a broader range of studies, including a number of UK studies, but most studies that evaluated new services were uncontrolled and many were presented at conferences rather than being published in peer-reviewed journals, limiting the data available.

Most of the research evidence included in this report evaluates some aspect of the quality, safety and/or clinical effectiveness of diagnostic testing in community or primary care settings. In the review of ultrasound scanning (see *Chapter 5*), a wide variety of applications of the technology was examined, including cardiac, GI, musculoskeletal and palliative care. There was some evidence that community services can guide decision-making, reduce referrals to secondary care and provide patients with quicker access to scanning and possibly subsequent treatment, if required.^{16,203} The lack of true control groups in most of the included studies makes it difficult to assess how a community-based service, for example with GPs or nurses performing scans, compares with the alternatives (particularly the widely favoured model of GP open access to secondary care ultrasound services). The best evidence included in this review did not

TABLE 42 Main models for community diagnostic services

Community/primary care setting	Secondary care setting (comparators)
Community diagnostic centre (offering multiple diagnostic services or specialising in a single test); possibly non-NHS provider ^a	Secondary care 'traditional' (via consultant referral)
Community outreach from secondary care ^a	Secondary care 'open access'
GPwSI (offering test in addition to normal GP services)	Rapid-access clinic (condition-specific)
Specialist nurse or advanced nurse practitioner [dedicated to test (e.g. spirometry) or condition (e.g. diabetes)]	
Mobile service delivered at GP surgery or other community setting (possibly by non-NHS provider) ^a	
Shared services within a primary care consortium (e.g. GP federation)	
Telediagnosis (interpretation/advice from secondary care)	

^a Community setting but not necessarily staff.

raise any major concerns about the quality or safety of ultrasound scanning in the community, given the availability of appropriate training and audit.²⁰³ However, one study from Australia found a poor rate of accuracy of diagnoses based on musculoskeletal community ultrasound scans,²³⁰ suggesting that there may be variation across indications and/or settings.

Compared with the ultrasound review, the review of diagnostic pathways for patients with breathlessness (see *Chapter 6*) found a larger body of evidence (although still of limited quality) and more studies from UK settings. The findings suggest that community-based services can be useful in identifying patients who can be managed in primary care and avoiding unnecessary referrals to secondary care. However, a similar finding was reported for open-access services in secondary care and there were no studies that compared these different service models. The option for GPs to manage a patient with breathlessness by a pragmatic trial of medication rather than referral for further diagnostic tests was not considered in the included studies.

Although this review included all types of diagnostic test used in the assessment of breathlessness, the majority of studies that assessed a specific test focused on spirometry. This is an important test, particularly in the diagnosis of COPD, but we found limited evidence of an impact of spirometry performed in GP surgeries on diagnostic decision-making and contradictory evidence of an impact on referrals. There is some evidence from the UK indicating that the accuracy of spirometry in the community is often suboptimal and there is also uncertainty over whether or not accuracy can be improved by training or educational interventions. An important output of this part of the project is the conceptual model (see *Figure 3*) which integrates evidence from intervention studies and qualitative research to summarise the wide range of factors that may affect longer-term outcomes of different service models available to GPs in diagnosing and managing patients with breathlessness.

A major limitation of the evidence in both the ultrasound and breathlessness pathway reviews was a lack of good-quality evidence on the cost-effectiveness of different models of different service provision. For example, only two studies included in each review reported on service costs. Decision-making around provision of diagnostic tests in community and primary care settings would ideally be supported by evidence not only on the costs and benefits of different service models (including costs associated with reconfiguring services) but also on associated practical and logistic issues. The other main section of this report (see *Chapter 4*) addresses this need. Our framework map and synthesis cover a broad range of diagnostic technologies and use an innovative framework, termed STEP-UP, to map the literature around logistic factors and considerations affecting their uptake and use. The STEP-UP framework covers skills, training, equipment, premises, user perspectives and the primary–secondary interface. The diverse range of tests and factors covered emphasises the multifactorial nature of decisions around diagnostic service provision.

A key finding of this part of the project (in line with the focused reviews in *Chapters 5* and *6*) is the limited availability of data and evidence on current UK practice and uptake of diagnostic services. In particular, the implications of attempting to improve diagnostic test provision by introducing several new services within a short time are unclear. The context in which new services are introduced and evaluated will differ between, for example, different conditions or pathways and different types of setting (e.g. city vs. rural). This variation makes it difficult to provide specific actionable messages from the mapping review. However, the STEP-UP framework offers the possibility of developing a rigorous approach to the evaluation and implementation of proposals for new community diagnostic services. The combination of the STEP-UP framework with an economic evaluation from a whole-system perspective appears particularly worthy of consideration.

Our experience suggests that there may be a need for additional evidence and data resources for decision-makers on diagnostic service delivery and organisation, possibly organised along the lines of the NIHR DECs. There appears to be a particular need to improve access to data on current levels and models of diagnostic provision in primary care and to project forward to address future priorities.

Strengths and limitations

This project was conducted by a team of investigators with diverse backgrounds and expertise, and followed protocols developed in advance (topics and protocols for *Chapters 4–6* were guided by the results of the initial mapping exercise). Particular strengths of the report include the initial mapping phase to gauge the quantity and quality of the evidence base and to guide selection of topics for detailed investigation; the use of systematic and documented search strategies, including extensive grey literature and internet searching; and risk-of-bias assessment supplemented by classifying evidence according to overall quality and relevance, enabling us to concentrate on synthesis of the most useful evidence. We thought that it was important to adopt an inclusive approach to reviewing this topic, including all types of study and both qualitative and quantitative evidence. This complicated some aspects of the review process, for example risk-of-bias assessment, but had the advantage of facilitating a report that reflects the complex range of factors that may influence decision-making regarding the location of diagnostic testing services closer to patients in primary care and community settings. Overall, the report documents the strengths and extensive limitations of the currently available evidence and provides suggestions for a clear research agenda underpinned by a practical methodological framework (STEP-UP) that can be used to support the development of future studies and evaluations at different levels of the health-care system.

We have not tried to cover all types of diagnostic technology in equal depth, choosing instead to provide focused reviews on logistics (see *Chapter 4*), on a specific widely used diagnostic technology (see *Chapter 5*) and on the components of pathways for diagnosing the underlying cause of breathlessness (see *Chapter 6*). Although this decision was informed by our initial mapping exercise, it inevitably means that some diagnostic tests have received relatively little attention. In particular, *in vitro*/POC diagnostic tests (covered only in *Chapter 4*) are the focus of a good deal of interest and may be suitable for both administration and interpretation by community/primary care settings. However, we believe that our decision to concentrate on those technologies with the greatest implications for possible changes to models of service delivery is justified based on the specific objectives of this study. The NIHR DEC's have been set up to research the clinical effectiveness and cost-effectiveness of *in vitro* diagnostics, with the centre in Oxford having a particular interest in tests suitable for primary care.¹¹

The three main strands of the project (logistics map and framework synthesis, ultrasound review and breathlessness pathway review) were specified in the overall protocol and conducted largely in parallel. The different approaches of the framework synthesis and the two focused reviews complemented one another and we intend to integrate them fully in further outputs from this project. However, there was inevitably some overlap between the logistics framework synthesis and the other two reviews in relation to ultrasound and respiratory tests. If permitted by the project timetable and resources, an alternative approach would have been to develop and validate the framework as the first stage of the process. This might have enabled us to bring together evidence around effectiveness and practical requirements for service delivery in a more seamless fashion. Such an approach could be considered for future evidence synthesis projects that seek to evaluate service delivery across a broad range of technologies and indications.

The project has inevitably been constrained by the time and staff resources available and this has limited our ability to carry out all review processes in duplicate. We do not believe that this is likely to have had a major impact on, for example, decisions on inclusion of studies, but the possibility of some effect at the margins cannot be ruled out.

An important limitation on the use of systematic review methods to obtain and synthesise evidence about service delivery and organisation in the UK NHS is the difficulty of obtaining, from publicly available sources, up-to-date information about what models of service are commissioned, where and from which providers. We identified many websites and pages describing relevant services but a comprehensive listing would have required extensive contacts with (> 200) CCGs and other NHS organisations, which was not possible with the methods and resources available to this project.

Implications for practice

1. Current policy in the NHS in the UK (specifically in England) favours the development of diagnostic services in community and primary care settings.³¹⁰ This is part of a general trend towards developing new models of care centred on primary care and allowing patients to be seen and treated close to home rather than in hospital. Across the broad range of diagnostic technologies considered (in differing degrees of detail) in this report, the two main areas with implications for practice appear to be (1) training, workforce and governance issues and (2) views and attitudes at the primary–secondary care interface.
2. The reviews reported in *Chapters 4–6* all consider aspects of training for health professionals delivering diagnostic services in the community. The findings suggest a need to both improve training and adapt it to the needs of health professionals working in community settings. The limited evidence included in the ultrasound review suggested that training needs will vary depending on the role of diagnostic ultrasound scanning in the practice of the individual or the service that employs them. None of the evidence looked at training for health professionals other than doctors. In particular, the training needs of ultrasonographers working in community settings, how these needs might differ from those of hospital-based staff and how best to deliver training to those working outside hospital structures have not been considered.
3. A link to secondary care may be important for governance and quality control of a community-based service, as highlighted in the critique of a community echocardiography service in the Netherlands.^{223,253} However, the review of logistic issues (see *Chapter 4*) noted that problematic issues may arise around the role of professional bodies whose function is both to oversee quality and safety and to represent the interests of particular professional groups.
4. We found little evidence related to the primary–secondary care interface in the UK NHS. The ultrasound review included a UK study from 1997²¹⁵ indicating little interest in community-based services from either GPs or hospital radiology departments (in terms of providing support and training). Open access to secondary care facilities was widely favoured. This is understandable, as this model allows hospitals to maintain their services and equipment while GPs can see their patients without having to worry about the potential workload and training implications of providing a service in the community or their own surgeries. However, open-access services are always at risk of additional costs if GPs order unnecessary tests. More recently, a study in the Netherlands²²⁴ found that orthopaedic surgeons largely distrusted ultrasound scans performed by physiotherapists in primary care. The diagnostic process was frequently restarted after referral rather than using the information supplied by the referring physiotherapist.
5. In the review of differential diagnosis of breathlessness, one study that explored diagnosis of heart disease found that there was a perceived lack of access to echocardiography in primary care which influenced the GP decision making process.⁸² Patients were referred for chest X-ray instead as it was easier and less costly. These studies suggest that barriers arising at the primary–secondary care interface can hinder the effective operation of community diagnostic services.

Implications for research

Specific research implications arising from individual focused reviews are presented in the relevant chapters. Overall research themes for community diagnostic services in general are summarised here. These reflect the main findings and implications for practice presented in *Implications for practice*.

1. There is a need for studies to compare the outcomes of different service models using robust study designs. Comparisons of ‘true’ community-based services (using community staff for test administration, interpretation and decisions about treatment/referral/further testing) with secondary care-based open-access services and rapid-access clinics would be particularly valuable. There are specific needs for economic evaluations and for studies that incorporate the effects of diagnostic decision-making in the community on the wider health system. For example, does the provision of services in the community stimulate demand for testing that would not otherwise exist (supply-induced demand), potentially

leading to overtesting and unnecessary investigations and appointments further along the patient pathway? Research on wider system impacts could investigate, for example, whether diagnostic testing in the community genuinely improves patient access or merely shifts demand from one part of the health system to another, with no overall benefit to the patient. Economic evaluations designed to support changes in services should take into account the costs of reconfiguring services, additional training, etc., as well as the costs and benefits of different service models.

2. Research into logistic and practical factors that can affect decision-making around diagnostic service provision could be based around a specific technology or focus on the needs of a particular condition or management pathway. For example, specific recommendations on research around training have recently been provided by the NIHR Oxford DEC.⁴⁵ The STEP-UP framework presented here, or its extended version (STEPPED-UP, also incorporating Public perspectives, Economics and Drivers), could be used as a framework for planning programmes of research and evaluation that reflect the complex range of factors that may influence decision-making in this area.
3. The above-noted difficulty in identifying what services are being commissioned and keeping up with local evaluations suggests that there may be a need to improve the availability of information in this area to decision-makers, researchers and the public. Preliminary research could be undertaken to establish if this is a true gap in the information resources available and if NHS decision-makers would find such information helpful. Given that some studies included in the reviews in this report were presented at conferences but not published, it would seem sensible to examine the barriers to full publication of NHS service evaluations and interventions that could potentially overcome them.

Conclusions

Overall, the evidence base for community- and primary care-based diagnostic services is limited, with very few controlled studies comparing different models of service. There is evidence from different settings that community-based services can reduce referrals to secondary care and allow more patients to be managed in primary care. Evidence on quality (including diagnostic accuracy and appropriateness of test ordering) and safety of such services is mixed.

In the absence of clear evidence of superior clinical effectiveness and cost-effectiveness, the expansion of community-based services has been driven by other factors. These include government policies to encourage moving services out of hospitals; the promise of reduced waiting times for diagnosis and potentially treatment; the availability of a wider range of suitable tests and/or cheaper, more user-friendly equipment (e.g. handheld ultrasound scanners); and the ability of commercial providers to bid for NHS contracts, potentially offering new and more flexible models of service. However, service development also faces a number of barriers, including issues related to staffing, training, governance and quality control. Perceptions and attitudes of health professionals and patients are particularly influential in the absence of clear evidence-based conclusions. Drivers and barriers vary according to the diagnostic technology involved and other contextual factors which can be addressed using the STEP-UP framework developed in this report.

The limited quantity and quality of the available research evidence means that there are many potential areas in which further research would be beneficial. In addition to assessing the clinical effectiveness and cost-effectiveness of different service models using controlled study designs, research should take into account the wider costs and benefits of reorganising services (e.g. additional training or new premises). It will also be important to ensure that new services are genuinely effective for patients and do not merely redistribute pressures from one part of the patient pathway to another.

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Contributions of authors

Duncan Chambers (Research Fellow) contributed to the systematic review methodology, study selection, data extraction, quality assessment, report writing and liaison with clinical experts. He also contributed to the preliminary literature mapping exercise and led the review reported in *Chapter 5*.

Andrew Booth (Reader in Evidence Based Information Practice) contributed to the systematic review methodology – conception of review, review methodology, study selection, data extraction, quality assessment and report writing. He also contributed to the preliminary literature mapping exercise and led the review reported in *Chapter 4*, including conception and development of the STEP-UP framework and associated methodology.

Susan K Baxter (Research Fellow) contributed to the systematic review methodology, study selection, data extraction, quality assessment and report writing. She also led the quantitative review reported in *Chapter 6*.

Maxine Johnson (Research Fellow) contributed to the systematic review methodology, study selection, data extraction, quality assessment and report writing. She also led the qualitative review reported in *Chapter 6*.

Katherine C Dickinson (Information Specialist) contributed to the literature searching and report writing. She also performed searches for the preliminary literature mapping exercise and the reviews reported in *Chapters 5* and *6*.

Elizabeth C Goyder (Professor of Public Health) contributed to the systematic review methodology, clinical input and advice, and liaison with clinical experts.

Data sharing statement

No new data have been created by this research.

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Appendix 1 Search strategies for literature mapping exercise

Search strategies/filters

Reviews strategy

1. primary care.tw.
2. general practi\$.tw.
3. primary health care.tw.
4. Community Mental Health Services/
5. Family Practice/
6. Home Care Services/
7. Physicians, Family/
8. Community Health Services/
9. Community Health Nursing/
10. Community Pharmacy Services/
11. Community Health Workers/
12. Preventive Health Services/
13. or/1-12 **Primary Care filter**
14. *Diagnostic Services/
15. *Clinical Laboratory Services/
16. *Genetic Testing/
17. *Mobile Health Units/
18. diagnostic service\$.ti,ab.
19. clinical laboratory service\$.ti,ab.
20. genetic test\$.ti,ab.
21. mobile health\$ unit\$.ti,ab.
22. mobile health\$ clinic\$.ti,ab.
23. (point of care testing or point-of-care testing or POCT or near patient testing or near-patient testing).ti,ab.
24. diagnos\$.ti,ab.
25. test\$.ti,ab.
26. 24 or 25
27. 26 and primary care.tw.
28. or/14-23,27 **Diagnostics terms**
29. 13 and 28
30. Meta-Analysis as Topic/
31. meta analy\$.tw.
32. metaanaly\$.tw.
33. Meta-Analysis/
34. (systematic adj (review\$1 or overview\$1)).tw.
35. exp Review Literature as Topic/
36. (review adj3 literature).ti,ab.
37. or/30-36
38. cochrane.ab.
39. embase.ab.
40. (psychlit or psyclit).ab.
41. (psychinfo or psycinfo).ab.
42. (cinahl or cinhal).ab.

43. science citation index.ab.
44. bids.ab.
45. cancerlit.ab.
46. or/38-45
47. reference list\$.ab.
48. bibliograph\$.ab.
49. hand-search\$.ab.
50. relevant journals.ab.
51. manual search\$.ab.
52. or/47-51
53. Review/
54. Comment/
55. Letter/
56. Editorial/
57. animal/
58. human/
59. 57 not (57 and 58)
60. or/53-56,59
61. 37 or 46 or 52 or 53
62. 61 not 60 **Reviews filter**
63. 29 and 62
64. limit 63 to yr="2000 –Current" **Date limit**

Comparative studies strategy

1. primary care.tw.
2. general practi\$.tw.
3. primary health care.tw.
4. Community Mental Health Services/
5. Family Practice/
6. Home Care Services/
7. Physicians, Family/
8. Community Health Services/
9. Community Health Nursing/
10. Community Pharmacy Services/
11. Community Health Workers/
12. Preventive Health Services/
13. or/1-12 **Primary Care filter**
14. *Diagnostic Services/
15. *Clinical Laboratory Services/
16. *Genetic Testing/
17. *Mobile Health Units/
18. diagnostic service\$.ti,ab.
19. clinical laboratory service\$.ti,ab.
20. genetic test\$.ti,ab.
21. mobile health\$ unit\$.ti,ab.
22. mobile health\$ clinic\$.ti,ab.
23. (point of care testing or point-of-care testing or POCT or near patient testing or near-patient testing).ti,ab.
24. diagnos\$.ti,ab.
25. test\$.ti,ab.
26. 24 or 25
27. 26 and primary care.tw.

28. or/14-23,27 **Diagnostics terms**
29. 13 and 28
30. clinical trial.pt.
31. comparative study.pt.
32. 30 or 31 **Comparative studies filter**
33. 29 and 32
34. limit 33 to yr="2000 –Current" **Date limit**

Search filters

Primary care search filter taken from Brown *et al.*³¹¹

Reviews filter adapted from the SIGN search filter resource: www.sign.ac.uk/methodology/filters.html#systematic.

Appendix 2 STEP-UP framework

TABLE 43 STEP-UP evidence map (granular version)

Human resources	
SKILLS	TRAINING
Skill mix	Training needs
Extended roles	Training in using equipment
Inappropriate test ordering	Training in interpretation
Accuracy	Training costs
Errors	Duration
Delay in diagnosis	
Quality assurance	
Logistics	
EQUIPMENT	PREMISES
Equipment for modality	Cost of premises
Equipment for analysis	Space for equipment
Consumable costs	Space for consumables
Maintenance	Space for staff
	Space for patients/waiting areas, etc.
	Health and safety
	Risk assessment
Communications and relationships	
USER PERSPECTIVE	PRIMARY–SECONDARY INTERFACE
Waiting times	Referrals
Acceptability	Changes to diagnosis pathways
Repeat procedures	Changes to management pathways
	Health service utilisation
	Relationships between staff
	Specialist support
	Attitudes of secondary providers
	General management

Appendix 3 Evidence and study identifiers for STEP-UP maps

Audiology

Definition: overall service delivery framework within which audiometry (hearing tests) are used to assess ability to hear different sounds and to determine if there are any problems (adapted from NHS Choices).

This map includes otoacoustic emissions; pneumatic otoscopy; pure tone audiometry; spectral gradient acoustic reflectometry; tympanometry.

This map excludes universal newborn hearing screening.

Contains public sector information licensed under the Open Government Licence v3.0.⁵²

Background

Ten per cent of adults in England experience hearing loss and would benefit from hearing aids or other forms of hearing management. However, 76% of these adults do not have hearing aids or other management. The impact of this unmet need is substantial and has been linked to depression, social isolation, employment problems, loss of independence and dementia.³¹² Hearing problems are widely reported as underdiagnosed and undertreated.³¹³

NHS Audiology services are complex health systems in complex environments. They provide 'end-to-end' care with newborn screening, diagnostic assessment of patients, dispensing of hearing aids and appropriate follow-up to ensure that good outcomes are obtained.³¹⁴ Historically, audiology services were commissioned from the acute sector and have had a low priority. First presentation in the UK is usually to the GP.

Audiology clinics were among the first diagnostic services to be relocated in primary care under the provisions of GP fundholding. As of 2014, 44% of CCGs were commissioning community-based hearing services to move care towards a patient-centred service. Neonatal hearing screening is excluded from the remit of this evidence map. Diagnostic interventions are required for developmental issues for children, occurrence of otitis media and the onset of age-related hearing degeneration in older patients. In addition, some GPs will investigate occupation-related hearing problems. In the UK, the vast majority of ear, nose and throat (ENT) problems are treated by the GP without reference to ENT.

Placing diagnostic audiology services in a community setting may improve access and availability of services, potentially leading to earlier presentation and intervention. The location of audiology services in a locality may improve equity of service provision in overcoming barriers related to transport services or finding extended time to attend an appointment. Hearing/balance problems often accompany systemic disorders (e.g. cardiovascular disease, diabetes or cancer) in which GPs already intervene.³¹⁵ Detecting hearing problems at an earlier stage may lead to the enhanced use of audiological services by geriatric and paediatric populations.

We did not identify any specific systematic reviews relevant to the locating of audiology diagnostic services in a primary care setting. A review by the Joanna Briggs Institute is examining the effectiveness of nurse-led ENT clinics on service delivery and clinical outcomes.³¹⁶ However, the protocol for the Joanna Briggs Institute review does not distinguish between locations of the clinics and, therefore, has limited applicability.

This proposed review does not have a specific focus on diagnostic interventions. Systematic reviews on the provision of specialist outreach clinics in primary care may be of relevance when looking at issues beyond those related to skills, roles and personnel.^{70,317} In addition, several UK-based national evaluations of specialist outreach clinics may inform the relative advantages of services delivered at a primary care location.³¹⁸

STEP-UP summary

Skills

An audiogram is a hearing test conducted under ideal listening conditions in a soundproof booth. The test includes different pitches and intensities and the results are conveyed in graphical form. When hearing loss is present, an audiogram helps to distinguish between conductive loss (outer/middle ear) and sensorineural loss (cochlea/cochlear nerve).³¹⁹ Hearing tests for children vary according to their age and level of understanding. For babies this may simply involve checking their neuronal response to sound or using behavioural observation audiometry. For children aged between 8 months and 3 years, visual reinforcement audiometry is used rewarding a child for turning to a sound by seeing a toy or puppet. For children older than 3 years, play audiometry can be used, with very similar results to an adult audiogram. Each ear can be tested separately.³¹⁹

Audiological investigation includes diagnosis of permanent childhood hearing loss, speech disorders and balance problems in children. Staff with whom GPs need to work include audiologists; vestibular rehabilitationists; tinnitus therapists; clinical, educational and family psychologists; otologists; speech and language therapists; educational audiologists; specialist social workers; and teachers. It may be helpful to distinguish between 'the small, specifically medical requirement, and the large, specifically audiological testing requirement', with the latter more completely reflecting the scale of audiology required to be done by community staff who do not specialise in audiology.

Few studies have compared the performance of specialist otolaryngologists with that of GPs in aspects of audiological practice. One such study compared the performance of US, South African and Greek otolaryngologists, paediatricians and GPs in recognising acute otitis media (AOM) and otitis media with effusion (OME) as presented in an otoendoscopic video evaluation test.³²⁰ Overall, the average correct diagnosis on the otoscopic video exam by otolaryngologists was significantly superior that by to GPs in all three countries.

There are no structured audiovestibular services for adults in primary care in the UK, although some services for adults are now provided in a primary care setting by GPWSEs in otology. Some providers have developed community-based services for common problems and hub-and-spoke services would support the provision of more rapid effective care for this group of patients. A significant proportion of paediatric audiological services, including hearing surveillance programmes, are provided by second-tier community services. In the UK, good practice guidance and standards and quality audit tools have been developed for audiology services. The Royal College of Physicians' document on audiovestibular medicine³²¹ specifies requirements.

STEP-UP summary statement With regard to SKILLS, audiology is attributed a MODERATE degree of implementation difficulty owing to initial difficulties in using the tympanometer or the pneumatic otoscope and ongoing concerns about the appropriateness of diagnosis and its implications for secondary care.

Training

A survey of UK GP management of tinnitus³²² revealed that almost all responders (99%) routinely performed otoscopy, but only 31% routinely performed a tuning fork test. When asked directly if tinnitus sufficiently impacted on their practice to warrant dedicated training, 28% of responders indicated that it did. Some indicated that they would approve of succinct (≈1 hour) training, either online or as part of a broader ENT workshop. When GPs were invited to comment on how they felt tinnitus management in primary care could be improved, the dominant theme was a desire for concise accessible training on tinnitus management.

The British Association of Audiological Physicians (BAAP) acknowledges the role of training for specialist GPs and practice nurses.⁶³

Several papers describe training for tympanometry for GPs (Australia)^{57,58} and for GPs and practice nurses (Denmark).⁵³ A 3-hour workshop to improve skills in use of tympanometry and pneumatic otoscopy provided GPs with a portable tympanometer.⁵⁷ GPs used their own otoscopes with an appropriate insufflator bulb supplied to enable pneumatic otoscopy. Content and outcomes for the course are described in an earlier report.⁵⁸ The workshop included pre-reading and access to an online training resource [Enhancing Proficiency in Otitis Media (ePROM)],⁵⁹ a didactic presentation on otitis media, expert presentations and demonstrations of use of tympanometry and pneumatic otoscopy, hands-on experience in pneumatic otoscopy and tympanometry and guided video examples. These brief training workshops were shown to significantly improve GP confidence for use of the techniques and for diagnosing OME.

The Danish course offered an update on middle ear disease, theoretical and practical information on tympanometry, technical presentation of two different tympanometers and practice performance of tympanometry.⁵³ Six weeks after the course, participants were asked about their experience with tympanometry, problems before and after the course, their experience with tympanometry in the last 2 weeks and how they evaluated the different elements of the course. The 1-day course improved the knowledge and practical skills of the participating GPs and nurses.

The effect of introducing tympanometry in combination with training to GPs was investigated in a prospective study with 40 GPs in Denmark.⁶⁰ Before the study, tympanometry instruction sessions were organised, during which otolaryngologists discussed their experience of middle ear diagnostics with the GPs. The diagnosis was changed in 26.4% after information from the tympanometry.

The BAAP recognises the importance of maintaining a safe environment through the training of staff. This relates to countering the threat of potential clinical risk through continuing education, working with peers and not single-handed, Deaf awareness training, child protection awareness, and training in infection control and protocols for sedation and general anaesthesia.⁶³

Numerous studies highlight the lack of otolaryngology (ENT) teaching in GP training and suggest both the degradation and the inadequacy of knowledge that GPs have acquired as medical students, particularly when managing complex ENT issues.³²³ Nurses with specialised ENT training can facilitate training of GPs and community nurses by running study sessions and providing ongoing support.

Considerable scope exists for the greater involvement of primary care in the management of patients with tinnitus. However, most GPs and their colleagues in primary care may need a specific programme of updating, education and training.⁶⁹ A well-trained primary care team could provide initial advice, exclude the existence of wax or external ear infections or other conditions which may contribute to patient's perceptions of tinnitus and give the necessary treatment.³²⁴ Professional audiology associations suggest that a specifically trained primary HCP with an appropriate documented level of competency in audiology (e.g. GPwSI in audiology/ENT) will be able to manage these patients and will triage the others according to agreed criteria. The majority of patients with non-troublesome tinnitus and those with additional hearing difficulty will be managed by the first level of audiology services. Others will be referred directly to specialist and supraspecialist audiology centres (the second and third levels of care). An educational intervention targeting GPs in Israel achieved an increase of numbers undertaking a hearing test from 19% to 49%, with little change in the control groups over a 2-year period.³²⁵

Several authors note that a diagnosis of AOM is problematic, pointing out the importance of formalized training which is typically expected to be, but is not universally delivered as, part of paediatric resident training.³²⁶ In Texas, only 66% of family practice residents used a pneumatic otoscope, and half of the residents had insufficient criteria in diagnosing AOM. Education in diagnostic criteria and equipment increased the use of the pneumatic otoscope.³²⁷

Three nurses were trained to perform tympanometry and spectral gradient acoustic reflectometry in checking for AOM.⁶¹ In one training session, lasting approximately 2 hours, the team taught the nurses the principles of tympanometry and spectral gradient acoustic reflectometry and how to perform examinations with these devices. During the study visits, one of the three nurses performed examinations. However, the clinical usefulness was reduced by the fact that these test results were obtained only at fewer than half of the asymptomatic visits owing to young unco-operative children, inexperienced nurses and the relative rarity of exclusive test results. The nurses were inexperienced when starting to perform examinations, and they gradually became more experienced during the study. Thus, in clinical practice, nurses would perform better if they were already experienced with the devices when starting to perform routine ear controls. The tympanometer (MicroTym2, Welch Allyn, Skaneateles Falls, NY, USA) used in the study has been found slightly difficult to handle, and better success rates could be obtained with a more easily handled tympanometer.⁶⁴

STEP-UP summary statement With regard to TRAINING, audiology is attributed a MODERATE degree of implementation difficulty owing to the facility of short courses to increase confidence in the use of equipment.

Equipment

Equipment most typically used by a practice would include tympanometer (see *Table 8*) and a pneumatic otoscope (see *Table 9*). Interventions following hearing screening generally involve referral to a hearing specialist or hearing aid rehabilitation.³¹³ The complexity of audiology equipment requirements in primary care can be extrapolated from examining ENT outpatient clinics. Seventy per cent of patients seen in one outpatient ENT clinic had some sort of diagnostic or treatment procedure, including 36 (31%) endoscopic examinations: both laryngoscopy and rigid nasendoscopy.³²⁸ Twenty-five patients (22%) needed a pure tone audiogram, 11 (10%) needed aural microscopy and two needed skin testing. Eighteen patients (16%) required complex imaging, 12 had CT scans, two had barium swallows, two had MRIs, one had ultrasound and one had a sialogram.³²⁸ In 2001, a prospective study of 1155 consecutive patients seen by one consultant in two different GP surgeries in Birmingham required such specialist equipment as audiometric assessment, the use of the flexible fibre-optic nasendoscope or rigid Hopkins rod rhinoscope, plain radiographs, examination under the operating microscope and skin testing for allergy.³²⁹ This equipment was available in the base hospital ENT outpatient department but may not be available in a primary care setting. Seventy-six per cent of all patients required an additional investigation or procedure (audiometric assessment 49%; flexible nasendoscope 14%; rigid nasendoscope 10%; radiology 4%; examination under microscope 4%; skin testing 5%; minor procedures 2%). There was very little difference between the proportions of new and follow-up patients needing these procedures. The usual consultation time was 12 minutes.

Ear, nose and throat outpatients are required to have the following range of equipment if they are to be considered by ENT UK (<https://entuk.org/>) as an adequate outpatient service: flexible fibre-optic nasendoscopy, Hopkins rod endoscopy, a soundproof facility, audiometry, tympanometry and microscopy. Most would support the availability of skin tests and plain radiography, although they are used in varying degrees. To avoid an extra visit to a hospital, these facilities would need to be made available in the GP surgery. However, the cost of purchasing and maintaining the equipment would deter most GPs from such investment.

Indicative equipment requirements are included in a BAAP policy document.⁶³ In addition to purchase cost, the cleaning and maintenance of the instruments need to be considered. Audiometers require regular calibration. Endoscopes require disinfection with glutaraldehyde between patients and adequate facilities that adhere to health and safety legislation are needed. Unless equipment is regularly used, the expense of purchasing and maintaining it and of training practice staff to care for it may not be justified. Expenditure on equipping and supporting frequently used ENT hospital outpatient departments and improving patient access to them might potentially represent better value for money.

With the introduction of portable and handheld equipment, tympanometry has become more feasible for a primary care setting. Future proofing of audiology equipment requires provision for otoacoustic emissions technology, initially used for newborn hearing screening but shown to have potential in small children³³⁰ and the aged. Acoustic reflectometry is a technique based on a sonar that enables the diagnosis of middle ear effusion. It has been suggested as offering a potential application for both patients and GPs.³³¹

In an evidence assessment, Takata *et al.*⁶⁶ conclude that, taking into account direct and indirect costs, pneumatic otoscopy is cheaper than tympanometry or acoustic reflectometry. Pneumatic otoscopy could be as effective as or better than tympanometry and acoustic reflectometry. However, the authors conclude that, for the typical clinician, pneumatic otoscopy should be easier to use than other diagnostic methods,⁶⁶ an observation not borne out in a qualitative investigation.⁵⁷ For this evidence assessment, the critical issue relates to the degree of training needed for the clinician to be as effective with pneumatic otoscopy as examiners in the studies reviewed in the report.

The BAAP recognises that clinical risk should be minimised by providing safe equipment (< 5 years old, regularly maintained and calibrated and appropriate to the clinical needs of the service, etc.).⁶³ Similarly, infection control, in relation to both equipment and consumables, is an important consideration. Good hygiene and infection control procedures are essential,⁶² especially with regard to tympanometry and the pneumatic otoscope. Single-use disposable tips should be used, if available.⁶²

STEP-UP summary statement With regard to EQUIPMENT, audiology is attributed a MODERATE degree of implementation difficulty owing to the fact that, beyond basic equipment, many needs for additional equipment will require follow-up in secondary care.

Premises

Space requirements for audiology equipment figure prominently in logistic considerations around the siting of audiology clinics. Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ includes provision for an adult hearing test room and a paediatric hearing test room.

Audiological services typically require a consulting room and a supporting nurse's room.⁶³ Despite the growth of purpose-built clinics and the increasing miniaturisation of audiology equipment, the inability of premises to accommodate treatment rooms for audiology services has been a reported obstacle to the relocation of hospital-based provision. Audiology places a particular requirement not only on the size of premises but also to take into account 'the acoustic features for those [with] audiology departments'.³³² Acoustic protection for hearing tests require rooms with special environmental characteristics.⁴⁶ There is limited evidence on health and safety aspects of audiology equipment.

The BAAP recognises the importance of maintaining a safe environment in countering potential clinical risk.⁶³ Relevant issues relate to safe equipment and minimisation of the risk of cross-infection.

STEP-UP summary statement With regard to PREMISES, audiology is attributed a MODERATE degree of implementation difficulty owing to the specific requirement for a soundproofed room.

User perspective

A Danish study reports slow dissemination of tympanometry despite the fact that reimbursement from the Danish National Health Service means that the equipment can be paid within 2 years in an average clinic with 85 tympanometries per year. The authors explain the slow diffusion, stating that the technology is difficult to understand and difficult to handle for the average GP.⁵³

An Australian study interviewed GPs after a brief 3-hour course on tympanometry and otoscopy.⁵⁷ Most GPs found that both tympanometry and pneumatic otoscopy were acceptable to carers and children, although some GPs stated that they preferred not to use pneumatic otoscopy as children sometimes found it

uncomfortable. Some GPs thought tympanometry was particularly useful for communicating with carers about ear disease, offering tangible 'proof' to parents of the GP diagnosis and support of the management plan.

Most GPs stated that both tympanometry and pneumatic otoscopy could assist in the diagnosis of otitis media without creating an undue time burden during the consultation.⁵⁷ However, this did not translate into a strong intention to use the techniques in the future. Whereas some GPs believed the techniques had improved the accuracy of their diagnoses of otitis media, for others uncertainty was created when the findings did not agree with their clinical judgement. The techniques were seen to have most value in the diagnosis and monitoring of OME. There was less agreement that the techniques were useful in diagnosis of AOM. Several GPs stated that neither tympanometry nor pneumatic otoscopy was needed for the diagnosis of AOM, as they were guided by other symptoms and signs.

Some GPs were concerned that by detecting effusions which were not clinically important there might be unnecessary health costs to patients and the community through increased GP follow-up and referral to audiologists and otolaryngologists.⁵⁷ Many GPs were unclear on the significance of negative pressure (type C) tympanometry⁵⁷ readings in general practice (see *Table 8*), which could potentially generate unnecessary GP follow-ups.

Tympanometry versus otoscopy

General practitioners expressed a preference for tympanometry based on ease of use and interpretation.⁵⁷ GPs believed that more training and experience was needed to become confident with pneumatic otoscopy than tympanometry.

Tympanometry

Three-hour training was reported by most GPs as adequate to allow them to incorporate tympanometry in their practice, the machine being largely self-explanatory and easy to use.⁵⁷ GPs could teach themselves how to perform tympanometry after the relatively brief introduction to the equipment, with the main challenge being interpretation of the tympanograms, which required them to refer back to written information they were given during training. Most GPs (9 out of 13) said that they would choose to continue to use tympanometry. However, GPs perceived the cost of the tympanometer to be prohibitive, given the low reimbursement for this service in the Australian universal health-care system. One participant expressed a strong intention to use tympanometry in the future and another to use both tympanometry and pneumatic otoscopy.

Pneumatic otoscopy

Pneumatic otoscopy was seen as the more difficult technical skill.⁵⁷ The most important barrier to using pneumatic otoscopy was GP uncertainty over whether there was true drum immobility or their technique was simply inadequate. Some GPs 'gave up' on pneumatic otoscopy.

Although by no means all those potentially presenting to audiological services in a primary context may be experiencing functional deafness, an important additional consideration relates to the patient experience of primary care venues. GP practices or primary care clinics may be less likely to have communication aids, such as text telephones, and their waiting room procedures (e.g. use of tannoy systems) may be considered inappropriate.³³³

There are no data on repeat procedures per se. However, evidence examining the utilisation of audiological equipment found that patients attending ENT outreach clinics held in GP surgeries with basic equipment often required an extra visit to hospital for further investigations. For such clinics to be cost-effective requires that they be well equipped and regularly used. In rural areas, community hospitals could provide this. However, in large cities where a hospital is usually only a short distance away, a user-friendly outpatient clinic would appear to offer relative advantage.

STEP-UP summary statement With regard to USER PERSPECTIVES, audiology is attributed a LOW degree of implementation difficulty in the light of only minor GP concerns with equipment and the referral pathway and difficulties with investigations involving small children.

Primary–secondary interface

General practitioners are required to identify the most common conditions and refer to the appropriate management pathway. Effective management of adult tinnitus patients requires quick triage and referral to an appropriate professional, given the potential for serious health concerns, and the often high level of distress experienced by tinnitus patients.³³⁴ Excessive waiting times have been addressed by a National Audiology Programme and variable care by a Good Practice Guide. The Good Practice Guide,⁶⁹ specifically for adults with tinnitus, informed commissioners and service managers about how to improve the service while still meeting the 18-week target. The Good Practice Guide⁶⁹ recommends strategies for tinnitus assessment, management, and referral at four different levels of the service: primary care (GPs), local community-based tinnitus services (audiologists and hearing therapists), specialist hospital-based centres (multidisciplinary teams that include audiologists, hearing therapists, ENT specialists, audiovestibular physicians and clinical psychologists) and supra-specialist assessment centres (multidisciplinary teams that can offer more complex audiological assessments, neurosurgical interventions and radiotherapy). Patient routes through the system were to be determined by clinical assessment and specific referral criteria, designed with service efficiency and equity of patient care in mind.

Alternatives to community provision of audiological services include outreach provision. A systematic review of outreach services in primary care found a direct counterpoint between the needs of the patient and the needs of the service.⁷⁰ Reported disadvantages concerned administrative costs, accommodation costs and inefficient use of specialists' time. Comparative studies showed that more patients expressed a preference for outreach clinics than for hospital-based clinics, and measures of patients' satisfaction and convenience generally were higher for outreach clinics. Studies did not show any consistent difference in health outcome between outreach and hospital-based clinics. Outreach clinics had higher direct costs to the health system than hospital-based clinics. Audiology clinics have been proposed as a prime candidate for the use of telehealth services.³³⁵

In one experience, 49% of cases required an audiological assessment, whereas 41% of patients required only an audiogram or a tympanogram. Consultant travelling time to outreach clinics is a further consideration. One study suggests that an estimated 492 additional patients (43%) could have been seen in the travelling time. Travelling to a distant site may also require two sessions of fixed NHS commitment. The evidence on patient satisfaction with outreach clinics is mixed, with patients being more concerned with the content rather than the location of their consultation. Benefits in terms of improved communication between GPs and hospital specialists are not always realised given a large workload.

A 2012 project,³³⁶ led by the Cardiff and Vale University Health Board in partnership with Cardiff University's School of Mathematics, focused on ENT and audiology outpatient services and aimed to improve ENT and audiology services by shifting care closer to home. A self-contained satellite facility within a GP practice sought to enable 5000–7000 people to receive secondary care hearing services in a primary care setting. The project explored the benefits to patients and the health economy of shifting care closer to home. The team also developed a toolkit to assist in decision-making and calculation of time and related costs. The model was developed with input from ENT and audiology staff, but can be applied to any specialty. As a consequence, 'do not attend' rates reduced from 13% to under 1%. There was a 62% reduction in patient travel time, 67% reduction in patient travel distance and 60% reduction in patient travel costs. This constituted a saving of £4.80 per appointment. With regard to patient satisfaction, patients gave the move an average score of 9 out of 10, with 70% giving a 10 out of 10 rating.

The Department of Health report *Improving Access to Audiology Services in England*³³⁷ included a specific commitment to apply service improvement tools. Eighteen audiology improvement pilot sites³³⁸ were set up to support and develop innovative ways to demonstrate measurable benefits of whole pathway

redesign.^{314,338} One project was Triage in Primary Care at University Hospitals of Leicester NHS Trust.^{71,339} Traditionally, patients needing a hearing aid would be referred by their GP to the audiology service: one appointment for assessment and one for fitting. Advances in technology ('open fit' hearing aids)⁷² mean that some patients can be assessed and fitted at the same appointment. If suitable patients can be identified before they arrive at audiology (i.e. if triaged in primary care), then the process becomes efficient for patients and service providers. The HearCheck Screener³⁴⁰ can identify age-related hearing problems and predict people who could benefit from intervention. It is a simple, low-cost, handheld device that produces a fixed series of six pure tones. The screening devices, which cost approximately £100 each, were loaned to the GPs in the pilot. Calibration is needed every 3 years and the devices are expected to last around 5 years. GPs were better able to brief patients on their condition, telling them that they may get a hearing aid at one appointment if suitable. At the end of the project, the audiology team was working with 11 practices. Two of the four original practices used health-care assistants to carry out the triage on their behalf.

Sherwood Forest Hospitals NHS Foundation Trust sought to overcome service bottlenecks by piloting direct access from primary care for patients with tinnitus. All local GPs were able to refer into the service. Clear referral criteria were drawn up for GPs to ensure that appropriate patients would be referred. The clinic was set up on the Choose and Book system to allow referrals to be accepted electronically. Data on all waiting times were recorded and a detailed patient satisfaction questionnaire was completed by all directly referred tinnitus patients. The numbers of patients requiring or requesting subsequent ENT consultations were recorded to ensure that all aspects of an efficient service were considered.

One hybrid model involves specialist outreach clinics administering hearing tests in the context of a hospital-based service and then to deliver the follow-up via a specialist outreach clinic sited within primary care. This obviates the need for specialist equipment to be housed in the primary care premises. However, if further tests are subsequently required, the need to be referred back to the hospital for testing could prove frustrating for clinician and patient alike.

In 2011, the audiology department from Devon Primary Care NHS Trust transferred to a new organisation: CHIME Social Enterprise Community Interest Company, an independent, not-for-profit company (www.chimehealth.co.uk/about-chime). At the time of writing (2014), CHIME was the only audiology department in the UK that had moved to this independent status, with other services expressing a wish that they too could make such a move.³⁴¹ By 2014, Specsavers had contracts for adult hearing services with 95 CCGs.^{342,343}

STEP-UP summary statement With regard to the PRIMARY–SECONDARY INTERFACE, audiology is attributed a MODERATE degree of implementation difficulty owing to dependence on secondary services for further investigation and yet the possibility of streamlined hearing aid pathways.

Conclusion

The provision of audiology services in primary care is complex in that it not only requires a wide variety of equipment and, optimally, an audiology-friendly environment, but also may necessitate access to other diagnostic services, most notably endoscopy or radiology. There is little evidence available to examine the impact of acquisition of audiology-related skills by primary care staff. Studies on provision of specialist outreach clinics (i.e. a hospital specialist operating in a primary care environment) offer supplementary data on equipment utilisation and premises. Current models being favoured within primary care audiology involve direct-access referral clinics or the provision of services under contract by commercial (or, alternatively, independent) providers.

Audiology (A1–83)

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Cardiac services

Definition: cardiac tests are used to diagnose and treat heart disease, such as heart failure and AF. Some tests are non-invasive; others are more invasive but potentially more useful for diagnosis of heart disease.

This map includes BNP, blood tests (specifically in the context of heart disease) (see also *Point-of-care testing*) and 24-hour ambulatory BP monitoring.

This map excludes chest X-ray (see *Radiology/X-ray*), electrocardiography (see *Electrocardiography*), echocardiography (see *Echocardiography*) and telecardiology.

Background

Cardiovascular diseases are the most common causes of premature death. The *National Service Framework for Coronary Heart Disease*³⁴⁴ sets out national standards for the diagnosis of coronary heart disease with explicit recognition of the role of primary care teams. A further National Service Framework chapter, *Arrhythmias and sudden cardiac death*,³⁴⁵ was published in 2005, which emphasised that patients with long-term conditions may be managed in primary care. It also highlighted better access to effective management of arrhythmias in all areas, including primary care. Developments in cardiac diagnostic services include 24-ambulatory BP monitoring.³⁴⁶

Around 900,000 people in the UK currently have heart failure.³⁴⁷ The ageing population and improved survival of individuals with ischaemic heart disease are likely to lead to a continuing rise in the prevalence of heart failure. The incidence of heart failure in the UK is less clear but the crude rate has been estimated to be 1.3 cases per 1000 population per year for those aged ≥ 25 years. The British Heart Foundation reported the incidence of heart failure in the UK in 2009 as 39.1 per 100,000 person-years.³⁴⁸ Overall, a GP with a patient population of 2000 will care for approximately 40–50 patients with heart failure and see two or three new cases each year.

Cardiac imaging equipment is therefore required in the primary care setting. The principal modalities of cardiac imaging are echocardiography (see *Echocardiography*), invasive contrast angiography, nuclear imaging, cardiac MRI (see *Magnetic resonance imaging*) and cardiac CT. Cardiac positron emission imaging is available in a few specialised centres, but not in primary care. Significant investment in cardiac services since the introduction of the *National Service Framework for Coronary Heart Disease* has enabled primary care teams to receive funding for equipment. However, it is difficult to track expenditure on equipment, making it problematic to know which cardiac diagnostic equipment is currently available in primary care.⁷⁶

STEP-UP summary

Skills

A UK study used 540 clinical scenarios, involving permutations of presenting symptoms (cough, bilateral ankle swelling, dyspnoea, fatigue) and levels of risk of cardiovascular disease, together with cardiovascular chest examination and ECG result, rated by GP experts. The experts concluded that natriuretic peptide testing should be the routine test for suspected heart failure when referral for diagnostic testing is considered appropriate.⁷³ Abnormal natriuretic peptides testing should be followed up with referral for echocardiography (see *Echocardiography*). A postal survey sought to identify services accessed by PCTs for patients with chronic heart failure.³⁴⁹ Natriuretic peptides were used by 61 (26%) PCTs and direct access to echocardiography was available to 163 (72%). The survey highlighted the variation of service models with different implications for the cost-effectiveness of service models for diagnosing heart failure.

In a survey on barriers to effective management of heart failure the majority of survey respondents who diagnosed LVSD used ECGs, chest radiography and clinical assessment, the exception being nurses. Around one-quarter of the nurses (23%) and half of the GPs (49%) were confident in interpreting the results of an ECG, whereas most cardiologists and general physicians (both 87%) were confident. One-third of nurses (33%) and two-thirds of GPs (65%) were confident in interpreting the results of an echocardiogram, whereas the majority of cardiologists and general physicians (98% and 85%, respectively) were confident. Cardiologists were more likely to use ECGs and chest X-rays (64% and 63%, respectively) than other groups; clinical assessment was almost never used by any group. This was reflected in the confidence levels in interpreting these results.⁷⁴

STEP-UP summary statement With regard to SKILLS, cardiac services is attributed a MODERATE degree of implementation difficulty owing to the range of diagnostic scenarios and investigations.

Training

Performance and interpretation of cardiac imaging requires a high level of skill, appropriate equipment and systems of governance and quality control. Cardiac imaging should be performed and interpreted only by suitably qualified and experienced individuals working in departments with appropriate facilities. Education and training in cardiac imaging should meet the present requirements specified by the GMC in curricula in cardiology and cardiac radiology, the future demands of revalidation and the requirements of allied professional groups. Improvement in the quality of cardiac imaging in the UK is a common aim of all members of the Imaging Council.⁷⁵

Staff training can have a significant impact on quality control. A survey of 170 general practices in one cardiac network suggests that the training of staff in the use of cardiac equipment is variable.⁷⁶ Training updates were not provided for 12-lead ECG in 20 practices (31%), static BP in 26 practices (39%), ambulatory BP in 21 practices (62%) and Holter monitors in 10 practices (71%). Responding practices indicated that staff require additional training in 12-lead ECG in 17 practices (27%), static BP in three practices (5%), ambulatory BP in 11 practices (32%), and Holter monitor in eight practices (57%).

A new extended GP role in cardiology was developed and piloted to enable GPs to diagnose and manage patients with mild to moderate heart failure or AF and to use diagnostics effectively in primary care.⁷⁷ Training entailed GPs participating in a four-session short course with ongoing clinical supervision. A mixed-methods evaluation found that participating GPs perceived the extended GP role as a professional development opportunity with the potential to reduce health-care utilisation and costs, through a reduction in referrals, while meeting the patient's wishes for the provision of care closer to home. Patient experience of the new GP service was positive. The standard of clinical practice was judged acceptable. Referrals fell during the study period. This 2014 report recommended further development and continuing evaluation of the model.

The BSE, the BSCMR (www.bscomr.org) and the British Society for Cardiac Imaging have endorsed voluntary accreditation procedures for their members. Accreditation has no statutory role but is provided to allow medical and non-medical practitioners to demonstrate that they have achieved a specified level of experience in an appropriate educational environment. Departmental accreditation procedures are primarily a quality improvement scheme designed to facilitate the introduction of quality control and to demonstrate that staff, equipment and processes reach specified standards.

STEP-UP summary statement With regard to TRAINING, cardiac services is attributed a LOW degree of implementation difficulty owing to the widespread availability of appropriate training and accreditation, although the underutilisation of training in basic cardiac equipment remains a concern.

Equipment

A survey of 170 general practices in one cardiac network suggests that provision of cardiac equipment, and training of staff in its use, is variable.⁷⁶ Few peer-reviewed or authoritative recommendations were

found for provision of cardiac equipment such as 12-lead ECG machines, Holter monitors or BP monitors (static or ambulatory) in primary care. Practices were asked whether or not they had a service contract, a maintenance contract and an identified responsible individual for the specified equipment. Service contract providers included local hospitals and equipment suppliers, while practice nurses are the group of staff most likely to be responsible for the equipment on a day-to-day basis.

Following the purchase and installation of equipment, there is a need for appropriate maintenance and training to ensure optimal use and patient safety.⁷⁶

Guidance and standards regarding equipment maintenance and training on primary care premises is difficult to identify,⁷⁶ typically being scattered across a range of stakeholder professional association.

The implementation of BNP will incur initial expenses including the purchase or hire of the analyser. Quality control issues relate to equipment and the purchase of limited shelf-life reagent strips. The cost of each BNP test is likely to be higher when relatively small numbers of tests are required and will reduce with volume.⁸⁰ A key source for an evaluation of the BNP POC testing kit is a 2011 Horizon Scanning report.⁸¹ A systematic review of RCTs concluded that for diagnosis in primary care, low BNP values may be used to rule out heart failure but, owing to poor specificity, high values cannot be used to rule in the condition.³⁵⁰

STEP-UP summary statement With regard to EQUIPMENT, cardiac services is attributed a LOW degree of implementation difficulty owing to developments in POC testing and the increased portability of equipment.

Premises

Most aspects of cardiac services have been accommodated in primary care for many years. Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ locates near-patient testing services (such as blood and gas) in the 'near-patient testing room' (contains public sector information licensed under the Open Government Licence v3.0).

Implications of equipment purchases such as ECG or echocardiography are reviewed elsewhere (see *Electrocardiography* and *Echocardiography*). The review was not able to identify information on the implications of providing an increased range of cardiac testing facilities in primary care, specifically in relation to implications for the premises. In particular, there was no information on the implications of stock maintenance and storage of POC tests such as BNP.

STEP-UP summary statement With regard to PREMISES, cardiac services is attributed an UNCERTAIN degree of implementation difficulty owing to a lack of information on the facilities required.

User perspective

A study in UK general practice examined the management of suspected heart failure.⁸² Some GPs requested a full blood count and urea and electrolytes on all their patients with suspected heart failure. Many GPs mentioned that they would arrange for chest radiography and some would arrange a 12-lead ECG. Some GPs excluded a diagnosis of heart failure on the basis of clinical examination and occasionally with the addition of a normal chest radiography. Very few GPs reported sending a patient for echocardiography to confirm a diagnosis of heart failure. A few GPs, who were mainly single-handed practitioners, reported that they would send all their patients to the rapid assessment cardiology clinic at the local hospital.⁸²

Most GPs mentioned the adequacy of facilities as an obstacle to diagnosing and managing patients with heart failure, specifically a lack of access to an echocardiogram. Another obstacle was not having enough time to deal with patients suspected of having heart failure. Even when practitioners were aware of the evidence about the validity of investigations or signs, the principal obstacle was the high demand by elderly patients, including the time these patients take getting dressed and undressed.⁸²

Some obstacles were directly related to the organisational aspects of services. Many GPs mentioned poor access to echocardiography as a barrier to diagnosing patients with suspected heart failure. Doctors also perceived that they were more likely to refer younger patients to the hospital. Not being fundholders was also viewed as a major obstacle, as these practices did not have open access to echocardiography. The GPs also reported interface problems with providers, who they perceived did not trust them to use the services appropriately.

Those few GPs and practices that admitted to routinely arranging echocardiograms for patients suspected of having heart failure were also more likely to report treating patients with angiotensin-converting enzyme inhibitors. These GPs were also more likely to be aware of the impact of heart failure on patients' morbidity and mortality.

Heart failure is perceived to be a difficult diagnosis to make in general practice because of problems with subtlety of clinical symptoms and signs; difficulty in differential diagnosis, especially in elderly patients with comorbidity; time constraints and generally increasing clinical and administrative workload for GPs, and lack of availability of diagnostic tests, including electrocardiography, chest radiography and echocardiography.¹⁰⁷ Other factors include a lack of confidence in interpreting the results of these, inertia or fear of initiating action because of anxieties about committing to an intensive course of action, including investigations, initiation, titration and monitoring of treatment, and patients' choices, including reluctance to be investigated or treated further.

STEP-UP summary statement With regard to the USER PERSPECTIVE, cardiac services is attributed a LOW degree of implementation difficulty owing to the non-invasive nature of most cardiac tests. However, the non-availability of echocardiology services remains a significant barrier.

Primary–secondary interface

Open-access services (echocardiography, stress testing, Holter monitoring) provided by secondary care have an important role to play. The service may simply provide an investigation or add value by providing interpretation and advice.⁸³ Open-access services may be provided either on hospital premises or in partnership with primary care in a community setting and should be quality assured with appropriate governance arrangements and regular systematic audit. A potential advantage is the inbuilt access to specialist cardiology opinion in the event of abnormal investigations.

A HTA systematic review and economic model of different diagnostic strategies for heart failure in primary care⁷⁹ analysed the impact of varying the sensitivity/specificity for BNP on the cost-effectiveness of BNP versus echocardiography. Heart failure referrals costs the NHS more than £5M per annum, use of BNP could result in a 30–40% reduction in referral to cardiology outpatient departments, resulting in a 25–40% cost saving.⁸⁰ NICE estimated a whole-pathway saving of almost £4M (2010) following the introduction of the test.⁸⁵

Only one economic evaluation focusing on POC BNP in a primary care setting is believed to exist.³⁵¹ This concluded that the adoption of BNP in primary care is likely to lead to fewer delayed diagnoses for symptomatic heart failure patients at a very small increased cost relative to referring all patients for an ECG. Results were subject to significant uncertainty relating to such parameters as the relative unit cost of the BNP test and ECG, and the accuracy and sensitivity of the assays.⁸¹

An alternative to a primary-care based approach involves using a local NHS trust laboratory. The NHS improvement report⁸⁴ concludes that this is often a more cost-effective option, citing a likely correlation between the number of tests and the cost per test. The more tests being done, the greater the likely cost–benefit. Quality control, equipment updates and staff training issues are routinely addressed within the remit of the local service provider. Points to consider are the length of time for the results to be returned (from < 24 hours up to 1 week), the courier service required to transport the samples to the provider, transport difficulties for patients and the importance of a robust service-level agreement.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, cardiac services is attributed a LOW degree of implementation difficulty owing to existing pathways for the management of heart disease and heart failure.

Conclusion

Benefits of a BNP service include rapid results, convenience for patients, early diagnosis and commencement of treatment. Centralising in one agreed location allows one GP practice to serve several surgeries: allowing results to be available within a few days, or even on the same day. Benefits include convenience for the patient, it is cheaper than doing the test in individual surgeries, and results may still be available within an acceptable time span (depending on the agreement). This type of service may involve the transportation of samples from or to the testing centre and this must be factored into planning.

In some parts of the UK, the introduction of BNP has led to increased numbers of echo tests being performed without an increase in true positives. This means that if the test is used indiscriminately, false-positive results may outnumber true positives. A local agreement may help to decide who should order the test or when access to ordering a BNP test is appropriate. A further consideration when calculating costs is that a percentage of positive BNP results will require an echocardiogram is also indicated. The cost of the BNP test will need to be added to the cost of an echocardiogram. Many studies have identified savings with an increase in the number of appropriate referrals once those testing negative had been set on alternative pathways of care. NT-proBNP concentrations increase with age in the normal population. Some areas, through collaboration and agreement, have introduced age-related 'cut-off' values when deciding which patients to refer for further investigations.

The NHS Improvement Heart Improvement Network has identified examples in the UK when BNP testing has been used as a means of 'rule-out' for echocardiography.⁸⁰ Some documents include economic information and cost analysis for the projects. NICE guidelines on the initial diagnosis of chronic heart failure and referral for echocardiography recommend use of BNP in combination with clinical assessment.⁸⁵ NICE guidelines recommend the measurement of serum natriuretic peptides in patients with suspected heart failure without previous myocardial infarction, and those with previous MI should be referred for an urgent echocardiogram.⁸⁵ Although several hospital laboratories carry out BNP testing, few return results within a day. POC BNP testing can considerably reduce turnaround time and could lead to earlier initial treatment, more timely referral and less uncertainty for patients. Using POC BNP levels to quickly rule out heart failure, could allow more rapid initiation of investigation of other causes of dyspnoea.

A UK HTA carried out a comprehensive systematic review and meta-analysis of all studies comparing the diagnostic accuracy of BNP testing to clinical examination by cardiologists in heart failure in all settings until 2006.⁷⁹ The review included 20 studies on the accuracy of BNP for the diagnosis of clinically defined heart failure. Four studies took place in primary care, one used the POC test and three used laboratory-based tests. These demonstrated a slightly lower sensitivity (84%) but similar specificity (73%). Eight of 16 studies reporting data on the accuracy of NT-proBNP for the diagnosis of clinically defined heart failure were conducted on samples from patients presenting in primary care (pooled sensitivity of 90%, a specificity of 60%), The HTA report also highlighted that the utility of BNP testing will depend on the pre-test probability of chronic heart failure in the patient.⁷⁹ BNP testing would contribute important diagnostic information as a negative test would reduce the post-test probability. A US technology assessment gave similar results.⁸⁶

A systematic review and meta-analysis of diagnostic accuracy of BNP testing for heart failure in the emergency department, in which 9 of the 11 studies used the triage system, showed that the ≤ 100 pg/ml cut-off value used in most studies has a sensitivity of 0.93 and specificity of 0.66.⁸⁷ Two other systematic reviews that included the same studies achieved similar results.^{88,89} However, most studies on the triage BNP system were performed in a US emergency setting and so cut-off values for primary care may be different.

Although a study investigating the impact of POC NT-proBNP testing with the Cobas h232 has yet to be carried out, feedback on its ease of use has been documented.⁹⁰ In this study the nurses on duty in the coronary care unit, who operated the device, found it simple to learn and handle. The Horizon Scanning report observes that most published studies have investigated the use of BNP in an emergency department or hospital setting.⁸¹ It concludes that more studies are required on the diagnostic accuracy of POC BNP tests in primary care.

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Electrocardiography

Definition: an ECG is a simple test used to check the heart's rhythm and electrical activity (NHS Choices).

This map includes portable ECGs.

This map excludes N/A.

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Electrocardiograms are seen as standard provision for many types of investigation. A survey of Irish GP rural practices in 2001 found that practices were most likely to include equipment such as ECGs and oxygen.³⁵² Developments in cardiac diagnostic services include 24-hour ambulatory BP monitoring and ambulatory electrocardiography for the diagnosis of arrhythmias in primary care.³⁴⁶ Given that the availability of ECG equipment is already likely to be highest among the equipment examined in this report, this section will selectively take a brief look at handheld ECG devices.

The wireless, electrode-free and portable nature of devices means fewer lifestyle restrictions on the patient. Patients can bring the device directly to their GP, who can 'review' the recorded ECGs and analyse them

directly. ECGs can be done on the spot by GPs, during a patient's medical review, to assess both rate and rhythm control, rather than organising a separate ECG appointment.

Current NICE guidelines for management of AF recommend patient-activated event recording to detect AF, if the AF is symptomatic and episodes last longer than 24 hours. Existing guidelines do not contain any recommendations about the use of electrode-free handheld patient-activated ECG devices.

STEP-UP summary

Skills

Wireless ECG equipment is easy to use. The challenge with ECG devices of any type lies in interpretation. A systematic review of ECG interpretation accuracy studies found that both physicians and computer software frequently made errors, compared with expert electrocardiographers; however, there was also frequent disagreement in interpretation between experts.⁹² The largest study investigated the ability of 42 GPs and 41 practice nurses to detect AF on ECGs generated during the SAFE (Screening for Atrial Fibrillation in the Elderly) study.⁹³ Overall, primary care practitioners could not detect AF on an ECG with sufficient accuracy to guide therapy (GP sensitivity 80%, specificity 92%; practice nurse sensitivity 77%, specificity 85%).

When interpreting ECG studies, it is important to distinguish the effect of using a simpler ECG from the effect of using a non-expert to interpret the trace.⁹⁵ Who reads the ECG appears to be a much more important factor than how the reading is obtained. Thus, relatively poor results of single-lead ECGs when interpreted by GPs were similar to the results obtained for 12-lead ECGs when read by GPs.⁹³ In contrast, two studies found high sensitivity (92% and 96%) and high specificity (96% and 98%) when a bipolar 'thumb' ECG was read by a cardiologist and a bipolar ECG was read by an experienced GP, respectively.^{353,354}

Interpretative software depends on the diagnostic algorithm that it uses. Three studies that evaluated the accuracy of computer software for detecting AF found similar results even though different software was employed.⁹⁵ This suggests that there may be some consistency between the algorithms used. Improvements in diagnostic algorithms in the future may make interpretative software good enough to become a diagnostic gold standard.

Quality control of the interpretation of ECGs is an important aspect of diagnosis of AF in primary care.⁹⁵ Potential strategies to address this are to provide training to HCPs who regularly read ECGs or to have ECGs centrally read. However, in connection with the latter, the performance of cardiologists when they had no patient contact was significantly poorer than when they were the ordering physician (72 vs. 94%).

STEP-UP summary statement With regard to SKILLS, ECG is attributed a LOW degree of implementation difficulty owing to the fact that a large majority of practices have the equipment, although interpretation is variable.

Training

The NICE guidance in relation to management of transient loss of consciousness advises that all service providers should have capacity to undertake 12-lead ECGs and that NHS England area teams should ensure that GP surgeries are able to undertake initial assessments with these patients and interpret the results competently. The guidance notes that skill can be lost in general practice if it is not used frequently and commissioners should ensure that training on interpretation is offered linked to local need (the national training cost is quoted to be £105 per person).⁹⁴ No additional training is required.³⁵⁵ The interpretation of readings from the ECG is included in standard medical and other HCP training. Some practices may feel that they are too small to develop expertise in ECG interpretation and it may present opportunities for local practices to work together rather than refer to secondary care.

In a survey of cardiac equipment use in a cardiac network, 64 responding practices (85%) had 12-lead ECG machines and 58 (91%) used these on a weekly or more frequent basis.⁷⁶ Eighty per cent of these machines had a service contract and an identified responsible individual in the practice to oversee this role. A higher proportion of registered nurses ($n = 64$, 97%) had received formal training in the use of ECG machines than GPs ($n = 47$, 73%), although the interpretation of ECG recordings is predominantly undertaken by GPs ($n = 60$, 94%) rather than registered nurses ($n = 8$, 13%). Substantive evidence on the training required to obtain and sustain competence in ECG interpretation is not available. Twenty-seven per cent of respondents reported that their practice members require additional training in 12-lead ECG use.

Most ECG machines have interpretative software, but combining interpretative software with GP interpretation does not improve the sensitivity of diagnosis significantly. The evidence suggests that GPs can detect AF on ECGs accurately, given appropriate training.⁹⁵

STEP-UP summary statement With regard to TRAINING, ECG is attributed a LOW degree of implementation difficulty owing to the availability of training provision, although many training needs are not fulfilled.

Equipment

A new ECG machine with installation and initial training costs about £2000 including VAT.⁹⁴ The reference standard test in diagnosing AF, a 12-lead ECG, is readily available, non-invasive and relatively inexpensive. Its main drawbacks are that it is time-consuming to use and requires some degree of privacy to perform. A single-lead ECG avoids the need for the patient to remove clothing and is quicker to perform than a 12-lead ECG. However, inevitably some information is lost, which may lead to a reduced ability to detect AF.

Increasingly, portable ECG machines have become an attractive option. Handheld ECG devices allow ECG readings to be stored on a portable device, for review at a later time, by transferring the data to a personal computer, 'playing back' the ECG on the device screen or transmitting the reading via 'telemedicine'. Unlike 12-lead ECGs, which require electrodes to be placed on the patient and connected to the ECG, handheld devices have integral electrodes. They require a patient's thumbs, fingers or palms to be placed on the device, and, in some cases, the holding of the device against the chest. The devices are battery powered and can store multiple ECG tracings. Some devices include an analysis function, whereby they instantly alert the user if a trace indicates an arrhythmia.

The Horizon Scanning report documents devices that can be used very quickly in primary care for screening or in acutely unwell patients, as well as a monitoring device over a period of time.^{96,356} The Merlin wristwatch (www.medgadget.com) is the most compact and portable device and may be ideal to use as an event recorder by patients at home. Memory capacity is important for devices used as event recorders at home. Some devices have capacity for storing approximately 100 readings of 30 seconds each. Other devices are independent of a telemedicine system, so they can be purchased and will operate on a standalone basis. Devices which have an analysis function to identify when a patient is in AF would be valuable for nurse-led or GP-led opportunistic screening for AF. A new device, the 'Cardiobip'TM (NewCardio), is yet to be available commercially (www.newcardio.com/products-cardio-bip.php). It uses telemedicine and is operated by holding the device against the chest and touching two integral finger electrodes.

Two devices could be used for screening for AF in the general population.⁹⁷ One is a finger probe similar to that used in general practice for pulse oximetry; the other is a modified BP monitor as used by patients to monitor their BP at home.⁹⁸⁻¹⁰⁰ The latter could be used either by people monitoring their own BP to self-screen for AF or by primary care professionals to opportunistically screen patients. These devices are able to adjust their sensitivity to optimise their value as screening devices. Studies evaluating newer technologies (e.g. finger probes and modified BP readings) suggest that a sensitivity of > 90% could be achieved while maintaining reasonable specificity.⁹⁵

A UK study³⁵⁵ performed in six general practices assessed the performance of a modified BP monitor and two single-lead ECG devices, as diagnostic triage tests for the detection of AF. One thousand ambulatory patients aged ≥ 75 years were diagnosed using a modified BP monitor and single-lead ECG devices, compared with reference standard of 12-lead ECG, independently interpreted by cardiologists. All three devices had a high sensitivity and are useful for ruling out AF. WatchBP is a better triage test than Omron autoanalysis because it is more specific. The study concluded that WatchBP performs better as a triage test for identifying AF in primary care than the single-lead ECG monitors. It does not require expertise for interpretation and its diagnostic performance is comparable with single-lead ECG analysis by cardiologists. It could be used opportunistically to screen elderly patients for undiagnosed AF at regular intervals and/or during BP measurement.

The AliveCor Heart Monitor and AliveECG apps are, respectively, a pocket-sized ECG recorder and a mobile device application for analysis and communication of the results.¹⁰¹ Two fingers from each hand are placed on the AliveCor Heart Monitor to record an ECG, which is transmitted wirelessly to the AliveECG app. Two clinical studies reported that the AliveCor Heart Monitor and the AliveECG app have sensitivity above 85% and specificity above 90% in identifying AF. An AliveCor Heart Monitor unit costs £62.49, excluding VAT; the AliveECG app is free of charge. If proven to be accurate and cost-effective in the primary care setting, these devices could improve the detection and management of AF, thus reducing the well-known risks of stroke, transient ischaemic attacks or heart failure in these patients.

STEP-UP summary statement With regard to EQUIPMENT, ECG is attributed a LOW degree of implementation difficulty owing to the availability of a wide range of relatively cheap and acceptably accurate equipment that can be matched to clinical need.

Premises

Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ locates ECG in the 'Examination/Therapy room' (contains public sector information licensed under the Open Government Licence v3.0). In the remaining literature, little detail is available of the premises in which ECGs, portable or not, are to be stored, cleaned or maintained. This corresponds with the findings from the survey of equipment from a UK cardiac network.⁷⁶

STEP-UP summary statement With regard to PREMISES, ECG is attributed an UNCERTAIN degree of implementation difficulty owing to insufficient detail about storage requirements.

User perspective

Portable devices are designed to be easy to use; it has been reported that 4-year-old children were able to use such a device. The ease-of-use, convenience and portable nature of these devices means implementation could see a better rate of patient compliance than to a Holter monitor in patients who use the device for home recordings. Future developments may see this technology being integrated into smartphones for wider applicability in clinical and home settings.¹⁰²

STEP-UP summary statement With regard to the USER PERSPECTIVE, ECG is attributed a LOW degree of implementation difficulty owing to the ease of use, particularly of wireless devices.

Primary–secondary interface

Excessive delays for cardiac patients waiting for a hospital appointment led Harrow PCT to establish a mobile cardiac task force based in the community, involving GPs, specialist nurses and health-care assistants supported by hospital-based heart disease specialists.¹⁰³ The service was delivered in community-based settings: in GP surgeries, community health-care centres and in patients' homes. The service used a portable ECG system to automatically store and analyse recorded ECG data using existing computer hardware. Every general practice in the area is networked to a central server, allowing patients' cardiac data to be requested by individual GPs and the results returned to them electronically. The service has reduced waiting times and improved patient care.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, ECG is attributed a LOW degree of implementation difficulty owing to the already integrated nature of the diagnostic and management pathway.

Conclusion

The increasing portability, ease of use and low prices of ECG equipment has led to an almost universal diffusion in NHS primary care. Issues therefore relate to choice of the most appropriate equipment for practice needs, including an optimal mix of static and portable equipment. The reduction in the number of leads in ECG systems makes them easier to use and more acceptable to both patient and clinician. Of particular value is the potential for small ECG devices to replace the 24-hour Holter monitor tests. Organisational issues concerning loans of, and maintenance for, equipment to patients may need to be addressed. Similar concerns will relate to ambulatory BP monitoring.

Electrocardiography (EC1–29)

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Echocardiography

Definition: an echocardiogram is a test that uses sound waves to create pictures of the heart. The picture is more detailed than a standard X-ray image. An echocardiogram does not expose the body to radiation.

This map includes portable and fixed echocardiography.

This map excludes other forms of ultrasound (see *Ultrasound*).

Patients with breathlessness and ankle oedema presenting to their GP may have heart failure. Echocardiography is the key investigation for assessing suspected heart failure patients. In 2003, the availability of echocardiography in the UK was rated as suboptimal.^{82,357}

STEP-UP summary

Skills

Echocardiography is pivotal in the management of heart failure as it can make the diagnosis, determine the aetiology and aid the planning of treatment.¹⁰⁴ Community echocardiography is also indicated for heart murmurs, AF and hypertension. In a study from the Netherlands, GPs used the open-access echocardiography service efficiently: only 24% of referrals did not yield relevant disease.¹⁰⁵ An echocardiography service must be integral to a general local plan for heart failure to avoid isolated open-access echocardiography. Community and hospital-based medical care should be located on a continuum.

Echocardiography in heart failure has a place alongside BNP and 12-lead ECG. If these investigations are normal, further investigation by electrocardiography is not indicated. Diagnosis of diastolic heart failure remains difficult and must be made from the clinical context and a complex echocardiogram. NICE guidelines state that Doppler two-dimensional (2D) echocardiographic examination should be performed to exclude important valve disease, assess the systolic (and diastolic) function of the (left) ventricle and detect intracardiac shunts.⁸⁵ NICE guidelines state that echocardiography should be performed on high-resolution equipment by experienced operators trained to the relevant professional standards.⁸⁵ Need and demands should not compromise quality. The reporting of echocardiography should be performed by those experienced in doing so.

A UK study¹⁰⁶ comparing community echocardiography with hospital echocardiography in 136 suspected heart failure patients found that community echocardiography gave results comparable with traditional hospital echocardiography for LVSD detection and for significant valvular disease detection.

STEP-UP summary statement With regard to SKILLS, echocardiography is attributed a MODERATE degree of implementation difficulty owing to difficulties in diagnosis.

Training

Echocardiography services must include provision for training, quality assurance, CPD, referral for a second opinion for difficult studies and clinical back-up if problems are identified by the echocardiography

procedure. The BSE has endorsed voluntary accreditation procedures for their members. The accreditation has no statutory role but aims to allow medical and non medical practitioners to demonstrate that they have achieved a specified level of experience in an appropriate educational environment. Some GPwSIs or practitioners with a special interest are already expert and experienced echocardiographers, with increasing numbers likely to be trained in general cardiology at diploma courses (e.g. South Middlesex and Bradford). Courses discuss the indications for and interpretation of echoardiography reports and also offer practical exposure to echocardiography. BSE accreditation in community echocardiography qualifies a GPwSI or practitioner with a special interest in standard echocardiography, being equivalent to the BSE adult accreditation process. It differs in reflecting a specific community focus, rather than hospital-based case mix. The accreditation involves a written examination and a log book of 200 cases. Accreditation is gained with experience and training in a BSE-accredited department or under supervision using a portable machine in the community, with regular sessions at a hospital department.

There is no definitive source of information on workforce levels needed to provide community echocardiography services. However, the British Cardiac Society report of June 2005³⁵⁸ suggests that each acute hospital should have a consultant cardiologist with a special interest in heart failure who spends two programmed activities per week (one programmed activity for a medical consultant = 4 hours) directly leading to the management of patients with heart failure including diagnosis and monitoring. In addition, the report suggest that 2.1 whole-time equivalent non consultant specialists per million population (nurse, physiologist, GPwSI, non-consultant medical) are needed to provide diagnostic services for patients with heart failure and 14.6 whole-time equivalent per million population are needed to provide monitoring services.

The provision of echocardiography services, regardless of their setting, must link with staff training and CPD, which in turn informs workforce planning. The recommendations in the Welsh Guidelines on Community Echocardiography endorse the BSE accreditation and reaccreditation process.²²⁰ A Royal College of Physicians' report highlighted the difficulty in recruiting suitable technicians for echocardiography. It cites the Whittington hospital, which established its own graduate training programme, but emphasises that solutions should preferably be national not local.

A minimum of 2 years is required to train a practitioner to BSE-accredited standards, whether they are a cardiology registrar, a cardiac physiologist, a GPwSI, a new entrant echocardiographer, a heart failure specialist nurse or other practitioner with a special interest. BSE accreditation in community echocardiography began in October 2004 and will qualify a GPwSI or a practitioner with a special interest in standard echocardiography. The process involves a written examination and a log book of 200 cases.

Echocardiography should be performed and reported by operators trained to the standards set by the BSE (i.e. they should hold accreditation in adult transthoracic echocardiography or adult community echocardiography). Echocardiographic images and data should be recorded and archived; ideally, this should be a digital system that enables telemedicine links. Clinical interpretation of the technical echocardiogram report should be provided by an appropriate clinical specialist (i.e. cardiologist or GPwSI in cardiology). Community echocardiography services should be linked to a local hospital-based echocardiography department. A local quality assurance system should be developed.

Notwithstanding acute shortages of staff who are trained and competent in performing and interpreting echocardiograms, the need and demand for echocardiography should not compromise quality. Quality assurance is of paramount importance in the delivery of all echocardiography services, including those in which patients are directly referred from primary care. BSE accreditation is mandatory for those performing community echocardiography.

As of 2010, Bradford City Teaching PCT offered a postgraduate diploma in cardiology for primary care practitioners with a special interest in conjunction with the University of Bradford. It was not possible to determine if this is still running.

In the UK study¹⁰⁶ comparing community echocardiography with community echocardiography, the community echocardiography was performed by a cardiology trained research fellow. The authors identified a need to assess whether or not other HCPs (e.g. nurses) could be trained to successfully to provide similar accuracy with community echocardiography.

STEP-UP summary statement With regard to TRAINING, echocardiography is attributed a MODERATE degree of implementation difficulty owing to the need for an extended period of certificated training.

Equipment

A 'standard echocardiogram' is required for all patients with suspected heart failure and is the required quality standard for community echocardiography. Echocardiograms should be performed on high-quality equipment, which includes high-resolution 2D imaging, tissue harmonic imaging, full-spectral Doppler and colour flow mapping (and, ideally, tissue Doppler capability). The recommended lifespan of echocardiography scanners is 5–7 years.²²⁰

Echocardiography includes at least five separate types of study.¹⁰⁴ The type of study is mainly determined by the clinical question, but also depends on the level of experience of the operator and the type of machine. Standard machines are usually required for standard and advanced studies. Portable systems are capable of ultrasonic stethoscopy and screening alone.¹⁰⁴ However, these divisions are not stable, as portable systems vary in their capability and simpler versions of advanced systems are being introduced for basic functions and without the ability to perform stress or contrast studies.

Advances in ultrasound technology have led to the development of smaller echocardiography machines that may be transported more easily to different sites in the community. Studies have found that smaller echocardiography machines, when used in hospitals by experts, are accurate for detecting LVSD and valvular disease.^{252,359} However, studies have not looked at the performance of these smaller echocardiogram machines in community settings where conditions may be different, such as suitable couches, lighting and a lack of immediate second opinion.

The standard ('standard transthoracic study, 'traditional') echocardiogram takes between 30 and 40 minutes to perform.⁷⁵ It is regarded as a formal cardiological investigation and should be documented and archived. The limited ('focused' or 'point of care') echocardiogram is directed at answering specific clinical questions (e.g. changes since a baseline echocardiogram). The procedure takes 5–10 minutes and should also lead to archived material and a formal report.^{104,220}

STEP-UP summary statement With regard to EQUIPMENT, echocardiography is attributed a LOW degree of implementation difficulty owing to the ease of use and portability of acceptable devices.

Premises

Community service settings for echocardiography may include mobile (including self-contained) units, community hospitals/diagnostic centres, primary care polyclinics/primary care centres/super surgeries, GP practice surgeries and other appropriate location (e.g. walk-in facilities, high street settings). Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ locates echocardiography in the 'Treatment room' (contains public sector information licensed under the Open Government Licence v3.0). This document does not provide detailed design guidance on specific rooms and spaces and refers to the following for guidance on generic rooms and spaces: Health Building Note 00-03, *Clinical and Clinical Support Spaces*.¹⁵³

Open-access community-based services can be located in a community hospital, clinic or GP surgery. The service should complement existing hospital-based provision and be integral to the delivery of heart failure services in a health community. There is no place for isolated stand-alone open-access echocardiography. The service should be delivered by an operator who is BSE accredited. The operator could be a GPwSI or a practitioner with a special interest.

Mobile echocardiography is typically provided by a third party (other than existing primary or secondary care providers), usually a private company. The mobility of the staff and equipment is able to service demand across a large geographical area. Portable systems can equally be provided in a community hospital, clinic or GP surgery but must match the type of echocardiograms performed. Standard echocardiograms require high-quality imaging, including second harmonics together with colour mapping and both pulsed and continuous wave spectral Doppler. Archiving is essential. The service must be integral to delivery of heart failure services and should be delivered by an operator who is BSE accredited. The service should be linked to the hospital-based service (preferably electronic) for second opinions and clinical back-up and to ensure quality assurance. Links to the hospital-based service will also facilitate training and CPD for staff, services and destabilisation of local provision.

Although the performance of smaller echocardiogram machines in community settings has been found to be comparable with that of larger machines in an acute setting, conditions may be different, such as the non-availability of suitable couches and the presence of suboptimal lighting.¹⁰⁶

STEP-UP summary statement With regard to PREMISES, echocardiography is attributed a LOW degree of implementation difficulty owing to the flexibility of locales and settings in which the technology may be administered.

User perspective

A UK qualitative study reports numerous barriers to the use of echocardiography in primary care, such as the lack of availability of diagnostic tests, including electrocardiography, chest radiography and echocardiography, and the lack of confidence in interpreting the results of these. The lack of access to echocardiography is a major obstacle.⁸² GPs are keen to have access to echocardiography and, where provided, use it appropriately.⁸²

A qualitative study of heart failure found that echocardiographic findings were used by 97% of cardiologists, 91% of general physicians, 52% of salaried GPs, 35% of GP partners and 31% of nurses. Cardiologists and nurses were more confident than GPs in using and interpreting echocardiography reports but expressed frustration about patients not routinely referred for echocardiography testing and the poor quality of referral information. Most participants felt that it was important to educate patients about their illness but some expressed concerns about informing patients of their diagnosis as this might lead to anxiety.¹⁰⁷

Perceived handicaps included the variability of open-access echocardiography in the same locality; several open-access services had been funded through pharmaceutical sponsorship but disappeared as 'monies dried up'. A further perceived problem was variability in echocardiography reporting, some by technicians and some by clinicians, and a lack of guidance for using the procedure or for standardising request forms. The reasons given included uncertainty about the importance of results and interpretation of technical reports, not being able to cope with echocardiography, many preferred to refer the patient to a consultant, and distance to nearest echocardiography clinic may inconvenience patients.

STEP-UP summary statement With regard to USER PERSPECTIVE, echocardiography is attributed a LOW degree of implementation difficulty owing to the ease of use and lack of invasive procedure.

Primary–secondary interface

The demand for echocardiography already exceeds the capacity of current services. GPwSI and practitioners with a special interest are expected to collaborate with hospital-based departments to accommodate increases in demand. The organisation of services should be based around a BSE-accredited department but organised as a network, avoiding barriers between community and hospitals. PCTs and hospital trusts must recognise that the needs of echocardiography extend beyond service delivery to include quality assurance, training and continuing education. Support will usually be provided by a hospital-based BSE-accredited department. The BSE-accredited department and community echocardiographer should ideally have an electronic link for second-opinions, quality assurance and clinical back-up.

The favoured model of care is probably the one-stop heart failure clinic, offering diagnosis and initial treatment while liaising with GPs and nurses for maintenance and palliative services. A community echocardiography service must always be considered in the context of the whole patient pathway for those with suspected heart failure. Services should extend between hospital and community bases as part of a continuum of care irrespective of organisational barriers. Alternatives to community echocardiography include open-access provision and standard provision from a hospital department. Structured, protocol-based referral and reporting processes must be built on effective communications between primary and secondary care. Provision should be subject to regular audit and/or peer review. A study of prescribed diuretics for indications of heart failure suggested that GPs should have a low threshold for referring patients for echocardiography.¹⁰⁸

The rapid-access heart failure clinic locates echocardiography within a heart failure 'one-stop shop' linking secondary care-based staff with primary care staff for ongoing care and tertiary staff for specific specialist advice. A patient with suspected heart failure will receive a clinical assessment, echocardiogram, ECG, BNP and chest radiography. The echocardiogram may have been performed as part of (1) an open-access hospital-based service, (2) a community-based service or (3) a mobile echocardiography service provided it has been conducted under BSE-accredited conditions. Each member of staff performing echocardiography should normally carry out at least 100 tests per year.

General practitioners are less likely to use open-access echocardiography when reports were technical and lacked a clinical opinion than when a clinician guided report was available. Local organisational factors around the provision of diagnostic services, such as open-access echocardiography, resources, lack of cardiologists and professional interactions between primary and secondary care shaped practice and decision-making processes among GPs.¹⁰⁷

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, echocardiography is attributed a MODERATE degree of implementation difficulty owing to the need for secondary care support in training, support and referral.

Conclusion

Echocardiography remains a skill with which continues to challenge significant numbers of primary care staff, including GPs. While administration of the technology is comparatively easy (cp. Ultrasonography), the challenge lies in interpretation of the readings. Some GPs may welcome the opportunity to pass on the responsibility for definitive diagnosis and resultant communication to secondary care. Substantive personal and organisational barriers remain in integrating the use of echocardiography into an integrated pathway that spans both primary and secondary care.

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Diabetic services

Definition: tests to establish the presence of diabetes or to monitor the progress of the condition, especially its sequelae relating to eye and foot consequences.

This map includes HbA_{1c}, diabetic retinopathy tests, diabetic neuropathy tests.

This map excludes POC tests of more general use (see *Point-of-care testing*).

Diabetes and its complications pose a major financial burden.³⁶⁰ In the UK NHS treatment costs for diabetes amount to £13.8B annually.³⁶⁰ Around 80% of health-care costs in the UK arise from inpatient care and medication costs for treating diabetes-related complications. Maintaining good glycaemic control through regular monitoring and treatment with glucose-lowering medications reduces the risk of developing future complications and is relatively cheap, accounting for approximately 17% of total NHS costs.³⁶⁰ Glycaemic control is monitored in people with diabetes by measuring HbA_{1c}. HbA_{1c} testing may be used either to

diagnose diabetes³⁶¹ or for long-term monitoring of glycaemic control in people with a diagnosis of diabetes. Test results from HbA_{1c} monitoring are used to make treatment decisions, and treatment thresholds will differ depending on the country, the patient's previous HbA_{1c} test result and individual clinician preferences. The monitoring of HbA_{1c} usually takes place in primary care settings where the patient needs to attend to have a venous blood sample taken. The sample is then sent for analysis using high-performance liquid chromatography, which is typically performed in a central laboratory. The test result is reported back to the clinician within a few days and the patient is then often required to make a second visit to the health centre or clinic to discuss the result with the physician or a specialist nurse.

New technologies have emerged facilitating the measurement of HbA_{1c} levels in blood, and thus contributing to a more streamlined and thereby improved patient–clinician encounter.³⁶² POC bench-top devices use a finger-stick capillary blood sample to provide a rapid test result. This means that the patient receives the result of their test typically within a few minutes.

STEP-UP summary

Skills

Diabetes is a complicated multisystem condition. As a consequence, it typically proves a complex condition to integrate into diagnostic testing, with many modalities being required to handle the condition and its eventual sequelae. However, general practice, in the UK and elsewhere, has extensive experience in managing the condition in a community setting. It is not a considerable extension to include diabetes testing in a primary care-orientated pathway of care. Universal screening for diabetes in general practice has been found to be low yield.³⁶³ More selective testing procedures are, therefore, required at a practice level.

Various devices are now available to measure HbA_{1c} outside the laboratory. One study sought to assess the performance of these POC instruments in the hands of nursing staff. Only one of four POC devices for HbA_{1c} compared favourably with a gold-standard chromatography method in a central laboratory. On the basis of results obtained by nursing staff, only the Bayer DCA, of the four devices tested, could be recommended for measurement of HbA_{1c} outside the laboratory.³⁶⁴

Similarly, dipstick tests for microalbuminuria are convenient, but their accuracy is uncertain. An Oxfordshire study aimed to assess the utility of urine dipstick testing for microalbuminuria in type 2 diabetes.¹⁰⁹ Results of single dipstick tests and sequences of dipstick and laboratory tests were compared with a clinical testing strategy based on current guidelines to assess the accuracy and estimate costs of testing. Testing strategies involving dipstick and laboratory measurements or dipstick tests had similar accuracy. The costs of using dipstick tests were overall lower than those of laboratory-based testing. The authors concluded that dipstick testing in this study did not reliably identify diabetes patients with microalbuminuria. Although dipstick testing would decrease testing costs, it could either fail to diagnose most patients with microalbuminuria or increase the numbers of patients retested depending on the dipstick used.

It has been suggested that finger-prick tests might be administered by optometrists in the high street as a route to detecting undiagnosed diabetes. A prospective study in the north of England found that screening in optometric practices provides an efficient opportunity to screen at-risk individuals who do not present to conventional medical services, and is acceptable and appropriate.³⁶⁵ Optometrists represent a skilled resource that could provide a screening service. Refinement of the list of risk factors used to make them more sensitive was suggested by the study. However, some have expressed concern that finger-prick tests do not represent a sufficient work-up for undiagnosed people with diabetes.

STEP-UP summary statement With regard to SKILLS, diabetic services are attributed a LOW degree of implementation difficulty owing to the existence of recognised pathways and guidance.

Training

Biochemical tests can be diagnostic and often necessary for monitoring metabolic and endocrine diseases, so it is important for GPs to know which tests are useful in a primary care setting and how to interpret these tests and understand their limitations. A GP does not only need to be able to undertake the relevant diabetes tests; they must also be able to interpret the results, assess the likely consequences in terms of the impact of the disease (e.g. neuropathy and retinopathy) and know how to manage the patient and the patient management pathway. Primary care professionals have built up considerable expertise in managing patients with diabetes and the tests are largely well established. A new domain of knowledge is POC testing for diabetes. A GMC Core Competency is to 'Understand the use and main limitations of tests commonly used in primary care to investigate and monitor metabolic or endocrine disease, e.g. fasting blood glucose, HbA_{1c}, urinalysis for glucose and protein, urine albumin: creatinine ratio, "near patient testing" (POC testing) for capillary glucose, lipid profile and thyroid function tests, and uric acid tests'.¹¹⁰

Blood glucose meters are a good example of POC tests, and central to result quality is high-quality training, robust internal quality control, external quality assurance schemes and effective process management.¹¹¹ In the past there have been a significant number of critical clinical incidents that occurred as a consequence of inpatients being treated on the basis of erroneous blood glucose meter results. HCPs were, therefore, encouraged to improve blood glucose meter result quality and reduce risks to patients.

STEP-UP summary statement With regard to TRAINING, diabetic services are attributed a LOW degree of implementation difficulty owing to the wide availability of training provision.

Equipment

In patients with existing diabetes, HbA_{1c} monitoring is usually performed every 3–6 months. It typically involves a nurse visit or phlebotomist for venepuncture, with follow-up 1–2 weeks later to discuss results. POC testing could provide more immediate therapeutic decisions and lead to fewer patient visits. This might result in improved diabetic control and practice efficiency. POC tests for HbA_{1c} demonstrated improved outcomes when used in a rural primary care clinic.¹¹² Greater intensification of therapy occurred when the HbA_{1c} was available at the time of the consultation (51% vs. 32%) and HbA_{1c} fell in the intervention group (8.4% to 8.1%; $p = 0.04$). Clearly, use of the POC testing or, at a minimum, availability of the result, should be co-ordinated with the consultation process.

Typically, the POC HbA_{1c} device uses a finger-stick drop of blood applied to a reagent cartridge, which is then inserted in a desktop analyser, where the analysis is performed, and HbA_{1c} is reported (as percentage and mmol/mol). The time to result is between 5 and 10 minutes. Some systems allow measurement of the urine albumin–creatinine ratio using a different reagent cassette. A wide range of literature reports on the accuracy of different POC HbA_{1c} tests. Several commentators question the suitability of many POC instruments for the accurate measurement of HbA_{1c}.³⁶⁶ A study comparing eight HbA_{1c} measurement devices to investigate imprecision, accuracy and bias reported that only three fell within the clinically relevant range.³⁶⁶

A prospective controlled trial comparing POC testing and standard laboratory testing in an urban primary care clinic showed that POC testing availability resulted in more frequent intensification of therapy when baseline HbA_{1c} was $\geq 7.0\%$ (51% vs. 32% of patients; $p = 0.01$). HbA_{1c} fell significantly in the POC test group (from 8.4 to 8.1%; $p = 0.04$) but not in the standard care group (from 8.1 to 8.0%; $p = 0.31$).¹¹² A primary care study among patients receiving active insulin titration showed that POC testing resulted in a greater proportion achieving HbA_{1c} < 7.0% than those with laboratory measurement.³⁶⁷ In contrast, a second RCT conducted in general practice in Leicestershire, UK, showed no significant change in the proportion of patients with HbA_{1c} < 7.0% when using POC testing at 12-months' follow-up.³⁶⁸ However, the investigators noted that it was 'difficult to organise their management of patients in such a way as to maximise the benefit from rapid testing for intervention group patients', implying that the results were not discussed with the patient at the time of the clinic visit. The study also indicated that POC testing was highly acceptable to patients and staff and confirmed there may be benefits such as time saving, reduced anxiety

and impact on patient management and job satisfaction.³⁶⁸ However, the study also identified high pre-existing levels of satisfaction with diabetes care and the survey failed to attribute increased patient satisfaction to rapid testing.

A large RCT undertaken in Australia found that POC testing was non-inferior to pathology laboratory testing in relation to the proportion of patients showing an improvement in their test results from baseline.³⁶⁹ A pragmatic UK RCT reported that near-patient testing for HbA_{1c} alone does not lead to outcome or cost benefits in managing people with type 2 diabetes in primary care, finding a non-statistical total cost difference of diabetes related care (£390 in the control group and £370 in the POC test group).³⁶⁸ However, this study had not managed to change how patients were managed and so presumably had not managed to influence the number of clinic visits. Further research is required into the use of rapid testing within an optimised patient management model.³⁶⁸

The UK RCT used the Bayer DCA 2000 which requires a finger-prick sample rather than formal venesection, with the result being ready in about 6 minutes. To observe National Service Framework for diabetes,³⁷⁰ requirements for quality control and both internal and external quality assurance procedures were used.³⁷¹

A UK HTA report of a study in diabetes clinics indicated providing that near-patient testing of HbA_{1c} results seemed to improve the process of care and aspects of patient satisfaction. The report recommended a prospective RCT of near-patient testing in diabetes clinics.³⁷²

STEP-UP summary statement With regard to EQUIPMENT, diabetes services are attributed a LOW degree of implementation difficulty owing to the increasing availability of POC tests and other portable equipment.

Premises

The review was unable to identify specific material relating to the implications of primary care diagnostic services in diabetes for premises. Front-line diabetic services have a long tradition of being delivered in primary care. Health Building Note 11-01, *Facilities for Primary and Community Care Services*, locates near-patient testing services (such as blood and gas) in the 'near-patient testing room' (contains public sector information licensed under the Open Government Licence v3.0).⁴⁶ This document does not provide detailed design guidance on specific rooms and spaces and refers to the following for guidance on generic rooms and spaces: Health Building Note 00-03, *Clinical and clinical support spaces*.¹⁵³ No specific detail was identified relating to the implications of storage and maintenance of increasing numbers of POC tests.

STEP-UP summary statement With regard to PREMISES, diabetic services is attributed an UNCERTAIN degree of implementation difficulty owing to insufficient detail on storage and stock maintenance requirements.

User perspective

Diagnostics for diabetes can include POC testing, screening for diabetic retinopathy and a variety of tests for specific diabetes-associated disorders. POC tests enable a clinician to perform the test, discuss of the test result and change medication, when necessary, during a single consultation. POC devices have been evaluated in some health-care settings.³⁶⁷ Few studies have been carried out in the UK, where widespread adoption of these technologies has been slower. A survey by the MaDOx team found that the majority of UK clinicians would like to use POC devices for HbA_{1c} testing¹¹³ but the reasons for low uptake are unclear. A study in the USA has shown that the main reasons for not adopting these new technologies are concerns about cost and instrument accuracy.³⁷³ Many patients prefer POC tests for HbA_{1c} testing because they get the result quickly and have the opportunity to discuss the result during a single consultation.³⁷³⁻³⁷⁵

Approximately 20% of people invited for DRS do not attend, with minority ethnic populations and people living in deprived areas less likely to attend and more likely to have worse retinopathy.¹¹⁴ Deprivation alone does not explain all of the uptake variability between GP practices and regions. Major barriers to attending can include misunderstandings about the importance of diabetes and personal risk factors, and patients' lack of awareness, psychological factors or practical obstacles.^{114,376}

In England, routine diabetes care and DRS are principally managed in primary care, whereas treatment for retinopathy takes place in secondary care. Issues surrounding diabetic retinopathy, therefore, have practice implications for medical and health professionals working in both settings.¹¹⁴ Patients appear to confuse routine retinal photography at optometry practices during eye examinations with DRS.¹¹⁴ Optometry photography may, therefore, impair more comprehensive coverage. The team also observed differences between patients screened at GP and those screened at optometrist practices, identifying that ease of making an appointment, including its time, and navigating home after the mydriasis drops, etc., appeared less problematic at GP practices. Furthermore, making patients responsible for arranging appointments in some regions, combined with encountering delays, could undermine the perceived importance of DRS. They also identified patients' misperceptions about their attendance regularity. The successful implementation of a new care pathway should address these factors and improve DRS attendance.

STEP-UP summary statement With regard to the USER PERSPECTIVE, diabetic services are attributed a LOW degree of implementation difficulty owing to accepted pathways and standards of care.

Primary–secondary interface

Initiatives to break the reported primary secondary divide in diabetes care include a West Sussex initiative in which services have been redesigned so that the primary care diabetes specialist nurses are employed by the PCT and work with nurses and GPs in general practice, but are themselves based at the secondary care diabetes centre. This model of care has enabled the primary care diabetes specialist nurses to function as part of the wider diabetes team, which encompasses all primary and secondary care clinicians, while not being isolated from their secondary care colleagues. Communication was set to improve once primary and secondary care computer systems were linked. Logistic barriers include the various computer systems used in the different practices, as the primary care diabetes specialist nurses have not been trained in either their use or their integration. In addition, practices do not have access to all of the results of blood tests carried out at the hospital. Therefore, further blood samples may be taken or decisions may be made based on results from the general practice system with no knowledge that the hospital may have more recent data. Communication was set to improve once primary and secondary care computer systems were linked.

The success of the model is attributed to a team approach towards managing diabetes services and patient care, aiming to prevent omission, fragmentation and duplication of services, while improving communication between primary and secondary care diabetes services.¹¹⁵

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, diabetic services are attributed a LOW degree of implementation difficulty owing to the existence of integrated pathways across primary–secondary care, notwithstanding the continuing 'divide' in some circumstances.

Conclusion

Diabetic services have a long tradition of being delivered as a two-tier service across the primary and secondary interface. Increasingly, the distinction is becoming blurred, as is the case for cardiac services (described in the previous section). In examining these technologies, it is most important to first define the optimal management pathway and then decide where to locate the various diagnostic interventions. A key consideration, therefore, is the existence of guidelines that make the basis for intervention, and for specific roles, manifestly clear for both patients and clinicians.

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Endoscopy

Definition: an endoscope is a long, thin, flexible tube that has a light source and a video camera at one end. Images of the inside of the body are relayed to a television screen. Endoscopes can be inserted into the body through a natural opening, such as the mouth and down the throat, or through the anus (NHS Choices).

This map includes flexible sigmoidoscopy.

This map excludes colonoscopy.

Contains public sector information licensed under the Open Government Licence v3.0.¹¹⁶

Endoscopy is the most common day-case procedure offered by the NHS and is frequently cited as a service that could be performed in primary care.¹¹⁸ Concerns have previously been expressed over safety, supervision, patient acceptability and cost-effectiveness. Initially, experiences from secondary care were extrapolated as a basis for British Society of Gastroenterology recommendations, with reservations expressed regarding whether or not endoscopy in primary care could be cost-effective.¹²⁰ A 2002 survey demonstrated that endoscopy services could be performed successfully and safely in primary care.¹¹⁸ In the face of long waiting lists in acute hospitals and resources released by fundholding, several endoscopy units were set up in primary care.

Endoscopy in primary care includes the use of gastroscopy, flexible sigmoidoscopy and colonoscopy. Services are typically delivered by GPs or nurses, with GPs being most likely to deliver the endoscopy procedure. Issues of training, qualifications, experience and premises are of prime concern because they are the essential to safe practice in endoscopy. Existing knowledge and practice is contained in guidance from the British Society of Gastroenterology and the Primary Care Endoscopy Group and in building guidance aimed at small acute hospitals.

STEP-UP summary

Skills

High standards of patient care, the avoidance of complications, accuracy in diagnosis, appropriate therapeutic manoeuvres and the cost-effective use of equipment depend on an endoscopy service being provided by skilled professionals. Many GPWIs in gastroenterology will probably have developed skills or expertise in endoscopy during hospital training. Competent GPs should be able to demonstrate that they have sufficient skills to ensure the safe and effective practice of adult endoscopy. A GPWIs in endoscopy will necessarily be able to demonstrate their competence in the use and interpretation of endoscopy. Commissioners subsequently need to ensure that the GP has the specific competences to meet the requirements of their service specification.³⁷⁷

Evidence suggests that more straightforward cases are handled in primary care, with more complex cases being directed straight to an acute hospital. For example, almost all patients who develop acute GI

bleeding are managed in hospital; there is no published literature relating to primary care and, therefore, the Royal College of Physicians/NICE guideline focuses on hospital care.³⁷⁸ Because of the risks, therapeutic gastroscopy, colonoscopy and endoscopy in children should be confined to hospitals, where support for the management of complications is present. Endoscopy procedures in primary care are typically 'performed on a selected population of otherwise fit patients', making comparison with secondary care unhelpful and irrelevant.¹¹⁸

A 2015 systematic review of the safety, competency and cost-effectiveness of nursing staff providing GI endoscopy services, although not examining a primary care context, reported the collective experiences of nurses working in metropolitan areas under the strict supervision and guidance of a specialist gastroenterologist.¹¹⁷ Nurse endoscopists were less cost-effective per procedure at year 1 than services provided by physicians, owing largely to the increased need for subsequent endoscopies, specialist follow-up and primary care consultations. However, the studies clustered between 1999 and 2001, making applicability problematic.¹¹⁷

More diagnostic endoscopies could be undertaken by trained nurses.³⁷⁹ However, a systematic review,¹¹⁷ based on studies from metropolitan units in which nurse endoscopists performed under the close supervision of specialists, found that the nurses were less cost-effective once readmissions and other consequences after 1 year had been taken into account. It is recommended that two people should assist with every endoscopy: a nurse to care for the patient and an assistant to help with the use of instruments and accessories.

STEP-UP summary statement With regard to SKILLS, endoscopy in primary care is attributed a HIGH degree of implementation difficulty owing to the range of skills and competencies required, the risk of serious consequences and the time taken to acquire the requisite competencies.

Training

Training for endoscopy is regulated by the JAG. All training must take place at JAG-approved units. Initially, all practitioners have to attend a formal training course (a JAG-compliant course) in that particular procedure. These courses include the principles and practice of safe endoscopy as well as the indications and contraindications for each type of procedure. GPwSIs should demonstrate that they have pursued training in line with JAG recommendations or have their competency assessed by a local accredited JAG trainer. In addition, the GP should have knowledge of the 15 endoscopy workforce competencies that pertain to a primary care setting. In 2002, 96% of GPs performing endoscopy had undergone training in, and continued to work in, a consultant-led endoscopy unit. About half of the same sample had undergone training courses in endoscopy.¹¹⁸

The RCGP considers that the training of GPwSIs in endoscopy must be considered ongoing and involve support from specialists. The GP must maintain a sufficient workload³⁷⁷ and continue to access support from other endoscopists and specialists. In 2002, the numbers of endoscopies performed in each primary care unit suggested an inefficient use of resources, but this was attributed to the fact that most units were considered to be still in their infancy. The Primary Care Society for Gastroenterology guidelines suggest that no unit should offer fewer than 200 cases of any flexible endoscopy per year and the endoscopist should have continuing association with a secondary care unit for a wider exposure to case mix.³⁷⁷ Clearly, if more investigative work is performed in primary care then those GPs involved will be less available for core general practice.

A 2002 survey concluded that simple diagnostic endoscopies could be performed safely in the primary care setting, leaving secondary care units to concentrate on patients requiring sedation, those who are acutely ill and those who require therapeutic procedures.¹¹⁸ The survey left unanswered questions about community-based endoscopy. These include the effectiveness of referral guidelines, reporting systems, numbers of failed or inadequate examinations requiring referral to specialist units, and the effects on workload in primary care where doctors in a partnership are involved in intermediate care provision. The economics of service provision was not investigated in the survey and neither was morbidity.¹¹⁸

Requirements from the RCGP are outlined for induction, mentoring, accreditation, reaccreditation and CPD. The GP will require appropriate professional insurance cover (e.g. medical defence organisation or NHS Litigation Authority). Professional documents emphasise the need for flexible and varied approaches to training and assessment, tailored towards the service that the GP will deliver.³⁷⁷ Assessment may include any combination of the following:

- observed practice
- demonstration of skills under direct observation by a specialist clinician
- reflective practice
- log book/portfolio of achievement
- observed communication skills, attitudes and professional conduct
- evidence of gained knowledge via attendance at accredited courses or conferences.

Although the accreditation of a practitioner as fit to provide endoscopy services is outlined by JAG, providing endoscopy services goes beyond this and requires fulfilment of the formal GPwSI accreditation process.³⁷⁷

The literature illustrates innovative approaches to endoscopy training. Endoscopy training is a particular candidate for simulation-based approaches. To develop a safe and effective endoscopy service, competent GPs are expected to demonstrate knowledge of the curriculum areas listed in the RCGP guidance.³⁷⁷

The development of GPwSIs in gastroenterology is supported in primary care. However, their clinical effectiveness and cost-effectiveness need to be researched. A comparatively strong body of evidence relates to their participation in diagnostic services, and the consequent need 'to develop and implement appropriate training and stringent assessment to ensure patient safety'.³⁷⁹

Training in instrument handling and disinfection forms an integral part of the training of nurses and other endoscopy assistants and it is essential that all staff involved in endoscopy are kept up to date with an ever-changing technology. These considerations are applicable wherever endoscopy is practised. GPs and their funding bodies must recognise them when considering establishing endoscopy in the community.

Support for endoscopy in primary care may be achieved through active membership of a professional society such as the Primary Care Society for Gastroenterology (www.pcs.org.uk) or the British Society of Gastroenterology. These associations also offer a mechanism for clinical governance. The British Society of Gastroenterology also hosts a national nurse endoscopist group.

The education and training of staff in health and safety matters is essential and should include the use of personal protective equipment and handling of spillage procedures. Compliance with legislation and regulations places a considerable demand on training and facilities for primary care providers, making the extent to which the use of these facilities justifies such levels of provision critical to a commissioning decision.

Guidance documents emphasise the extended length of time required to train a GPwSI in endoscopy. As a consequence, they suggest that extended contracts of longer than 3 years' duration should be considered.³⁷⁷ The same guidance suggests that all appropriate training should be completed within a 5-year framework.

Notwithstanding the above focus on GPs, commissioners may also develop specialist endoscopy services using other practitioners (e.g. nurses and other HCPs). Competences for NHS-employed staff providing specialist care in community settings are typically assessed through the knowledge and skills framework.³⁷⁷

STEP-UP summary statement With regard to TRAINING, endoscopy in primary care is attributed a MODERATE degree of implementation difficulty owing to the availability of courses, the clear definition of a curriculum, the existence of specialist groups and the variety of training methods available that mitigate, to some degree, the wide range of skills and competencies required.

Equipment

Endoscopy 'incurs significant cost through its high usage rate of consumables coupled with significant capital costs (e.g. endoscope systems)'.¹¹⁹ When endoscopy is performed in a setting outside a hospital unit, such as in a cottage hospital, diagnostic and treatment centre or GP surgery, facilities, staffing and equipment should be of the same quality.² GPs and their funding bodies must consider whether or not the associated high capital outlay is justified and whether or not it is cost-effective to provide a service to their own and their colleagues' patients. The availability of primary care endoscopy services may help to challenge any monopolies among NHS or commercial providers.

Anaesthetic and resuscitation facilities must be provided on site for the management of sedated patients. Adequate equipment must be available, together with safe facilities for its cleaning and maintenance. Endoscopes and their accessories are expensive and relatively delicate, requiring careful handling and correct maintenance. The BSG has recommended that the care, maintenance and use of endoscopes and the numerous accessories involved requires a high level of technical competence among medical and nursing staff, comparable with that in the operating theatre.

In a US context the American Academy of Family Physicians reports that economics favour the hospital laboratory over provision in family practice.³⁸⁰ Equipment, including video and photography equipment, intravenous medications and supplies, and nursing staff are provided as part of an overall service. However, provision in a hospital environment, at a set fee, is consistently higher than when the procedure is performed in the family physician's office. Although the health economics and funding systems are markedly different, it is likely similar considerations apply in the UK.

Rigid sigmoidoscopy, a safe, simple, inexpensive procedure, is being displaced increasingly by fibre sigmoidoscopy. The technique is reportedly easy to learn. The demands for colonoscopy and fibre sigmoidoscopy far exceed availability in the UK. These services will inevitably expand rapidly in the next few years.

In 1994 a specification was produced for an endoscopy unit.¹²⁰ This included upper GI endoscopes and a fibre sigmoidoscope, a light source, a procedure trolley, an endoscopy trolley, three suction machines, an automated washing machine and three pulse oximeters. In 2002, 75% of the endoscopes used were made by Olympus and the remaining were predominantly Pentax endoscopes.¹¹⁸ The examination needs to be performed on a 'tipping' trolley so that the patient may be tilted head or feet down. The life expectancy of the equipment will require replacement over a 5- to 10-year period. Constant improvements to technology are taking place and equipment may become obsolete before the end of its natural life. Underutilisation of equipment will invariably lead to waste. Correspondence from Canada reports that supplies and consumables accounted for approximately half of all expenditure in an endoscopy unit.¹¹⁹

Cleaning and decontamination of endoscopes should comply with BSG and COSHH guidelines.¹²¹ In a 2002 survey, units using flexible endoscopes all used automatic washing machines to sterilise the instruments and the most commonly used sterilising fluids were glutaraldehyde (66%) and peracetic acid (33%).¹¹⁸ The BSG has published recommendations in a report on aldehyde disinfectants and health in endoscopy units.¹²² Glutaraldehyde is most commonly used for the disinfection of flexible GI endoscopes and it is toxic, irritant and allergenic. The disinfection of flexible endoscopes should be performed in the automated washer/disinfector following the thorough brushing of the channels. The disinfection of equipment should take place away from clinical areas and where suitable extraction and ventilation equipment can be utilised.¹²⁰

The cost of endoscopy reflects such factors as the cost of capital investment, staffing, disposables, accessories and the number of procedures undertaken. Capital expenditure required to establish an endoscopy unit requires a considerable investment even when only relatively simple diagnostic procedures are planned.

STEP-UP summary statement With regard to EQUIPMENT, endoscopy in primary care is attributed a HIGH degree of implementation difficulty owing to the capital costs of purchase, the expense of consumables, the precautions required for cleaning and maintenance and the risks associated with glutaraldehyde.

Premises

Requirements for an endoscopy unit, typically based in an acute hospital, are outlined in Health Building Note No. 52¹²³ and in the *User's Guide to Achieving a JAG Compliant Endoscopy Environment*.¹²⁴ These documents have some, albeit limited, applicability for general practice. Similarly, guidelines from the World Endoscopy Organization specify design principles for a digestive disease endoscopy unit.³⁸¹ Health Building Note 11-01, *Facilities for Primary and Community Care Services*, suggests that 'most invasive procedures and certain procedures using rigid endoscopes can take place in a generic treatment room'.⁴⁶

Building costs may involve erecting new accommodation or adapting existing buildings. The costs of installing fume extraction equipment may also be a factor. Standards of care in purpose-built, well-equipped primary care premises need not fall noticeably short of those in a general hospital, particularly when staff are well-trained and experienced at endoscopy.¹¹⁸ Endoscopy should be performed in a unit that complies with JAG guidelines for safe endoscopy.¹²⁴ When conscious sedation is used, facilities for resuscitation and recovery should be available to the same standard as in an acute hospital. Endoscopy needs to be practised in a purpose-designed area with adequate space and easy accessibility. Instruments, their accessories, monitoring equipment and all the necessary drugs need to be readily to hand. Staff must be able to move freely, and at times quickly, around a patient. Patients may need room for manoeuvre onto trolleys before, during and after endoscopy. Staff need room in which to perform resuscitation manoeuvres. Space is required for appropriate equipment. Suction needs to be available to clear the mouth and pharynx of saliva and any regurgitation of gastric contents. Oxygen must be available. In general practice, any endoscopy facility is likely to be used for multiple purposes but due consideration must be given to the care, storage and security of endoscopy equipment. A separate, properly equipped cleaning and disinfection area will be required to fulfil the COSHH requirements.¹²¹

A separate, and perhaps shared, appropriately staffed patient preparation and recovery area will be required and depending on the workload and patient turnover, space will be needed for one or more trolleys. Monitoring facilities and supplemental oxygen will also need to be available in this area. From time to time patients require overnight admission for observation during unexpectedly prolonged recovery.

STEP-UP summary statement With regard to PREMISES, endoscopy in primary care is attributed a HIGH degree of implementation difficulty owing to the high capital costs of specific accommodation for equipment and the requirements to provide a safe environment for operation of the equipment and for cleaning.

User perspective

Consumer preference is frequently cited as a major driver for a move towards primary care endoscopy services. However, the public is relatively poorly informed of the risks, the precautions and the importance of staff training and experience as they contribute to safe endoscopy. Endoscopy procedures should be performed to recognised levels of safety and accuracy, ensuring patient comfort and satisfaction. The lack of severe symptoms, fear of pain, concerns of sedation, comorbidity and competing life demands have been reported by patients as barriers to performing an endoscopic investigation.¹²⁵ A Greek qualitative study, recruiting from primary care patients, found that those refusing upper endoscopy were predominantly female and over the age of 50 years.¹²⁵

In a qualitative study of UK ethnic groups, focus groups were used to explore barriers to the uptake of flexible sigmoidoscopy screening among UK ethnic minority populations. Anxiety regarding the invasiveness of the test, the bowel preparation and fear of a cancer diagnosis were common barriers across all ethnic groups. Language difficulties, failure to meet religious sensitivities and the expression of

culturally influenced health beliefs were all discussed as specific barriers to uptake. Ethnically tailored health promotion and GP involvement were recommended as ways of overcoming such barriers.¹²⁶

STEP-UP summary statement With regard to the USER PERSPECTIVE, endoscopy in primary care is attributed an assessment of UNCERTAIN given that attitudes of patients and staff to endoscopy in primary care are not well explored.

Primary–secondary interface

Hospital-based endoscopy depends largely on highly trained specialists. These specialists have acquired a wider clinical knowledge of gastroenterology over and above simple endoscopic interpretation. Conflicts of access and perceived vested interest are best resolved by improving communication between GPs, specialists, patient groups, purchasers and provider units. Current difficulties may occur when patients encounter difficulty in qualifying for an urgent referral, have to wait too long or experience varying quality in treatment.³⁸²

Alternatives to a GP-based community service include greater 'open' access to hospital facilities by GPs and 'outreach' clinics performed by hospital-based consultants in community hospitals or individual/group practices. It has also been suggested that mobile units could provide a peripatetic service comparable with radiography or breast screening. Reports have suggested that open access may result in more appropriate selection of patients for whom the investigation is appropriate.¹²⁷

A survey of Irish GPs³⁸³ examined the availability of radiologic and endoscopic services. In all services, access to diagnostics for public patients is unacceptably long when compared with that for private patients. As a consequence, GPs may refer patients inappropriately to overcrowded emergency departments in order to access diagnostic tests. This can be an unnecessarily traumatic experience, particularly for elderly patients, and places an extra costly burden on hospital services. The vast majority of respondents indicated that increased access to diagnostics would facilitate them to reduce the number of referrals to both emergency and outpatient departments, reduce unnecessary admissions and improve the quality of referrals overall.

STEP-UP summary statement With regard to the PRIMARY–SECONDARY INTERFACE, endoscopy in primary care is attributed a MODERATE degree of implementation difficulty given existing working relationships with secondary care but the need to refer more serious or complex cases to an acute hospital setting.

Conclusion

The potential to offer endoscopy in primary care has been long recognised and it may make an important potential contribution to the disease management pathway. It no longer holds the high level of risk that it was once perceived to have. Developments in more flexible diagnostic tools have helped to make it easier to conduct. It continues to occasion fear among patients, particularly those who are older and female. Physical requirements for the premises, for example for disinfection and storage of the equipment, may be prohibitive in an ordinary-sized general practice. However, they may more easily be accommodated in purpose-built clinics or community hospitals.

Endoscopy (En1–43)

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Genetic testing

Definition: genetic testing is a type of medical test that identifies changes in chromosomes, genes, or proteins. The results of a genetic test can confirm or rule out a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder.

This map includes testing for inherited genetic conditions and for genetic risk factors indicating a predisposition to particular conditions, e.g. cardiac conditions.

This map excludes newborn heel screening.

Definition is public domain information reproduced from US National Library of Medicine: Genetics Home Reference.¹²⁸

Background

Over-the-counter genetic tests are becoming increasingly plentiful.³⁸⁴ Primary care health professionals will increasingly be exposed to commercial testing both when patients are contemplating genetic testing and when they return after being given the results of such tests.³⁸⁵ Health professionals increasingly need to become 'genetically literate'.¹⁴² It has been estimated that at least 1 in 10 of the patients seen in primary care has a disorder with a genetic component. Three main themes of genetics in primary care relate to identifying patients with, or at risk of, a genetic condition, the clinical management of genetic conditions and communicating genetic information (including genetic counselling).³⁸⁶

Genetic screening tests can involve molecular, biochemical and other types of analyses, or even the use of family history questionnaires, to predict which individuals are at risk of developing or transmitting (or both) a genetic condition.³⁸⁷ Some tests are strong predictors of disease occurrence, but many are subject to a

high degree of uncertainty. It can be difficult for those who have positive screening results to decide how best to proceed, as the proposed interventions vary greatly depending on the disease in question, and they are not always highly effective and might also involve certain risks.³⁸⁷

Predictive genetic tests differ from traditional medical tests in part because they directly affect other individuals who may not have wanted such information. Depending on family size, the number of possibly affected family members can be quite large and the risk is never trivial. Another way in which predictive genetic tests differ from traditional medical tests is the time frame they span. Traditional medical tests typically ascertain an individual's condition at that moment, whereas genetic tests purport to reveal something about a possible future state or condition. Strictly speaking, predictive tests are not new in medicine. Cholesterol levels have been used for years to predict cardiac disease, and nuclear imaging routinely guides the need for further intervention in patients with chest pain. However, genetic testing presents a new set of conditions and new levels of complexity and uncertainty not found in traditional predictive tests.

STEP-UP summary

Skills

Skills for genetic testing relate to understanding which patients to test, what tests to order and how to interpret the results of these tests. Importantly, they also require being able to handle the counselling and communication issues associated with testing and the test result.¹²⁹ A Dutch survey of knowledge of genetics and genetic tests revealed general levels to be poor, with GP knowledge being poorer than that of paediatricians and gynaecologists.¹³⁰ Knowledge of DNA (deoxyribonucleic acid) testing was particularly deficient. The factors associated with higher knowledge scores included more recent graduation, having taken an elective course in genetics and providing genetic counselling in their own practice. This suggests that GPs will demonstrate an improved knowledge of genetics with the changing workforce dynamics and changes in emphasis in medical education and other HCPs. At least for the moment, the supply of genetics professionals is inadequate to meet increasing demand and the expansion of genetic knowledge will cause the primary care physician to be increasingly called on to provide genetic services.

STEP-UP summary statement With regard to SKILLS, genetic testing is attributed a HIGH degree of implementation difficulty owing to inadequate knowledge of genetics, challenges in interpretation and the need for skills in communicating and handling the outcome of the test.

Training

Generally, primary care practitioners have received minimal training in clinical genetics. Various methods are required to support practitioners to develop these genetic skills and knowledge, including changes to the undergraduate curriculum. Postgraduate training and assessment in primary care should include approaches to developing and examining the outlined genetic skills. However, these will require clinical teachers themselves to acquire good genetic knowledge and skills.

As with GPs, empirical evidence of the learning needs of practitioners in relation to genetic testing reveals widespread deficits in knowledge and skills, and low confidence levels. Provision of nursing education in genetics is uneven. Significant progress has been made in the identification of learning outcomes for nurses. Research on the delivery of genetics education is limited. Skills-based training, clinical scenarios and assessment have all been identified as factors that can promote learning. Many studies of nurses' knowledge of genetics reveal gaps in professional competence and/or education.¹³² New initiatives are under way to support genetics education and its integration into professional practice. Further research is needed on the most effective forms of educational delivery. E-learning extends the possibility of this type of training across a wide number of staff scattered across general practices.

The role of computer decision support and clinical decision aids is mentioned by some authors.³⁸⁸

The additional cost of software, and the time spent to learn and use such tools, needs to be factored in alongside equipment costs.

Clinicians need guidance to help them introduce genetic tests, communicate their results and explain their implications.³⁸⁹ Primary care providers are interested in learning more about who should receive genetic testing and what tests are available. Training in counselling and risk communication is desired, as are 'just-in-time' resources to guide clinical decisions.¹³¹ Primary care providers are eager to learn about genetic medicine. Educational efforts should build on primary care providers' prior knowledge base, highlight the clinical relevance of genetic medicine to primary care practice, and emphasise 'red flags': cues to alert primary care providers to a potential genetic contribution. Shared decision-making has been advocated, and 75% preferred this approach with their patients. Physicians who preferred their patients to play an active role in decision-making were more likely to report encouraging patients to look for information, and to report having enough time to discuss decisions in visits.³⁹⁰

The science of genetics will impact every aspect of health care, from primary care to specialised care.¹³³ Nurses are on the front line and are expected to recognise patterns of disease that may indicate a possible genetic link, educate the family about the implications of a potential genetic susceptibility and refer the family for counselling. Each nurse should, thus, acquire a minimum basic knowledge of genetics. Those who educate and counsel should attend formal education provision.

Given the complexity and limitations of genetic testing, there is a need to develop and disseminate clinical guidelines and to educate physicians.³⁹¹ Clinicians need guidance to help them introduce genetic tests, communicate their results and explain their implications.³⁸⁹ Additional, more innovative methods are required, including management guidelines and computerised pedigree drawing and decision support.³⁹² Online resources will become increasingly useful for both health professionals and their patients.

STEP-UP summary statement With regard to TRAINING, genetic testing is attributed a MODERATE degree of implementation difficulty owing to the need to receive significant training and ongoing support in offering genetic services.

Equipment

Genetic testing is expensive and time-consuming given the sheer scale of the genes that need to be examined. Although robotics and high-throughput sequencing greatly speed sequencing, the process remains expensive and laborious. Commercial sequencing may take 3 or 4 weeks for results.³⁹³ Existing screening methods possess reduced sensitivity and specificity in comparison with this current gold standard of sequence analysis. The necessary pre-test and post-test counselling that must accompany such testing is best measured in hours, not minutes. A systematic review of genetic tests in primary care was published in 1999.¹³⁴ This mapping review has been unable to find a more recently published review. Specific searching for such a systematic review is recommended before considering whether or not to commission further work.

STEP-UP summary statement With regard to EQUIPMENT, genetic testing is attributed a LOW degree of implementation difficulty owing to increasing numbers of direct to consumer POC tests.

Premises

The mapping review was unable to identify any items that specifically described requirements to house genetic testing facilities in general practice or community premises. Health Building Note 11-01, *Facilities for Primary and Community Care Services*, locates near-patient testing services (such as blood and gas) in the 'near-patient testing room' (contains public sector information licensed under the Open Government Licence v3.0).⁴⁶ This document does not provide detailed design guidance on specific rooms and spaces, and refers to the following for guidance on generic rooms and spaces: Health Building Note 00-03, *Clinical and Clinical Support Spaces*.¹⁵³ It is unclear what tests should be provided and what the implications are with regard to the management of stock.

STEP-UP summary statement With regard to PREMISES, genetic testing is attributed an UNCERTAIN rating for implementation difficulty owing to the shortage of studies describing how tests might be accommodated. Co-ordinated approaches with regard to storage may relate to POC tests.

User perspective

Commentators question how quickly genetics will deliver clinically useful tests and knowledge to primary care and if it will initially raise more questions than answers.³⁹⁴ Concerns are expressed about the potential harm from the inappropriate use of genetic testing. It is believed that primary care practitioners are reluctant to adopt responsibility for genetic testing. In a survey of family physicians,¹³⁵ respondents felt that genetic tests would be more useful for breast cancer and hemochromatosis than for Alzheimer's disease, heart disease or diabetes. Individuals who believed themselves more familiar with genetic tests were more likely to anticipate that genetic testing would impact significantly on their future practice (23.1% vs. 13.4%). Respondents had little exposure to direct-to-consumer genetic tests, but most felt that they were more likely to cause harm than benefit.¹³⁵

Qualitative studies on attitudes to genetic tests in primary care, from both practitioner and patient perspectives, are plentiful. This mapping study has focused on studies of genetic tests in general or studies that include multiple conditions, in the interests of transferability. However, numerous qualitative studies were found for individual genetic conditions. This mapping review did not identify any qualitative systematic reviews of attitudes to genetic tests specifically in a primary care setting, although such reviews in general health contexts do exist. Given the plentiful nature of qualitative evidence, a systematic review, specifically of genetic tests in primary care, may be warranted. A more comprehensive search should be undertaken before considering whether or not to commission further work.

Unlike cholesterol level or a pap smear, a genetic test directly examines one's unique genetic code and thereby addresses individuality on a deeper level. Fears of genetic discrimination are widespread and, partly for these reasons, genetic information typically occupies a privileged position with respect to privacy and informed consent. Findings from qualitative studies of patient viewpoints report misunderstandings concerning genetic tests, for example that genetic tests are more predictive than they actually are, and that they are predictive of behaviours for which no markers have in fact yet been discovered.¹³⁶ A qualitative study of genetic testing for risk of coronary heart disease found that the test was acceptable. However, patients were unclear how to interpret the meaning of the test and rarely used it to initiate appropriate action.¹³⁷

Findings from qualitative studies of provider viewpoints report that cost of testing consistently appears as the most frequently cited barrier to genetic testing.¹³⁸⁻¹⁴⁰ GPs also rate their baseline knowledge of genetics as uniformly poor.³⁹⁵ GPs are most confident when eliciting family history and providing psychosocial support and least confident when discussing risks/benefits of genetic testing and in counselling. GPs were more likely to refer to genetics counselling services when they were confident in their knowledge of referral criteria and core competencies in genetics, and when they were aware of the programme and where to refer.³⁹⁶

STEP-UP summary statement With regard to USER PERSPECTIVES, genetic testing has LOW implementation difficulty for patients and MODERATE difficulty for clinicians because patients already have access to direct to consumer genetic tests but GPs are cautious about the ramifications of interpretation.

Primary–secondary interface

Studies in the UK have evaluated community genetic counsellors acting as outreach workers¹³⁴ from the genetics clinic to liaise with local general practices. Such practitioners are either genetic nurses¹⁴¹ or genetic counsellors, and they can fulfil a dual role of filtering referrals to the geneticist and providing basic genetic information.¹⁴² Genetic nurse counsellors, specifically in a cancer genetics context, were found to perform not significantly differently from conventional cancer genetic services in two RCTs in Scotland and Wales.¹⁴³ Although the nurses were located in regional genetics services the possibility of locating such nurses in primary care or, indeed, of offering liaison nurse roles located in general practice should be investigated. Such roles hold significant workforce requirements. Development of primary care specialists, possibly working in conjunction with community genetic counsellors, has been suggested to offer an intermediate point of referral between general practice and specialist genetic clinics. A third allied model is to train a specific practitioner from each practice in genetic skills to act as an in-house expert, supported by electronic resources.¹⁴²

A study from the USA found that communication between primary care physicians and genetics specialists is suboptimal. Improvement is needed in identifying and referring adult patients to genetic services.³⁹⁷ Primary care physicians are less comfortable than specialists with identifying patients for referral and with discussing genetics.³⁹⁸ The largest barriers to referral were lack of programme awareness and limited knowledge regarding patient eligibility, improved insurance coverage and antidiscrimination legislation.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, genetic testing is attributed a MODERATE degree of implementation difficulty owing to a high dependence on secondary care expertise, support and follow-up provision.

Conclusion

Because of the uncertainties around the benefits and harm from genetic testing, the clinical implications of a specific genetic test will require careful evaluation, including information about cost-effectiveness, before widespread adoption is recommended.¹⁴² With thousands of tests being developed, it is important to ensure that these are matched to meaningful intervention. Rather than focusing on the organisation and service delivery of specific individual tests, the priority is to organise services that can adapt to emerging technologies, their interpretation and their implications for patient support and counselling.

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Magnetic resonance imaging

Definition: MRI is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body (NHS Choices).

This map includes portable MRI and (exceptionally for this review) commercial service provision.

This map excludes N/A.

N/A, not applicable.

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Background

The drive to improve primary care access to imaging services is encapsulated in the Department of Health's 2008 documents *Care Closer to Home*⁴⁹ and *NHS Next Stage Review: Leading Local Change*,⁵⁰ chaired by Lord Darzi. These documents champion the introduction of change through 'disruptive innovation', that is, change involving radical service redesign, centred on improving the quality of care that patients receive and with an emphasis on devolving key aspects of care pathways from secondary to primary care 'to empower the frontline'.³⁹⁹

As part of the reshaping of imaging services in primary care, independent-sector providers – possibly the most high-profile of which is the London NHS Diagnostic Service – have been closely involved in the planning, delivery and auditing of direct-access imaging in primary care.⁵¹ The response from primary care in London has been positive. For example, the Croydon Federation of General Practices audited its interaction with the London NHS Diagnostic Service, concluding that the service provides a high-quality service and rapid access to imaging in a way that provides 'value-for-money', improves clinical management, and enhances the patient experience. The perception in primary care is that improved access redefines standards of service delivery. Patient-centricity is promoted through attempts to optimise choice and convenience by providing imaging not only closer to home but also at an appropriate time. The timeliness of the service has improved, with a maximum waiting time for diagnostics of 2 weeks (compared with standard 6-week waiting times at many local secondary care institutions). The nature of the interaction between primary care and the independent provider is also reported to be 'mould-breaking' in terms of the 'can-do', proactive, facilitative and communicative attitudes of the provider, held up in contrast to relationships with local secondary-care providers. The Croydon Federation has concluded that there is an overwhelming 'buy in' from local general practices and their patients. Clinical management in primary care has been facilitated and onward referral to secondary care reduced by one-third. The beneficial effect of direct-access imaging on the effective functioning of the Department of Health 18-week referral-to-treatment targets in secondary care centres is also cited by all parties as a real and objective outcome of the service.⁵¹ A range of independent-sector providers is similarly supplying direct-access imaging to primary care elsewhere in the country by using static and mobile MRI scanners within PCTs and GP practices, and through mobile ultrasound services. The London NHS Diagnostic Service differs in being centrally procured and by effectively acting as a formal pilot scheme for primary care direct access.⁵¹

STEP-UP summary

Skills

To provide a MRI service requires that staff undertake sufficient current MRI practice, and a sufficient number of examinations to maintain competency in every area of MRI. Staff interpreting the images and providing a clinical report should fulfil the following requirements:¹⁴⁵

- UK Registered Radiologists on the GMC Specialist Register undertaking sufficient current clinical practice within that modality. A consultant radiologist must have undertaken planned regular clinical MRI sessions in their current job plan.

- Radiographers currently registered with the Health and Care Professions Council who have performed regular sessions of MRI examinations within the last 12 months.
- A minimum of 1 year's experience.
- All staff maintain their CPD in accordance with their professional body guidelines.
- Meet the specification set out in the 'National Occupational Standards for Imaging' (RD5: produce MRI images for diagnostic purposes).

STEP-UP summary statement With regard to SKILLS, MRI is attributed a MODERATE degree of implementation difficulty owing to the requirements for experience and training.

Training

The BSCMR (www.bscmr.org) has endorsed voluntary accreditation procedures for their members. These have no statutory role but are provided to allow both medical and non-medical practitioners to demonstrate a specified level of experience in an appropriate educational environment. In the case of MRI, the BSCMR and British Society for Cardiac Imaging support the criteria developed by the US-based Society for Cardiovascular Magnetic Resonance and do not separately accredit individuals.

In this rapidly changing field, the following standards are currently applicable:

- *Making the Best Use of a Department of Radiology*, 6th edition – RCR 2007⁴⁰⁰
- *Standards for the Communication of Critical, Urgent and Unexpected Significant Radiological Findings* – RCR 2008⁴⁰¹
- *Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use* – MHRA Device Bulletin 2007.⁴⁰²

STEP-UP summary statement With regard to TRAINING, MRI is attributed a MODERATE degree of implementation difficulty owing to the ongoing need for professional development and updating.

Equipment

Magnetic resonance imaging has entered common use as part of the standard equipment portfolio over the last 10 to 15 years.¹⁵⁹ Three distinct classes of MRI scanners are marketed and sold by manufacturers and suppliers:

- specialised MRI scanners, which have been designed for niche applications, such as orthopaedics
- whole-body imaging systems, where the technology has improved to allow for higher-field strength magnets at lower cost
- specialised cryogenic and non-cryogenic electromagnets, designed for interventional and imaging work.

The following are commissioned requirements for MRI equipment, which should meet or exceed the following:

- Fixed or mobile units shall contain one full-body MRI scanner with a magnetic strength of at least 1.5 Tesla.
- Equipment should comply with the Guidelines for Magnetic Resonance Equipment in clinical use, MHRA (2007) as updated, superseded and replaced from time to time.¹⁴⁶
- Equipment should be a maximum of 7 years old.
- Electrical safety testing is required annually with regular maintenance and quality assurance testing.
- Details of maintenance contracts to include regular and emergency service cover must be provided.
- Replacement schedule must be available with the maximum age of equipment of 7 years.

Most MRI scanners are currently only utilised on a '9 to 5' basis, and therefore these high-cost assets are not delivering value for a significant proportion of any given day. The extension of working hours would utilise the equipment more efficiently and might also offer appointments at times that are more convenient for the patient. Routine maintenance could be performed out of hours, with quality assurance procedures performed prior to a clinical session.

STEP-UP summary statement With regard to EQUIPMENT, MRI is attributed a HIGH degree of implementation difficulty owing to the prohibitive cost of an installation.

Premises

There is no specific provision for MRI in Health Building Note 11-01, *Facilities for Primary and Community Care Services*.⁴⁰³ Commissioners will need to consider mobile or static sites. All facilities, including mobile units, are required to have a minimum of a patient reception and waiting area, either on the unit or nearby, access to a toilet and access to appropriate levels of security. We found no specific guidance on housing MRI units in primary care. However, elements of the government document *Facilities for Diagnostic Imaging and Interventional Radiology* (Health Building Note 6) will apply to primary care premises.¹⁵⁹ This document claims to have recognised trends in primary care imaging but does not acknowledge a primary care context for MRI (chapter 13 on magnetic resonance imaging, pp. 118–32).¹⁵⁹ The requirements for space for conventional MRI as specified by this document would be prohibitive to a general practice setting. More realistic is to consider the place of mobile MRI units and their requirements (chapter 14 on Mobile vehicle scanning units to include CT/MRI and positron emission tomography).¹⁵⁹ A mobile unit will require space for a control area, an examination room and, if needed, a technical room. There will be no room for patient support areas, which will, therefore, have to be provided within the remaining primary care facilities.

STEP-UP summary statement With regard to PREMISES, MRI is attributed a HIGH degree of implementation difficulty owing to exacting requirements for the facilities and supplies.

User perspective

Access to MRI is seen as a way to reduce diagnostic uncertainty. Early access to MRI compared with referral to an orthopaedic specialist did not alter GPs' diagnosis or treatment plans but significantly increased their therapeutic confidence.⁴⁰⁴ Because MRI equipment is typically housed in secondary care we were unable to find qualitative research relating to attitudes to MRI specifically in a community setting. Items on perspectives of MRI provided by acute hospitals from GPs and their referred patients would indirectly inform this issue. However, these will require a supplementary search strategy.

STEP-UP summary statement With regard to USER PERSPECTIVE, MRI is attributed an UNCERTAIN degree of implementation difficulty owing to the shortage of published experience on MRI in a primary care context.

Primary–secondary interface

A MRI service needs to work with other providers to offer an integrated service. This includes third-sector organisations providing help and support for patients. The role of local clinical networks is particularly important. It is equally important to achieve good engagement with all stakeholders. Key to the successful integration of MRI services is consideration of the management pathway, irrespective of which facilities are located in the primary or secondary sectors of local health service provision.

An alternative to primary care services housing their own staff and equipment in their premises is offered by the London NHS Diagnostic Service. The London NHS Diagnostic Service was established by the InHealth Group in 2007 following competitive tendering. Local PCTs and federated general practice groups utilise the service, which charges for imaging services including ultrasound, plain film and MRI at standard tariff costs. MRI reporting is provided by groups of NHS-based consultant radiologists operating within an independent organisation affiliated with the private provider. The aim is to offer access to diagnostic imaging services comparable with those provided in secondary care.⁵¹ This popular model of service delivery avoids the heavy capital expenditure required for purchasing the MRI equipment.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, MRI is attributed a MODERATE degree of implementation difficulty owing to dependence on secondary care support facilities and/or commercial providers.

Conclusion

Ultimately, MRI provision did not meet the criteria for this review in terms of services and staff managed in a primary care setting. The most common model was of service provision under contract by an external provider. This sidesteps many of the considerations from the STEP-UP framework, for example training and equipment, except from a commissioner and quality assurance customer perspective. The implications of offering MRI services have not been explored and represent a potential line of future exploration.

Magnetic resonance imaging (M1–24)

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Point-of-care testing

Definition: POC testing is defined as any analytical test performed for an individual by a HCP outside the conventional laboratory setting.¹⁴⁷

This map includes CRP, D-dimer, faecal occult blood, haemoglobin, HbA_{1c}, infectious disease testing, INR, lipid profiles, nose/throat swab for influenza, platelet count, procalcitonin biomarkers, quantitative β -human chorionic gonadotropin, throat swab for group A streptococci, urine albumin–creatinine ratio, urine leucocytes or nitrite, urine pregnancy test, urine strips and whole-blood lactate.

This map excludes BNP (see *Cardiac services*), blood glucose, HbA_{1c} (see *Diabetes services*), cholesterol screening, pregnancy tests and respiratory POC tests (see *Respiratory tests*).

Background

Point-of-care tests are a significant growth area in the worldwide market of diagnostics. As the NHS moves its focus closer to the patient primary care, doctors and commissioners need to take stock of which new POC tests should be used, and why.² POC tests have been developed for many common blood tests, such as lipid profiles, HbA_{1c}, CRP, INR and urine albumin-to-creatinine ratio. The traditional set of POC tests

includes blood glucose testing, blood gas and electrolytes analysis, rapid coagulation testing, rapid cardiac markers diagnostics, drugs of abuse screening, urine strips testing, pregnancy testing, faecal occult blood analysis, haemoglobin diagnostics, infectious disease testing and cholesterol screening. In the past 5–10 years the following tests were added: HbA_{1c}, BNP, whole-blood lactate, D-dimer and CRP.⁴⁰⁵

Point-of-care testing holds potential benefits for primary care in trading off accuracy against availability.⁴⁰⁶ POC testing assumes that an immediate result actually makes a difference to the patient's management and outcome. The technical complexity and specialist nature of many diagnostic technologies sees them being placed in centralised laboratories, typically processing samples from multiple general practice facilities. Centralisation of diagnostic provision in this way may lead to long delays between the collection of samples and the receipt of results at the general practices. The receipt of results has, to a certain extent, been speeded up with the advent of communication technologies including, first, fax and second, e-mails and text messages. However, there is no immediate way of reducing the time taken to collect and process samples, other than locating the processing facilities nearer to the POC, either by delivering results at the practice itself or through using mobile facilities. Delays in testing and, for some tests, the need to travel to a secondary care facility may result in fewer patients undergoing tests and to delays in initiating treatment, where necessary.

An international survey in 2014 attempted to identify demand for POC tests in five different countries.¹¹³ As well as the UK and the USA, it included two countries with leading reputations for POC testing. The survey also identified those conditions for which GPs would most like to have availability of/access to tests. In both cases selective data of UK results are presented below (*Tables 44 and 45*) against cumulative international supply or demand to minimise the effect of national practice.

Certain conditions were not afforded prominence in the UK but appeared in the lists of other countries. These are included below in the context of a possible Horizon Scan of emerging priorities.

- Australia: chronic and acute renal conditions (excluding urinary tract infection).
- Belgium and the Netherlands: infections and sexually transmitted diseases.
- Belgium: acute and chronic renal impairment.
- Netherlands: appendicitis.
- USA: strep throat, influenza, infectious mono and sexually transmitted diseases.

STEP-UP summary

Skills

To practise competently, the user of POC testing equipment must have the knowledge and skills for safe and effective practice when working without direct supervision; they must recognise and work within the limits of competence, keeping knowledge and skills up to date and take part in appropriate learning and practice activities that maintain and develop their competence and performance.¹⁴⁸

A primary concern relating to POC is quality assurance. In the mid-1980s and 1990s, several groups of pathologists, particularly clinical chemists, produced guidelines for decentralised laboratory work. Collaboration between pathology laboratories and primary care is essential if POC testing is to be safely and effectively utilised. Primary care practitioners cannot ignore the issues of both internal and external quality control steps in the validation of test results. To produce standardised and clinically effective anticoagulation management, correct procedures need to be followed in terms of internal and external quality control procedures, liaison with the local laboratory for assessing precision and accuracy of the system and standard operating procedures to ensure optimum care.

Standard operating procedures would include clinical governance, risk management and also implementation of risk reduction strategies. This would be achieved by careful patient selection, internal

TABLE 44 Conditions for which respondents would like a POC test to help them diagnose conditions: top 10 in UK (N = 1109)

Condition	Per cent (n)
UTI	47 (521)
PE/DVT	43 (478)
Diabetes	35 (385)
Acute cardiac disease	25 (282)
INR/anticoagulation	18 (199)
Pregnancy	16 (178)
Anaemia	15 (162)
Heart failure	11 (124)
COPD/asthma	10 (116)
Chest infection/cough/LRTI	9 (102)

DVT, deep-vein thrombosis; LRTI, lower respiratory tract infection; PE, pulmonary embolism; STD, sexually transmitted disease; UTI, urinary tract infection.
As it was impossible to split PE from DVT when respondents listed PE/DVT as a single condition, results are lumped together.

TABLE 45 Point-of-care tests that at least 25% of respondents in the UK reported currently using by percentage of GPs who reported using the tests

	UK (N = 1109), % (n)	Total (N = 2770), % (n)
Urine pregnancy test	80 (887)	81 (2236)
Urine leucocytes or nitrite	90 (993)	81 (2234)
Blood glucose	69 (760)	80 (2209)
INR	43 (476)	31 (852)
Haemoglobin	16 (174)	28 (784)
Faecal occult blood	13 (143)	20 (567)
Throat swab for group A streptococci	15 (164)	20 (547)
C-reactive protein	15 (163)	19 (528)
Quantitative β -human chorionic gonadotropin	17 (193)	19 (520)
HbA _{1c}	17 (183)	15 (406)
Nose/throat swab for influenza	6 (61)	12 (328)
Platelet count	15 (163)	10 (290)

and external quality control procedures, a regular audit process and ensuring relevant, complete and accurate documentation of the clinic process.

The internal quality control supplied by the manufacturer should be performed at the start of each clinic, and external quality assurance provided either by collaboration with a hospital laboratory or through a quality assurance scheme, such as National External Quality Assessment Service, should be performed regularly.

Liaison with a local laboratory is essential for support with staff training and the external quality assurance scheme and to refer patients difficult to control to designated specialist care, or if there are any concerns with regard to POC device performance or results.

STEP-UP summary statement With regard to SKILLS, POC tests is attributed a MODERATE degree of implementation difficulty owing to exacting requirements for quality assurance.

Training

The training of health professionals to manage POC should include an understanding of the specific POC device used, setting up and using the device, recording of results and quality assurance materials, health and safety, disposal of sharps and the COSHH regulations.¹²¹

A Department of Health evaluation compared Thrombotrak with a manual system using the same thromboplastin. The authors of the report concluded that, 'The system is extremely simple to use and requires no previous knowledge of coagulation instrumentation]. The two hour training given on-site was completely adequate and, backed up by the instruction manual, ensured trouble free user operation'.⁴⁰⁷

STEP-UP summary statement With regard to TRAINING, POC tests is attributed a MODERATE degree of implementation difficulty owing to the need to identify which to use, what they mean and how to integrate them within existing clinical practice.

Equipment

As with all in vitro diagnostic equipment, new POC equipment should be thoroughly evaluated prior to clinical implementation to ensure that reliable results are consistently obtained.¹⁴⁹ In the UK, this is performed on a voluntary basis at the manufacturers' discretion by the MHRA of the Department of Health. Although no specific guidelines for the INR calibration of POC devices are currently available, it is accepted that calibration should be performed by the manufacturers using the same procedure as conventional laboratory systems. Calibration as performed by the manufacturers typically cannot be altered by the operator. New POC coagulometers are currently under evaluation with the MHRA and will have further field evaluations in the primary care setting. The MHRA investigates, first, the electrical, mechanical and microbiological safety of the device and, second, the performance in terms of ease of use, reliability, imprecision, comparability, calibration, sensitivity and interfering factors.

Studies comparing CRP with procalcitonin found that procalcitonin has greater sensitivity and specificity for distinguishing bacterial and viral infection in hospital settings. However, studies show that procalcitonin does not yet add sufficient value for decision-making in primary care,^{150,408,409} whereas CRP POC testing appears better in correctly predicting the absence of radiographic pneumonia.¹⁵⁰ A Cochrane review concluded that a POC biomarker (e.g. CRP) to guide antibiotic treatment of acute respiratory infections in primary care can significantly reduce antibiotic use.¹⁵¹ Studies included in the final analysis included randomised and cluster RCTs from England, Wales and six other countries to demonstrate that using CRP POC tests in primary care can significantly reduce the initial prescribing rate of antibiotics.

Until fairly recently, high-quality evidence in the form of RCTs to support POC testing has, however, been lacking. A systematic review limited to lipids, HbA_{1c}, INR and urinary albumin-to-creatinine ratio determinations identified RCTs, but none was of sufficiently similar design to allow a meta-analysis.⁴¹⁰ Measurements of HbA_{1c}, albumin-to-creatinine ratio and lipids are of structured care. A RCT conducted in UK general practice randomised patients in practices to have their results by POC test or from the central laboratory.³⁶⁸ The POC test results were available at the time of the consultation with the GP and the outcome measure was the proportion of patients achieving good metabolic control (i.e. HbA_{1c} < 7.0%). On completion of the trial after 12 months, there was no significant difference in the proportion of patients within the therapeutic range (37% vs. 38%). However, the management of patients in the POC test group was not different from that in the group who had normal care. The difference between the results of the

primary and secondary care trials may be due to the presence of better-controlled patients in the UK study compared with the Australian study, all of whom were on insulin.

For a Department of Health evaluation, Thrombotrak was compared with a manual system using the same thromboplastin. Differences in the measured INR were 'small enough to be deemed acceptable'.¹⁵⁴ The trial demonstrated that nurse-led primary care anticoagulation clinics using POC testing and computerised decision support software had comparable outcomes in terms of INR control with routine hospital outpatient management.⁴⁰⁷ The nurses involved were trained by laboratory personnel before managing anticoagulation clinics. Training involved theoretical aspects of anticoagulation management, including INR monitoring and measures of control, as well as practical training in using the POC device and computerised decision support software, and quality control procedures.

A study exploring discrepancies of approximately 20% in INR between two POC systems concluded that systems require improved International Sensitivity Index calibration by manufacturers along with better methods of quality control.⁴¹¹ However, even in so-called expert laboratories there can be significant differences in the INR obtained.¹⁵⁴ An editorial discusses quality issues in relation to providing a safe INR service outside the laboratory.¹⁵⁴ One randomised crossover trial comparing the use of a coagulometer within a community clinic and a hospital laboratory showed that results generally compared well.⁴¹²

Although studies have demonstrated that the use of POC tests for the measurement of INR is feasible and practical, concerns are expressed about discrepancies between results obtained on near-patient testing devices and those obtained in hospital laboratories. However, small differences will naturally occur because of differences in the thromboplastin reagent used to derive the result.¹⁵⁴ More significantly, none of the abovementioned reports indicate significant clinical management differences associated with the use of POC tests.

For other tests that might anticipate strong demand in primary care (e.g. POC-tests for lipids and HbA_{1c}, and non-invasive bilirubin meters), there is often little evidence of clinical utility in primary care.² The Horizon Scanning series has examined several POC technologies. The topics are itemised in *Appendix 4*. POC testing for D-dimer in conjunction with the Wells criteria can rule out lower-leg deep-vein thrombosis in about half of patients presenting with suspected deep-vein thrombosis in primary care.^{2,413}

STEP-UP summary statement With regard to EQUIPMENT, POC testing is attributed a LOW degree of implementation difficulty owing to ease of testing and ready availability of equipment and supplies.

Premises

Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ locates near-patient testing services (such as blood and gas) in the 'near-patient testing room' (contains public sector information licensed under the Open Government Licence v3.0). This document does not provide detailed design guidance on specific rooms and spaces and refers to the following for guidance on generic rooms and spaces: Health Building Note 00-03, *Clinical and Clinical Support Spaces*.¹⁵³ It is unclear what tests should be provided and what the implications are with regard to the management of stock.

STEP-UP summary statement With regard to PREMISES, POC testing is attributed an UNCERTAIN rating for implementation difficulty owing to the shortage of studies describing how tests might be accommodated. Co-ordinating approaches with regard to storage may relate to genetic tests.

User perspective

Point-of-care tests do not simply offer improved accessibility to GPs and other practice staff. By far the largest potential market for POC is believed to be the patient self-management market. For example, the monitoring of anticoagulation through INR testing technologies is offered by increasingly accessible and affordable technologies. Paradoxically, the greater the ease with which tests might be severed from existing secondary care domination of supply by primary care services, the correspondingly greater the likelihood of

these tests bypassing primary care altogether, by going direct to consumer. Clearly, the expansion of POC testing facilities in primary care should factor in the supply and demand of self-management technologies.¹⁵⁴

A qualitative systematic review of seven studies has summarised the perceived benefits of POC tests.¹³ GPs welcomed POC tests because they offered the prospect of enhanced immediate diagnosis and treatment. Diagnostic POC tests reduced diagnostic certainty and increased confidence in clinical decisions. POC tests were particularly welcomed as a way of ruling out serious infections. This was found for both GPs who had used and those who had not used diagnostic POC tests.

Although POC tests were perceived, on the whole, to enhance patient care (if the tests were accurate), exceptions were noted. Diagnostic POC tests would not be helpful when serious complications arise from viral illnesses. It was believed that patients would be convinced, reassured and more satisfied in their GP's decisions if POC tests had been used, compared with if they had received no test. In particular, a test result confirming a GP's decision not to prescribe antibiotics would help them to 'sell' this decision to patients and manage patient expectations for antibiotics, leading to shared decisions with patients. GPs with different levels of experience of using diagnostic POC tests had similar perceptions that they would help to reassure patients and lead to more effective targeted treatment without alienating or upsetting patients.

A general assumption is that patients would like to have POC tests available. However, the qualitative review found that several participants were concerned that patients may not like testing.^{13,414} This may be a particular concern for procedures involving children.¹³ Not all GPs feel comfortable interpreting and explaining diagnostic test results, particularly intermediate results which could lead to increased uncertainty in patients. They expressed a need for training.¹³ Overall, primary care clinicians believe that POC tests increase diagnostic certainty, help target treatment, educate and empower patients, and improve the relationship between clinicians and patients by enhancing communication and shared decision-making. Clinicians were also concerned about cost, over-reliance – in that POC tests could undermine clinical skills – and limited usefulness.¹³

Some issues are not unique to POC testing, but also apply to laboratory testing in general. In addition to the barriers to POC test use identified here, other reasons for the lack of widespread use may include a lack of needs assessments of primary health-care clinicians, resulting in discordance between the tests that they want/would use frequently and those that are produced.

The findings of the qualitative systematic review emphasise, for POC tests specifically but also for community diagnostics more generally, that the issues are not simply technical and organisational. The attitudes of primary care clinicians are integral to understanding if and how POC tests are to be implemented more widely. Further qualitative systematic reviews associated with community diagnostic technologies will help in understanding and anticipating the user (in the broad sense of clinician and patient). In particular, communicating the benefits of individual POC tests more widely and more precisely may help in stimulating more widespread adoption of POC testing in primary care. The review focused on blood POC tests in primary care; further research is needed to confirm whether or not the issues raised here apply to other types of POC tests (e.g. urine tests, respiratory samples).

Both GPs and patients appear to find using CRP acceptable, with one Dutch study showing CRP POC testing to have little effect on GP workload in 50% of practices.⁴¹⁵ Patients were satisfied to be provided with the results of a reassuringly low CRP POC test rather than receiving an antibiotic prescription. CRP testing has a role as an adjunct in effective communication with patients; clinicians and patients all recommend seeing the CRP in conjunction with the overall assessment and caution against over-reliance on CRP results in isolation of clinical assessment.

Moreover, procalcitonin has not yet been proven to be suitable for deployment as a POC test in general practice, with a turnaround time (depending on the system) of 18–30 minutes; CRP POC tests, by contrast,

have a turnaround time of < 5 minutes, thereby giving a result within the ambit of a standard NHS GP consultation.

Primary care staff may derive increased satisfaction from being able to resolve patient problems without being dependent on referral for tests or on a further delayed encounter when results are available. However, referral for confirmatory tests and for treatment may still be required, so this advantage does not apply in all circumstances.

Studies of patient satisfaction consistently reveal that most patients like POC INR testing as it is typically more convenient for them, contributing to patient-centred care. A UK GP trial found no significant differences in the satisfaction of UK patients receiving POC testing and that of patients who had their HbA_{1c} levels from the central laboratory.⁴¹⁶ In contrast, an Australian trial found that satisfaction generally increased for patients, POC test device operators and GPs over the course of the trial.³⁶⁴ An observational study also found a significant increase in patient satisfaction after POC testing, with patients reporting that POC testing was convenient and motivated them to manage their condition better.⁴¹⁷ Quantitatively significantly more patients preferred a POC INR testing service when compared with usual care.⁴¹⁸ Patients demonstrated improved capacity to make appointments, spent less time at the appointment, experienced less pain and received improved communication about their medication dosage.⁴¹⁸

STEP-UP summary statement With regard to USER PERSPECTIVES, attitudes to POC testing between patients and clinicians differ, resulting in a MODERATE rating for implementation difficulty from clinicians and a LOW rating for implementation difficulty for patients.

Primary–secondary interface

Provision of primary care POC test diagnostic services is variable and may be dependent on the corresponding provision of local hospital facilities. In seeking to reduce variation, some PCTs are commissioning laboratories to provide a satellite service from the central laboratory to primary care sites. Such laboratories employ a hub-and-spoke method of delivery but have not been evaluated for clinical effectiveness.

The General Medical Services Contract offers remuneration for a 'national enhanced service' for anticoagulation services, which includes the development and maintenance of a register, a call and recall system, appropriate training and audit procedures. Funding for the service is given for four different levels of service, with level 4 accruing the highest funding.

Testing in primary care reduces dependency of primary care clinicians on hospital-based services, many of which are outside their own control. Increasingly, primary care stakeholders are being involved in the specification and development of hospital-based diagnostic services operating, in fact, as the informed customer. Other dependencies, that will necessarily continue for most modalities, lie in access to training, advice and specialist referral.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, POC testing is attributed a MODERATE degree of implementation difficulty as it may facilitate earlier diagnosis but has a potentially unpredictable effect on demand for secondary care services.

Conclusion

Evidence so far indicates that POC testing systems have great potential for primary care with clear quality-of-life benefits for patients. The implementation of POC testing technologies requires collaboration between manufacturers, pathology laboratories and general practice as well as adherence to a recognised external quality assurance scheme. Diagnostic technologies need to improve both accuracy and precision.

The increased availability of a test is likely to increase the usage of that test. Increased use may indicate previously unmet need, may constitute an inappropriate response or may simply reflect a growth in

demand. In practices where desktop analysers are introduced, the rate of testing increases, but these extra tests do not inform changes in diagnosis or management.¹⁵⁴ However, such studies often fail to acknowledge the effect of tests in reducing the uncertainty experienced by both doctor and patient.

From the perspective of GPs, the likely benefits of introducing POC tests include increased diagnostic certainty, more efficient care, and fewer (re)consultations.¹³ Barriers to the implementation of POC tests must be addressed, some by primary care and others elsewhere. The accuracy of POC tests in primary care populations must be addressed by manufacturers. Policy-makers and clinicians should carefully consider the role and impact of POC tests in primary care in relation to GP roles. Against a backdrop of reductions in health service funding, attention must be paid to how POC tests are to be funded.¹³

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Radiology/X-ray

Definition: an X-ray is a quick and painless procedure commonly used to produce images of the inside of the body (NHS Choices).

This map includes chest X-ray and partial CT scanning.

This map excludes echocardiography and MRI.

Contains public sector information licensed under the Open Government Licence v3.0.¹⁵⁵

Background

The Department of Health's document *Our Health, Our Care, Our Say* spelled out a commitment to providing more diagnostic testing in primary care.³⁹⁹ This is seen as a route to reducing the total number of secondary care referrals and speeding up the patient journey when referral is appropriate. For this to occur requires that GPs are comfortable with a greater range of diagnostic tests and confident that better direct access to testing will not lead to a reduction in patient care and outcome.

Radiology involves three components: acquiring a digital image, using a computer to analyse the computer-based image and information management (including picture archiving and storage). Increasingly it involves the transmission of images through communication technologies so that images and reports can be viewed anywhere in the NHS. GPs are beginning to take an interest in seeing their patients' medical images, especially with the development of special interests and primary-to-primary referrals. Concern has been expressed that 'as the availability and power of imaging grows, skills in history taking and physical examination decline'.⁴¹⁹

Consultation for a road map for the RCGP in 2007 found general support for the concept of community hospitals, or a modern variant of a diagnostic centre, assuming that they were properly resourced. The report articulated that 'The time has come for diagnostic radiology to sever its secondary care cord and move into primary care'. Facilities based in community hospitals would house MRI, CT and ultrasound, with GPs and radiologists working together to get the right diagnosis.³

There is a drive to improve support for patients at home and in the community by enhancing primary care services and thus avoiding unnecessary referrals to secondary care. For this to be successful, there needs to be appropriate support for clinical colleagues in primary care.

It is well established that early diagnosis is key to the management of such patients. Not only does such early diagnosis lead to better outcomes but a negative investigation can exclude disease, reassuring the patient and doctor and avoiding further unnecessary anxiety.

It is, therefore, timely to consider what constitutes best practice in clinical imaging services focusing on primary care. In doing so this guide will support local NHS clinical imaging departments in remaining the preferred provider of imaging services to their local CCGs.

There is increasing momentum in improving access to diagnostic imaging for primary care physicians and allied health professionals.⁴¹⁹ Although direct access arrangements have existed for several years in many centres in the UK, the shift of diagnostic resource from secondary to primary care creates a fundamental change regarding how service provision may operate.

Many hospital trusts have developed direct access services for plain radiography provision to primary care over the past few years, with a smaller proportion providing access to ultrasound and MRI. A high proportion of independent hospitals also offer direct access to imaging to GPs, usually through local engagement with PCTs. Hence the RCR continues to promote its *Making the Best Use of a Department of Radiology* document.²¹⁸ However, primary care physicians in many locations feel that there are significant limitations in their freedom to access imaging, particularly CT and MRI, at secondary care locations. Furthermore, deficiencies persist in relation to the timeliness and convenience of access to imaging and the communication of imaging results provided by hospital trusts. In short, there are issues relating to the level of 'customer service' provided by secondary care to primary care physicians.⁵¹

Clinical Commissioning Groups have strong incentives to promote direct access to diagnostics. Many CCGs are seeking to improve the efficiency of the service supplied by the imaging providers with whom they choose to contract. There is an impetus to reduce waiting times for diagnostics to ≤ 2 weeks; to improve patient choice and convenience in terms of the location and time of scanning; and to refocus diagnostic provision onto primary care. Many PCTs are embracing the independent sector market to achieve timeliness of diagnostics provision and to devolve access to diagnostics far more widely and 'closer to home'.⁵¹ This 'power shift' from secondary care to primary care and from NHS-led provision to the independent sector has major implications for UK radiologists and radiology services.⁵¹

STEP-UP summary

Skills

Radiology is a well-documented profession with well-developed education, training and curricula. For example, the RCR produces a *Specialty Training Curriculum for Clinical Radiology*.¹⁵⁶ Training must include the equipment and its intended application. It will also include related topics such as health and safety, radiation protection and control of infection.¹⁵⁷ RCR guidance for clinical radiographers emphasises quality assurance issues. It would be challenging for a small radiological unit based in primary care to achieve the adherence to standards and quality control required by a fully-established radiological department.

STEP-UP summary statement With regard to SKILLS, radiology/X-ray is attributed a MODERATE degree of implementation difficulty owing to the need to satisfy the expectations created by the curriculum and quality assurance procedures.

Training

General practitioners and GP educators must ensure that primary care is armed with the appropriate knowledge and tools to take advantage of the shift in the imaging paradigm.⁴¹⁹ The Health and Social

Care Act 2012⁴²⁰ directed a specific focus on the commissioning of clinical imaging services, under the 'any qualified provider' agenda. Commissioners must ensure that clinical and quality standards are met. Imaging must be undertaken in line with accepted, agreed evidence-based guidelines, with full knowledge and application of statutory obligations, in particular the *Ionising Radiation (Medical Exposure) Regulations 2000 (Statutory instrument 2000 No. 1059)*⁴²¹ and subsequent amendments.

Patients should have timely access to appropriate imaging provided by a service with proven clinical governance structures in place, by appropriately trained staff using appropriately maintained equipment, with underlying compliant 24/7 IT support. Imaging services should have knowledge of, and access to, necessary onward referral pathways.

Comprehensive clinical imaging services in the NHS provide patients, GPs and other referrers and commissioners with direct access to essential core services. The quality of any clinical service can be judged by patient outcomes, patient safety, patient and user experience and efficiency. Five components need specific attention:

1. patient access
2. patient information
3. GP/referrer access
4. clinically appropriate imaging
5. integration into pathways of care.

The RCR and the SCoR have developed the ISAS and the associated accreditation scheme. Patients, GPs, referrers and commissioners can be assured that ISAS-accredited services are delivering the highest quality of services.

Potential sites for primary care clinical services include larger health-care centres, stand-alone diagnostic centres and, in some situations, mobile options. Commissioners need to balance improved access against the potential increased cost and reduced efficiency of service/staff utilisation.

An important issue when agreeing such standards within an imaging service for primary care is that the patients' care and well-being is not compromised either by unnecessary delays in the result of an imaging study being available or by an incomplete or substandard report being produced because not all of the required information or expertise was available within a deadline.

Patient choice requires that patients have access to relevant information about the quality of any imaging service that is available to them. Such information should include details of the qualifications and experience of those HCPs providing the service and details of how such a service is integrated into the care pathway. Referring clinicians should inform the patient of the purpose of the investigation and how it may affect their management. Although they may seek to minimise anxiety that serious life-threatening conditions might be uncovered, such conversations should occur before the referral, with both referrer and patient being aware of the limitations of imaging and the possibility of no definitive result or outcome.

STEP-UP summary statement With regard to TRAINING, radiology/X-ray is attributed a HIGH degree of implementation difficulty owing to extensive and specialist training requirements.

Equipment

One study in primary care reports that patient management by the GP changed in 60% of patients following chest radiography. Chest radiography substantially reduced the number of referrals and initiation or change in therapy, and more patients were reassured by their GP. This confirms that chest radiography is an important diagnostic tool for GPs.¹⁵⁸

STEP-UP summary statement With regard to EQUIPMENT, radiology/X-ray is attributed a LOW degree of implementation difficulty owing to established practices and procedures for using X-ray equipment.

Premises

Radiation protection is a major consideration when using X-ray equipment. Health Building Note 11-01, *Facilities for Primary and Community Care Services*, locates X-ray services in a purpose-built 'X-ray room' with lead shielding (contains public sector information licensed under the Open Government Licence v3.0).⁴⁶ It suggests the idea of an 'imaging cluster' that will require such facilities as X-ray rooms, image control/reporting room and changing rooms, suggesting that these facilities should be clustered together alongside other dedicated imaging rooms, where provided. Health Building Note 11-01 also provides an illustration of the imaging cluster concept.⁴⁶ Examination rooms housing X-ray equipment should incorporate radiation shielding to contain the controlled radiation area. Rooms have to meet the requirements of the Ionising Radiations Regulations 1999,¹⁶⁰ which have much stricter limits than earlier regulations on radiation exposure to the public from man-made sources of radiation. Chapter 4 of Health Building Note 6, entitled 'General X-ray imaging or radiography',¹⁵⁹ includes specifications for space and for basic equipment. It does not specifically outline requirements for a primary care setting.

STEP-UP summary statement With regard to PREMISES, radiology/X-ray is attributed a MODERATE degree of implementation difficulty owing to the need for accommodation with radiation protection and shielding.

User perspective

When ordering radiological tests, clinicians in primary care consider such factors as the potential impact on the clinical outcome for the patient, the probability of significant findings based on the clinical picture and the sensitivity/specificity of the test.⁴²² Secondary considerations include patient reassurance, medico-legal and compensation issues and the costs and risks of the investigation. It is not always possible to realise benefits from a normal examination into patient reassurance.¹⁵⁸ In one primary care study, only 50% of patients felt reassured by having had a chest radiograph and 25% recorded that the radiograph was of little value to them because no referral or treatment followed the investigation. Decision-making in primary care, especially in patients with chronic conditions, is less often influenced by the radiological report.

Once patients have had an imaging investigation, they expect the results to be available to their GP without delay. It is desirable to report the majority of cases within 1 working day. Urgent cases in which the report has an impact on the immediate management of the patient need to be reported at the time of examination and to be made available to the referrer. All reports should be communicated electronically via a reporting system that can push both key images and the report directly into the patient management system. This needs to incorporate a clear audit trail with regard to receipt/action. An agreed system should be in place for the handling of urgent or unexpected results in line with the RCR guidance.

Timeliness of test, and then the result, is thus a key question for patients when referred for an imaging test. Convenience of time and place is a third important consideration. A prompt and appropriate response helps in meeting patients' psychological and social needs.

STEP-UP summary statement With regard to USER PERSPECTIVES, radiology/X-ray is attributed a LOW degree of implementation difficulty owing to the familiarity of X-ray arrangements.

Primary–secondary interface

The Department of Health has been seeking to facilitate imaging tailored to the needs of primary care, and thus combat a perceived 'secondary care imaging agenda'. The independent sector is involved in this process, particularly because the provision of diagnostics by the independent sector has created new expectations for imaging services, especially in relation to waiting times and quality of service. The involvement of the independent sector in shifting imaging from secondary to primary care is perceived as being 'disruptively innovative'. It is viewed as important in the continued drive to achieve 'zero waits' for the diagnostic aspect of clinical pathways. In support of this, tariffs for primary care direct access have been unbundled from overall clinical pathway tariffs.⁵¹

When GPs have access to diagnostic testing from primary care and clear referral guidelines they are likely to use imaging resources as efficiently as hospital doctors.⁴²³ However, local variation in direct access to imaging tests remains, especially for the more complex investigations. Imaging must be undertaken primarily to benefit patients. If implemented correctly, improving imaging access should shorten the patient pathway, facilitate better patient care and produce savings across the health-care economy. One study reported a change in proposed management for 60% of patients referred for chest radiography from primary care.⁴²⁴ Benefits to the referring practice included streamlined referrals to secondary care (first-time referral to the appropriate specialty), an overall reduction in secondary care referrals and improved prescribing.

The aspirational goal for clinical imaging services is to have a no-wait culture through appropriate and timely 'choose and book' arrangements. Almost all imaging should be performed as soon as possible from receipt of referral; this should normally occur within 2 weeks. This does, however, have clear implications for resources but would be expected to deliver tangible benefits, not only in shortening patient pathways but also in reducing secondary care referrals and hospital admissions.

A secondary care provider seeking to compete in the 'direct-access imaging market' will probably need to increase the local equipment and staffing resource.⁵¹

Radiology services, and radiologists themselves, will face significant pressure either to demonstrate optimised efficiency or to adapt to new working arrangements tailored to increase throughput and work intensity. The radiology profession may experience pressure to undergo benchmarking of its performance. Radiology departments (including radiologists) may need to become more 'customer-friendly', both to primary care professionals and to their patients. The way in which reports are structured and communicated by radiologists will also need to be adapted to for primary care.⁵¹

Those commissioning imaging services should seek to offer an integrated pathway across primary and secondary care. They should seek to avoid destabilising other necessary imaging services to the population for which they are responsible, for example 24/7 emergency access, which requires an increased workforce and resource overheads. The use of alternative providers may result in a reduction in staff and resources that compromises other emergency and other urgent imaging services within the locality. A further concern is education and training issues. If a significant volume of imaging is delivered outside the traditional NHS providers, this will potentially reduce trainees' access to appropriate learning opportunities and material, as already experienced with, for example, the outsourcing of ultrasound and musculoskeletal MRI.⁴²⁵ Commissioning groups should not allow patient care to be disadvantaged by inappropriate financial drivers.

When primary care commissioning is supported with auditable standards for waiting times and turnaround times, there is the prospect that follow-up examinations could be booked at the time of the first consultation. The radiological report can, therefore, be available in a timely fashion, reducing GP frustration and patient delay. Traditional providers of NHS clinical imaging, based in secondary care hospitals, must seek to balance demands from both secondary and primary care for their services. Decisions on providing such services must be patient-centred and seek to secure the best outcome for the patients.

Despite pessimistic predictions, direct access to diagnostics in general practice appears to increase demand for testing but does not reduce appropriateness of testing or diagnostic yield.^{383,423,426} Direct access to CT scanning and MRI led to a good diagnostic yield in a study from Edinburgh. When guidelines for chronic daily headache were provided to GPs facilitating appropriate access to CT of the brain, the referral rate was only 1.2%. A London-based group explored the effect on patient management of direct access to diagnostic imaging. Three core components supported appropriate GP referrals – (1) referral guidelines, (2) structured referral forms and (3) clinical triage with telephone feedback to GPs – suggesting alternative tests or contraindications to testing.^{383,423,426} Thirty-two per cent of patients referred for echocardiography were found to have an abnormal report but only 29% of these were referred to secondary care as the majority were managed in primary care. Overall, 71% of patients referred for diagnostic imaging were managed in the primary care setting.¹⁶¹

Alternatively, when direct-access imaging is supplied locally by the independent sector, secondary care providers may have to downsize, impacting on radiologist recruitment and existing work plans and patterns. Radiologists might adopt a mixed portfolio, working for both their NHS employer independent-sector providers. Increasingly, secondary care radiologists will be required to provide 'second opinions' on imaging and reports sourced externally. Such demands will likely have to be factored into future job planning.⁵¹

Logistical difficulties relating to independent provision of direct-access diagnostics may occur when suboptimal clinical referral information or lack of access to previous imaging in the primary care setting increase the need for unnecessary subsequent investigation or referral. Nevertheless, the shift to direct access for imaging seems so strong that such considerations are unlikely to prove 'show stoppers'.⁵¹ This paradigm shift in imaging provision is likely to have wide-reaching effects on the way in which radiologists practise, and requires proactive involvement by UK radiology bodies.⁵¹ The limited uptake of direct access by GPs highlights a need to engage GPs in the planning and implementation of new services.⁴²⁷

Direct access may result in reduced waiting times from presentation to testing and treatment.⁴²⁷ A review found that direct access to diagnostic tests allows GPs to manage a substantial number of patients who would otherwise have been referred to the hospital outpatient department.⁴²⁸ Limited information is available on costing associated with increased access to diagnostics for GPs versus hospital-based access only. An appropriate costing model would factor in the cost of an initial outpatient department appointment, the average number of patients referred for CT from the OPD and the average number given a further follow-up appointment minus the cost of the direct access to CT and reduction in referral to outpatients departments.⁴²⁹ The DAMASK (Direct Access to Magnetic Resonance Imaging: Assessment for Suspect Knees) RCT for direct access to MRI for knee problems in the UK resulted in increased costs, offset by a statistically significant improvement in health-related quality of life.⁴³⁰

In a survey of Irish GPs, O'Riordan *et al.*^{383,426} examined the availability of radiologic and endoscopic services. In all services, access to diagnostics for public patients is unacceptably long when compared with that for private patients. As a consequence, GPs refer patients inappropriately to overcrowded emergency departments in order to access diagnostic tests. This can be unnecessarily traumatic for elderly patients, and places an extra costly burden on hospital services. The vast majority of GPs indicated that increased access to diagnostics would help them to reduce the number of referrals to emergency and outpatient departments, reduce unnecessary admissions and improve the overall quality of referrals.

STEP-UP summary statement With regard to the PRIMARY–SECONDARY INTERFACE, radiology/X-ray is attributed a MODERATE degree of implementation difficulty owing to uncertainties about the new provider arrangements.

Conclusion

Imaging services are facing what has been described as a paradigm shift. Although the increase in competitiveness and a market orientation ultimately holds the prospect of higher standards and expectations, this is being realised on only a small local scale at present. There is considerable uncertainty in this particular area of diagnostic provision, making it very difficult to predict what will happen in the short term.

Radiology (R1–32)

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Respiratory tests

Definition: respiratory tests measure how much air is moved in and out of the lungs, how successful the lungs are at getting oxygen into the blood stream and if there are problems in the lungs that can be seen in images of the lungs.

This map includes lung function tests.

This map excludes spirometry (see *Spirometry*) and CRP (see *Point-of-care testing*).

The Department of Health outcomes strategy for people with COPD and asthma⁴³¹ and its companion document⁴³² outline the aspirations for high-quality care in COPD and asthma. There is, however, evidence of suboptimal care, including substantial variation in standards in COPD care across England⁴³³ and deficiencies in the assessment of the acute asthma attack.⁴³⁴

STEP-UP summary

Skills

A systematic review of 30 primary care studies from around the world¹⁶² evaluated the diagnostic ability of GPs in relation to respiratory diseases, such as acute respiratory infections, tuberculosis, asthma and COPD. In relation to asthma and COPD, studies show either overdiagnosis or underdiagnosis. Variation for asthma

varied from 54% underdiagnosis to 34% overdiagnosis, whereas for COPD this ranged from 81% for underdiagnosis to 86.1% for overdiagnosis. For acute respiratory infections, inclusion of a complementary test for diagnosis led to an improvement in diagnostic accuracy. GPs showed a low level of knowledge about tuberculosis. The review highlighted a significant need to improve the skills and knowledge of GPs.

With increasing affordability and recognition of its clinical applications, there is an increasing interest of the role of the oximeter in primary care. Data concerning the influence of pulse oximetry on patient management and on the extent of oximetry use in the general practice setting are scarce. Several studies identify the role and potential of the oximeter as a screening tool in assessing hypoxia in primary care.^{163–166} Pulse oximetry technology has relevance to COPD, asthma, community-acquired pneumonia and paediatric assessment, as well as for preparations for a possible influenza pandemic, trends in primary care emergency-care provision, demographic changes and alterations in the case mix of patients encountered in primary care. Other obvious trends include the increasing prevalence of adults with congenital heart disease encountered by GPs. Increased use of pulse oximetry (supported by training and quality assurance) must be appropriate. Clinically appropriate testing should ensure that the expected health benefits exceed the expected negative consequences by a sufficiently wide margin that the test is worth doing.

Factors affecting displayed readings and causing errors relate mainly to light transmission, perfusion or pulse detection. Pulse oximetry can be inaccurate in patients with poor peripheral circulation, excessive sweating, presence of carbon monoxide (e.g. in smokers), nail varnish/synthetic nails, light interference, as a motion artefact, abnormal haemoglobin and dark or jaundiced skin.⁴³⁵ Documentation of the pulse oximetry test, as with all clinical procedures, is essential. This should detail the actual reading, any activity (at rest or walking), whether the patient was breathing room air or oxygen (if so, what flow rate and percentage) and any other factors that might have influenced the reading (e.g. tremor or cold hands).

STEP-UP summary statement With regard to SKILLS, respiratory tests are attributed a LOW degree of implementation difficulty owing to the existence of well-established testing technologies.

Training

A draft working document outlines possible roles for a GPwSI, using respiratory medicine as a model. It envisages the role of a GPwSI in respiratory medicine as primarily one of leadership and service development (i.e. as a GP lead in respiratory medicine in a primary care organisation). This contrasts with specialties, such as ENT or dermatology, when the GPwSI has a predominantly clinical role. In addition, the draft document envisaged that the 'gold standard' qualification for a GPwSI would be a diploma in respiratory medicine. A modified draft document proposes a hybrid framework that combines a generic RCGP framework with a respiratory disease-specific framework. Improving access to spirometry was agreed as a top priority by GPwSIs in respiratory care.¹⁶⁷ The Primary Care Respiratory Society UK has developed quality standards which can act as the basis for a training programme.⁴³⁶ GPwSIs in respiratory care are envisaged to support a nurse-led spirometry service.¹⁶⁷

The guideline recommends that pulse oximetry should be available in all locations where emergency oxygen is used, including primary care. Pulse oximetry should be used if considering oxygen administration in acute stroke and myocardial infarction, as high flow oxygen has been shown to produce vasospasm and potentially worsen outcomes.

STEP-UP summary statement With regard to TRAINING, respiratory tests are attributed a LOW degree of implementation difficulty owing to the ease of use of most equipment.

Equipment

Pulse oximeters give a non-invasive estimation of the arterial haemoglobin oxygen saturation.⁴³⁷ The gold standard for measurement of oxygen saturation remains arterial blood gas analysis. Arterial blood gas analysis is invasive, painful, time-consuming and costly, provides only intermittent information on patient status, and there is a delay between sampling and results. The measurement of pulse oximetry is a suggested

disease management strategy to identify patients with chronic lung disease who would benefit from long-term oxygen therapy.⁴³⁸ Performing spirometry for the detection of airflow obstruction in symptomatic patients will probably identify those who will benefit from bronchodilator therapy. However, as yet there are no feasible tests to assist in targeting β_2 -agonist and antimuscarinic inhaled therapy specifically, nor are there tests to identify who will benefit from other therapeutic options. Pulse oximeters are increasingly used during endoscopy and other diagnostic procedures, and as part of pulmonary function testing. Data on the role of pulse oximeters in detecting hypoxia in general practice are limited. A minority of GPs reported that they used a pulse oximeter to measure pulse rate (9%) or to assess respiratory status (20%).¹⁷⁷

It is not possible, within the constraints of this mapping review, to cover all types of respiratory equipment, so pulse oximetry has been used as an example. Spirometry is covered separately (see *Spirometry*) and also features in the accompanying review on breathlessness symptoms.

Pulse oximeters are available, highly portable and increasingly less costly to purchase.¹⁸¹ Many models are available for purchase from numerous manufacturers.⁴³⁷ Prices can vary from around £50 to £300. Sizes vary from small pocket-sized models to bench-top displays. Smaller versions are more easily 'misplaced'. Considerations when choosing the instrument include size, battery capability and robustness.¹⁷⁹ In primary care, especially when carried in diagnostic bags, the equipment needs to be reliable, reproducible, safe, accurate, robust, portable, cost-effective and simple to use.¹⁷⁸ If buying pulse oximeters for a practice/community setting is being considered, it may be worth discussing with colleagues who use pulse oximeters regularly (especially if they use pulse oximeters in a community setting, e.g. respiratory nurse specialists). The NICE Centre for Evidence Based Purchasing has published an evidence review, market review and buyers' guide for pulse oximeters, providing a list of pulse oximeters with evidence of accuracy and performance.¹⁷⁹ Pulse oximetry is as useful in the management of children as in adults, and the same ranges are applicable. Many 'adult' pulse oximeters can be used in children over the age of 2 years. Below the age of 2 years more specialised oximeters are generally preferred.

Most available pulse oximeters are accurate between oxygen saturations of 70% and 100%, with a range of $\pm 2\%$. The oximeters are calibrated during manufacture and most have an internal check system to ensure that calibration remains valid. Those using the machine are responsible for ensuring that it is in good working order, stored correctly (according to manufacturers' recommendations) and regularly serviced. Probes should be appropriate for the site of monitoring (e.g. finger or ear sensor), cleaned regularly and checked for obvious faults such as loose connections or wires.

The use of pulse oximetry in primary care is still in its infancy.¹⁸³ Its advantages are that it is quick, non-invasive, reproducible and accurate in most circumstances, and minimal training is necessary. Its disadvantages are that it needs maintenance, has accuracy limitations in some patients and may not provide a clinical benefit to patient care if used indiscriminately. Practices planning to use oximetry in daily practice need to consider how they will handle an isolated low reading in an otherwise well patient, and under what circumstances readings should be taken. The implications for an individual general practice depend on the population demographic and the resources or time used by having an oximeter in the surgery. A portable pulse oximeter costs £300–400 and needs recalibration every 3 years. If a practice considers it appropriate to buy spirometry equipment and ECG machines, purchase of an oximeter is of a similar degree.

Probes are an infection control risk. Cleaning procedures, according to manufacturers' recommendations, must be performed between patients.¹⁸¹ Dirty probes can also reduce the accuracy of results because the light will not be effectively transmitted. Risks associated with pulse oximetry include burns and pressure ulcers but this is due to prolonged use at a single site, which would rarely be an issue in primary care.

STEP-UP summary statement With regard to EQUIPMENT, respiratory tests are attributed a LOW degree of implementation difficulty owing to portability, increasingly cheap equipment and ease of use.

Premises

Little detail is available on the implications of respiratory tests for primary care premises. If patients are being assessed in an area with a high level of artificial light (e.g. operating theatre fluorescent lighting), this can falsely reduce the readings.^{180,181}

STEP-UP summary statement With regard to PREMISES, respiratory tests are attributed an UNCERTAIN degree of implementation difficulty owing to the lack of detail on storage and stock space requirements.

User perspective

Interviews with family practitioners¹⁷⁴ found that they considered pulse oximetry especially of value when on an out-of-office-hours shift, as a supportive tool to decide whether or not to send a patient to an emergency department or to refer them to a medical specialist. The family practitioners also considered pulse oximetry of additional value to direct their decisions on which medication to prescribe in case of an exacerbation of COPD. All interviewed family practitioners stated that a pulse oximeter should be included in the standard equipment package of a practitioner. They considered pulse oximetry as an adjunct in diagnostic assessment of patients, not a full diagnostic tool by itself.

Pulse oximetry, as an alternative to arterial blood gas monitoring, avoids the pain associated with that invasive procedure. A qualitative study of patients' experience of spirometry found that whereas patients were generally ambivalent about spirometry, they unanimously expressed abhorrence and dread associated with arterial blood gas.⁴³⁹ Patients also expressed variation in a clinician's proficiency in undertaking the procedure accompanied by relief when they were able to perform this speedily, successfully and with minimal discomfort. Local anaesthesia mitigates the painfulness of the arterial blood gas procedures but this is not universally offered.

To reduce the likelihood of inaccurate readings in patients undergoing pulse oximetry, HCPs should always ensure that a patient's nail varnish is removed, if present, a patient's hand is warmed if cold on presentation and that the probe is correctly positioned and clean. Two particular challenges arise when measuring oxygen saturation in young children. First, they may be difficult to examine and not want to stay still while the oximeter reading is taken. Second, small digits (fingers) are more likely to have poor perfusion and a reading may not be obtainable.

STEP-UP summary statement With regard to USER PERSPECTIVES, respiratory tests are attributed a LOW degree of implementation difficulty as they tend to be well understood and well tolerated.

Primary–secondary interface

Several countries have developed respiratory assessment units to improve the diagnosis of respiratory diseases such as asthma and COPD and to overcome problems with misdiagnosis. These services are heterogeneous and may include spirometry,¹⁸⁷ review of medical history⁴⁴⁰ or radiography and oxygen saturation assessments.²⁷⁴ The review may consist of paper-based information or may involve a face-to-face review or consultation²⁹² with components of the diagnostic services mentioned above.²⁷⁴ The services are also delivered by a diverse range of HCPs such as respiratory nurses,²⁷⁴ GPs²⁷⁵ or respiratory specialists.²⁹⁰ Centralisation of spirometry via a dedicated service has previously been discussed as a solution but has not been trialled in the UK.⁴⁴¹ To date, UK models have included within-practice services, peripatetic services and centralised services, usually in a local hospital.

A community respiratory assessment unit was established to optimise diagnosis of respiratory disease by providing focused history-taking, quality-assured spirometry and evidence-based guideline-derived management advice.¹⁸² Based in a London secondary care hospital, this was a nurse-led facility, staffed by two specialist respiratory nurses with extensive experience of caring for respiratory diseases in both hospital and the community. Access to a respiratory specialist for advice was always available. All local GPs had access to the service. GPs were informed about the unit by means of a letter from the executive director of the PCT, as well as a personal visit from the community respiratory assessment unit nurses to each primary

care practice. A 4-year review found that one-third of suggested diagnoses of COPD by the GP were incorrect, resulting in the inappropriate prescribing of inhaled therapies. The authors identified significant financial, ethical and safety implications and highlighted a need for either diagnostic centres (community respiratory assessment unit) or alternative peripatetic practice-based services operating to quality-controlled standards. Similar findings have been reported in a UK cross-sectional study.⁴⁴²

STEP-UP summary statement With regard to the PRIMARY-SECONDARY INTERFACE, respiratory tests is attributed a MODERATE degree of implementation difficulty owing to dependencies on follow-up secondary care diagnosis and treatment.

Conclusion

The evidence base to support pulse oximetry is limited, but there are several areas in which further work may demonstrate benefits from the application of this technology in primary care.¹⁸³ Quantitative studies involving the rate of admission to hospital of acute respiratory illness might evaluate this device further in acute illness scenarios. Further qualitative studies could examine GPs' experiences of the use of portable oximeters. It is conceivable that the oximeter could be used in health promotion, for example in encouraging patients to give up smoking. Although no clinician would base treatment solely on its readings, there is some evidence for the usefulness of pulse oximetry in general practice. It is not yet clear whether or not its use has any effect on diagnosis or patient-defined outcomes.

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Spirometry

Definition: spirometry is a simple test used to help diagnose and monitor certain lung conditions by measuring how much air someone can breathe out in one forced breath (NHS Choices).

This map includes portable spirometry.

This map excludes other respiratory tests (see *Respiratory tests*).

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Spirometry measures air flow and volume. Spirometry identifies the presence of airflow obstruction; this may be reversible as in asthma or fixed as in COPD. Spirometry is the gold standard for the diagnosis, assessment and monitoring of COPD, and may assist the diagnosis of asthma. It can also contribute to the diagnosis of other causes of dyspnoea. There is no single diagnostic test for COPD. Spirometry is used to confirm or refute COPD after comprehensive clinical history has identified risk factors and symptoms. There is, however, evidence of suboptimal care, including variation in the quality of primary care spirometry.

Background information on the clinical effectiveness and cost-effectiveness of spirometry is largely derived from the primary care diagnostic technology update entitled *Spirometry in primary care for case finding and management of chronic obstructive pulmonary disease*.⁴⁴³ A 2005 technology assessment from the US Agency for Healthcare Research and Quality is also useful.⁴⁴⁴

STEP-UP summary

Skills

No systematic reviews specifically examine the effects of migrating spirometry testing from a hospital context to primary care. A diagnostic technology update has summarised much of the evidence, with an emphasis on effectiveness.⁴⁴³ Two systematic reviews^{444,445} conducted for the US Preventative Service Task Force have looked at the use of spirometry for population screening for COPD. A relevant review protocol exploring case finding for COPD in primary care using a wide range of methods is available, but the systematic review itself does not yet seem to have been published.⁴⁴⁶

A study of spirometry carried out by GPs in primary care found that in 95% of cases fewer than five trials were required to achieve the highest quality grade, concluding that spirometries undertaken in general practice are of acceptable quality and reproducible in only 60% of measurements.¹⁸⁵ The results of this study suggest a need for high-quality initial training and refresher training for spirometry.

Another study investigated the feasibility of practice nurses undertaking case-finding spirometry in general practice.⁴⁴⁷ Although the study involved only small numbers of diagnoses, it was concluded that the practice nurses required more training than they were originally given, again highlighting the importance of high-quality training if spirometry were to be used successfully in primary care. In a small study of 45 patients in Leicester, Akhtar and Wilson²⁶¹ compared the results of spirometry testing in primary care with those obtained at a pulmonary function laboratory. They also explored whether differences were due to technique or equipment. They concluded that spirometry results obtained by practice nurses were lower than those obtained in a laboratory, leading to practice nurses overestimating severity.

A study conducted with community pharmacists found that 73% of spirometries carried out by pharmacists were of acceptable quality, as judged by lung function experts in an acute setting.¹⁸⁶ Ongoing challenges related to selection of a suitable spirometric screening test and to maintaining the quality of spirometric tests in primary care.

A further study investigating the quality of spirometry in primary care found > 15% of the tests being sent from primary care to specialists to analyse lacked complete data.¹⁸⁷ Almost 40% of those that were complete were reported by specialists to be unacceptable. The results showed unacceptable quality in the provision of spirometry in primary care for patients with COPD, suggesting that adequate training must be given if spirometry is to be performed appropriately in primary care.

Poorly performed spirometry can lead to incorrect diagnosis and treatment. All HCPs undertaking diagnostic spirometry should meet accredited quality assured standards. Standards for diagnostic spirometry have been published, including a suggested process for working through a spirometry trace.⁴⁴⁸ Primary care practitioners should be encouraged to perform spirometry wherever the quality has been demonstrated to be good (against American Thoracic Society/European Respiratory Society quality goals).⁴⁴⁹

STEP-UP summary statement With regard to SKILLS, spirometry is attributed a MODERATE degree of implementation difficulty owing to the skills required to obtain a valid reading.

Training

According to the document *A Guide to Performing Quality Assured Diagnostic Spirometry*, spirometry should be performed only by people with appropriate training (training standards defined in the document).⁴⁴⁸ Training should cover both performance of the test and interpretation of the findings. Poorly performed spirometry produces misleading results. Training for operators, with regular updates and quality audits, is fundamental. Spirometry manufacturers can provide training in the use of their equipment, and some run spirometry courses. Most COPD training courses include training in spirometry.

The National Institute for Health and Care Excellence recommends that health professionals involved in caring for COPD patients should have access to spirometry and be able to interpret the results.⁴⁵⁰

Spirometry can be performed by any health-care worker who has undergone appropriate training and who keeps his or her skills up to date. The GP Quality and Outcomes Framework⁴⁵¹ requires diagnosis in primary care to be confirmed post bronchodilator. The 2010 NICE guidance similarly recommends spirometry be conducted post bronchodilator.⁴⁵²

The evidence base in general encourages use of training programmes.⁸¹ However, a RCT in Australia, where 26 intervention practices received comprehensive spirometry training and 14 control practices provided usual care, concluded that training in spirometry did not result in any measurable improvement in the use of spirometry, quality of management of asthma or patient outcomes in primary care.¹⁸⁹

A longitudinal study in Denmark demonstrated that the improved education of staff enhanced the use of spirometry in hospital outpatients with COPD, indicating the importance of staff training.¹⁹⁰ Further education has also been shown to increase GPs' use of spirometers¹⁹¹ and also improve their capacity to diagnose clear-cut pathologies.²⁶⁹ New methods for teaching spirometry should be evaluated. E-learning holds several advantages in this context and is especially beneficial in helping trainees with data interpretation.⁴⁵³

Advances in technology and widespread internet and mobile phone use open up the possibility of automated data transfer from community- or home-based spirometry to primary care teams (or respiratory support team).⁴⁴³ The use of remote and home monitoring is currently under investigation. The need for accreditation is under review.

STEP-UP summary statement With regard to TRAINING, spirometry is attributed a LOW degree of implementation difficulty owing to the success of short training courses for skills acquisition.

Equipment

Spirometry measures air flow and volume using varying types of equipment, all of which should conform to international standards. The American Thoracic Society and European Respiratory Society have jointly published comprehensive guidelines on the minimum performance specifications for spirometers.⁴⁵⁴ These standards have been interpreted in a UK context by the General Practice Airways Group.⁴⁵⁴ Many handheld or desktop devices have evidence for good accuracy compared with respiratory laboratory standards.^{193,455} However, it is considered essential to follow up reduced handheld/screening spirometry with full quality assured diagnostic spirometry to confirm or refute the findings.

The document *A Guide to Performing Quality Assured Diagnostic Spirometry*⁴⁴⁸ specifies the following equipment requirements and standards:

- a spirometer which meets the ISO standard 267823
- one-way mouthpieces and nose clips
- bacterial and viral filters (as indicated in selected patients)
- height measure and weighing scales – calibrated according to manufacturer's instructions

- nebuliser or single-patient-use volumatics (for post-bronchodilator spirometry and reversibility testing)
- single-patient use mask/mouthpiece for nebuliser
- short-acting bronchodilators as per guidelines.

The document also specifies requirements for quality assurance. A user-friendly guide to buying a spirometer has been produced.⁴⁵⁶ The National Asthma Council Australia provides a useful list of factors to consider when purchasing a spirometer in its *Spirometer Users and Buyers Guide*.¹⁹²

Handheld and desktop spirometers detect flow volume and rates using a variety of flow sensors. Several devices are available on the market, and one study reviewed the technical properties of 10 different spirometers designed for use in general practice.¹⁹³ The devices were tested in laboratory and primary care settings, and user-friendliness was assessed. For an overview of devices on the market and their reported accuracy, see the detailed spirometry report at the Department of Primary Health Care MaDOx.⁴⁵⁷

Some devices can transfer data by telephone (landline or mobile phone). Many have storage capacity and allow for use in the field (for surveys or patient use), so data can be downloaded at a later date for analysis.

Disposables include mouthpieces and other consumables. Spirometers should be regularly cleaned and sterilised, as they may become reservoirs of micro-organisms. In a small study of 16 spirometers in South Australia, microbiological contamination was present in three.¹⁹⁴ The three practices concerned all reported having a written spirometer-cleaning protocol in place. The frequency of spirometer disinfection did not match the manufacturers' recommendations, highlighting a need for stricter hygiene measures for spirometer maintenance in general practices.

A Dutch study examined 50 desktop spirometers in general practices and found that, on average, they slightly overestimated FEV and FVC values, with some devices showing substantial deviations.⁴⁵⁸ Spirometers, therefore, need to be calibrated yearly and verified before each session. A preventative spirometer maintenance and quality assurance regimen will include:

- regular cleaning
- calibration checks
- equipment maintenance to ensure that the spirometer is operating correctly
- regular review to ensure ongoing test quality.

Regular validation of the calibration is ideally performed with an accurate syringe before each testing session. The overall performance of the spirometer can be checked by regularly testing a healthy subject. Records should be kept of each calibration and the test results from healthy subjects. Ideally, a spirometer should have a graphical display to allow technical errors to be detected. It should be able to produce a hard copy. Regular calibration is essential. Some spirometers need to be calibrated before each session using a calibration syringe; others hold their calibration between annual services.

Three types of spirometer are commonly used in primary care:

1. Small, handheld meters which provide digital readings are the cheapest option and small enough to fit into a medical bag. The lack of graphs can make it difficult to judge when the procedure is complete. Predicted charts and a calculator are needed to interpret the results.
2. Portable meters with integral printers are more expensive but they undertake all of the calculations, including reversibility. Small displays of the volume–time graph help to monitor the blow and the print-out includes a flow–volume loop.
3. Systems that work with a computer to display a graph and provide a print-out. Integral memories allow data to be recorded outside the practice and uploaded when convenient.⁴⁵⁹

The Spanish agency CatSalut has produced very helpful technical requirements for spirometers and calibration syringes.⁴⁶⁰

STEP-UP summary statement With regard to EQUIPMENT, spirometry is attributed a LOW degree of implementation difficulty owing to improvements in ease of use, cost and portability.

Premises

Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ locates spirometry testing services in an 'examination/therapy room' (contains public sector information licensed under the Open Government Licence v3.0). In an economic analysis on the economics of initiating office spirometry in a six-man internal medicine group in Kirksville, MO,⁴⁶¹ the spirometry laboratory occupied < 147 square feet. Initial testing could occur in community locations or surgery waiting rooms, but diagnosis should be confirmed in line with recommendations from the NICE and the British Thoracic Society.⁴⁴³

STEP-UP summary statement With regard to PREMISES, spirometry is attributed a LOW degree of implementation difficulty owing to the facility to apply portable spirometry in a variety of primary care settings.

User perspective

Two qualitative studies have looked at attitudes of doctors to the use of spirometry. Accessibility of equipment does not figure prominently as an identified barrier. This corroborates quantitative studies that show that, even when equipment is available, as few as one-third of patients receive a spirometry investigation.⁴⁶²

Evidence suggests that spirometry is underutilised and that guidelines that recommend spirometry to confirm airflow obstruction among patients with suspected COPD are not routinely followed. Not all potential users accept the value of spirometry as a tool that will impact on practice or patient welfare.⁴⁶³ Some doctors fail to use spirometry as they believe that little or nothing can be done to help patients who continue to smoke.¹⁹⁶ Reported barriers to the use of spirometry include poorly designed and unduly complex spirometers with too many confusing parameters of limited value, lack of availability of spirometers, poor or no teaching in medical schools and the perceived lack of an evidence base demonstrating the value and cost-effectiveness of spirometry.⁴⁶⁴

In a UK context only, specialist registrars and GPwSIs in undergraduate education spontaneously cited spirometry as a diagnostic tool.¹⁹⁷ When asked explicitly about spirometry, other grades cited unfamiliarity and inability to interpret the results as key factors inhibiting their use of spirometry. Junior doctors (Foundation Year 2) specifically noted lack of encouragement, reinforcement or even basic information about obtaining spirometric equipment from senior colleagues, whereas respiratory specialist registrars and GPs viewed spirometry as essential.¹⁹⁷

General practitioners stated that they now felt that they had more access to spirometry than in the past and they were highly aware of the value of spirometry, perhaps reflecting its inclusion as a quality marker in the NHS General Practitioners' contract. GPs in the study commented on the need for retraining, confirmed by a further study which showed that only 33% of general practices were confident at interpreting spirometry and 58% were confident at using spirometers.³⁰⁴

The UK study may be limited by including only GPs who were uniformly enthusiastic about spirometry, given their special interest in teaching undergraduates and the fact that they had been recruited via an educational update session.¹⁹⁷ A focus group study in Chicago, IL, found that, in general, primary care physicians believed that spirometry was not necessary to confirm the diagnosis of COPD.¹⁹⁸ Health system barriers specific to spirometry use were not identified, suggesting that the availability of spirometry was not a perceived barrier. The findings suggest that the use of spirometry among primary care physicians may first require the establishment of their belief that spirometry is actually useful in diagnosing COPD. A study

of 25 GP practices in the USA found that 75% failed to use spirometry in their diagnosis of COPD.⁴⁶⁵ The reasons cited for non-use included lack of time and staffing.⁴⁶⁵

The availability of equipment seems to be a less important factor, with spirometers often available but not used. Almost 75% of Australian GPs reported having a spirometer in their practice, but only 12% had used it to review patients with asthma within the year prior to the study.⁴⁶⁶ Similar underuse has been observed in primary care in Sweden and in Spain. A 2008 study from the USA produced more optimistic conclusion, with the authors reporting that 74% of primary care physicians responding to a questionnaire said that they used spirometry in the diagnosis of COPD, although the actual frequency of use was not measured.

Spirometry is a reliable, simple, non-invasive, safe and non-expensive procedure.⁴⁶⁷ However, there are some challenges with its acceptability. A false positive could lead to unnecessary diagnostic testing and stress. A false negative can lead to a false sense of being healthy; a smoker may not give up smoking, for example, leading to further problems later in life. Spirometry has been suggested as a motivational tool to help smokers to quit smoking. However, the evidence does not offer a clear conclusion on whether or not spirometry increases motivation and success in quitting smoking.⁴⁶⁸ The impact of providing a smoker with a 'healthy' reading is not clear.

STEP-UP summary statement With regard to USER PERSPECTIVES, spirometry is attributed a LOW implementation difficulty for clinicians and a MODERATE difficulty for patients. The equipment is becoming easier to use but may require multiple attempts for a patient to make their technique acceptable.

Primary–secondary interface

The increased availability of spirometers in primary care offers the potential for wider use. Newer spirometers are user-friendly and have the capacity for self-monitoring. With the advent of telemedicine and internet transmission of data, many more patients could have access to a diagnostic screening and/or monitoring.

Konstantikaki *et al.*¹⁹⁹ compared an open spirometry programme with a case-finding programme providing spirometry to high-risk subjects selected by primary care physicians. A network of primary care physicians was created after invitation and all participants received training on COPD and spirometry. The study team visited 12 primary care settings over a 1-year period. Spirometry was performed in all eligible participants. The proportion of newly diagnosed COPD was 27.9% in the case-finding programme, compared with 8.4% in the open spirometry programme ($p < 0.0001$). The average cost for a new diagnosis of COPD was €173 in the open spirometry programme and €102 in the case-finding programme. Thus, a case-finding programme involving primary care physicians was more cost-effective for identification of new cases of COPD than an open spirometry programme.

A Spanish study has examined the economic impact of telespirometry, compared with standard spirometry.⁴⁶⁹ Although telespirometry costs more per unit than standard spirometry (€47.80 vs. €39.70) (2013), the quality of the telespirometry procedure is superior (84% good quality vs. 61%). The cost-effectiveness analysis concludes that telespirometry is 23% more expensive and 46% more effective. Health-care costs consequently fall as the number of lung function tests performed by telespirometry rises.

A US office spirometry study conducted 1179 spirometry tests and clinic revenue showed a \$40,000 surplus over operating costs over 1 year.⁴⁷⁰ The service often resulted in the new diagnosis of obstructive lung disease that had not been previously made. This became the foundation for initiating care for these patients. Having on-site service in this small community saved patients the time and cost of travelling 100 miles to have spirometry carried out in a specialist's office.⁴⁷⁰

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, spirometry is attributed a LOW degree of implementation difficulty owing to the existing referral pathways for asthma and COPD, etc.

Conclusion

Spirometry equipment has frequently figured in GP practices, alongside other requisite equipment such as ECGs. It is similarly benefiting from the move to miniaturisation as well as from demand for end-user friendly devices. However, the availability of the technology should not disguise the fact that interpreting spirometry readings, and indeed deciding to use the equipment in the first place where it is readily available, remains a significant barrier to effective utilisation of the technology.

Spirometry (Sp 1–111)

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Ultrasound

Definition: an ultrasound scan, sometimes called a sonogram, is a procedure that uses high-frequency sound waves to create an image of part of the inside of the body (NHS Choices).

This map includes portable and fixed ultrasound.

This map excludes echocardiography (see *Echocardiography*) and neonatal screening for dysplasia of the hip.

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Ultrasound provides instant images and can be used at the bedside or in an office for rapid diagnosis, whereas other imaging methods take time to process. Ultrasound images can be saved or printed for reference, but, unlike MRI scans and CT scans, performance and interpretation are much more dependent on the skill and experience of the operator. Ultrasound examinations are undertaken by practitioners from a wide range of professional backgrounds and in many different clinical settings.

General practitioner ultrasound scanning appears to offer an alternative to traditional hospital-based services. Over recent years the technology has become more portable and less prohibitive in cost. As early as 2002, the question 'Ultrasound scanning by general practitioners: is it worthwhile?'²⁰³ was being asked. At approximately the same time the Norwegian Knowledge Centre for the Health Services⁴⁷¹ assessed the available evidence on the use of ultrasonography in the primary health care setting. They concluded that, notwithstanding the increasing availability of high-quality, cheap and compact equipment, there was very limited evidence for the diagnostic accuracy and clinical benefit of using diagnostic ultrasound in primary care. This contrasts with an abundance of literature regarding its use in acute hospitals. This imbalance makes the 'transfer value' for ultrasound technology uncertain, particularly given that the primary care population is one of low disease prevalence. Knock-on effects for secondary care were also incapable of being anticipated at this time. Training and education for ultrasound has implications for the continuum of medical education: basic medical education – further education in general medical practice – certification procedures (accreditation) and documented CPD (recertification). Furthermore, the cost implications for primary health-care services were unknown. The review concluded that there is a need for clinical studies based on general practice to address the diagnostic value and clinical effect (including the cost-effectiveness) of ultrasonography use. Fundamentally, against a backdrop of decreasing costs, greater portability and more common usage, this situation remains unchanged.

STEP-UP summary

Skills

Ultrasound is a highly operator-dependent imaging modality and requires skills that take time to acquire. Imaging must be undertaken by trained and experienced practitioners and, even then, perfect images may not be obtained in every patient. Regardless of who undertakes them or where they are undertaken, ultrasound examinations must be of a high quality as they have a direct effect on patient management. Skill mix in ultrasound in primary care has grown organically, with boundaries often ill-defined.

Faster diagnosis has to be offset against 'risks to the patient from false positive diagnoses that generate additional procedures or tests, and false negatives that miss potentially serious pathology'.²⁰¹ Medical ultrasonography is 'fraught with scope for diagnostic error'.²⁰¹ Ultrasound images can be saved or printed for reference, but, unlike MRI scans and CT scans, performance and interpretation are much more dependent on the skill and experience of the operator. Ultrasound has a reputation as a simple, easy test. It is easy to perform but interpreting the results is not so easy and features can be overlooked.⁴⁷² Ultrasound takes clear images of muscle, soft tissue, fluid and bone surfaces, but it is not good at penetrating bone or air. This limits its use in the skull, chest and abdomen. Ultrasound has no known long-term side effects, but it has a more limited scope than other imaging methods. There are limits to the depth of penetration that can be achieved, so images of structures deep inside the body can be difficult to capture, particularly in obese patients.

STEP-UP summary statement With regard to SKILLS, ultrasound is attributed a MODERATE degree of implementation difficulty owing to its being very operator dependent.

Training

Ultrasound, if carried out correctly in the appropriate clinical situation, is one of the most effective diagnostic tools in health care. As ultrasound machines become cheaper, more reliable and highly portable, GPs are increasingly using them to make on-the-spot diagnoses of many conditions without having to consult an imaging expert.²⁰¹ The fact that it is safe to carry out, relatively inexpensive and can

be provided in most clinical facilities makes ultrasound one of the most commonly requested examinations in the field of diagnostic imaging. Ultrasound examinations are undertaken by practitioners from a wide range of professional backgrounds and in many different clinical settings. Guidance emphasises that whoever does the training must be trained, as ultrasound require both experience and expertise. There is no physical risk to the patient but there is a risk of false negatives or false positives.⁴⁷²

The National Ultrasound Steering Group of the British Medical Ultrasound Society recommended in 2008 that local clinical governance boards be established to oversee the training, supervision and audit of all providers of ultrasound imaging services.²⁰² The RCR recommends that ultrasound training for medical non-radiologists should be to the same standard as for radiologists, albeit restricted to the relevant area of their clinical expertise. Providers should ensure that ultrasound users are adequately trained and that this is maintained through adequate audit and quality assurance systems.

Many factors affect the quality of ultrasound examinations, including appropriate training, experience, the equipment itself, clinical leadership, audit, general support and having sufficient time to undertake the examination and compile a clinically relevant report. Those undertaking ultrasound examinations, regardless of their professional background, must meet the standards of best clinical practice, substantiated by appropriate audit and good governance processes. Clear, effective clinical leadership is also essential if the ultrasound service provider is to achieve timely, accurate, clinically relevant reports. Documents relating to ultrasound service provision are available from organisations such as the RCR, the SCoR, the British Medical Ultrasound Society and the former United Kingdom Association of Sonographers (the United Kingdom Association of Sonographers merged with the SCoR on 1 January 2009). Ultrasound providers are encouraged to seek accreditation from ISAS. In England it is a legal requirement that providers of diagnostic and screening ultrasound services are registered with the Care Quality Commission.

Machines should not be used away from specified clinical areas and operators must be clearly instructed not to go beyond defined and agreed protocols. Focused ultrasound training standards have been published by the RCR.²⁵⁶ Support from the manufacturer is an important consideration when purchasing a machine. Such support should include the availability of specialists for particular clinical applications, the availability of appropriate training courses and resources for repair and maintenance. Manufacturers should specify the minimum number of years over which they will supply spare parts and the necessary resources for repairs.

Rapid changes in technology make it important to undertake a formal review and replacement policy. High-specification ultrasound scanners will often have a longer useful life than basic or middle-range equipment. Depending on the outcomes of a review, a decision can then be made whether to continue to use the equipment or to obtain a replacement machine. By far the most important reason for replacement is a clinically significant change in performance as revealed by regular quality assurance or unfavourable image quality when compared with newer ultrasound machines, leading to an increase in inconclusive reports.

An employer or manager should record the statutory or voluntary registration status of all ultrasound practitioners. Ultrasound practitioners should be registered with the relevant statutory regulatory body, where appropriate, or with the relevant voluntary registration body. Ultrasound practitioners must hold recognised qualifications, including qualifications approved by the Consortium for the Accreditation of Sonographic Education, or equivalent, either from overseas or in the UK. Consortium for the Accreditation of Sonographic Education-accredited universities and professional bodies such as the RCR and Royal College of Obstetricians and Gynaecologists offer a range of different training methods.

Employment and registration

Ultrasound practitioners come from a wide range of professional backgrounds, including radiologists, radiographers, nurses, midwives, physicists, physiotherapists, obstetricians and clinical scientists. Ultrasound practitioners who are medically qualified will be registered with the GMC as a doctor with a licence to practise. Ultrasound practitioners not registered with the GMC will often be registered with a statutory

regulatory body such as the Health and Care Professions Council or the Nursing and Midwifery Council. Examples include radiographers, physiotherapists and some clinical scientists. Ultrasound practitioners for whom statutory registration is not possible can apply for voluntary registration with the Public Voluntary Register of Sonographers which is administered by the College of Radiographers. Statutory registration for sonographers was recommended by the Health and Care Professions Council to the Secretary of State for Health in 2009 but new groups are not receiving statutory registration except where evidence demonstrates a level of risk to the public that warrants the costs of regulation.

Different bodies have different interpretations of what experienced means in practice. One study found that doctors need to be involved in more than 200 cases during training to develop an acceptable level of competence. The RCR's guidelines on ultrasound training for non-radiologists give varying minimum number of examinations depending on the specialty.²⁵⁶ Available courses are modelled on training for radiographers and the time commitment is impractical, such as block release courses, for full-time clinicians.

STEP-UP summary statement With regard to TRAINING, ultrasound is attributed a LOW degree of implementation difficulty owing to the widespread availability of training courses and opportunities.

Equipment

The absence of ionising radiation, the ability to deliver in the community closer to the patient's home and the comparatively low cost of the equipment make ultrasound the first-choice examination for many clinical conditions. Ultrasound machines, once the size of washing machines and used solely by radiologists and sonographers in radiology departments, have become cheaper, smaller and more portable. Miniaturisation enables the latest models to be pocket sized. Ultrasound machines use variation in the way that high-pitched sound waves penetrate different tissues to generate images. Patients are not exposed to the risks of ionising radiation associated with CT or radiography. It is also now cheap, costing £56 for a scan of more than 20 minutes compared with £217 for a MRI scan (2013 NHS tariffs). The latest portable machines produce images that are almost the same quality as that of the larger machines; and they are easy to use, durable and cost as little as £5000.²⁰¹ Images obtained with a portable ultrasound machine are usually not stored, and a decision on this is made at the time by the clinician doing the scan.

Ultrasound machines are increasingly used by non-radiologists as part of the clinical examination or to assist in practical procedures such as the insertion of a central line. The number of GPs buying their own ultrasound machines has also gradually increased. The price of an ultrasound machine has reduced significantly to £5000–10,000 (2010), resulting in more widespread use.⁴⁷²

Ultrasound scanners can be physically moved with ease, presenting a risk that machines may be inappropriately used for clinical tasks for which they were never intended and to which they may be ill suited. The role of the operator is critical and matching the operator knowledge and competence level to the equipment features is essential, to include the key machine characteristics, how these characteristics match to clinical need, features to be considered when purchasing a machine, and the associated environmental and organisational systems needed to support efficient use of the machine. In addition, service providers will need to ensure that the equipment continues to perform at the required level and have strategies for withdrawing it from service when this is no longer the case.

Ideally, ultrasound scanners should provide excellent images of diagnostic quality at all times. However, this is not implementable as an objective description of machine performance. However good the machine might be technically, some patients will present insurmountable challenges. The user must be clear about which applications are paramount for each scanner, devise metrics of quality and take and archive representative images encapsulating desired features. This enables the machine performance to be mapped over time. The user should specify, as precisely as possible, the investigation(s) for which each machine is optimised. Representative images indicating the performance of each machine should be

archived on an annual basis and these should be monitored as part of the audit system in place in the department, and also with any bench-top testing that takes place.²⁰⁴

The choice of scanner should be matched to the type and nature of the workload. However, occasionally functionality in primary care may be sacrificed with reduced size and weight. For the purposes of review and audit, all images obtained should be recorded, stored on a picture archiving and communication system and linked to the report. However, this may not always be part of the functionality of a portable device. Physicians in many medical specialties are thought to be using POC scanning, but the scale on which this is happening is not yet clear: these scans are not systematically recorded in the same way as scans performed by imaging experts. Essential and desirable functions are covered in the document *Standards for the Provision of an Ultrasound Service*.²⁰⁴

In 2002 a cost analysis and an assessment of quality of GP scans, based on a clinical audit and a postal survey of patients' preferences in the Grampian region of Scotland, reported that the unit cost of a scan was higher in the practice than at the hospital.²⁰³ However, when all of the costs for a scanning episode were considered, the total and average costs were lower in the practice because of the avoidance of hospital visits. The results showed that the quality of GP scanning, subject to further training, was considered to be sufficient to continue scanning at the practice. Although the study provides some evidence to support GP scanning, further research on diagnostic accuracy and alternative models of care is still required.

The potential uses of ultrasonography in primary care include screening for abdominal aortic aneurysm,⁴⁷³ musculoskeletal diagnosis⁴⁷⁴ and echocardiography (already covered in *Echocardiography*). Further research is required to examine specific issues relating to risk and safety.

In August 2015, the *British Journal of Cardiology* reported the launch of an 'ultrasound on demand' scheme.⁴⁷⁵ The monthly fee-based scheme offers a basic service with a further range of high-specification ultrasound packages on a pay-as-you-go basis. This allows ultrasound services to be tailored to both current and future needs as demand and patient workload change. 'Ultrasound on demand', launched by Philips, is a flexible scheme with 50 options and access to advanced facilities, such as three-dimensional transoesophageal echocardiography, which previously may have been limited by the restrictions of upfront investment costs. Staff can explore new imaging options and upgrade and alter systems without locking in capital expenditure budgets. Additional functionality is only charged when used. Coupled with this is the benefit of advanced data analytics, which provide in-depth information on utilisation of services. These data are often difficult to obtain from traditional IT systems and should facilitate strategic planning and rationalisation of service delivery. It remains to be seen how this scheme compares with traditional leasing systems.

STEP-UP summary statement With regard to EQUIPMENT, ultrasound is attributed a LOW degree of implementation difficulty owing to its portability, ease of use and the absence of radiation risk.

Premises

Health Building Note 11-01, *Facilities for Primary and Community Care Services*,⁴⁶ locates ultrasound services in a generic treatment room. The environment in which a scanner is housed has a demonstrable effect on its performance. The size of the machine relative to the size of the room in which it is to be used is a key consideration. Other issues to be considered include the scanning couch and operator seating, the display monitor, the room heating and lighting, hygiene, infection and cleanliness and electrical and IT provision.⁴⁷⁶ The couch, the seating, the transducer and the display should be ergonomically compatible. The size of the monitor will probably be a compromise between being able to accommodate it and not occasioning operator fatigue through an overly small screen.

Room lighting should be subdued but not render movement hazardous. Excess room temperatures must be avoided. The electrical supply should support the demands of the scanner, the couch and any accessories. IT links to picture archiving and communication systems are important and trailing leads are to be avoided.⁴⁷⁶

A key consideration in harnessing the diagnostic technology effectively is provision of 'safe, comfortable areas for "stacking" the patients so that the expensive equipment and staff can work to maximum efficiency'.⁴⁷⁷

STEP-UP summary statement With regard to PREMISES, ultrasound is attributed a LOW degree of implementation difficulty owing to increasing developments in miniaturisation and portability.

User perspective

A patient preference study for 500 patients from a GPs' list and 250 consecutive patients scanned at a Grampian general practice found that patients preferred to be scanned at the practice. They were prepared to wait up to an extra 5 days to enact their preference.²⁰³ Patients were prepared to accept a reduction in the accuracy of scanning of up to 3.5% in being able to realise their choice. Patients were not concerned about which member of staff actually carried out the ultrasound scan.

Skills and willingness were not sufficient factors in themselves to prompt rural family practitioners to utilise ultrasound.²⁰⁵ Economic considerations (i.e. equipment cost and remuneration) were seen as being more important.²⁰⁵ Significantly, 78% had undergone training and used ultrasound in another setting; 94% reported that they would consider using ultrasonography in their medical practice office.

STEP-UP summary statement With regard to USER PERSPECTIVES, ultrasound is attributed a LOW degree of implementation difficulty owing to its being well accepted among clinicians and well tolerated among patients.

Primary–secondary interface

The number of ultrasound examinations performed by imaging experts has increased on average by 5.2% every year for the past 10 years, according to Department of Health data, and imaging experts (radiologists, radiographers and sonographers) are struggling to keep up with the growing demand. Their numbers are increasing, but not quickly enough, and some health-care providers are choosing not to invest in their expertise. The Centre for Workforce Intelligence projects a 45% increase in demand for ultrasonography by 2025 as a result of population ageing and the growing popularity of this kind of scanning.²⁰¹

With increasing pressure on ultrasound services as a result of the number of requests, changing patterns of service delivery and a shortfall in the qualified workforce, there have been concerns that the quality of some ultrasound examinations has been affected. Sometimes large groups of patients have had to be recalled for repeat ultrasound examinations. Reports and images of examinations performed by one provider are also not always available to others, with individual scans being repeated before treatment in secondary care is initiated. A 2002 audit of a small series of patients demonstrated that use of an ultrasound scanner at a Grampian general practice reduced the numbers of hospital scans, outpatient and inpatient visits, and emergency admissions.²⁰³

The RCR is concerned about a national shortage of trained sonographers to deliver training. To train others, radiology departments will need additional staff, space and equipment. It is not sufficient to rely on the goodwill of the local radiologists. Ultimately, ultrasonography should be taught to everyone in medical school. However, there will be a skills gap in ultrasonography for some time to come.

Blackpool Fylde and Wyre Hospitals Foundation Trust extended primary care ultrasound as a NHS Improvement initiative.²⁰⁶ Long waiting times for routine ultrasound examination, accompanied by patients arriving late for appointments owing to parking difficulty, and a limited choice for patients in terms of time and location of appointment required an innovative service response. The trust negotiated the use of a PCT facility, off the main district general hospital site, and acquired a portable ultrasound machine to provide community-based ultrasound. They also changed sonographer rotas to ensure that as much scanning time as possible was undertaken off the main site. Some sonographers required initial mentoring in total independent practice but there was no resistance to this change of working practice. Booking systems were centralised, offering all patients a choice of scanner site and more choice regarding the time of the scan.

Improvements included 30–40% of routine outpatient work being performed off the main site (more local scanning with better parking), improved patient satisfaction and increased patient choice of scanning venue.

STEP-UP summary statement With regard to PRIMARY–SECONDARY INTERFACE, ultrasound is attributed a LOW degree of implementation difficulty owing to its being comparatively easily implemented in primary care and likely shifting demand from secondary care.

Conclusion

Ultrasound is one of the fastest growing areas of diagnostic technology application, excluding POC testing. There is substantive concern that this might not be translating into clinical benefit. Ultrasound, notwithstanding its portability and ease of use, carries requirements for quality assurance. These must be monitored and met if the technology is to achieve its potential clinical benefit. Furthermore, there is a need to examine the impact of ultrasound scans on the referral and secondary care pathways.

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Appendix 4 Search strategies and related information for Chapter 5

Bibliographic database searches

Overview/methods

- MEDLINE via Ovid SP.
- EMBASE via Ovid SP.
- The Cochrane Library [Cochrane Database of Systematic Reviews (CDSR) CENTRAL, DARE, NHS EED, HTA].
- CINAHL.
- Web of Science.
- Citation searches of key titles.

Grey literature searches.

Along with some general searching via a search engine such as Google, the following websites will be searched:

- Oxford DEC

websites of service providers.

The grey literature element of the searches is likely to be informed by our contact with clinical experts, who may be able to suggest particular resources/websites of interest.

Table of results

Please note: the dates on which the searches were performed and any keywords applied to the results are included in the table below.

	Results	Keywords
MEDLINE	399	\$\$MEDLINE
EMBASE	786	\$\$Embase
Cochrane CDSR	6	\$\$Cochrane; \$\$CDSR
Cochrane CENTRAL	69	\$\$Cochrane; \$\$CENTRAL
Cochrane DARE	0	\$\$Cochrane; \$\$DARE
Cochrane NHSEED	1	\$\$Cochrane; \$\$NHSEED
Cochrane HTA	0	\$\$Cochrane; \$\$HTA
CINAHL	88	\$\$CINAHL
Web of Science	1012	\$\$WoS
Total	2361	
Total after duplicates have been removed		

*Search strategies***MEDLINE**

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R).

Date range searched: 1946 to present.

1. primary care.tw. (73,475)
2. general practi\$.tw. (63,013)
3. primary health care.tw. (15,134)
4. Community Mental Health Services/ (16,715)
5. Family Practice/ (59,984)
6. Home Care Services/ (27,904)
7. Physicians, Family/ (14,697)
8. Community Health Services/ (27,031)
9. Community Health Nursing/ (18,468)
10. Community Pharmacy Services/ (2926)
11. Community Health Workers/ (3300)
12. Preventive Health Services/ (10,983)
13. or/1-12 (266,862)
14. *Diagnostic Services/ (1050)
15. *Clinical Laboratory Services/ (94)
16. *Genetic Testing/ (12,574)
17. *Mobile Health Units/ (1937)
18. diagnostic service\$.ti,ab. (1039)
19. clinical laboratory service\$.ti,ab. (121)
20. genetic test\$.ti,ab. (12,848)
21. mobile health\$ unit\$.ti,ab. (52)
22. mobile health\$ clinic\$.ti,ab. (21)
23. (point of care testing or point-of-care testing or POCT or near patient testing or near-patient testing).ti,ab. (1722)
24. diagnos\$.ti,ab. (1,713,087)
25. test\$.ti,ab. (2,238,771)
26. 24 or 25 (3,649,705)
27. 26 and primary care.tw. (24,271)
28. or/14-23,27 (51,331)
29. 13 and 28 (25,005)
30. Ultrasonography/ (63,040)
31. ultrasonic diagnos\$.ti,ab. (1831)
32. (ultrasound adj3 imaging\$).ti,ab. (10,337)
33. (ultrasonic adj3 imaging\$).ti,ab. (1257)
34. sonograph\$.ti,ab. (44,065)
35. ultrasound scan\$.ti,ab. (7157)
36. Echocardiography/ (67,752)
37. (echocardiography or echocardiogram).ti,ab. (85,365)
38. (echo adj2 cardi\$).ti,ab. (555)
39. us.fs. (203014) – extra line added in after protocol agreed? .fs = floating subheading for ultrasound
40. or/30-39 (350,310)
41. 29 and 40 (429)
42. limit 41 to yr="1995 –Current" (399)

EMBASE

Database: EMBASE.

Date range searched: 1974 to 9 February 2015.

1. primary care.tw. (94,182)
2. general practi\$.tw. (80,437)
3. primary health care.tw. (17,154)
4. general practice/ (70,635)
5. home care/ (48,838)
6. general practitioner/ (66,185)
7. community care/ (48,583)
8. community health nursing/ (25,539)
9. pharmacy/ (56,513)
10. health auxiliary/ (3304)
11. preventive health service/ (21,752)
12. or/1-11 (416,412)
13. *preventive health service/ (10,515)
14. *laboratory diagnosis/ (7391)
15. *genetic screening/ (10,737)
16. diagnostic service\$.ti,ab. (1325)
17. clinical laboratory service\$.ti,ab. (154)
18. genetic test\$.ti,ab. (18,829)
19. mobile health\$ unit\$.ti,ab. (48)
20. mobile health\$ clinic\$.ti,ab. (23)
21. (point of care testing or point-of-care testing or POCT or near patient testing or near-patient testing).ti,ab. (2587)
22. diagnos\$.ti,ab. (2,318,322)
23. test\$.ti,ab. (2,853,121)
24. 22 or 23 (4,722,933)
25. 24 and primary care.tw. (33,613)
26. or/13-21,25 (80,950)
27. 12 and 26 (44,826)
28. echography/ (232,573)
29. ultrasonic diagnos\$.ti,ab. (2176)
30. (ultrasound adj3 imaging\$.ti,ab. (13,738)
31. (ultrasonic adj3 imaging\$.ti,ab. (1435)
32. sonograph\$.ti,ab. (57,024)
33. ultrasound scan\$.ti,ab. (9892)
34. echocardiography/ (135,270)
35. (echocardiography or echocardiogram).ti,ab. (129,663)
36. (echo adj2 cardi\$.ti,ab. (1157)
37. or/28-36 (452,549)
38. 27 and 37 (824)
39. limit 38 to yr=" 1995 –Current" (786)

The Cochrane Library

#1 (primary care):ti,ab,kw

#2 (general practi*):ti,ab,kw

#3 (primary health care):ti,ab,kw

- #4 MeSH descriptor: [Community Mental Health Services] this term only
- #5 MeSH descriptor: [Family Practice] this term only
- #6 MeSH descriptor: [Home Care Services] this term only
- #7 MeSH descriptor: [Physicians, Family] this term only
- #8 MeSH descriptor: [Community Health Services] this term only
- #9 MeSH descriptor: [Community Pharmacy Services] this term only
- #10 MeSH descriptor: [Community Health Workers] this term only
- #11 MeSH descriptor: [Preventive Health Services] this term only
- #12 (or #1–#11)
- #13 MeSH descriptor: [Diagnostic Services] this term only
- #14 MeSH descriptor: [Clinical Laboratory Services] this term only
- #15 MeSH descriptor: [Genetic Testing] this term only
- #16 MeSH descriptor: [Mobile Health Units] this term only
- #17 (diagnostic service*):ti,ab
- #18 (clinical laboratory service*):ti,ab
- #19 (genetic test*):ti,ab
- #20 (mobile health* unit*):ti,ab
- #21 (mobile health* clinic*):ti,ab
- #22 (point of care testing or point-of-care testing or POCT or “near patient testing” or “near-patient testing”):ti,ab
- #23 diagnos*:ti,ab
- #24 test*:ti,ab
- #25 #23 or #24
- #26 (primary care):ti,ab,kw
- #27 #25 and #26
- #28 (or #13–#22, #27)
- #29 #12 and #28

- #30 MeSH descriptor: [Ultrasonography] this term only
- #31 (ultrasonic diagnos*):ti,ab
- #32 (ultrasound near/3 imaging*):ti,ab
- #33 (ultrasonic near/3 imaging*):ti,ab
- #34 sonograph*:ti,ab
- #35 (ultrasound scan*):ti,ab
- #36 MeSH descriptor: [Ultrasonography] this term only
- #37 (echocardiography or echocardiogram):ti,ab
- #38 (echo near/2 cardi*):ti,ab
- #39 (or #30–#38)
- #40 #29 and #39 Publication Year from 1995 to 2015

Cumulative Index to Nursing and Allied Health Literature

Search ID#	Search terms
<input type="checkbox"/> S39	S28 AND S38
<input type="checkbox"/> S38	S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37
<input type="checkbox"/> S37	TI echo N2 cardi* OR AB echo N2 cardi*
<input type="checkbox"/> S36	TI (echocardiography or echocardiogram) OR AB (echocardiography or echocardiogram)
<input type="checkbox"/> S35	(MH "Echocardiography")
<input type="checkbox"/> S34	TI ultrasound scan* OR AB ultrasound scan*
<input type="checkbox"/> S33	TI sonograph* OR AB sonograph*
<input type="checkbox"/> S32	TI ultrasonic N3 imaging* OR AB ultrasonic N3 imaging*
<input type="checkbox"/> S31	TI ultrasound N3 imaging* OR AB ultrasound N3 imaging*
<input type="checkbox"/> S30	TI ultrasonic diagnos* OR AB ultrasonic diagnos*
<input type="checkbox"/> S29	(MH "Ultrasonography")
<input type="checkbox"/> S28	S11 AND S27
<input type="checkbox"/> S27	S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S26
<input type="checkbox"/> S26	S24 AND S25
<input type="checkbox"/> S25	TI primary care OR AB primary care
<input type="checkbox"/> S24	S22 OR S23
<input type="checkbox"/> S23	TI test* OR AB test*
<input type="checkbox"/> S22	TI diagnos* OR AB diagnos*
<input type="checkbox"/> S21	TI ((point of care testing or point-of-care testing or POCT or near patient testing or near-patient testing)) OR AB ((point of care testing or point-of-care testing or POCT or near patient testing or near-patient testing))

Search ID#	Search terms
<input type="checkbox"/> S20	TI mobile health* clinic* OR AB mobile health* clinic*
<input type="checkbox"/> S19	TI mobile health* unit* OR AB mobile health* unit*
<input type="checkbox"/> S18	TI genetic test* OR AB genetic test*
<input type="checkbox"/> S17	TI clinical laboratory service* OR AB clinical laboratory service*
<input type="checkbox"/> S16	TI diagnostic service* OR AB diagnostic service*
<input type="checkbox"/> S15	(MM "Mobile Health Units")
<input type="checkbox"/> S14	(MM "Genetic Screening")
<input type="checkbox"/> S13	(MM "Clinical Laboratories")
<input type="checkbox"/> S12	(MM "Diagnostic Services")
<input type="checkbox"/> S11	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10
<input type="checkbox"/> S10	(MH "Community Health Workers")
<input type="checkbox"/> S9	(MH "Community Health Nursing")
<input type="checkbox"/> S8	(MH "Community Health Services")
<input type="checkbox"/> S7	(MH "Physicians, Family")
<input type="checkbox"/> S6	(MH "Home Health Care")
<input type="checkbox"/> S5	(MH "Family Practice")
<input type="checkbox"/> S4	(MH "Community Mental Health Services")
<input type="checkbox"/> S3	TI primary health care OR AB primary health care
<input type="checkbox"/> S2	TI general practi* OR AB general practi*
<input type="checkbox"/> S1	TI primary care OR AB primary care

Web of Science

# 43	1012	#42 AND #33 <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 42	214,889	#41 OR #40 OR #39 OR #38 OR #37 OR #36 OR #35 OR #34 <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 41	875	TS=(echo near/2 cardi*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 40	80,759	TS=(echocardiography or echocardiogram) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 39	22,367	TS=(ultrasound scan*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 38	41,540	TS=(sonograph*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 37	4012	TS=(ultrasonic near/3 imag*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>

# 36	21,771	TS=(ultrasound near/3 imag*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 35	4086	TS=(ultrasonic diagnos*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 34	74,311	TS=Ultrasonograph* <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 33	50,783	#32 AND #13 <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 32	199,981	#31 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 31	45,861	#30 AND #29 <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 30	134,510	TS=(primary care) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 29	4,124,771	#28 OR #27 <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 28	3,063,325	TS=(test*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 27	1,330,265	TS=(diagnos*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 26	207	TS=("near-patient testing") <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 25	207	TS=("near patient testing") <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 24	650	TS=(POCT) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 23	4726	TS=(point-of-care testing) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 22	11,169	TS=(point of care testing) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 21	1868	TS=(mobile health* clinic*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 20	1046	TS=(mobile health* unit*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 19	2693	TS=(clinical laboratory service*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>

# 18	13,056	TS=(diagnostic service*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 17	917	TS=(Mobile Health Unit*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 16	130,577	TS=(Genetic Test*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 15	2693	TS=(Clinical Laboratory Service*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 14	13,056	TS=(Diagnostic Service*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 13	327,081	#12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1 <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 12	7060	TS=(Preventive Health Service*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 11	7844	TS=(Community Health Worker*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 10	1604	TS=(Community Pharmacy Service*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 9	9727	TS=(Community Health Nursing) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 8	33,166	TS=(Community Health Service*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 7	21,656	TS=(family physician*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 6	14,835	TS=(Home Care Service*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 5	42,922	TS=(Family Practice) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 4	10,099	TS=(Community Mental Health Service*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 3	68,124	TS=(primary health care) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 2	124,796	TS=(general practi*) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>
# 1	134,510	TS=(primary care) <i>Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH Timespan=1995-2015</i>

Internet and grey literature searches

Google searches

((**"primary care"**) AND diagnostic* AND (ultrasonography OR ultrasound OR ultrasonic OR sonography OR sonograph OR echocardiography OR echocardiogram))

Results: <http://tinyurl.com/l3usvtx>

((("primary care") AND diagnostic* AND (ultrasonography OR ultrasound OR ultrasonic OR sonography OR sonograph OR echocardiography OR echocardiogram))) **site:.ac.uk**

<http://tinyurl.com/lgrjkjk>

((("primary care") AND diagnostic* AND (ultrasonography OR ultrasound OR ultrasonic OR sonography OR sonograph OR echocardiography OR echocardiogram))) **site:.nhs.uk**

<http://tinyurl.com/kkl9x53>

((**"primary health care"**) AND diagnostic* AND (ultrasonography OR ultrasound OR ultrasonic OR sonography OR sonograph OR echocardiography OR echocardiogram))

Results: <http://tinyurl.com/mhcv8um>

<http://tinyurl.com/k2ebqy4%20site:.ac.uk>

<http://tinyurl.com/l9mvxv%20site:.nhs.uk>

((**"family practice"**) AND diagnostic* AND (ultrasonography OR ultrasound OR ultrasonic OR sonography OR sonograph OR echocardiography OR echocardiogram))

Results: <http://tinyurl.com/k4hzk7o>

<http://tinyurl.com/mjovk6k%20site:.ac.uk>

<http://tinyurl.com/mrm7p52%20site:.nhs.uk>

((**"community health services"**) AND diagnostic* AND (ultrasonography OR ultrasound OR ultrasonic OR sonography OR sonograph OR echocardiography OR echocardiogram))

Results: <http://tinyurl.com/lc9gbho>

<http://tinyurl.com/ky85re3%20site:.ac.uk>

<http://tinyurl.com/m9eupph%20site:.nhs.uk>

((**"point of care testing" OR "point-of-care testing" OR POCT OR "near patient testing" OR "near-patient testing"**) AND diagnostic* AND (ultrasonography OR ultrasound OR ultrasonic OR sonography OR sonograph OR echocardiography OR echocardiogram))

Results: <http://tinyurl.com/mtsk6en>

<http://tinyurl.com/n7t2pm2%20site:.ac.uk>

<http://tinyurl.com/l9rotf3%20site:.nhs.uk>

Searches of specified websites

Companies providing services

InHealth

Ultrasound AND diagnosis = 101 results: www.inhealthgroup.com/search/gss/ultrasound%20AND%20diagnosis

Results include word variations.

Sonograph AND diagnosis = 3 results:

www.inhealthgroup.com/search/gss/sonograph%20AND%20diagnosis

Results include word variations.

Echocardiograph AND diagnosis = 94 results: www.inhealthgroup.com/search/gss/echocardiograph%20AND%20diagnosis

Results include word variations.

CareUK

Ultrasound AND diagnosis: www.careuk.com/search/careuk/ultrasound%20diagnosis

Ultrasound AND diagnostics: www.careuk.com/search/careuk/ultrasound%20diagnostics

Sonograph AND diagnosis = 0 results

Echocardiograph AND diagnosis = 0 results

Fountain Medical Diagnostic Services

No search feature.

Diagnostic Healthcare

Search feature does not produce relevant results.

Ultrasound is available as an option from the list of services on the home page.

GP Care

Ultrasound + diagnosis = 63 results: www.gpcare.org.uk/site/search/?q=Ultrasound%2Bdiagnosis+&srchBtn=&m=

Ultrasound + diagnostics = 57 results: www.gpcare.org.uk/site/search/?q=Ultrasound%2Bdiagnostics+&srchBtn=&m=

Sonograph + diagnosis = 17 results: www.gpcare.org.uk/site/search/?q=Sonograph%2Bdiagnosis+&srchBtn=&m=

Sonograph + diagnostics = 5 results: www.gpcare.org.uk/site/search/?q=Sonograph%2Bdiagnostics+&srchBtn=&m=

Echocardiograph + diagnosis = 0 results

Echocardiograph + diagnostics = same 5 results as sonograph+diagnostics

Services for specific conditions

Arrhythmia (South Gloucestershire)

Hosted on GP Care website that was searched as part of item 1 (see previous page).

Community cardiology service (Imperial College Healthcare NHS Trust)

Searches for medical technologies do not provide any results.

There are a handful of results for 'diagnostics', although this is obviously searching across the whole Imperial College Health care website and results may therefore not be relevant to the community cardiology service.

www.imperial.nhs.uk/search/index.htm?UserText=diagnostics&fSearchSubmit=%253E&searchSite=imperialweb&searchSection=services&Level1Id=209&searchMode=title

Dedicated diagnostic centres

Harvant NHS Diagnostic Centre

No search feature.

Mid & South Buckinghamshire NHS Diagnostic Centre

No search feature.

Rotherham NHS Diagnostic Centre (located at Community Health Centre)

No search feature.

Additional searches

Open Grey

A search for "Primary care" AND ultrasonography AND daignos* found the following thesis: Community ultrasound A study of the factors influencing transfer into primary care in the context of a shift in service provision (<http://hdl.handle.net/10068/509919>).

Appendix 5 Data extraction tables for Chapter 5

Data extraction of level 1 studies

Study (authors and year)	Everett and Preece 1996 ²²²
Type of study/document	Empirical level 1 ✓ Empirical level 2 Level 3
Study design	Non-comparative study
Country	UK (England)
Setting	Community health centre
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Obstetric
Staff involved	Involved in doing the test and interpreting the results Senior midwife or GP (both had received ultrasound training at the local general hospital)
Research question/objectives	To compare the presence of foetal heart movement at the patient's initial scan with subsequent fetal survival during the first 20 weeks of pregnancy
Research methods	The community ultrasound clinic was set up in 1986 and data were collected for the first 3 years. Data were recorded for the initial scan, the diagnoses of non-viable pregnancies and the outcome of viable pregnancies at 20 weeks (from the patient's health centre records)
Results/data	240 women with bleeding in early pregnancy were scanned. Community ultrasound scanning had a sensitivity of 97% and specificity of 98% for predicting fetal survival to the 20th week of pregnancy. Results of scanning were unclear in eight cases; six patients received a second scan and two were referred to hospital. No fetal heart movement was detected in 117 women and all subsequently miscarried. Authors stated that 'many women were given the option of delaying their hospital admission to the following day, some of whom miscarried at home without being admitted to hospital'
Main findings	Community ultrasound scanning made it possible to quickly identify if pregnancies were viable and make appropriate arrangements, avoiding unnecessary bed rest when miscarriage was inevitable and providing strong reassurance to women with viable pregnancies
Comments	This was not an evaluation of the general practice ultrasound clinic per se but it demonstrated potential benefits of the service in diagnosing patients more quickly and potentially avoiding hospital visits and/or admissions

Study (authors and year)	Wordsworth and Scott 2002 ²⁰³
Type of study/document	Empirical level 1 ✓ Empirical level 2 Level 3
Study design	Cost analysis based on audit data; audit of scan quality; discrete choice experiment
Country	UK (Scotland)
Setting	Rural general practice
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	General

Study (authors and year)	Wordsworth and Scott 2002 ²⁰³
Staff involved	Involved in doing the test and interpreting the results Two GPs (source of training not reported)
Research question/objectives	To evaluate the impact of GP ultrasound scanning on the use of NHS resources and to elicit patient preferences around ultrasound scanning
Research methods	Cost analysis comparing costs of scanning at the health centre vs. scanning at the local teaching hospital; clinical audit of quality of GP scans; discrete choice experiment to elicit patient preferences for who performed the scan, where and acceptable levels of waiting time and accuracy. Effects on patient management compared actual patient management with consensus of what would have been done if GP scanning had not been available
Results/data	Analysis of costs and assessment of scan quality were based on 131 patients scanned over 6 months. Patient preference study used a random sample of 500 patients from practice list and 250 consecutive patients scanned at the practice GP scanning reduced the number of referrals (14.8% vs. 29.9%), emergency hospital admissions (7.8% vs. 13.4%) and hospital scans (0.8% vs. 23.6%). Cost per scan was higher for GP scanning (£36.37 vs. £20.32) but the average cost per episode was lower (£148 vs. £183 (predicted)). Assessment of scan quality revealed a need for further training and it was recommended that GPs should scan more patients per year Response rates for patient preference study were 41% for non-scanned patients and 37% for the scanned group. Patients preferred to be scanned at the practice and were prepared to wait an extra 5.5 days and accept a 3.5% reduction in scan accuracy for their choice. Who carried out the scan was not considered important
Main findings	The results of the study provide some evidence to support GP scanning. Further research was recommended, specifically on relative accuracy of GP and hospital scans; effects of providing the service on GP workload and stress; and alternative models of care such as a radiographer scanning at the practice
Comments	A limitation of the study was its retrospective design and the fact that comparisons were based on hypothetical management rather than an actual control group. The study was performed in a rural setting and patient preferences could be different in an area with closer proximity to hospital services

Study (authors and year)	Salihefendic <i>et al.</i> 2009 ²²⁹
Type of study/document	Empirical level 1 ✓ Empirical level 2 Level 3
Study design	Cohort
Country	Bosnia-Herzegovina
Setting	Primary care clinics
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Abdominal
Staff involved	Involved in doing the test and interpreting the results Two radiologists
Research question/objectives	To assess the influence of abdominal ultrasound on patient management in general practice
Research methods	Comparative study comparing a primary care clinic with direct access to ultrasound scanning (experimental) with a clinic accessing ultrasound by referral to secondary care (control). The reporting is very unclear but the study appears to be attempting to compare ultrasound performed by GPs in primary care clinics with ultrasound obtained by referral to secondary care. What the authors appear to have done is performed scans on patients referred from two primary care clinics, one with direct access to ultrasound and one without, that is, those who GPs say they would scan in each setting. Although not explicitly stated in the paper,

Study (authors and year)	Salihefendic <i>et al.</i> 2009 ²²⁹
	they also appear to have examined the entire patient sample (via records or even by performing a scan on them as well) to identify patients with a theoretical indication for ultrasound. They must also have asked GPs about anticipated patient management before and after knowing the scan results but this is not reported in the methods
Results/data	383 out of 1539 patients in the experimental group and 175 out of 1878 in the control group were scanned. Graph suggests that theoretical indications for ultrasound were present in 416 (experimental) and 336 (control) patients. In the control group, 46 patients (26%) had no abnormalities detected by ultrasound. Abdominal ultrasound resulted in a change in anticipated patient management in 54% of patients, including a reduction in anticipated referrals to medical specialists
Main findings	Authors stated that the use of ultrasound in primary care clinics reduces time to establish a final diagnosis, reduces the need for more expensive tests and can give an early diagnosis of benign and malignant tumours
Comments	The value of this study is limited by lack of clarity about the methods and findings

Level 2 studies

English-language full papers

Study (authors and year)	Goldberg <i>et al.</i> 2003 ²³⁰
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Retrospective diagnostic accuracy study
Country	Australia
Setting	Hospital assessment of tests performed in community settings
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Musculoskeletal
Staff involved	Involved in doing the test and interpreting the results Ultrasound scans were performed by 109 different radiologists on 336 patients. The majority of patients (number not reported) were referred by their doctor for consideration for surgical intervention for full-thickness rotator cuff tear
Research question/objectives	To assess the accuracy of diagnostic ultrasound examinations for diagnosis of full-thickness rotator cuff tears in general community practice
Research methods	Diagnostic ultrasound findings were compared with results of single-contrast arthrography (reference standard) and in 225 cases with findings at surgery. Arthrograms were interpreted by a consultant radiologist and one of the study authors (blinded to clinical and radiological findings). Time from diagnostic ultrasound to arthrography averaged 47 days (range 1–120 days). There were no reports that any patient suffered trauma between the two investigations
Results/data	The accuracy of diagnostic ultrasound was 0.38, sensitivity 0.24 and specificity 0.61. Positive and negative predictive values were 0.49 and 0.34, respectively. There were 155 false negatives and 51 false positives based on the diagnostic ultrasound reports. Findings from surgery and arthrography agreed in all cases, supporting use of the latter as reference standard
Main findings	Diagnostic ultrasound examination in general community settings is not a reliable tool for diagnosis of full-thickness rotator cuff tears
Comments	Authors noted that other studies reporting higher accuracy were relatively small and generally came from units with a special interest in ultrasound

Study (authors and year)	Grubel 2011 ²³¹
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Retrospective diagnostic accuracy study
Country	USA
Setting	Community private practice
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Abdominal
Staff involved	Involved in doing the test and interpreting the results One gastroenterologist, who had undertaken formal ultrasound training as part of a German internal medicine programme
Research question/objectives	To assess the diagnostic accuracy and value for clinical management of ultrasound performed by a gastroenterologist in a community practice
Research methods	Records from March to December 2009 were retrospectively reviewed. Diagnostic accuracy of ultrasound was assessed for patients who subsequently underwent CT, MRI or endoscopic retrograde cholangiopancreatography. Influence of ultrasound findings on subsequent clinical management was also assessed
Results/data	310 patients underwent ultrasound. Abdominal pain, nausea and vomiting, and abnormal liver function tests were the most common indications. Ultrasound findings guided clinical management in two out of three patients (exact numbers not reported). 84 patients subsequently had CT, MRI or endoscopic retrograde cholangiopancreatography within 1 month. A normal ultrasound result was confirmed in 35 out of 40 patients (88%). Abnormal findings were confirmed in 41 out of 44 patients (93%). Ultrasound missed three (4%) significant clinical lesions but no malignancy was overlooked
Main findings	Gastroenterologist-operated ultrasound provides fast and accurate information for the diagnosis and management of abdominal disorders
Comments	

Study (authors and year)	Heikkinen <i>et al.</i> 2005 ²³²
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Cohort
Country	Finland
Setting	Primary care (patients with dyspepsia investigated by GPs in four health centres)
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Abdominal
Staff involved	Involved in doing the test and interpreting the results Ultrasound scanning was performed by an experienced radiologist blinded to the results of clinical, laboratory and endoscopic investigations
Research question/objectives	To assess the role of ultrasound in evaluating dyspepsia and to assess the long-term clinical relevance of minor findings found by ultrasound scanning in patients with functional dyspepsia

Study (authors and year)	Heikkinen <i>et al.</i> 2005 ²³²
Research methods	400 consecutive patients with dyspepsia were recruited. Following ultrasound and gastroscopy, patients were divided into two groups. Endoscopy-positive patients (140) had a final diagnosis identified by endoscopy, while endoscopy-negative patients (260) had no final diagnosis after endoscopy. After further diagnostic work-up, 55 of the endoscopy-negative patients were diagnosed with an organic disease; the remainder were invited to participate in a follow-up study. Follow-up patients received a repeat ultrasound scan 6–7 years after the initial scan and performed by the same radiologist
Results/data	In the endoscopy-negative group, gallstones were detected by ultrasound in 21 patients but were only considered to be the cause of symptoms in nine cases. No malignant lesions were detected. In the endoscopy-positive group a malignant tumour in the kidney was suspected in three patients but only one was confirmed. Several minor findings were revealed by ultrasound Of 260 endoscopy-negative patients, 180 were eligible for follow-up ultrasound and 135 received it. Two significant findings were diagnosed: a small renal cancer and hydronephrosis
Main findings	Wide untargeted use of abdominal ultrasound in evaluating patients with dyspepsia following a gastroscopy is not necessary. Repeated ultrasound examination in people with functional dyspepsia is not recommended and rarely changes the diagnosis
Comments	Relevant to diagnostic yield of ultrasound vs. no ultrasound in an unselected primary care population

Study (authors and year)	Laine <i>et al.</i> 1998 ²³³
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Prospective diagnostic accuracy study
Country	Finland
Setting	Primary care (two health centres covering populations of 30,000–37,000 people)
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Sinus
Staff involved	Involved in doing the test and interpreting the results 12 GPs performed ultrasound scans and interpreted the results. GPs at one centre received standard information on the use of the ultrasound machine from the manufacturer; the other centre had used this machine for 6 years. One of the study principal investigators also performed ultrasound scans but results were not reported
Research question/objectives	To assess the diagnostic accuracy of ultrasound, clinical examination and radiography for diagnosing acute maxillary sinusitis in primary care
Research methods	Ultrasound, clinical examination and radiography (interpreted by experienced radiologists) were performed on consecutive adult patients with suspected acute maxillary sinusitis. Sinus irrigation (reference standard) was performed as soon as possible after ultrasound and radiography
Results/data	Full data were available for 39 patients. Sensitivity of GP ultrasound was 61% and specificity 53%. For ultrasound combined with clinical examination, sensitivity was 70% and specificity 37%. Radiography was the most accurate test (sensitivity 61%; specificity 98%). Poor accuracy of ultrasound was mainly due to a large number of false-positive diagnoses
Main findings	Accuracy of ultrasound in primary care was lower than results reported from specialist practice. More attention should be paid to education and quality management in the use of ultrasound in primary care
Comments	Study limited by small sample size as noted by authors and attributed to unwillingness to undergo sinus puncture

Study (authors and year)	Landers and Ryan 2014 ²³⁴
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	New Zealand
Setting	Palliative care service
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Other (scans performed to assess need for drainage in patients with abdominal ascites and to place the drains safely)
Staff involved	Involved in: doing the test; interpreting the results Specialist palliative care physician and palliative care registrar performed the scans. One of the operators undertook a 1-day course aimed at GPs and non-radiology specialists
Research question/objectives	To evaluate the use of portable ultrasound scanning in the management of abdominal ascites
Research methods	Patient data were prospectively entered into a database over a 12-month period. Charts of all patients were retrospectively reviewed to complete the database and check outcomes
Results/data	Forty-one scans were performed on 32 patients. All except three patients had cancer, with ovarian ($n = 7$) and pancreatic ($n = 4$) cancers being most common. Fluid was present in 19 cases and drains were placed in 17 of these. Twenty-five ultrasounds were completed at home and nine of these patients went on to have paracentesis (drainage). Clinical notes reported relief of symptoms in 8 out of 17 patients who received drainage. There were no major complications, although one procedure did not obtain any fluid and was abandoned
Main findings	Bedside ultrasound allowed some scans and subsequent procedures to be performed at home, increasing convenience for the patient and reducing time spent at the hospital
Comments	Identified limitations include small sample, retrospective data collection and poor quality of documentation, as well as being based on only one centre and two operators

Study (authors and year)	Mäkelaä and Leinonen 1996 ²³⁵
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	Finland
Setting	Primary care (14 health centres with varying facilities for imaging)
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Sinus
Staff involved	Involved in doing the test and interpreting the results 161 GPs agreed to participate; details of training were not reported
Research question/objectives	To assess the effect of imaging techniques on the diagnostic pattern of acute maxillary sinusitis in primary care
Research methods	GPs filled in a questionnaire for each consultation with a patient with suspected sinusitis covering symptoms and their duration; signs on physical examination; diagnostic methods used; diagnosis and how certain they were about it; treatment; control visits ordered; sick leaves; and referral to specialists. Diagnostic tests evaluated were ultrasound, radiography and clinical impression. Availability of imaging techniques was analysed as an independent variable but the behaviour of individual GPs was not evaluated

Study (authors and year)	Mäkelaä and Leinonen 1996 ²³⁵
Results/data	<p>GPs returned 502 questionnaires, of which 446 met inclusion criteria. Imaging was available in 337 cases (radiography 60, ultrasound 101 and both in 176); 109 cases could be judged only by clinical examination</p> <p>When available, ultrasound was used in 82–92% of cases and radiography in 6–32%. Sinusitis was diagnosed in 84–88% of cases when only ultrasound or radiography could be used and 77% when both techniques were available. GPs' confidence in their diagnosis was 39% for clinical examination only, 45% for radiography, 58% for ultrasound and 66% for both technologies. Authors suggested that the convenience of immediate availability of ultrasound may be important for its use. Sensitivity and specificity of ultrasound varied according to the cut-off point and classification used</p>
Main findings	When available, ultrasound is widely used for diagnosing sinusitis in Finnish primary care. Accuracy of diagnosis could be increased by improving the interpretation of ultrasound findings
Comments	All data based on GP reports/records

Study (authors and year)	Pallan <i>et al.</i> 2005 ¹⁶
Type of study/document	<p>Empirical level 1</p> <p>Empirical level 2 ✓</p> <p>Level 3</p>
Study design	Cohort
Country	UK (England)
Setting	Primary care
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	General
Staff involved	<p>Involved in doing the test and interpreting the results</p> <p>Community service: independent radiographer</p> <p>Hospital service: NHS Trust staff</p>
Research question/objectives	To assess the advantages and disadvantages of a radiographer-delivered, primary care-based diagnostic ultrasound service compared with a hospital open-access service
Research methods	Random samples of patients who had used the two services in 2001/2 were identified, as were all GP principals in the area. Waiting times, patient and GP satisfaction were assessed using postal questionnaires. Clinical quality was assessed by review of stored ultrasound images. Access to secondary care following an abnormal scan result was mapped using patient records. Unit cost data were collected for the cost study
Results/data	Response rates were 52.9% (100/189) for the community service patient survey, 44.6% (82/184) for the hospital patient survey and 80.6% (29/36) for the GP survey. Patient characteristics did not vary greatly between the groups. Mean wait for an appointment was 17.4 days (95% CI 15.8 to 19 days) for the community service and 44.5 days (95% CI 38.8 to 50.2 days) for the hospital service. Patients were highly satisfied with both services but GPs were markedly less satisfied with the hospital service. Access to secondary care was not systematically different between services. Quality of stored images and reports was comparable between services. Cost per abnormality detected was higher for the community service (£108 vs. £77) but the difference was not statistically significant
Main findings	The community service reduced waiting times and was of comparable quality with the hospital service. Authors considered that this benefit, together with high patient and GP satisfaction, may justify the possibly higher cost per abnormality detected
Comments	Retrospective study design

Study (authors and year)	Scholten-Peeters <i>et al.</i> 2014 ²²⁴
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Cross-sectional survey
Country	The Netherlands
Setting	Secondary care
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Musculoskeletal
Staff involved	Involved in doing the test and interpreting the results Not applicable
Research question/objectives	To evaluate the opinions and experiences of Dutch orthopaedic surgeons and radiologists about DMUS performed in primary care by physiotherapists or GPs
Research methods	Cross-sectional survey using a questionnaire developed by the authors with the aid of focus groups. Orthopaedic surgeons ($n = 388$) and radiologists ($n = 450$) in the South and Central regions of the Netherlands were invited to participate by e-mail
Results/data	Response rate was 213/838 (25.4%). Most respondents (93.4%) worked in a hospital. Over 90% of radiologists performed DMUS themselves, whereas most surgeons (93.5%) referred patients to a radiologist and only 1.9% performed DMUS themselves Most respondents (86.3%) thought that radiologists were the most appropriate staff to perform DMUS, with only 2.9% choosing physiotherapists and 0.5% GPs. Among radiologists, 21.8% thought radiological technicians were most appropriate. Perceived advantages of DMUS in primary care included faster diagnosis and treatment (23.9%), avoiding referrals (21.1%), cost savings (21.1%) and better indication for referral (17.4%). 48% of respondents saw no advantages in primary care DMUS. Disadvantages mentioned were false-positive results (71.4%); lack of experience (70%); insufficient education (69.5%); not able to relate DMUS results to other forms of diagnostic imaging (65.7%); and false-negative results (65.3%). Only 5.6% believed that primary care DMUS had more advantages than disadvantages Most respondents trusted the DMUS knowledge of specific radiologists; smaller percentages trusted specific physiotherapists (13.3%) and GPs (3.4%). The majority of respondents repeated DMUS in secondary care for those who had a scan in primary care (no number/percentage reported)
Main findings	Radiologists and orthopaedic surgeon in the Netherlands showed low trust in the DMS knowledge of physiotherapists and GPs. Results should be interpreted cautiously because of the low response rate and uncertain generalisability to other countries
Comments	

DMUS, diagnostic musculoskeletal ultrasound.

Study (authors and year)	Thoomes-de Graaf <i>et al.</i> 2014 ²³⁶
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Cohort (diagnostic reliability)
Country	The Netherlands
Setting	Primary care physiotherapy

Study (authors and year)	Thoomes-de Graaf <i>et al.</i> 2014 ²³⁶
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Musculoskeletal
Staff involved	Involved in: doing the test; interpreting the results 13 physiotherapists with > 1 year of experience of diagnostic ultrasound, including > 100 diagnostic ultrasounds of the shoulder; nine experienced radiologists who specialised in musculoskeletal complaints and regularly performed diagnostic ultrasound of the shoulder
Research question/objectives	To evaluate the degree of agreement on the interpretation of diagnostic ultrasound in patients with shoulder pain between physiotherapists and radiologists
Research methods	Part of a larger cohort study. Patients who received diagnostic ultrasound from a primary care physiotherapist visited a radiologist within 1 week for a second scan. Patients and radiologists were blinded to the physiotherapist's diagnosis. Four primary diagnostic categories were identified. Agreement was assessed using Cohen's kappa. Kappa values of 0.81–1.00 were considered as almost perfect agreement; 0.61–0.80 substantial; 0.41–0.60 moderate; 0.21–0.40 fair; 0.01–0.20 slight; and < 0.01 poor. Subgroup analyses were performed based on experience and education of the physiotherapists
Results/data	65 patients were enrolled and 13 physiotherapists and 9 radiologists performed diagnostic ultrasound. The overall kappa across all four diagnostic categories was 0.36 (95% CI 0.29 to 0.43), indicating fair agreement. There was good agreement on diagnosis of full-thickness tears (kappa 0.63, 95% CI 0.31 to 0.94). In subgroup analyses, kappa values were higher for more experienced physiotherapists [0.43 (95% CI 0.25 to 0.63) vs. 0.17 (95% CI -0.15 to 0.50)] and for those with advanced rather than basic training [0.43 (95% CI 0.27 to 0.60) vs. 0.09 (95% CI -0.30 to 0.48)]
Main findings	Agreement between physiotherapists and radiologists is borderline substantial for full-thickness tears and slight to moderate for other diagnoses. More experience and training of physiotherapists may increase reliability
Comments	

Study (authors and year)	van Gorp <i>et al.</i> 2013 ²²³ and van den Brink 2013 ²⁵³
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Cohort
Country	The Netherlands
Setting	Primary care
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Echocardiography
Staff involved	Involved in doing the test and interpreting the results Test performed by ultrasound technicians Interpretation by cardiologists from Erasmus Medical Centre
Research question/objectives	To evaluate an open-access echocardiography service provided independently of the regional hospitals
Research methods	Patients referred for open access echocardiography between April 2011 and April 2012 were eligible for the study. Referring GPs were asked what they would have done with this patient if open-access echocardiography had not been available. After the GP had received the results and contacted the patient, they were asked by telephone what management had been initiated; whether or not they had followed the cardiologist's advice; and if they thought the echocardiogram had been of benefit. GPs were also asked to estimate waiting time for echocardiography via referral to a cardiologist

Study (authors and year)	van Gorp <i>et al.</i> 2013 ²²³ and van den Brink 2013 ²⁵³
Results/data	155 patients were referred to the open-access service and full data were available for 105. GPs reported that they referred fewer patients to a cardiologist than they would have done without the service [36 (34%) vs. 97 (92%)] and managed more patients themselves [65 (62%) vs. 10 (10%)]. Cardiologist advice was reportedly followed in 25 out of 31 cases (81%). In 127 cases (82%), the GP thought the echocardiogram was beneficial for decision-making. Waiting time for echocardiography via referral was estimated at 5 weeks, compared with 6 days via the community open-access service
Main findings	Of 55 patients with suspected heart failure, the Dutch clinical guideline for heart failure was followed for 34 (62%); for 13 (24%) patients, neither ECG nor NT-proBNP was performed The open-access service reduced referrals to cardiologists, saved time and enabled GPs to manage more patients themselves. However, adherence to diagnostic guidance for heart failure was suboptimal
Comments	Study compares actual with hypothetical management rather than having a true control group Critique of this study in van den Brink 2013. ²⁵³ Issues mentioned: open-access was independent of local hospitals; ultrasound technicians insufficiently trained at first and certification not mentioned; cardiologists had insufficient information; and uncertain legal consequences. Van den Brink stated that open-access echocardiography could mislead the patient into thinking they are receiving state-of-the-art treatment when this is not the case

Study (authors and year)	Varonen <i>et al.</i> 2003 ²³⁷
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Prospective diagnostic accuracy study
Country	Finland
Setting	Primary care (nine health centres)
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Sinus
Staff involved	Involved in doing the test and interpreting the results 35 GPs performed ultrasound scans and interpreted the results. GPs received a small group tutorial on the use of ultrasound from an experienced ENT specialist
Research question/objectives	To assess the accuracy of symptoms, signs and ultrasound findings for diagnosis in patients with clinically suspected AMS in the context of a randomised trial of AMS therapy, using radiography as a reference standard
Research methods	Patients with a clinical diagnosis of AMS were recruited. Data on symptoms and signs were collected for all patients. Ultrasound scans were classified as sinusitis or non-sinusitis for both maxillary sinuses. At one health centre, patients had sinus radiography between 15 and 60 minutes after the ultrasound examination, which acted as a reference standard. Ultrasound results were frozen and printed and later read by an ENT specialist blinded to the patient's clinical status. Interpretations were compared with those of the GPs
Results/data	150 patients were recruited, of whom 32 received radiography. Prevalence of AMS was 74 out of 148 (50%) in those with ultrasound results and 13 out of 32 (41%) in the subgroup with radiography results. Sensitivity of the best combination of signs/symptoms was 71% (95% CI 56% to 87%) and specificity 42% (95% CI 25% to 59%). Using radiography as reference standard, sensitivity of ultrasound was 92% (95% CI 83% to 100%) and specificity 95% (95% CI 87% to 100%) with the patient as unit of analysis. With sinuses as the unit of analysis, sensitivity of ultrasound was 71% (95% CI 59% to 82%) and specificity 91% (95% CI 85% to 98%). Agreement between GP and specialist interpretation of ultrasound was moderate (kappa 0.47). Authors noted that the use of ultrasound or radiography would reduce antibiotic prescriptions by a half in patients with clinically diagnosed AMS

Study (authors and year)	Varonen <i>et al.</i> 2003 ²³⁷
Main findings	With practice and training, primary care physicians can perform sinus ultrasound as accurately as specialists, potentially reducing unnecessary use of antibiotics. Symptoms and clinical examination were not reliable in AMS diagnosis
Comments	AMS, acute maxillary sinusitis.

English-language conference abstracts

Study (authors and year)	Gallagher <i>et al.</i> 2012 ²⁴²
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	Ireland?
Setting	Primary care
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Echocardiography
Staff involved	Involved in doing the test and interpreting the results Unclear who performed the test. Echocardiograms were reviewed by a consultant cardiologist
Research question/objectives	To evaluate outcomes from a community outreach clinic for diagnosis of heart failure
Research methods	GPs were given direct access to natriuretic peptide testing followed by facilitated access to echocardiography in the community. Echocardiograms were reviewed by a consultant cardiologist and patients with abnormal echocardiogram results were reviewed by a heart failure nurse specialist and a consultant cardiologist in a primary care centre. Referrals over the initial 6 months of the service were analysed
Results/data	Of 66 patients who completed assessment, 37 had echocardiography; 23 were abnormal and 17 patients diagnosed with heart failure
Main findings	Direct access to diagnostics and specialist review in the community offer the opportunity for elderly patients to access specialist care in a timely manner
Comments	Unclear if community service or hospital outreach

Study (authors and year)	Hoyer <i>et al.</i> 2007 ²⁴³
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	Germany
Setting	Not applicable

Study (authors and year)	Hoyer <i>et al.</i> 2007 ²⁴³
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Echocardiography
Staff involved	Involved in doing the test and interpreting the results Not applicable
Research question/objectives	To evaluate the supra-regional success of a structured training programme in handheld echocardiography and POC brain natriuretic peptide testing for GPs
Research methods	The training programme was delivered to 24 GPs at each of two cardiology centres. After each session, GPs were tested against experts in a multiple choice quiz
Results/data	In both centres, concordance of BNP quiz results was > 90% after the first session. Data for the echocardiography quiz are presented. Total training time for echocardiography was 225 ± 34 minutes at centre 1 and 236 ± 28 minutes at centre 2
Main findings	GPs could determine presence or absence of heart failure using handheld echocardiography after < 4 hours of expert teaching
Comments	No full publication detected

Study (authors and year)	Singh <i>et al.</i> 2009 ²⁴⁴
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	UK (England)
Setting	One-stop diagnostic clinic
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Echocardiography
Staff involved	Involved in doing the test and interpreting the results Unclear who performed and interpreted echocardiography. Clinic was run by a 'primary care physician specialist'
Research question/objectives	To evaluate the role of a one-stop clinic in validating the diagnosis of heart failure in the community
Research methods	A retrospective study examined outcomes of patients referred to the clinic between January 2002 and December 2007. All patients received tests including trans-thoracic echocardiography
Results/data	In 6 years, 1008 patients were referred. Of these, 292 (29%) had confirmed LVSD on echocardiography. For the 716 without LVSD, an alternative cause for symptoms was identified in 578 (81%)
Main findings	Only 29% of patients with suspected heart failure in the community had proven LVSD. The ability to provide alternative diagnoses for most patients without LVSD was seen as an advantage of the one-stop clinic over open-access echocardiography
Comments	Unclear if community- or hospital-based service

Foreign-language papers (limited data extraction)

Study (authors and year)	Blanchet and Thierry 2015 ²³⁸
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Qualitative research (semi-structured interviews and focus group)
Country	France
Setting	Primary care (GPs from Savoie and Haut-Savoie)
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	General
Staff involved	Involved in doing the test and interpreting the results Not applicable
Research question/objectives	To identify barriers to use of ultrasound by GPs in the office setting
Research methods	An interview guide was developed and semistructured interviews were conducted with eight GPs. A focus group involved six GPs (two trainees were also present). Interviews were transcribed and data coded independently using the process of triangulation. Themes and subthemes were identified and agreed between the authors. NVivo software (QSR International, Warrington, UK) was used to code and classify the data
Results/data	Data saturation was achieved by the individual interviews (no new themes emerged from the focus group). None of the GPs was currently using ultrasound; seven stated an interest in using it and five had undergone training. Fifteen principal themes were identified, which the authors summarised as lack of experience with ultrasound in general practice; mastering ultrasound scanning techniques; uncertain relevance of ultrasound scanning in general practice; the GPs' own reluctance to use the technique; and possible legal issues
Main findings	In addition to identifying the barriers to use of ultrasound, the authors discussed how to overcome them, including teaching basic ultrasound to medical students and creating a degree in general practice ultrasound. They also suggested further research to better define the place of ultrasound in French general practice
Comments	Grey literature (thesis). In French with English abstract

Study (authors and year)	de la Figuera <i>et al.</i> 2012 ²³⁹
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative
Country	Spain
Setting	Primary care (four health centres)
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Echocardiography
Staff involved	Involved in doing the test and interpreting the results Not reported (assumed to be primary care staff but not explicitly stated)
Research question/objectives	To analyse the clinical adequacy of the application, performance and diagnostic decisions resulting from echocardiograms requested by GPs

Study (authors and year)	de la Figuera <i>et al.</i> 2012 ²³⁹
Research methods	Retrospective review of medical records and echocardiography reports
Results/data	Data on 684 patients who underwent echocardiography in 2006–7 were analysed. 84% of requests were appropriate and 79.7% showed the presence of disease. Echocardiography results influenced decision-making in > 35% of cases: 17.1% were referred to a cardiologist, 10.5% had their treatment changed and 9.6% were referred for additional tests
Main findings	Use of echocardiography was highly appropriate and the results influenced clinical decision-making in a high percentage of cases. Authors concluded that echocardiography should be available to all GPs
Comments	Percentages used as reported, exact numbers not always clear

Study (authors and year)	Esquerra <i>et al.</i> 2012 ²⁴⁰
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Cohort (diagnostic reliability)
Country	Spain
Setting	Hospital radiology department and primary care centre
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	Abdominal
Staff involved	Involved in doing the test and interpreting the results GPs undertaking training in ultrasound; radiologists
Research question/objectives	To assess the effect of training GPs in low complexity abdominal ultrasound on their diagnostic competence
Research methods	Selected patients undergoing low complexity abdominal ultrasound were scanned independently by a GP and radiologist who were blinded to each other's findings. The kappa score was calculated for the primary diagnosis (pathological vs. normal) and for the ultrasound for each abdominal organ. A kappa of 0.8 or more was considered to indicate a good level of training. An interim analysis was performed after 6 months of training and a final analysis at the end of the study (1 December 2006 to 31 March 2008)
Results/data	Two GPs underwent training involving a course of 100 hours of teaching followed by 112 hours based in the hospital radiology department. 120 patients needing low complexity abdominal ultrasound were selected from a total of 868 ultrasound examinations scheduled. In the interim analysis, kappa for the primary ultrasound diagnosis was 0.85. At the end of the study the overall kappa score was 0.89 (95% CI 0.82 to 0.98). Kappa values were high (> 70%) for individual organs except for the pancreas (0.38) and spleen (0.48). For the primary diagnosis, GP scans had a sensitivity of 95.5% (95% CI 91.8% to 99.2%) and specificity of 94.3% (95% CI 90.2% to 98.5%)
Main findings	It is feasible for trained GPs to perform low complexity diagnostic abdominal ultrasound
Comments	Small sample means results may not be widely generalisable

Study (authors and year)	Evangelista <i>et al.</i> 2013 ²⁴¹
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Cohort (diagnostic reliability)
Country	Spain
Setting	Urban primary care centre
Application of ultrasound (e.g. echocardiography, GI, musculoskeletal, obstetric)	'Pocket' echocardiography
Staff involved	Involved in doing the test and interpreting the results GP trained in pocket echocardiography; expert cardiologist. GP had received recommended basic training for non-cardiologists
Research question/objectives	To assess the diagnostic value of pocket echocardiography performed by a GP in patients with arterial hypertension
Research methods	Patients with arterial hypertension underwent examination by a GP using pocket echocardiography. Studies were assessed by an expert cardiologist, blinded to the GP's findings, and analysed quantitatively by computer software
Results/data	Data for 393 consecutive patients seen between January 2011 and January 2012 were analysed. Pocket echocardiography took < 5 minutes and quality of images was good or acceptable in 98% of cases. Agreement between GP and cardiologist was rated very good (kappa > 0.83) for dimensions of the left ventricle, left atrium and ascending aorta, interventricular septum thickness, aortic regurgitation and aortic valve sclerosis. Agreement was rated good (kappa > 0.71) for mitral regurgitation and mitral valve calcification. Six out of 228 significant lesions diagnosed by the cardiologist were missed by the GP
Main findings	Pocket echocardiography performed by a GP as an extension of clinical assessment provides an early diagnosis of significant cardiac lesions which may improve therapeutic management
Comments	Appears to be based on a single GP, again limiting generalisability of findings

Appendix 6 Characteristics of included level 3 studies for *Chapter 5*

Study (authors and year)	Study design	Setting	Research question/methods	Main findings	Limitations
Aitken 1999 ⁴⁴	Qualitative	English NHS	Qualitative study aiming to identify issues that are important when transfer of ultrasound services to a community setting is considered; understand the views of users and providers; and understand factors affecting the decision process. Used eight focus groups followed by a questionnaire study of 1167 service providers and users	Overall, 353 health professionals and 495 patients completed the questionnaire. In addition to obstetric monitoring, gynaecology and routine abdominal ultrasound were seen as services that could be community-based. Respondents suggested the service could be located at a health centre or GP surgery and staffed by radiographers. Key issues were communication (with secondary care), quality and training. Hospital-based clinicians were concerned about the quality of service possible in a community setting and the possibility that inappropriate funding could result in two inefficient services	Thesis, not peer-reviewed publication. Covers pregnancy monitoring as well as diagnostic ultrasound
Bono and Campanini 2007 ²⁴⁵	Descriptive	Italian primary care	Describes training courses organised by METIS (scientific society of the Italian Federation of GPs)	Courses began in autumn 2006. Trained GP ultrasonographers expected to handle up to 40% of scan requests	No data on outcomes or updated reports located
Cardiac Networks Co-ordinating Group 2006 ²²⁰	Expert group report	Welsh NHS	Expert group recommendations based on consensus statement from the BSE and other policy documents	Outlines possible models and workforce issues. Stresses the importance of quality assurance. Whatever model is adopted should link into a BSE-accredited hospital department	No updates located
Colquhoun <i>et al.</i> 1995 ²⁴⁶	Editorial (expert opinion)	English NHS	Expert opinion as to the best way to provide access to echocardiography for GPs	Favours open access to hospital facilities as the best model of service	Expert opinion but represents views of BSE and British Cardiac Society
Doddy 2009 ²⁴⁷	Descriptive	English NHS (general practice)	Describes author's use of ultrasound as a GP, including training, costs, indications and perceived benefits	GP ultrasound has numerous benefits, including peace of mind and improved understanding for patients and avoidance of unnecessary referrals	Represents experience of one GPwSI
Hoelscher <i>et al.</i> 2013 ²⁴⁸	Review	Emergency care	Literature review	Use of transcranial ultrasound for pre-hospital diagnosis of stroke has the potential to significantly improve management	Non-systematic review

Study (authors and year)	Study design	Setting	Research question/methods	Main findings	Limitations
Hussain <i>et al.</i> 2004 ²⁴⁹	Feasibility study	English NHS (GP training)	Evaluation of real-time videoconferencing between a GP surgery and university department of radiology for training and supervision of GPs performing ultrasound of the bladder, prostate and kidneys. Fifteen patients were randomly selected for comparison of hard-copy and transmitted images	Of 105 transmitted images, 90% were classified as diagnostic and 10% were classified as non-diagnostic. Agreement of technical quality scores for transmitted and hard-copy images was poor ($\kappa = 0.04$). Authors concluded that teleultrasound is feasible in primary care. The GP involved benefited from regular ultrasound training and supervision	Again, involved a single GPwSI
Mjølstad <i>et al.</i> 2012 ²⁵⁰	Feasibility study	Norwegian primary care	Evaluation of GPs' ability to evaluate left ventricular function using pocket ultrasound. Seven GPs participated and received 8 hours of supervised training. Their findings were compared with those of cardiologists	Among 92 patients, GPs were able to obtain a standard view and measure same (septal mitral annular excursion) in 87% of cases. Their findings did not differ from those of the cardiologists. Authors concluded that with targeted training GPs could use pocket ultrasound to assess left ventricular function	Still a relatively small sample
NIHR DEC Oxford 2014 ⁴⁵	Review	Primary care	Horizon Scanning report (non-systematic literature review) on portable (POC) ultrasound	Several research gaps were identified covering identification of priority needs; evaluation of technical capabilities; and consensus over training, competency demonstration, medical legal issues and regulatory approval	Echocardiography excluded, no report found
Ottenheijm <i>et al.</i> 2011 ²⁵¹	RCT protocol	Dutch primary care	Protocol of RCT comparing therapy based on ultrasound findings vs. usual care for patients with shoulder pain	Trial to provide evidence on the cost-effectiveness of ultrasound for diagnostic triage in primary care	No published results identified: author contacted
Robinson <i>et al.</i> 1997 ²¹⁵	Survey	English NHS	Assessment of provision of ultrasound services to primary care in northern England and attitudes of GPs and radiologists towards training GPs to perform ultrasound. Based on postal surveys of GPs (67% response), practice managers (59%) and radiologists (68%)	Around half of GPs did not have direct access to ultrasound for obstetric referrals and 22% for non-obstetric referrals. 52% of GPs were moderately or very interested in ultrasound training but only 3/13 radiology departments were willing to provide training. 73% of GPs preferred an open-access service vs. 15% for a practice-based service	

Study (authors and year)	Study design	Setting	Research question/methods	Main findings	Limitations
Scholten-Peeters <i>et al.</i> 2014 ²²⁴	Survey	Secondary care	To evaluate the opinions and experiences of Dutch orthopaedic surgeons and radiologists about DMUS performed in primary care by physiotherapists or GPs	Radiologists and orthopaedic surgeon showed low trust in the DMUS's knowledge of physiotherapists and GPs	Low response rate (25%); results may not be generalisable
Senior <i>et al.</i> 2003 ²⁵²	Review	Primary care	Review of pros and cons of handheld echocardiography and BNP for detecting LVSD	Further research is required but authors noted that plasma BNP estimation may rule out LVSD, leaving only those with high values requiring echocardiography	Non-systematic review
Siu <i>et al.</i> 2013 ²⁰⁵	Survey	Primary care	Survey to determine current practice and opinions of family physicians in Yukon, Canada, regarding bedside ultrasonography performed in community settings	Respondents had substantial experience in bedside ultrasonography and the vast majority were ready to use the technology in community settings. However, the skills and willingness of the physicians have not translated into actual use. Respondents considered economics (equipment cost and remuneration) as the biggest barrier, followed by confidence, reliability and skill maintenance	Small sample; results may not be generalisable
Vicente-Moliner <i>et al.</i> 2009 ²⁵⁴	Review	Primary care	Review of ultrasound in primary care based on searches on INAHTA, PubMed and scientific societies from 1996 to 2006	A small number of relevant articles were found (no details or synthesis presented), contrasting with a high level of activity reported by the scientific societies in organising work groups, courses, etc.	Spanish language, used mainly as reference source
Xiao 2003 ²⁵⁵	Review	Primary care	Review of early handheld echocardiography devices	Handheld echocardiography is expected to reduce referrals and waiting times for hospital echocardiography services. Its use is limited by inability to detect subtle changes and by the need for training	Non-systematic review

DMUS, diagnostic musculoskeletal ultrasound; INAHTA, International Network of Agencies for Health Technology Assessment.

Appendix 7 Quality assessment tables for Chapter 5

Quality assessments using the Downs and Black checklist²²⁶

Checklist question	Salihefendic <i>et al.</i> 2009 ²²⁹	Pallan <i>et al.</i> 2005 ¹⁶	van Gurp <i>et al.</i> 2013 ²²³
1. Aim clearly described	Yes	Yes	Yes
2. Outcomes clearly described	No	Yes	Yes
3. Patient characteristics clearly described	Yes? (See comments)	Yes? (See comments)	Yes
4. Interventions clearly described	Yes	Yes	Yes
5. Principal confounders clearly described	No	No	No
6. Main findings clearly described	No	Yes	Yes
7. Random variability for the main outcome provided	No	Yes	No
8. Adverse events reported	No	No	No
9. Loss to follow-up reported	No	Yes? (See comments)	Yes
10. Actual <i>p</i> -value provided for main outcome	No	No	Yes
11. Sample asked to participate representative of the population	Yes	Yes	Yes
12. Sample agreed to participate representative of the population	Yes	Unable to determine	Yes
13. Staff participating representative of the patient's environment	Unable to determine	Yes	Yes
14. Attempt to blind participants	No	No	No
15. Attempt to blind assessors	No	No	No
16. Data dredging results stated clearly	Unable to determine	Yes	Yes
17. Analysis adjusted for length of follow-up	Yes?	Yes	Yes
18. Appropriate statistics	Unable to determine	Yes	Yes
19. Reliable compliance	Yes	Yes	Yes
20. Accurate outcome measures	Unable to determine	Yes	Yes
21. Same population	No	Yes?	Yes
22. Participants recruited at the same time	Yes	Yes	Yes
23. Randomised?	No	No	No
24. Adequate allocation concealment?	No	No	No
25. Adequate adjustment for confounders?	No	No	Unable to determine

Checklist question	Salihefendic <i>et al.</i> 2009 ²²⁹	Pallan <i>et al.</i> 2005 ¹⁶	van Gorp <i>et al.</i> 2013 ²²³
26. Loss to follow-up taken into account?	No	Unable to determine	No
27. Power calculation	? No sample size calculation, unclear what relevant sample size would be	? Sample size calculation was reported	? Sample size calculation was reported
Comments	3. Mentions all patients plus exclusions; diagnosis only reported	3. Inclusion criteria very limited but appropriate for this type of study; diagnosis only reported 9. Percentage of patients for whom records were not available	No actual control group 3. Brief inclusion criteria and table 17. Similar follow-up for all 25. Adjusted for 'nesting'

Yes? indicates a lower degree of certainty about the judgement.

Quality assessments using the Canadian Institute of Health Economics tool for case series

	Everett and Preece 1996 ²²²	Wordsworth and Scott 2002 ²⁰³	Heikkinen <i>et al.</i> 2005 ²³²	Landers and Ryan 2014 ²³⁴	Mäkelä and Leinonen 1996 ²³⁵
1. Hypothesis/objective clearly stated?	Yes	Yes	Yes	Yes	Yes
2. Participant characteristics described?	Partially reported	No	Yes	Yes	Yes
3. More than one centre?	No	No	Yes	No	Yes
4. Eligibility criteria stated?	Yes?	Yes	Partially reported	Yes?	Yes
5. Participants recruited consecutively?	Yes?	Yes	Yes	Unclear	Unclear
6. Participants at a similar point in the disease?	Yes?	Unclear	Unclear	Unclear	Yes?
7. Intervention clearly described?	Yes	Yes	Yes	Yes	Partially reported
8. Co-interventions reported?	No	No	Unclear	Yes	Yes
9. Outcome measures established a priori?	Yes	Partially reported	Partially reported	Partially reported	Partially reported
10. Outcomes measured with appropriate methods?	Yes	Yes	Yes	Unclear	Yes
11. Outcomes measured before and after intervention?	No	No	Yes	Yes	No
12. Were statistical tests appropriate?	Unclear?	Unclear	Yes	Unclear	Yes

	Everett and Preece 1996 ²²²	Wordsworth and Scott 2002 ²⁰³	Heikkinen <i>et al.</i> 2005 ²³²	Landers and Ryan 2014 ²³⁴	Mäkelä and Leinonen 1996 ²³⁵
13. Length of follow-up reported?	Yes? (See comments)	Yes	Yes	No	Unclear
14. Loss to follow-up reported?	Yes?	Yes (see comments)	Yes	Yes	Yes
15. Estimates of random variability provided?	No	No	No	No	No
16. Adverse events reported?	No?	Yes	No	Yes	No
17. Conclusions supported by results?	Yes	Yes	Yes	Partially reported	Yes
18. Competing interests and funding sources reported?	No	Partially reported	No	Partially reported	No
19. Study conducted prospectively?	Unclear (see comments)	No	Yes	No	Yes
20. Were outcome assessors blinded to intervention status?	No	No	No	No	No
Comments	20-week assessment could be considered as follow-up? Results reported for all included participants Appears to be retrospective but not explicitly stated	Considers actual patient management (table 1) as case series Results reported for all patients (actual management) Adverse events = issues indicating need for further training	Case series because only one group in follow-up Patients recruited consecutively to original study	No statistical tests or discussion but reason fairly clear 16. Adverse events of paracentesis, not ultrasound per se	

Yes? indicates a lower degree of certainty about the judgement.

Quality assessment of economic studies

	Wordsworth and Scott 2002 ²⁰³	Pallan <i>et al.</i> 2005 ¹⁶
1. Was a well-defined question posed in an answerable form?	Yes?	Yes?
2. Was a comprehensive description of the competing alternatives given?	Yes	Yes
3. Was the effectiveness of the programmes or services established?	Yes?	Can't tell
4. Were all the important relevant costs and consequences for each alternative identified?	Yes?	No?
5. Were costs and consequences measured accurately in appropriate physical units?	Can't tell	Can't tell
6. Were costs and consequences valued credibly?	Yes?	Can't tell
7. Were costs and consequences adjusted for differential timing?	No	No

	Wordsworth and Scott 2002 ²⁰³	Pallan <i>et al.</i> 2005 ¹⁶
8. Was an incremental analysis of costs and consequences of alternatives performed?	Can't tell	Yes
9. Was allowance made for uncertainty in the estimates of costs and consequences?	Yes?	No
10. Did the presentation and discussion of study results include all issues of concern to users?	Can't tell	Can't tell
Comments	1. NHS viewpoint, although not stated explicitly 6. Source for costs cited 7. But probably not relevant due to short time frame	1. NHS viewpoint, although not stated explicitly 6. Source of cost data not reported 7. But probably not relevant due to short time frame

Yes? indicates a lower degree of certainty about the judgement.

Quality assessment using the QUADAS tool for diagnostic studies (Cochrane Collaboration version)

	Goldberg <i>et al.</i> 2003 ²³⁰	Grubel 2011 ²³¹	Laine <i>et al.</i> 1998 ²³³	Thoomes-de Graaf <i>et al.</i> 2014 ²³⁶	Varonen <i>et al.</i> 2003 ²³⁷
1. Was the spectrum of patients representative of the patients who will receive the test in practice? (Representative spectrum)	Yes	Yes	Unclear	Unclear	Unclear
2. Is the reference standard likely to classify the target condition correctly? (Acceptable reference standard)	Yes	Yes	Yes	Yes	Yes
3. Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests? (Acceptable delay between tests)	Unclear	Yes	Yes	Yes	Yes
4. Did the whole sample or a random selection of the sample, receive verification using the intended reference standard? (Partial verification avoided)	Yes	No	Yes	Yes	No
5. Did patients receive the same reference standard irrespective of the index test result? (Differential verification avoided)	Yes	Unclear	Yes	Yes	Yes

	Goldberg <i>et al.</i> 2003 ²³⁰	Grubel 2011 ²³¹	Laine <i>et al.</i> 1998 ²³³	Thoomes-de Graaf <i>et al.</i> 2014 ²³⁶	Varonen <i>et al.</i> 2003 ²³⁷
6. Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)? (Incorporation avoided)	Yes	Yes	Yes	Yes	Yes
7. Were the reference standard results interpreted without knowledge of the results of the index test? (Index test results blinded)	Yes	Unclear	Unclear	Yes	Yes
8. Were the index test results interpreted without knowledge of the results of the reference standard? (Reference standard results blinded)	Yes	Yes	Yes	Yes	Yes
9. Were the same clinical data available when test results were interpreted as would be available when the test is used in practice? (Relevant clinical information)	Yes	Yes	Yes	Yes	Yes
10. Were uninterpretable/intermediate test results reported? (Uninterpretable results reported)	Yes	Yes	Yes	Yes	Yes
11. Were withdrawals from the study explained? (Withdrawals explained)	Yes	Yes	Yes	Yes	Yes
Comments	10. There seem to be no uninterpretable results 11. All patients included in analysis	3. Reference test within 1 month 4/5. Verification a major issue for this study, which is not a standard diagnostic study 10. There seem to be no uninterpretable results or withdrawals	1. Some potential patients did not consent	1. Patients were trial participants 2. Radiologist finding treated as reference standard 10. No uninterpretable results?	1. Patients were trial participants

Appendix 8 Companies providing diagnostic ultrasound services

Service provider	URL
Beverly Community Ultrasound	www.cqc.org.uk/location/1-485585806
Care UK	www.careuk.com/news/nhs-patients-benefit-ultrasound-services-shakeup
Community Outpatients	www.communityoutpatients.co.uk/ultrasound
Deepings Practice	www.deepingspractice.co.uk/Ultrasound_Clinician.php
Diagnostic Healthcare Ltd	www.diagnostichealthcareltd.com/
Diagnostic Ultrasound Coventry	www.duc-ultrasound.co.uk/index.htm
Diagnostic Ultrasound Services (Oxtd)	www.oxtdultrasound.com/
Essex Ultrasound	www.essexultrasound.co.uk/nhs.html
Excell Ultrasound	www.excellultrasound.co.uk/
Global Diagnostics	www.globaldiagnostics.co.uk/healthcare_partners/testimonials.asp
GP Care	www.gpcare.org.uk/site/nhspatients/ultrasound/
Health Harmonie	www.healthharmonie.co.uk/gp-commissioners/direct-access-ultrasound/
Horizon Health	horizonhealth.co.uk/ultrasound.php
InHealth	www.inhealthgroup.com
IVS (Independent Vascular Services)	www.ivs-online.co.uk/nhs-product/customers/primary-care-trusts-pcts/
Peninsula Ultrasound	www.peninsulaultrasound.co.uk/
Physiological Measurements Ltd	www.physiologicalmeasurements.com/community-ultrasound.php
Suffolk GP Federation	www.suffolkfed.org.uk/pages/ultrasound.php
The Ultrasound Centre	www.theultrasoundcentre.co.uk/#!aboutus/c66t
Ultrasound Direct	www.ultrasound-direct.com/about-us/nhs-direct-access-ultrasound/
Ultrasound Now	www.ultrasoundnow.co.uk/nhs/
Yorkshire Health Solutions	www.yorkshirehealthsolutions.com/#!community-ultrasound/c63o

AQP, any qualified provider; HCP, Health Professions Council.

Appendix 9 Search strategies and related information for Chapter 6

Table of results

Searches performed: 3 July 2015.

	Results
MEDLINE	786
EMBASE	1624
Cochrane CDSR	27
Cochrane CENTRAL	198
Cochrane DARE	1
Cochrane NHS EED	2
Cochrane HTA	1
CINAHL	125
Web of Science	678
Total	3442
Total after duplicates have been removed	2075

Search strategies

MEDLINE

1. primary care.tw. (77,439)
2. general practi\$.tw. (64,660)
3. primary health care.tw. (15,642)
4. Community Mental Health Services/ (16,875)
5. Family Practice/ (60,364)
6. Home Care Services/ (28,354)
7. Physicians, Family/ (14,826)
8. Community Health Services/ (27,489)
9. Community Health Nursing/ (18,588)
10. Community Pharmacy Services/ (3045)
11. Community Health Workers/ (3475)
12. Preventive Health Services/ (11,290)
13. or/1-12 (274,163)
14. dyspnea/ (16,034)
15. dyspn?ea.ti,ab. (33,559)
16. breathless\$.ti,ab. (3655)
17. (short\$ adj2 breath).ti,ab. (5496)
18. (breath\$ adj2 difficult\$).ti,ab. (1558)
19. orthopnea.ti,ab. (431)
20. spirometry/ (17,974)

21. spirometry.ti,ab. (11,698)
22. respiratory care.ti,ab. (1548)
23. respiratory service\$.ti,ab. (73)
24. (community adj3 respiratory).ti,ab. (1421)
25. or/14-24 (75,124)
26. diagnostic services/ (1783)
27. nursing diagnosis/ (3904)
28. diagnos\$.ti,ab. (1,781,010)
29. mobile health units/ (3052)
30. mobile health unit\$.ti,ab. (53)
31. mobile health clinic\$.ti,ab. (23)
32. rapid access clinic\$.ti,ab. (38)
33. one stop shop\$.ti,ab. (376)
34. (point of care testing or point-of-care testing or POCT or near patient testing or near-patient testing).ti,ab. (1867)
35. or/26-34 (1,788,486)
36. 13 and 25 and 35 (914)
37. limit 36 to yr="2000 –Current" (786)

EMBASE

1. primary care.tw. (99,530)
2. general practi\$.tw. (83,237)
3. primary health care.tw. (17,910)
4. general practice/ (72,724)
5. home care/ (50,319)
6. general practitioner/ (69,001)
7. community care/ (49,886)
8. community health nursing/ (25,766)
9. pharmacy/ (58,551)
10. health auxiliary/ (3607)
11. preventive health service/ (22,758)
12. or/1-11 (431,957)
13. dyspnea/ (99,727)
14. dyspn?ea.ti,ab. (51,589)
15. breathless\$.ti,ab. (5393)
16. (short\$ adj2 breath).ti,ab. (10,087)
17. (breath\$ adj2 difficult\$).ti,ab. (2495)
18. orthopnea.ti,ab. (910)
19. spirometry/ (29,794)
20. spirometry.ti,ab. (17,853)
21. respiratory care.ti,ab. (2182)
22. respiratory service\$.ti,ab. (130)
23. (community adj3 respiratory).ti,ab. (1819)
24. or/13-23 (154,821)
25. nursing diagnosis/ (3767)
26. diagnos\$.ti,ab. (2,425,045)
27. mobile health unit\$.ti,ab. (50)
28. mobile health clinic\$.ti,ab. (24)
29. rapid access clinic\$.ti,ab. (128)
30. one stop shop\$.ti,ab. (533)
31. (point of care testing or point-of-care testing or POCT or near patient testing or near-patient testing).ti,ab. (2840)

32. or/25-31 (2,429,314)
33. 12 and 24 and 32 (1770)
34. limit 33 to yr="2000 –Current" (1624)

The Cochrane Library

- #1 (primary care):ti,ab,kw
- #2 ("general practi*"):ti,ab,kw
- #3 (primary health care):ti,ab,kw
- #4 MeSH descriptor: [Community Mental Health Services] this term only
- #5 MeSH descriptor: [Family Practice] this term only
- #6 MeSH descriptor: [Home Care Services] this term only
- #7 MeSH descriptor: [Physicians, Family] this term only
- #8 MeSH descriptor: [Community Health Services] this term only
- #9 MeSH descriptor: [Community Health Nursing] this term only
- #10 MeSH descriptor: [Community Pharmacy Services] this term only
- #11 MeSH descriptor: [Community Health Workers] this term only
- #12 MeSH descriptor: [Preventive Health Services] this term only
- #13 (or #30–#38)
- #14 MeSH descriptor: [Dyspnea] this term only
- #15 dyspn?ea:ti,ab
- #16 breathless*:ti,ab
- #17 (short* near/2 breath):ti,ab
- #18 (breath* near/2 difficult*):ti,ab
- #19 orthopnea:ti,ab
- #20 MeSH descriptor: [Spirometry] this term only
- #21 spirometry:ti,ab
- #22 (respiratory care):ti,ab
- #23 (respiratory service*):ti,ab
- #24 (community near/3 respiratory):ti,ab

- #25 (or #14–#24)
- #26 MeSH descriptor: [Diagnostic Services] this term only
- #27 MeSH descriptor: [Nursing Diagnosis] this term only
- #28 diagnos*:ti,ab
- #29 MeSH descriptor: [Mobile Health Units] this term only
- #30 (mobile health unit*):ti,ab
- #31 (mobile health clinic*):ti,ab
- #32 (rapid access clinic*):ti,ab
- #33 (one stop shop*):ti,ab
- #34 (point of care testing or point-of-care testing or POCT or "near patient testing" or "near-patient testing"):ti,ab
- #35 {or #26-#34}
- #36 #13 and #25 and #35 Publication Year from 2000 to 2015

Cumulative Index to Nursing and Allied Health Literature

- S35 S12 AND S24 AND S34
- S34 S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33
- S33 TI ("point of care testing" or "point-of-care testing" or "POCT" or "near patient testing" or "near-patient testing")
OR AB ("point of care testing" or "point-of-care testing" or "POCT" or "near patient testing" or "near-patient testing")
- S32 TI "one stop shop*" OR AB "one stop shop*"
- S31 TI "rapid access clinic*" OR AB "rapid access clinic*"
- S30 TI "mobile health clinic*" OR AB "mobile health clinic*"
- S29 TI "mobile health unit*" OR AB "mobile health unit*"
- S28 (MH "Mobile Health Units")
- S27 TI diagnos* OR AB diagnos*
- S26 (MH "Nursing Diagnosis")
- S25 (MH "Diagnostic Services")
- S24 S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23
- S23 TI community N3 respiratory OR AB community N3 respiratory
- S22 TI "respiratory service*" OR AB "respiratory service*"
- S21 TI "respiratory care" OR AB "respiratory care"
- S20 TI spirometry OR AB spirometry
- S19 (MH "Spirometry")
- S18 TI orthopnea OR AB orthopnea
- S17 TI (breath* N2 difficult*) OR AB (breath* N2 difficult*)
-

S16 TI short* N2 breath OR AB short* N2 breath
 S15 TI breathless* OR AB breathless*
 S14 TI dyspn?ea OR AB dyspn?ea
 S13 (MH "Dyspnea")
 S12 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11
 S11 (MH "Community Health Workers")
 S10 (MH "Pharmacy Service")
 S9 (MH "Community Health Nursing")
 S8 (MH "Community Health Services")
 S7 (MH "Physicians, Family")
 S6 (MH "Home Health Care")
 S5 (MH "Family Practice")
 S4 (MH "Community Mental Health Services")
 S3 TI "primary health care" OR AB "primary health care"
 S2 TI "general practi*" OR AB "general practi*"
 S1 TI "primary care" OR AB "primary care"

Web of Science

# 32	678	#31 AND #23 AND #13 <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 31	1,181,490	#30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 30	2033	TS=("point of care testing" or "point-of-care testing" or POCT or "near patient testing" or "near-patient testing") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 29	449	TS=("one stop shop*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 28	53	TS=("rapid access clinic*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 27	13	TS=("mobile health clinic*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 26	29	TS=("mobile health unit*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 25	29	TS=("mobile health unit*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 24	1,179,784	TS=(diagnos*) <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>

# 23	19,976	#22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 22	1726	TS=(community NEAR/3 respiratory) <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 21	57	TS=("respiratory service*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 20	628	TS=("respiratory care") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 19	8267	TS=(spirometry) <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 18	286	TS=(orthopnea) <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 17	916	TS=(breath* NEAR/2 difficult*) <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 16	2952	TS=(short* NEAR/2 breath) <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 15	2324	TS=(breathless*) <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 14	3913	TS=(dyspn?ea) <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 13	113,080	#12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1 <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 12	541	TS=("Preventive Health Service*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 11	1585	TS=("Community Health Worker*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 10	169	TS=("Community Pharmacy Service*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 9	243	TS=("Community Health Nursing") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 8	561	TS=("Community Health Service*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 7	6628	TS=("family physician*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 6	874	TS=("Home Care Service*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>

# 5	3730	TS=("Family Practice*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 4	567	TS=("Community Mental Health Service*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 3	10,717	TS=("primary health care") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 2	37,362	TS=("general practi*") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>
# 1	73,830	TS=("primary care") <i>Indexes=SCI-EXPANDED, SSCI, CPCI-S, CPCI-SSH Timespan=2000-2015</i>

Appendix 10 Quality assessment tables for Chapter 6

Tool for assessing the quality of intervention studies

Potential risk of bias	Bias present?	Detail of concerns
1. Selection bias: method used to generate the allocation sequence, method used to conceal the allocation sequence, characteristics of participant group(s)	Yes/no/unclear	
2. Performance bias: measures used to blind participants and personnel and outcome assessors, presence of other potential threats to validity	Yes/no/unclear	
3. Attrition bias: incomplete outcome data, high level of withdrawals from the study	Yes/no/unclear	
4. Detection bias: accuracy of measurement of outcomes, length of follow-up	Yes/no/unclear	
5. Reporting bias: selective reporting, accuracy of reporting	Yes/no/unclear	

Tool for assessing cohort studies

1. Did the study address a clearly focused question/issue?
2. Is the research method (study design) appropriate for answering the research question?
3. Were there enough subjects (employees, teams, divisions, organisations) in the study to establish that the findings did not occur by chance?
4. Was the selection of the cohort/panel based on external, objective and validated criteria?
5. Was the cohort/panel representative of a defined population?
6. Was the follow up of cases/subjects long enough?
7. Were objective and unbiased outcome criteria used?
8. Are objective and validated measurement methods used to measure the outcome?
9. Is the size effect practically relevant?
10. How precise is the estimate of the effect? Were CIs given?
11. Were reasonable attempts made to account for confounding factors?
12. Can the results be applied to other settings?

Tool for assessing the quality of survey studies

Did the study address a clearly focused research question?

Is the study design appropriate for answering the research question?

Is the method of selection of the subjects clearly described?

Was the way the sample was obtained likely to be free of selection bias?

Was the sample of subjects representative with regard to the population to which the findings will be referred?

Was the sample size based on pre-study considerations of statistical power?

Was a satisfactory response rate achieved?

Are the measures (questionnaires) likely to be valid and reliable?

Was the statistical significance assessed?

Are CIs given for the main results?

Were reasonable attempts made to account for confounding factors?

Can the results be applied to other settings?

Quality appraisal tool for qualitative studies

1. Was there a clear statement of the aim of the research?	Yes/no
2. Is a qualitative methodology appropriate to address the aims of the research?	Yes/no
3. Was the recruitment strategy appropriate to the aims of the research?	Yes/no/unclear
4. Were the data collected in a way that addressed the research issue?	Yes/no/unclear
5. Has the relationship between researcher and participant been adequately considered?	Yes/no
6. Have ethical issues been taken into account?	Yes/no/unclear
7. Was the data analysis sufficiently rigorous?	Yes/no
8. Is there a clear statement of findings?	Yes/no

Assessment of intervention studies (randomised and non-randomised controlled trials and before-and-after studies)

Study and year	Selection bias	Performance bias	Attrition bias	Detection bias	Reporting bias	Other concerns
Akhtar and Wilson 2005 ²⁶¹	No	No Blinding not appropriate	Yes	No	No	Non-randomised design Higher dropout from pulmonary function lab 'first' group
Burgos 2011 ²⁶⁴	Yes	No Blinding not appropriate	No	No	No	No information on method of allocation or concealment. Some baseline differences
Burri <i>et al.</i> 2012 ²⁶⁵	Yes	No Blinding not appropriate	No	No	No	Some baseline differences (<i>p</i> -values not given)
Carr <i>et al.</i> 2011 ²⁶⁷	No	No Blinding not appropriate	No	No	No	
Lusardi <i>et al.</i> 2006 ²⁷⁹	Unclear	No Blinding not appropriate	Yes	No	No	No reporting of groups at baseline 135/333 completed: no reporting of differences

Study and year	Selection bias	Performance bias	Attrition bias	Detection bias	Reporting bias	Other concerns
Masa <i>et al.</i> 2011 ²⁸⁰	Yes	No Blinding not appropriate	No	No	No	No information on method of allocation or concealment Age difference between groups at baseline
Poels <i>et al.</i> 2006 ²⁸⁴	No	No	No	No	No	
Tomonaga <i>et al.</i> 2011 ²⁸⁸	Unclear	No Blinding not appropriate	No	No	No	No information on method of allocation or concealment

Assessment of cohort study

Study and year	1	2	3	4	5	6	7	8	9	10	11	12	Comments/concerns
Van der Mark <i>et al.</i> 2014 ²⁸⁹	Yes												

Assessment of cross-sectional studies (including service data analyses)

Study and year	1	2	3	4	5	6	7	8	9	10	11	12	Comments/concerns
Borg <i>et al.</i> 2010 ²⁶³	Yes	Yes	Yes	Yes	Yes	No	NA	Yes	Yes	No	Yes	Yes	
Cawley <i>et al.</i> 2011 ²⁶⁸	Yes	Yes	Yes	Yes	Yes	No	NA	Yes	Yes	No	Yes	Yes	
Chavannes <i>et al.</i> 2004 ²⁶⁹	Yes	Yes	Yes	No	Yes	NR	NR	Yes	Yes	Yes	Yes	Yes	Selection bias: GPWSts in spirometry
Hassett <i>et al.</i> 2006 ²⁷⁴	Yes	Yes	No	No	Yes	No	NA	Yes	Yes	No	Yes	Yes	16 of 33 practices 'selected' (unclear)
Jones <i>et al.</i> 2005 ²⁷⁵	Yes	Yes	Yes	Yes	Yes	No	No	Yes	No	No	Yes	Yes	7 of 14 practices declined
Lodewijks-van der Bolt <i>et al.</i> 2007 ²⁷⁸	Yes	Yes	No	No	Yes	No	NA	Yes	Yes	No	Yes	Yes	Not clear how the sample was obtained
Starren <i>et al.</i> 2012 ¹⁸²	Yes	Yes	Yes	Yes	Yes	No	NA	Yes	Yes	No	Yes	Yes	
Thijssing <i>et al.</i> 2014 ²⁸⁷	Yes	Yes	Yes	Yes	No	No	NA	Yes	No	No	Yes	Yes	All GPs had spirometer linked to computer
van Heur <i>et al.</i> 2010 ¹⁰⁵	Yes	Yes	Yes	Yes	Yes	No	NA	Yes	Yes	No	Yes	Yes	
Walker <i>et al.</i> 2006 ²⁹⁰	Yes	Yes	No	Yes	Yes	No	NA	Yes	Yes	No	Yes	Yes	
White <i>et al.</i> 2007 ¹⁸⁷	Yes	Yes	Yes	Yes	Yes	No	NA	Yes	Yes	Yes	Yes	Yes	Convenience sample
Wolfenden <i>et al.</i> 2009 ²⁹²	Yes	Yes	Yes	Yes	Yes	No	NA	Yes	No	No	Yes	Yes	

NA, not applicable; NR, not reported.

Quality assessment of level 1 and level 2 papers

Study and year	Clear statement of the aims	Qualitative methodology appropriate	Recruitment strategy appropriate	Data collected to address research issue	Relationship researcher/ participant	Ethical issues	Rigour of data analysis	Clear statement of findings	Details/comments
Level 1									
Roberts <i>et al.</i> 2011 ¹⁹⁷	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Low
Level 2									
Armstrong <i>et al.</i> 2012 ²⁹³	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Low
Birt <i>et al.</i> 2014 ²⁹⁴	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Low
Corner <i>et al.</i> 2005 ²⁹⁵	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Low
Corner <i>et al.</i> 2006 ²⁹⁶	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Low
Dennis <i>et al.</i> 2010 ²⁹⁷	Yes	Yes	Yes	Yes	No	Unclear	Yes	Yes	Low
Goeman <i>et al.</i> 2005 ²⁹⁸	Yes	Yes	Yes	Yes	No	Yes	Unclear	Yes	Low
Joo <i>et al.</i> 2013 ¹⁹⁸	Yes	Yes	Yes	Yes	No	Unclear	Unclear	Yes	Some aspects are not reported in sufficient detail
Khunti <i>et al.</i> 2002 ⁸²	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	Low
Tod <i>et al.</i> 2008 ²⁹⁹	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Low
Walters <i>et al.</i> 2005 ³⁰⁰	Yes	Yes	Yes	Yes	No	No	Unclear	Yes	Brief summary paper
Walters <i>et al.</i> 2008 ³⁰¹	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	This paper reports the same study as Walters <i>et al.</i> ³⁰⁰

Appendix 11 Search strategies for Chapter 4

Stage 1

Setting	Primary Care or General Practice or Community Care
Intervention	Diagnostic Techniques and Procedures; Diagnostic Services; Diagnostic Tests or One of the following modalities: Audiology; Point of Care Testing; Cardiac Services; ECG; Echocardiography; Diabetic Services; Endoscopy; Genetic Testing Laboratory Tests; Magnetic Resonance Imaging; Radiology/X-Ray Respiratory Tests; Ultrasound 'direct access imaging' 'direct access mri' 'rapid access cardiology'
Factors/considerations	Barrier\$or Facilitator\$or Logistic\$or Feasib\$OR/organisation & administration

Stage 2

Domain	Concepts	Search terms
Setting	Primary Care or General Practice or Community Care UK	Family Practice Great Britain
Modalities	Audiology Cardiac Services ECG Echocardiography Diabetic Services Endoscopy Genetic Testing Laboratory Tests Magnetic Resonance Imaging Point of Care Testing (haemoglobin A1c (HbA1c) and urine albumin: creatinine ratio (ACR) on patients with diabetes, total cholesterol, triglyceride and high density lipoprotein cholesterol on patients with hyperlipidaemia, and INR on patients on anticoagulant therapy) Radiology/X-Ray Respiratory Tests Ultrasound	exp Diagnostic Techniques, Otological exp Diagnostic Techniques, Cardiovascular exp Echocardiography exp Endoscopy exp Genetic Testing exp Magnetic Resonance Imaging Point-of-Care Systems exp Radiography exp Diagnostic Techniques, Respiratory System exp Ultrasonography

Domain	Concepts	Search terms
Factors/considerations	Skills & expertise: Skill mix; Extended roles; Inappropriate Test Ordering	Physician's Practice Patterns
	Training: Training Needs; Training Costs; Duration	
	Equipment: Equipment for modality and for analysis; consumable costs	Diagnostic Equipment
		Equipment Safety
		Equipment Design
		Equipment Failure
		Equipment Failure Analysis
		Maintenance
	Premises: Cost of Premises; Health & Safety	
	User perspective: Waiting Times; Acceptability; Repeat Procedures	
	Primary-secondary interface: Referrals, Changes to Diagnosis or Management Pathways	/utilisation

Appendix 12 Horizon Scanning reports

Horizon Scanning reports (<http://madox.org/horizon-scanning-report>) are compiled on priority technologies for specific clinical questions. They provide an overview of emerging technologies and related clinical advantages with specific reference to patient group and use, assessing importance and documenting previous research. The reports also identify the outstanding research questions as well as expected outcomes.

Each report is evaluated by a panel of experts and more detailed secondary reports are compiled on selected technologies. Reports are disseminated to the NIHR HTA programme and commissioners.

- A portable handheld electronic nose in the diagnosis of cancer, asthma and infection.
- Alternative sampling methods for collection of urine specimens in older adults.
- Autoimmune markers for the diagnosis of rheumatoid arthritis in primary care.
- Automated lung sound analysis for asthma.
- Dermoscopy for the diagnosis of melanoma in primary care.
- Diagnostic technology: genotyping polymorphisms affecting warfarin metabolism.
- Diagnostic technology: handheld ECG monitors for the detection of AF in primary care.
- Estimating central blood pressure and arterial stiffness in primary care using non-invasive automated pulse wave analysis.
- Handheld HeartScan ECG monitor for detecting atrial fibrillation in primary care.
- Handheld nerve conduction measurement devices for carpal tunnel syndrome.
- iPhone, iPod and iPad (Apple Inc., Cupertino, CA, USA) add-on or plug-in medical devices.
- Non-contact infrared thermometers.
- POC blood test for ketones in diabetes patients.
- POC B-type natriuretic peptide testing.
- POC international normalised ratio coagulometers for self-management of oral anticoagulation.
- POC test for CRP.
- POC test for HbA_{1c}.
- POC test for cardiac troponin.
- POC test for procalcitonin to improve the early diagnosis of serious bacterial infections in patients presenting in primary care.
- POC test for the analysis of lipid panels.
- POC test for total white blood cell count.
- POC testing for coeliac disease.
- POC testing for hepatitis C virus.
- POC testing for thyroid-stimulating hormone.
- POC tests for influenza in children.
- POC urine albumin-to-creatinine ratio test for the early detection and management of renal disease and as a risk factor for cardiovascular disease.
- Pulse oximetry in primary care.
- Screening instruments for frailty in primary care.
- Spirometry in primary care for COPD case finding, self-monitoring and remote technology.
- Testing for *Chlamydia trachomatis* in primary care using self-taken swabs.
- The D-dimer test for ruling out deep-vein thrombosis in primary care.
- Transcutaneous bilirubin measurement.

Published versions

Nicholson *et al.*,⁴⁷⁸ Wang *et al.*,⁴⁷⁹ Goel *et al.*,⁴⁸⁰ Mahtani *et al.*,⁴⁸¹ Khangura *et al.*,⁴⁸² Plüddemann *et al.*,⁴⁸³ Plüddemann *et al.*,⁴¹³ Plüddemann *et al.*,⁴⁸⁴ Parkes *et al.*,⁴⁴³ Plüddemann *et al.*,⁴⁸⁵ Plüddemann *et al.*,⁴⁸⁶ Plüddemann *et al.*,⁴³⁷ and Plüddemann *et al.*³⁶²

Appendix 13 Data extraction tables for Chapter 6

Intervention papers

Study (authors and year)	Akhtar and Wilson 2005 ²⁶¹
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Comparative study. Non-randomised
Country	UK (Leicester)
Setting	Primary care
Training/equipment	
Staff involved	
Research question/objectives	To compare the accuracy of nurse use of spirometry vs. a centralised laboratory
Research methods	Forty-five patients were assessed at both their local practice by a nurse and a pulmonary function laboratory. The results obtained were compared
Results/data	Practice nurses underestimated FEV ₁ and FVC. The mean difference in FEV ₁ was 0.109 l (6.69%, 95% CI 2.88% to 9.51%) compared with a bellows spirometer, and 0.07 l (6.2%, 95% CI 0.89% to 8.25%) when the same type of spirometer was used. The mean difference in FVC was 0.413 l (15.0%, 95% CI 9.3% to 20.6%) when compared with bellows, and 0.267 l (10.2%, 95% CI 4.1% to 16.2%) when the same type of spirometer was used. All differences were statistically significant ($p < 0.05$). Agreement on categorisation of COPD was moderate (kappa 0.46) with practice nurses overestimating severity. Compared with Pulmonary Function Laboratory categorisation for the presence or absence of COPD using bellows spirometers, the sensitivity of practice nurse spirometry was 0.93 (95% CI 0.76 to 0.99) and specificity was 0.65 (95% CI 0.38 to 0.86)
Main findings	Spirometry results obtained by practice nurses were lower than those obtained in a specialised laboratory, with the potential for overdiagnosis of COPD severity
Comments	
FEV ₁ , forced expiratory volume in 1 second.	

Study (authors and year)	Borg <i>et al.</i> 2010 ²⁶³
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	Australia
Setting	Rural health facilities
Training/equipment	A 14-hour spirometry course facilitated by respiratory scientists with at least 5 years' experience
Staff involved	Nurses, physiotherapists
Research question/objectives	To determine whether or not a 14-hour course provides sufficient skill to obtain valid results and whether or not follow-up training improves validity

Study (authors and year)	Borg <i>et al.</i> 2010 ²⁶³
Research methods	Participants underwent follow-up assessments against ATS criteria 5, 7 and 9 months after the initial course. Further education was provided after the reviews at 5 and 7 months
Results/data	Fifteen participants from 10 sites completed the three reviews. Adherence to ATS criteria was 40% at 5 months, 67% at 7 months and 87% at 9 months. Retrospective review found that 37%, 60% and 58% of tests at 5, 7 and 9 months, respectively, met ATS criteria and had correctly selected the best test
Main findings	Authors concluded that a 14-hour spirometry course does not provide sufficient skill to perform spirometry to ATS criteria and short-term follow-up is important for improving test validity
Comments	
ATS, American Thoracic Society.	

Study (authors and year)	Burgos 2011 ²⁶⁴
Type of study/document	Empirical level 1 ✓ Empirical level 2 Level 3
Study design	Comparative study 18 primary care centres: 12 randomised to intervention arm and 6 to control arm
Country	Spain
Setting	Primary care
Training/equipment	Nurses received 2 days' training which included performing 'several manoeuvres' and discussion on standardisation. Nurses in intervention arm in addition had access to a website with educational content and via this able to ask questions of and receive feedback from a co-ordinator regarding the quality of spirometry Disposable and pre-calibrated pneumotachograph-based spirometer (Datospir 110) or an ultrasound transit time-based spirometer (EasyOne) used, connected to a computer. The computer program used was one module of an information and communication technology platform used to manage chronic patients
Staff involved	Thirty-four nurses, five co-ordinators and three telecommunication engineers
Research question/objectives	To evaluate a web-based application
Research methods	A total of 4581 patients with respiratory symptoms identified by 150 GPs and tested with spirometry by nurses who had access to web application or not. Acceptability of intervention reported by GPs and usability rated by nurses
Results/data	Over a 12-month period the intervention group presented 71.5% high-quality spirometries, the control group 59.5% high-quality tests ($p < 0.001$). No change over time for the intervention group whereas the quality in the control group reduced between months 1 and 12 ($p = 0.011$). The intervention nurses also carried out more spirometry tests over the study period. 97% of GPs rated the web functionality as acceptable, 26% reported problems of implementation. Nurse scores for usability over 50 for efficiency, effect, helpfulness and learning-ability
Main findings	The intervention increased the proportion of high-quality spirometry tests (by around 20%) and decreased the percentage of very low-quality spirometries. The application was perceived to be acceptable and useful
Comments	

Study (authors and year)	Burri <i>et al.</i> 2012 ²⁶⁵
Type of study/document	Empirical level 1 ✓ Empirical level 2 Level 3
Study design	Comparative study RCT
Country	Switzerland
Setting	Primary care
Training/equipment	BNP measured via collecting venous blood sample in a tube containing a rapid fluorescence immunoassay (from Biosite Diagnostics). All GPs were 'repeatedly trained' in the most appropriate use of BNP levels
Staff involved	No detail of who provided the training
Research question/objectives	To evaluate whether or not adding BNP testing in primary care would improve the evaluation and diagnosis of patients with breathlessness
Research methods	323 patients seen by 29 primary care physicians: 160 in the control arm (conventional diagnosis) and 163 in the additional BNP intervention arm
Results/data	There was less further diagnostic testing in the BNP group (33% vs. 45% of patients $p = 0.02$). The time to initiation of appropriate treatment (associated with less further testing) reduced by 12 days in the BNP group ($p = 0.01$). In the BNP group 66% of patients began appropriate treatment on the day of presentation vs. 53% in the control group ($p = 0.02$). The number of hospitalisations for dyspnoea, the number of days in hospital or the number of outpatient visits were not significantly different between the groups at 3 or 12 months. There was no difference in severity of dyspnoea at 3 months; both groups had improved
Main findings	The use of BNP in primary care improved diagnostic certainty and time to initiation of treatment but appeared to have few benefits for service delivery costs at 3 or 12 months
Comments	

Study (authors and year)	Carr <i>et al.</i> 2011 ²⁶⁷
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Before-and-after study
Country	UK (England)
Setting	Primary care (one general practice)
Training/equipment	Educational intervention involving a presentation by a GPwSI in respiratory medicine, a visit from a local secondary care consultant and a visit from a secondary care specialist nurse
Staff involved	GPs, nurses
Research question/objectives	To assess the impact of an educational intervention on the quality of spirometry
Research methods	Retrospective audit followed by re-audit following educational intervention
Results/data	Forty-five spirometry reports were assessed in each audit. Before the intervention, 17/45 (38%) post-bronchodilator spirometry tests were technically flawed. After the intervention, 1/44 (2%) was flawed. Chest clinic referrals fell from 28/45 (62%) to 14/44 (32%)
Main findings	The authors concluded that technical quality of spirometry can be audited and in-house education can significantly reduce spirometry errors with a possible follow-on effect on referrals
Comments	

Study (authors and year)	Cawley <i>et al.</i> 2011 ²⁶⁸
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study. Retrospective cohort, patients who attended clinic 2008–10
Country	USA
Setting	Spirometry clinic in a primary care physician office
Training/equipment	The spirometer Workstation software and flow transducer. Checked and calibrated at the beginning of each day
Staff involved	A pharmacist who was a registered pulmonary therapist and certified pulmonary function technologist
Research question/objectives	What was the added value of a pharmacist-led spirometry clinic?
Research methods	Patients > 8 years of age with cough, shortness of breath, pulmonary diagnosis or other pulmonary symptoms referred by physicians in the primary care clinic or other physicians outside the clinic for spirometry testing. Testing was carried out by a clinical pharmacist. The pharmacist also carried out patient interview, performed pulse oximetry, recommended pharmacological intervention, provided drug education and smoking cessation literature
Results/data	Estimated each patient would require a 1 hour 15 minutes appointment to carry out testing. Cost calculated as Medicare reimbursement fee = US\$85.80 per patient. A total of 51 patients attended appointments offered (of 65 scheduled). Subsequent physician consultation or further testing was required for 27.4% of patients
Main findings	Authors report study demonstrates that pharmacists can accurately perform spirometry and optimise pharmaceutical care for patients, although only data relating to this are number requiring further services
Comments	Data mostly relate to characteristics of patients and describes the medications required, with few regarding accuracy or impact of clinic

Study (authors and year)	Chavannes <i>et al.</i> 2004 ²⁶⁹
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study. Cross-sectional
Country	Netherlands
Setting	Primary care
Training/equipment	2 × 3-hour sessions of training with an interval of 1 month
Staff involved	39 GPs with an interest in spirometry and involved in vocational training
Research question/objectives	To compare the achievements of trained GPs in spirometric diagnosis with an expert consensus panel (1) and to assess the influence of spirometry on the GPs' decision-making (2)
Research methods	Standardised case descriptions (× 12) developed from actual cases, designed by a GP and pulmonologist. The cases depicted a range of respiratory conditions as well as normal respiration and their typical flow–volume curves. Participating GPs worked through two sets of six cases each that were assessed in random order by a research assistant within a period of 1 year. Assessment followed presentation of patient history and physical examination data including FEV, FEV ₁ /FVC and flow–volume curves. GPs had to select a diagnosis from a list

Study (authors and year)	Chavannes <i>et al.</i> 2004 ²⁶⁹
	<p>Prior to the assessment the 12 cases had been judged by an independent panel including pulmonologists and the judgments of two researchers were in 100% concordance with these. These judgements formed the 'gold standard'</p> <p>Clinical outcomes were analysed, also the impact of spirometry on GP decision-making</p> <p>SPSS: univariate analyses and logistical regression</p>
Results/data	<p>Three GPs dropped out, one retired and two lost interest</p> <p>A total of 444 cases were assessed. Concordance with the expert panel in terms of obstruction was 91.3% (95% CI 86.8% to 95.8%). Normal spirometry obtained 77.9% (95% CI 70.2% to 85.6%) correct answers, incorrect manoeuvres reached a score of 64.9% (95% CI 54.0% to 75.8%), and rare pathological curves were recognised in 41.3% (95% CI 32.1% to 50.5%) of cases. Positive predictive values (probability of righteously labelling disease) revealed a range of values between 0.87 (normal curves) and 0.49 (rare pathology)</p> <p>The number of diagnoses considered by the GPs reduced following the use of spirometry, creating less uncertainty (from a mean of 2 diagnoses per case, range 1–8 to a mean of 1.35, range 1–6). More than one diagnosis was considered in 59.6% (95% CI 55.1% to 64.1%) of cases before spirometry, whereas after spirometry more than one diagnosis was considered in 31.2% (95% CI 26.9% to 35.5%) of cases (odds ratio 0.266, 95% CI 0.200 to 0.353). The probability of referral changed from 6.0% (95% CI 3.8% to 8.2%) to 31.7% (95% CI 27.4% to 36.0%) as a result of spirometry (odds ratio 7.26, 95% CI 4.71 to 11.2)</p>
Main findings	<p>There was a reduction in the number of alternative diagnoses but an increase in referral rates and diagnostic prednisolone courses. The establishing of a diagnosis in patients with respiratory morbidity may have improved, but this probably leads to an increased use of additional diagnostic procedures or specialist care, at least initially. Trained GPs differentiated between normal and obstructive disease patterns, while indicators of rare and mixed pathology were often missed</p>
Comments	<p>FEV₁, forced expiratory volume in 1 second; SPSS, Statistical Product and Service Solutions.</p>

Study (authors and year)	Hassett <i>et al.</i> 2006 ²⁷⁴
Type of study/document	<p>Empirical level 1</p> <p>Empirical level 2 ✓</p> <p>Level 3</p>
Study design	<p>Non-comparative study. Cross-sectional – analysis of referral patterns, questionnaire to GPs and patients</p>
Country	<p>UK (London)</p>
Setting	<p>A community respiratory assessment unit. The unit was based in a hospital adjacent to a respiratory nursing service by was described as a 'community service' and also provided peripatetic service to practices furthest away from base</p>
Training/equipment	<p>Nurses trained at Education for Health centre in use of spirometry. GPs sent educational materials on causes of breathlessness, asthma guidelines and aids to differential diagnosis. The nurses also visited each practice. Chairperson of PCT also wrote to GPs about the service</p>
Staff involved	<p>2 × specialist nurses with experience in respiratory medicine, assistance provided by GP colleagues and a local respiratory consultant</p>
Research question/objectives	<p>To evaluate a community respiratory assessment unit service</p>
Research methods	<p>16 GP practices initially included, with 17 added 6 months later. GPs referred patients for patients diagnosed or with suspected COPD or asthma or for unexplained cough or breathlessness. Analysis of referral data and satisfaction survey to GPs and patients</p>

Study (authors and year)	Hassett <i>et al.</i> 2006 ²⁷⁴
Results/data	<p>364 patients referred in first 12 months of service, age range 18–90 years, 36% smokers. Significant differences in referral rates between practices. Most frequent reason for referral was suspected or definite COPD (57% of referrals). One-quarter of these patients had no abnormalities detected. 28% of referrals were for definite or suspected asthma, with 34% of these having airway narrowing detected</p> <p>There was a 48% response rate to questionnaire ($n = 41$), all but two GPs had used the service, 51% satisfied and 46% very satisfied with service, 88% felt patients had benefited from service. GPs reported that 58% of cases would have been referred to a specialist hospital respiratory outpatient clinic if the unit did not exist, 53% would have had a trial of therapy (answers not mutually exclusive). Patient satisfaction high (99% rated experience of unit as good, very good or excellent)</p>
Main findings	The reason for the referral (suspected COPD/asthma) was often not confirmed on assessment. Satisfaction rates for the unit were high
Comments	The paper presents data on average referral rates over the time frame of the unit's existence; however, it provides no analysis

Study (authors and year)	Jones <i>et al.</i> 2005 ²⁷⁵
Type of study/document	<p>Empirical level 1</p> <p>Empirical level 2 ✓</p> <p>Level 3</p>
Study design	Non-comparative study. Cross-sectional data
Country	UK (England: Plymouth)
Setting	GP practices
Training/equipment	Practice staff education (spirometry, data interpretation, COPD management). Spirometry clinics offered bronchodilator and steroid reversibility assessments
Staff involved	Trained respiratory nurse specialist experienced in practice nursing and a GP with a 'respiratory special interest'
Research question/objectives	To evaluate a mobile spirometry service
Research methods	Practices that were known to own a spirometer were offered practice staff education and/or spirometry clinics
Results/data	<p>Fourteen practices randomly selected from those known to have a spirometer; seven accepted the service. Of those who declined, three reported already well organised, three failed to respond and one quoted time restraint issues. Total cost of the study was £6189 after deduction of set-up expenses of £107 per new patient diagnosed with COPD</p> <p>A total of 98 patients assessed during study; only six found to have normal lung function</p>
Main findings	The service enabled the diagnosis and treatment of many new cases of COPD
Comments	Limited data (e.g. reported high satisfaction with service but no data)

Study (authors and year)	Lodewijks-van der Bolt <i>et al.</i> 2007 ²⁷⁸
Type of study/document	<p>Empirical level 1</p> <p>Empirical level 2 ✓</p> <p>Level 3</p>
Study design	Non-comparative study. Analysis of referrals 2002–6
Country	The Netherlands

Study (authors and year)	Lodewijks-van der Bolt <i>et al.</i> 2007 ²⁷⁸
Setting	Echocardiography service in a local hospital
Training/equipment	Hospital-based equipment
Staff involved	Staff in echocardiography unit
Research question/objectives	To evaluate an open-access echocardiography service
Research methods	Patients referred to the open access service by GPs following examination, 107 of 471 patients referred for dyspnoea. Echocardiography carried out without referral to a cardiologist
Results/data	No cardiac abnormality was found in 28% of patients
Main findings	The service identified around one-quarter of patients with no cardiac abnormality who may otherwise have been referred to a cardiologist (no data, however, making this comparison)
Comments	The paper predominantly contains clinical data regarding the characteristics of patients referred

Study (authors and year)	Lusuardi <i>et al.</i> 2006 ²⁷⁹
Type of study/document	Empirical level 1 ✓ Empirical level 2 Level 3
Study design	Comparative study. RCT
Country	Italy
Setting	Primary care
Training/equipment	Two educational meetings of 4 hours each provided to GPs by 'reference specialists'. Portable electronic spirometer (Spirobank Office)
Staff involved	GPs and pulmonary specialists
Research question/objectives	To assess the value of consultations including spirometry
Research methods	A total of 57 centres and 570 GPs were recruited to either the standard consultation arm of the study or consultation using spirometry intervention arm. Following the consultations referrals were sent to pulmonary specialists (with the GP diagnosis/intervention removed). The GP diagnosis and specialist diagnosis were then compared to calculate the rate of agreement for each group. The main symptoms at the moment of the consultation were cough in the majority of patients, followed by dyspnoea, wheezing and chest tightness
Results/data	Of the 224 patients with one or more respiratory symptoms assessed, there was agreement on diagnosis between GPs and specialists in 78.6% of cases in the intervention group compared with 69.2% in the standard evaluation group ($p = 0.35$). In the intention-to-treat analysis, the respective percentages of concordant diagnosis were 57.9 and 56.7 ($p = 0.87$). The average time for each visit was 14 ± 5.2 minutes; the mean time required to instruct patients for spirometry was 5.6 ± 3.1 minutes; the performance of spirometry took on average 6.4 ± 3.5 minutes. Spirometry findings in the normal range were obtained for 61.8% of patients. A diagnosis of asthma was made by GPs in 32.1% of patients and COPD in 29.1%
Main findings	There was no significant difference between diagnostic accuracy for GPs who had access to spirometry and those who did not. The authors associated this with the study being underpowered. The authors note that regular use of spirometry tended to decrease progressively within a few months if there are no reinforcing recalls or retraining, despite most GPs rating spirometry as useful
Comments	The study had issues with recruitment and randomisation

Study (authors and year)	Masa <i>et al.</i> 2011 ²⁸⁰
Type of study/document	Empirical level 1 ✓ Empirical level 2 Level 3
Study design	Comparative study, randomised crossover
Country	Spain
Setting	Online community spirometry (patient in primary care has consultation with pulmonary specialist in hospital pulmonary function laboratory)
Training/equipment	Spirometer VMax 20, spirometry performed in line with recommended standards/guidelines. Software analysed if end-of-test criteria had been met. Calibration checks carried out. Technician remotely controlled the computer that had the spirometer software installed (VMax SensorMedic) using another computer with VNC Free Edition software. Two additional computers with webcam used for teleconference
Staff involved	Two technicians with 15 years each experience carried out the spirometry, consultations scheduled to take 20 minutes
Research question/objectives	To assess the value of online spirometry
Research methods	Patients aged 14–74 years, entered spirometer room alone, asked to sit in front of computer and initiate the spirometer under instruction via teleconference. One in five patients also had conventional spirometry performed in person by technician
Results/data	Data for 261 of 283 patients; only five patients were unable to complete the spirometry successfully. Most patients were smokers or ex-smokers with generally mild dyspnoea. Online vs. conventional difference intention-to-treat analysis: FVC, $p = 0.492$; FEV ₁ , $p = 0.211$; FEV ₁ /FVC%, $p = 0.466$
Main findings	Online spirometry values were not significantly different from those obtained via conventional procedures
Comments	

Study (authors and year)	Poels <i>et al.</i> 2008 ²⁸⁴
Type of study/document	Empirical level 1 ✓ Empirical level 2 Level 3
Study design	Comparative study. Cluster RCT
Country	The Netherlands
Setting	Primary care
Training/equipment	Spirometry expert system (SpidaXpert). Provides levels of FEV ₁ /FVC and FEV ₁ and also a textual interpretation which provides information on and suggestions for additional testing/treatment options
Staff involved	An expert panel
Research question/objectives	To investigate the effect of supplementing test results with additional information on GP decision-making
Research methods	A total of 78 GPs visited by a research assistant and given a presentation with a number of case studies to work through to discuss their diagnosis and management. First, only medical history and medications presented for GP to decide diagnosis/management; second, GPs received the spirometry test results and were asked to reconsider diagnosis and management in light of this information. Intervention group GPs received spirometry test results, flow–volume curve, graphical curve and textual notes. GPs in control group received test results, flow–volume curve and volume–time curve (sham/placebo information) only. An expert panel of two chest physicians, a GP with specific expertise in spirometry and a health scientist agreed diagnosis for the case studies used

Study (authors and year)	Poels <i>et al.</i> 2008 ²⁸⁴
Results/data	There was no difference between the groups in terms of agreement between GP diagnosis and expert panel diagnosis for COPD odds ratio 1.08 (95% CI 0.7 to 1.66), asthma odds ratio 1.13 (95% CI 0.7 to 1.8), absence of respiratory disease (odds ratio 1.32, 95% CI 0.61 to 2.86)
Main findings	Additional information (support) provided by a computerised system had no detectable benefit on GP accuracy of diagnosis
Comments	FEV ₁ , forced expiratory volume in 1 second.

Study (authors and year)	Starren <i>et al.</i> 2012 ¹⁸²
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study. Four years of data from operation of service
Country	UK (London)
Setting	Community respiratory assessment unit based in a hospital
Equipment/training	Spirometry carried out following national and international guidance. Calibration completed on a weekly basis and cleaning on a daily basis
Staff involved	Was staffed by a specialist respiratory nurse for first 2 years, subsequently run by a community respiratory nursing team. Team had access to a professor of respiratory medicine/consultant in integrated respiratory medicine
Research question/objectives	To audit a centralised community respiratory service
Research methods	All local GPs had access to the service
Results/data	A total of 1156 referrals were received over the 4 years (range 217–348 per year). 65% of patients referred smoked. 162 did not attend and 30 could not complete the spirometry assessment. GPs of 49% of newly referred patients stated they would have referred to a specialist outpatient clinic if the service had not been available. 28 of the 32 practices used the service. Half of those referred for suspected COPD were confirmed as having it (138 of 265). 79 were referred for unexplained breathlessness: 41 of these were diagnosed as having non respiratory cause, 14 had a restrictive defect, 6 were diagnosed with COPD, asthma could not be excluded in 17, and for one no explanation for symptoms could be found
Main findings	The community respiratory assessment unit reduced diagnostic inaccuracy. Approximately one-third of COPD diagnoses made in the community were incorrect with potentially high levels of inappropriate prescribing. The study was unable to draw meaningful conclusions regarding asthma referrals
Comments	The same service as the Hassett <i>et al.</i> ²⁷⁴ study. However, although it references this study it does not say that it is linked and the authors are different

Study (authors and year)	Thijssing <i>et al.</i> 2014 ²⁸⁷
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study. Cross-sectional data
Country	The Netherlands
Setting	GP practices
Training/equipment	KSYOS TeleConsultation system, GPs received 1 hour of on-site training to use if were not already using. Dedicated help desk available

Study (authors and year)	Thijssing <i>et al.</i> 2014 ²⁸⁷
Staff involved	A total of 158 GPs and 32 local pulmonologists
Research question/objectives	To evaluate a web-based teleconsultation service
Research methods	GPs who were in possession of a spirometer that could be linked to a computer were recruited. GPs could use telepulmonology consultation for any patients they considered suitable. GP completed patient medical history and uploaded four PDF files of the patient's spirometry results via the teleconsultation system and sent to the local pulmonologist. Pulmonologist required to respond within 2 working days: e-mail/telephone reminders sent if this exceeded. Pulmonologist provided description of findings, diagnostic considerations, advice and asked any additional questions. Answered two mandatory questions – diagnosis COPD? Yes/no/unsure; is a visit to a specialist required? Yes/no/inapplicable. GP could send one more round of questions
Results/data	A total of 1958 consultations were sent by 158 GPs between April 2009 and November 2012. COPD diagnosed in 23%, unsure 16%, no 61%. The authors report that 69% of teleconsultations were made for the purpose of receiving advice, and of these 18% led to referral. They calculated that 31% of referrals were intended to prevent a physical referral, and 68% of prevented a referral (402 patients). Overall percentage of prevented referrals was calculated to be 27% 92% of GPs indicated that they had learned from the pulmonologist's response. Response was received an average of 18 hours after request sent
Main findings	Teleconsultation was perceived to be a useful service by GPs and reduced numbers who might otherwise be referred
Comments	Calculation of referrals prevented based on total number of patients referred, divided by total GP self-report of whether they would have referred
PDF, portable document format.	

Study (authors and year)	Tomonaga <i>et al.</i> 2011 ²⁸⁸
Type of study/document	Empirical level 1 ✓ Empirical level 2 Level 3
Study design	Comparative study, RCT
Country	Switzerland
Setting	Primary care
Training/equipment	A 3-in-1 POC testing analyser: a bedside Cardiac Reader (Roche Diagnostics) that assesses cardiac troponin T, N-terminal pro-brain natriuretic peptide, D-dimer in heparinised venous blood within 8–12 minutes. GPs in the intervention group received advice on interpretation of the test results
Staff involved	GPs
Research question/objectives	To evaluate the addition of POC testing to GP diagnosis
Research methods	A total of 218 patients presenting with chest pain or symptoms of dyspnoea were assessed by GPs using conventional diagnosis methods or GPs with the addition of POC testing. Physicians could choose which biomarker tests were necessary. Patients returned 3 weeks later and the physicians reviewed the diagnosis
Results/data	Total of 79 clinicians from 68 practices. In the intervention group the working diagnosis made at first visit was confirmed at second visit in 76% of cases. For the control group the diagnosis was confirmed in 60% of cases ($p = 0.002$). The tests showed good sensitivity and specificity. Acute coronary syndromes were correctly ruled out in 92% of patients in the intervention group vs. 78% in the control group
Main findings	Use of the tests improved diagnostic accuracy for heart failure, thromboembolic events, acute coronary syndromes
Comments	The assessment of accuracy was in most cases GP diagnosis on the second visit. Some patients were referred on and diagnostic accuracy was assessed by specialist report for them (numbers of these not specified)

Study (authors and year)	Van der Mark <i>et al.</i> 2014 ²⁸⁹
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study. Cohort study
Country	The Netherlands
Setting	Primary care
Training/equipment	None
Staff involved	GPs
Research question/objectives	To evaluate the usefulness of a questionnaire assessing the likelihood of developing asthma
Research methods	A total of 771 children aged 1–5 years presenting at GP surgery with shortness of breath/coughing/wheezing were assessed. Presence of asthma versus no asthma later assessed at 6 years. These data were used to develop a prediction system (Clinical Asthma Prediction Score). This has a scale of 0–11 and is based on age, family history, reported symptoms, environmental factors and allergies
Results/data	A score of < 3 had a negative predictive value for asthma of 78.4%. A score of > 7 had a positive predictive value of 74.3%
Main findings	The scoring system for pre-school children with symptoms can be a useful decision aid in asthma diagnosis
Comments	

Study (authors and year)	Walker <i>et al.</i> 2006 ²⁹⁰
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study. Clinical records reviewed
Country	UK (Liverpool, England)
Setting	Practices within one district
Training/equipment	Non-computerised wedge bellows spirometer (Vitalograph), volume and time calibration performed daily and comparison against a biological control carried out weekly. Bronchodilator reversibility testing also available
Staff involved	A total of 29 GPs were able to refer to service, where a respiratory technical officer with more than 25 years of experience performed spirometry. A consultant respiratory physician reviewed spirometry data to produce a report which was sent back to referees: obstructive, normal or restrictive, and likely diagnosis of asthma, COPD or other. Management left entirely to referring GP
Research question/objectives	To evaluate an open-access spirometry clinic
Research methods	GPs advised on appropriate patients to refer (smokers or ex-smokers > 40 years with respiratory symptoms). Referred using standard pro forma to a 'health suite in the local community'
Results/data	A total of 1508 referrals were made January 1999 to December 2003 (2.6% of the patient population in that area). Median referral rate was 1.8%; 28% of referrals did not meet age or smoker referral criteria. Of those referred, 39% had no existing diagnosis, 30% had asthma and 29% had COPD. Following testing, 128 patients were newly diagnosed with asthma or COPD and 46 patients had their diagnosis changed. In total, 22 of the 139 COPD patients (17%) were referred to secondary care within 6 months of testing. No onward referral data were provided for other patients
Main findings	The spirometry clinic increased rates/accuracy of diagnosis and improved treatment
Comments	Additional data available on pharmacological management

van Heur <i>et al.</i> 2010 ¹⁰⁵	
Study (authors and year)	This paper adds more recent data to the Lodewijks-van der Bolt <i>et al.</i> 2010 ²⁷⁸ paper
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study. Analysis of referrals December 2002–March 2007. In 2007 GPs were sent a questionnaire on management
Country	The Netherlands
Setting	Echocardiography service in local hospital
Training/equipment	Echocardiography in hospital, Philips SONOS 5500 system, ECONCERT digital storage and retrieval system
Staff involved	Staff in echocardiography unit: performed by one of four cardiologists with experience in cardiac imaging or a resident under supervision. Results were interpreted by the cardiologist
Research question/objectives	To evaluate an open-access echocardiography service
Research methods	Patients referred to the open-access service by GPs following examination. Echocardiography was carried out without referral to a cardiologist. Results of the examination were returned to the GP with a comment on how to manage the patient
Results/data	A total of 625 patients were referred over the time period of the study. The service had been used by 81% of GPs in the local area over this time (average one patient per GP per year). Of the referrals, 32% had been for dyspnoea; 24% of the echocardiograms showed no disease. Patients were recommended for referral to cardiology in 28.7% of cases, and the GP followed this advice and made the referral in 71% of these Comparing the first 250 patients with the last 250, fewer referrals for dyspnoea were made in 2007, more for cardiac murmur or other indications. The proportion of patients with no cardiac abnormality found increased (32.8% in 2007 vs. 22% in 2002). More advice was given to GPs in later patients
Main findings	The majority of patients referred had a cardiac abnormality, although the finding of an abnormality following referral decreased slightly over the years
Comments	Action taken by GP finding based on survey data

White <i>et al.</i> 2007 ¹⁸⁷	
Study (authors and year)	White <i>et al.</i> 2007 ¹⁸⁷
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study. Cross-sectional
Country	UK (London)
Setting	Primary care
Training/equipment	Practices provided with an electronic handheld spirometer (MicroLoop®, Micro Medical) with personal computer-based software. Staff received training provided at the lung function laboratory of the local respiratory medicine unit of one group 2-hour session followed by two 3-hour individual clinical tuition sessions. Practices received reimbursement of £10 for the cost of each spirometry test. The built-in electronic spirometry interpreter was switched off for the duration of the study
Staff involved	Tests were carried out by practice nurses in five of the practices and by a care assistant in one
Research question/objectives	To evaluate the usefulness of remote specialist reporting of spirometry

Study (authors and year)	White <i>et al.</i> 2007 ¹⁸⁷
Research methods	Test results were e-mailed as attachments to primary care clinicians (GPs in five practices and a practice nurse in one) and to the local respiratory specialists for remote interpretation. The interpretation of the results was evaluated in terms of acceptability of the test, diagnosis, severity of impairment, management advice and confidence in the interpretation of the test. Analysis of agreement on acceptability, diagnosis and severity was evaluated by comparing interpretation by the primary care clinician with that by the specialist
Results/data	Six practices e-mailed 312 tests over 3 months. Clinically significant disagreements between GPs and specialists were identified in regard to diagnosis in 49/168 (29%) tests ($\kappa = 0.39$, 95% CI 0.25 to 0.55) and in regard to severity in 62/191 (32%) tests ($\kappa = 0.53$, 95% CI 0.43 to 0.63)
Main findings	Remote reporting of primary care spirometry results was feasible and provided useful additional information for GPs. However, there were high levels of unsatisfactory quality of community-performed spirometry
Comments	

Study (authors and year)	Wolfenden <i>et al.</i> 2006 ²⁹²
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study. Review of referral patterns
Country	UK (London)
Setting	Open-access spirometry clinic in a hospital
Training/equipment	Not reported
Staff involved	Consultant respiratory physician
Research question/objectives	To examine the type of patients referred to an open-access spirometry clinic
Research methods	A total of 200 patient referrals were examined from 10 general practices. GPs could refer with a suspected or actual diagnosis, to a clinic one morning each week. Spirometry carried out by consultant respiratory physician
Results/data	A total of 51% of referrals were for diagnosed or suspected COPD. Just over half of these were found to have airway obstruction. Airway obstruction was rarely observed in those patients referred for stated or suspected asthma
Main findings	Spirometry needed in order to establish correct diagnosis of COPD so referrals for suspected or stated were appropriate. Home peak flow monitoring rather than referral may be more helpful for those with suspected asthma
Comments	

Conference abstracts

Study (authors and year)	Backler <i>et al.</i> 2011 ²⁶²
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	UK (England)

Study (authors and year)	Backler <i>et al.</i> 2011 ²⁶²
Setting	Secondary care open-access pulmonary function testing service
Training/equipment	Not reported
Staff involved	Respiratory physiologists and consultants
Research question/objectives	Early evaluation of open-access service
Research methods	Referrals for pulmonary function testing were received directly from GPs. Quality assured spirometry, gas diffusion and static lung volume tests were performed. Feedback was obtained by GP and patient questionnaires
Results/data	Data for 18 referrals were analysed. Pre- and post-test diagnoses agreed in 11 (61%) cases. Four referred patients had normal test results, eight had COPD, three asthma and three 'other diagnosis'. Thirteen (72%) were referred to this service instead of the outpatient chest clinic. All GPs were satisfied or very satisfied with the service
Main findings	Authors stated that the service has been successfully started, the main difficulty being low awareness in primary care. Three-quarters of patients who used the service have subsequently been managed in primary care, with an estimated saving of £1800 to the health system
Comments	Secondary care open access

Study (authors and year)	Callister <i>et al.</i> 2011 ²⁶⁶
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Before-and-after study
Country	UK (England)
Setting	Local NHS services, including self-referral chest X-ray service
Training/equipment	Not reported
Staff involved	GPs, community health educators, community matrons, respiratory nurses and pharmacists
Research question/objectives	To evaluate a self-referral chest X-ray service provided as part of an intervention to improve early detection and diagnosis of lung cancer
Research methods	Public awareness of lung cancer symptoms was assessed using the validated Cancer Awareness Measure. A social marketing approach was used to increase awareness and promote early referral for chest X-ray among health professionals and the public. A service was established where patients aged ≥ 50 years could self-present for chest X-ray after 3 weeks of cough or other chest symptom without medical referral. All community HCPs were encouraged to direct symptomatic patients to the self-referral service
Results/data	Pre-campaign market research involving 630 members of the public revealed poor knowledge of early lung cancer symptoms. The marketing communication campaign, HCP campaign and self-referral chest X-ray service all began in January 2011. During the first 7 weeks 95 patients presented for self-referral chest X-ray, of whom three had confirmed lung cancer. There was a 30% increase in the number of GP-ordered chest X-ray compared with the same period in 2010 (mean 557, SD 65 per week vs. mean 428, SD 55, respectively; $p < 0.001$), and a 70% increase in fast-track lung cancer clinic referrals compared with 2010 as a whole (mean 16.0, SD 6.0 per week vs. mean 9.4, SD 3.1, respectively; $p < 0.05$)
Main findings	Authors stated that further data on chest X-ray rates and number of lung cancer diagnoses, stage and treatment, and outcomes will be needed to evaluate this approach
Comments	Main focus is awareness campaign

Study (authors and year)	Denis <i>et al.</i> 2013 ²⁷⁰
Type of study/document	Empirical level 1 Empirical level 2 Level 3 ✓
Study design	Non-comparative (descriptive study)
Country	The Netherlands
Setting	Primary care
Training/equipment	CASPIR is an interactive course for GPs and their staff. The course consists of five modules and a yearly refresher course. The course was developed in co-operation with GPWSIs, respiratory technicians and pulmonary physicians
Staff involved	GPs, nurses
Research question/objectives	Descriptive evaluation of CASPIR programme
Research methods	Descriptive summary of programme outcomes
Results/data	Since the programme began in 2008, 270 base courses have been given, 3136 GPs and 2146 nurses have participated and 150 refresher courses have followed. More than 90% of participants passed all modules and exams. An estimated 80% of the target population of health professionals have completed the training
Main findings	Authors stated that formal training is required for spirometry to be used effectively in primary care. Refresher courses are important to maintain skills
Comments	CASPIR, COPD, asthma, SPIRometry.

Study (authors and year)	Diar Bakerly and Roberts 2009 ²⁷¹
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	UK (England)
Setting	Community COPD clinic
Training/equipment	Not reported
Staff involved	Consultant respiratory physician and respiratory nurse consultant
Research question/objectives	To evaluate a consultant-led specialist community COPD clinic intended to deal mainly with severe or difficult to diagnose COPD
Research methods	Referral criteria were developed before the service was introduced and included a chest radiograph and spirometry prior to referral. The clinic was widely advertised to clinicians in primary and secondary care
Results/data	A total of 203 patients were seen, of whom 117 (58%) were new patients and the remainder were follow-ups or transfers of care from secondary care clinics. Average waiting time from referral was 30.2 days. 65% of patients were referred from primary care, 18% from secondary care and 13% from the integrated COPD team. 97 (83%) patients had COPD as the primary diagnosis and only eight (6%) did not have COPD, with three referrals considered inappropriate. 26 (22.2%) new patients required extra tests including blood tests, full pulmonary function tests and CT scans; however, most blood tests were conducted in general practice
Main findings	Authors concluded that community COPD clinics provide easy access to specialist advice. Inappropriate referrals to these clinics did not appear to be a problem. These clinics may therefore have a role in the management of patients with COPD
Comments	Outreach

Study (authors and year)	Fois <i>et al.</i> 2014 ²⁷²
Type of study/document	Empirical level 1 Empirical level 2 Level 3 ✓
Study design	Non-comparative study
Country	Italy
Setting	Primary care
Training/equipment	Short course on performance and interpretation of telespirometry
Staff involved	GPs, specialists
Research question/objectives	To evaluate whether or not telespirometry performed in GPs' offices can improve early diagnosis of obstructive airway disease
Research methods	Ten GPs enrolled current or ex-smokers with or without respiratory symptoms and people with respiratory symptoms but no history of asthma or COPD. Telespirometry data were sent online for interpretation by a pulmonary specialist and the results returned to GPs in real time
Results/data	A total of 198 patients were enrolled and telespirometry quality was acceptable in 76% of cases
Main findings	Telespirometry, performed by GPs, may improve the early diagnosis of obstructive airway disease
Comments	Interpretation in secondary care

Study (authors and year)	Harris <i>et al.</i> 2012 ²⁷³
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	UK
Setting	Community (primary care)
Training/equipment	Not reported
Staff involved	Trained general practice staff
Research question/objectives	To evaluate the validity of spirometric testing performed in the community
Research methods	Retrospective study of 405 patients found to have abnormal screening spirometry performed in the community
Results/data	The majority (45%) of patients had moderate COPD. 32% and 11% were found to have severe and very severe COPD, respectively. The mean FEV ₁ in the community (1.52 l) was slightly higher than the pulmonary function laboratory (1.49 l)
Main findings	
Comments	Mainly relates to patients with already-established COPD diagnosis, so only limited relevance to review

FEV₁, forced expiratory volume in 1 second.

Study (authors and year)	Kaplan and Lerner 2013 ²⁷⁶
Type of study/document	Empirical level 1 Empirical level 2 Level 3 ✓
Study design	Survey
Country	Canada
Setting	Primary care
Training/equipment	Teaching programme and tool for interpretation of spirometry
Staff involved	Primary care physicians
Research question/objectives	To assess trainees' attitudes to the training programme and tool
Research methods	Post-programme survey
Results/data	Response rate was 88% (121/138). Most participants (63%) were not currently performing spirometry. Almost all (98%) found the tool helpful for interpreting spirometry, with 93% intending to use it in practice in the future
Main findings	Authors concluded that the training programme and spirometry interpretation tool enable most participants to feel comfortable about interpreting spirometry results
Comments	

Study (authors and year)	Lau <i>et al.</i> 2014 ²⁷⁷
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	UK (England)
Setting	Community breathlessness service
Training/equipment	Not reported
Staff involved	Members of a tertiary heart failure team
Research question/objectives	To assess the potential clinical utility of a breathlessness clinic for detecting heart failure and other cardiorespiratory disorders
Research methods	Primary care physicians were invited to refer patients for one-stop testing, including ECG, BNP, spirometry, echocardiography, cardiopulmonary exercise testing and clinical assessment
Results/data	Of 191 patients assessed over 2.6 years, breathlessness was the presenting symptom in 82%, oedema in 12% and cough in 4%. Sixty-four patients were known to have pre-existing cardiac conditions (including 13 with heart failure) and 56 had pre-existing respiratory conditions. A cause for the patient's breathlessness was found in 80% with a new cardiac diagnosis made in 17% and new respiratory diagnosis in 10%; 38% of patients were reassured with no requirement for further secondary-level investigations or review
Main findings	Only a small proportion of subjects with unselected referral to a community breathlessness service had heart failure requiring further expert investigation and management. Authors concluded that this approach offers a streamlined assessment with the additional potential for fully reassuring patients of the absence of significant cardiac or respiratory disease
Comments	Outreach

Study (authors and year)	McNeill <i>et al.</i> 2012 ²⁸¹
Type of study/document	Empirical level 1 Empirical level 2 Level 3 ✓
Study design	Non-comparative study
Country	The Republic of Ireland
Setting	Primary care
Training/equipment	Not reported
Staff involved	Respiratory scientists, GPs
Research question/objectives	To assess the value of respiratory scientist-led spirometry clinics in primary care
Research methods	Spirometry clinics were held at four primary care centres. Clinics were intended for people who had not previously undergone spirometry. Patients were referred directly to the clinics and were selected according to GOLD guidelines
Results/data	Of 104 patients given appointments, 82 were tested, of whom 35 had normal spirometry, 41 had COPD, 2 had possible restrictive lung disease and 2 unreliable data. One centre used only 50% of the available slots
Main findings	Authors concluded that the success and efficiency of this type of service is dependent on GP support for the spirometry clinics
Comments	Outreach

GOLD, Global Initiative for chronic obstructive Lung Disease.

Study (authors and year)	Metting <i>et al.</i> 2013 ²⁸²
Type of study/document	Empirical level 1 Empirical level 2 Level 3 ✓
Study design	Non-comparative study
Country	The Netherlands
Setting	Primary care
Training/equipment	Not reported
Staff involved	GPs, technicians, specialists (pulmonologists)
Research question/objectives	To describe a service implemented in the Netherlands to help GPs in diagnosing and managing patients with asthma or COPD
Research methods	GPs can refer patients with evidence of respiratory problems to the service for assessment and advice. Patients complete a history questionnaire, the Clinical COPD Questionnaire and the Asthma Control Questionnaire, and spirometry is performed by a trained technician. The pulmonologist inspects the data online, without seeing the patient, and sends the GP the results along with a diagnosis and treatment advice
Results/data	The service has included ≈12,000 patients from 359 GPs and ≈2000 new patients are included yearly. In 78% of cases, the specialist was able to diagnose patients based on online information
Main findings	Authors concluded that this service has proven to be a feasible collaboration system between GPs and specialists
Comments	Interpretation in secondary care

Study (authors and year)	O'Herlihy <i>et al.</i> 2013 ²⁸³
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	The Republic of Ireland
Setting	Community COPD clinic
Training/equipment	Not reported
Staff involved	Members of COPD outreach team
Research question/objectives	To evaluate a COPD satellite clinic based in a primary care centre
Research methods	Review of patient records
Results/data	Of the patients reviewed (number not reported), 50% had COPD and 25% had asthma diagnoses confirmed; the remainder had no significant respiratory problem
Main findings	The authors concluded that satellite clinics can provide a time saving and cost-saving alternative to the traditional hospital based outpatient clinic model for those thought to have COPD
Comments	Outreach

Study (authors and year)	Punwani <i>et al.</i> 2014 ²⁸⁵
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	UK (England)
Setting	Community pharmacies in south-west London
Training/equipment	Pharmacists attended standardised training sessions to help them identify people at risk of COPD and/or lung cancer for referral to secondary care
Staff involved	Pharmacists from 43 pharmacies
Research question/objectives	To evaluate a community pharmacy pathway to increase awareness and early diagnosis of lung cancer
Research methods	A referral template was created based on the two week rule pathway for suspected lung cancer. Patients were referred to local secondary care clinics where clinical assessment, chest X-ray and spirometry were performed. Feedback was obtained via questionnaires
Results/data	Of 66 referrals over 6 months, 55 were considered appropriate. A new diagnosis of COPD was made in 30% of patients referred
Main findings	Community pharmacists are an acceptable and underused resource for identifying and referring patients with symptoms of previously undiagnosed COPD who may also be at risk of lung cancer
Comments	Appears to meet inclusion criteria assuming patients presented to pharmacist complaining of breathlessness

Study (authors and year)	Schermer <i>et al.</i> 2013 ¹⁹⁵
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Comparative before-and-after study
Country	The Netherlands
Setting	Primary care
Training/equipment	CASPIR and Cohesie spirometry training programmes
Staff involved	GPs and practice nurses (CASPIR); practice nurses and assistants (Cohesie)
Research question/objectives	To evaluate the impact of the two training programmes on quality of spirometry tests
Research methods	Random samples from practices' spirometry databases were reviewed before and after training. Primary outcome was the proportion of 'adequate' tests
Results/data	Twenty-nine practices (15 CASPIR and 14 Cohesie) took part and 1065 tests were reviewed. For CASPIR 39.1% of tests were adequate before training and 51.0% after training (odds ratio 1.60, 95% CI 1.12 to 2.30). Before CASPIR training two practices (13.3%) reached the desired performance level (60% adequate tests); after training seven (46.7%) did so. For the Cohesie programme, pre- and post-training rates were 45.3% vs. 44.1% (odds ratio 0.93, 95% CI 0.65 to 1.33) for the primary outcome. At pre-training four Cohesie practices (28.6%) reached the performance level, but after training only one practice (7.1%) did so
Main findings	The authors concluded that structured spirometry training seems to improve test quality but does not necessarily produce desired levels of quality in every practice
Comments	CASPIR, COPD, asthma, SPIrometry.

Study (authors and year)	Sallaway <i>et al.</i> 2011 ²⁸⁶
Type of study/document	Empirical level 1 Empirical level 2 ✓ Level 3
Study design	Non-comparative study
Country	Canada
Setting	Open-access spirometry laboratory (no further details reported)
Training/equipment	Not reported
Staff involved	Not reported
Research question/objectives	To describe the pattern of referrals and characteristics of patients referred from primary care with suspected asthma or COPD
Research methods	Referral records from October 2008 to March 2010 were analysed
Results/data	Of 2140 patients who attended for spirometry, 1671 (78%) were investigated by post-bronchodilator spirometry; of these, 428 were classified as obstructive (according to American Thoracic Society guidelines)
Main findings	A significant proportion of referrals to the service yielded abnormal results. The authors stated that a continued effort to improve access to spirometry and promote these services is essential. As availability increases, emphasis should be placed on educating HCPs in the importance of spirometry for early detection and monitoring of pulmonary disease
Comments	The setting was unclear, may be secondary care open-access service

Study (authors and year)	Willey <i>et al.</i> 2013 ²⁹¹
Type of study/document	Empirical level 1 Empirical level 2 Level 3 ✓
Study design	Non-comparative study
Country	USA
Setting	Community-based primary care practice
Training/equipment	Not reported
Staff involved	Pharmacist(s)
Research question/objectives	To describe the experience and preliminary outcomes of pharmacist-led care for patients with respiratory disorders
Research methods	Medical record review of patients referred to the pharmacist by physicians for investigation of respiratory symptoms between May 2011 and September 2012
Results/data	Pharmacist interventions included detailed history taking and spirometry. Thirty-four patients were assessed by spirometry, which met American Thoracic Society quality standards in 82.5% of tests. The pharmacist made various recommendations that were implemented, including smoking cessation, medications and specialist referral
Main findings	The authors concluded that these preliminary results support pharmacists expanding their role by providing patient care services, including spirometry, to patients with respiratory disorders
Comments	

Qualitative data extractions

Citation	Armstrong <i>et al.</i> 2012 ²⁹³
Country	UK
Setting	Community
Dyspnoea/specific condition	Pulmonary hypertension
Application of model/pathway	Anderson's model of total patient delay
Research question/objectives	To investigate patient experiences of the pathway to receiving a diagnosis of PAH to inform care provision
Research methods	Data collection: Face-to-face interviews, experience of living with PAH Mapping of 'individual journey' using pictorial representation Analysis: Thematic analysis
Population/sample	Patients: members of the Pulmonary Hypertension Association ($n = 30$) Age: mean 56.3 years. Gender: 18 female; 12 male
Recruitment	From the Pulmonary Hypertension Association UK database
Main findings relevant to the research question	General Road to diagnosis was emotional for both the patient and their family. Use of Anderson's Model to structure findings Specific issues Many delayed visit to a doctor for over 1 year

A patient appraisal process was evident when symptoms, including breathlessness, had been present for extended periods, having gradually crept on

Breathlessness had different meanings (e.g. getting unfit, getting old or a symptom of a virus)

Smokers who had recently given up assumed smoking to cause the breathlessness

Period of perseverance; tried to rectify reduced fitness level (younger participants continued regardless)

For some, avoidance strategies were used and activities were adapted to the severity of breathlessness

Covering up of symptoms

Delayed decision to seek medical opinion until either patient or family member acknowledged the seriousness

Diagnosis was not necessarily made at first visit to a doctor and for all participants there was a phase of attendance with no outcome

Misdiagnosis was common; PAH reported as not being recognised or understood by clinicians

Many tests carried out and repeated

Multiple referrals to specialists

Owing to not having a diagnosis, patients tried to carry on as normal even when symptoms were worsening

Diagnosis provoked positive and negative emotions. For some, the way that diagnosis was disclosed was reported as inappropriate or lacking empathy. Positive experiences included acknowledgement from staff of the delay in reaching a diagnosis

Some patients felt ill informed about PAH and for some it was the first they had heard of it

Patients felt more reassured at specialist centres where they received more information

Potential limitations

Range in time since diagnosis (< 1 year to > 10 years). The health service could have changed during this time. However, the authors point out that patients' reflections were similar regardless of the time lapse

PAH, pulmonary arterial hypertension.

Citation	Birt <i>et al.</i> 2014 ²⁹⁴
Country	UK
Setting	Primary care referrals to specialist respiratory clinics
Dyspnoea/specific condition	Lung cancer
Application of model/pathway	Model of pathways to treatment
Research question/objectives	To explore symptom appraisal and help-seeking decisions for patients referred to specialist respiratory services with lung cancer symptoms
Research methods	Data collection: face-to-face interviews. Open-ended questions to explore the participant's appraisal of symptoms and help-seeking decisions Analysis: framework analysis

Population/sample	<p>Patients ($n = 35$)</p> <p>$n = 17$ diagnosed with lung cancer, $n = 18$ diagnosed with other conditions</p> <p>Age: mean 65 years. Gender: 15 female; 20 male</p>
Recruitment	When patients were referred to specialist respiratory clinics by GPs who reported symptoms of potential lung cancer
Main findings relevant to the research question	<p>General</p> <p>Little evidence that patients received adequate advice from their GPs about symptom monitoring or reasons to return for review</p> <p>Specific issues</p> <p>There were similarities in patient appraisal of lung cancer to that of other conditions</p> <p>When a symptom was difficult to recognise or was attributed to ageing or smoking, or could be self-managed, the appraisal phase was extended</p> <p>Difficult to recognise a change in respiratory function, particularly in the presence of comorbidities such as COPD</p> <p>Some participants alerted to the symptom during consultations for other conditions</p> <p>Alternative explanations for the cause, such as anticipated changes with age, or smoking</p> <p>Some tried to contain and self-manage symptoms; occasionally there was a reported dislike of attending the doctor's surgery</p> <p>Decision to consult a HCP triggered by patient, disease, health-care factors. Symptoms recognised by family/friends as presented in the 'Be Clear on Cancer Campaign'</p> <p>No reports that smoking inhibited help-seeking</p> <p>Limited access to health care and competing responsibilities delayed help-seeking for a few</p> <p>Over half consulted GP within 30 days of noticing symptoms; usually interpreting it as a chest infection</p> <p>If symptom appraised as self-limiting or not requiring medical attention (e.g. allergy, muscle strain), help-seeking was delayed until symptoms did not resolve as expected</p> <p>For older participants, symptoms were often attributed to the ageing process</p> <p>General satisfaction with outcome of first consultation unless prescribed treatment not effective. In this case the process of reappraisal started. Not always easy decision to consult a doctor again</p> <p>A minority reported GP as dismissive of symptoms and concerns</p>
Citation	Corner <i>et al.</i> 2005 ²⁹⁵ (from reference list); Corner <i>et al.</i> 2006 ²⁹⁶ (from reference list)
Country	UK
Setting	Primary/secondary care interface
Dyspnoea/specific condition	Lung cancer
Application of model/pathway	Similar to model of pathways to treatment (although the model is not cited)
Research question/objectives	To explore pathway to diagnosis among a group of patients recently diagnosed with lung cancer
Research methods	<p>Data collection: interviews. To map pre-diagnosis symptom history and the events leading up to diagnosis</p> <p>Analysis: event charts of the pathway to diagnosis; thematic analysis</p>

Population/sample	Patients with recently diagnosed lung cancer ($n = 22$) Age: median = 68 years (range 42–82 years). Gender: 10 female, 12 male
Recruitment	From outpatient clinics
Main findings relevant to the research question	<p>General</p> <p>Event charts highlighted delays in diagnosis attributed to patients and GP. GP attendance led to speedy outcomes which may indicate response to recent guidelines</p> <p>Specific issues</p> <p>Thirty symptoms recorded (breathlessness 5/22), all of which were reported as new leading up to diagnosis</p> <p>Patients did not always act on symptoms even when noticeable</p> <p>Symptoms were often self-managed until this became difficult</p> <p>Symptoms were often not interpreted as serious (unless accompanied by haemoptysis) or signifying lung cancer</p> <p>Time between first recalled changes in health and action by patient: median 7 months</p> <p>However, the time lapse between trigger to act and visiting the GP tended to be short</p> <p>Half of participants recalled symptoms lasting > 1 year before visiting the GP</p> <p>For most there was little or no contact with the GP during this time</p> <p>Little association with change of health and being ill and, even for smokers, the possibility of lung cancer was not considered (usually attributed to increasing age instead)</p> <p>Lack of evidence that smokers expected to be treated promptly, possibly due to campaigns that leave smoking patients feeling that they do not deserve the same care as others. This may also lead to delay in help-seeking</p> <p>Potential limitations</p> <p>Not all patients had chest symptoms and other symptoms were experienced. Patient reports of their symptoms differ from those listed in guidance for lung cancer diagnosis</p>
Citation	Dennis <i>et al.</i> 2010 ²⁹⁷
Country	Australia
Setting	Primary care
Dyspnoea/specific condition	Asthma
Application of model/pathway	None reported
Research question/objectives	To explore difficulties faced by GPs when trying to diagnose asthma in adults, and whether or not patient characteristics influence the process
Research methods	Data collection: focus groups. Current evidence for making the diagnosis of asthma Analysis: thematic analysis
Population/sample	GPs ($n = 18$) Gender: 5 female, 13 male 15 had > 10 years of experience as a GP
Recruitment	Purposeful sampling of a database of research-interested GPs/identified through membership database of local Divisions of General Practice

Main findings relevant to the research question

General

Reported GP confidence in theoretical stages of diagnosis process but more challenging in reality. Spirometry was a challenge, especially when few practice nurses were available to assist. Patient willingness to know about their condition was a factor in diagnosis; some patients may not disclose their symptoms

Specific issues

GPs were familiar with Australian guidelines for asthma management

GPs confident about symptoms and signs of asthma but less so about using spirometry to diagnose asthma

Lack of confidence particularly apparent in diagnosing children or elderly but more in those with history of allergies such as hay fever, or young, fit adults

GPs recognised the need to rule out conditions such as lung cancer and COPD

The issue of time was raised in different contexts, such as consultation availability and time to discuss with patient and carry out spirometry and other tests, as well as continuity of care over time. It could take several visits to confirm a diagnosis

Willingness of patient to become involved in decision-making was reported as having impact on accurate diagnosis. Lack of patient engagement may delay diagnosis for another time

Doctor–patient relationship important

Sometimes challenging to persuade patients to return for follow-up visits, resulting in symptom management (this was especially a problem for professionals who are busy at work)

Patients with comorbidities tended to miss symptoms of asthma or attribute the symptoms to other conditions

Some patients were already taking antiasthma medication by the time they first consulted their GP

Patients who smoked or were overweight might not disclose their symptoms for fear of a lecture on healthy lifestyle

Potential limitations

Some issues raised by GPs likely to be exacerbated by primary care organisation in Australia (less relevant to countries with different systems such as NHS)

Comments

Applicability

In Australia, general practice operates as fee-for-service, funded by Medicare. Patients do not have to register with a particular GP or practice. This impacts continuity of care, as patients may visit different GPs or practices. GPs were not confident about using spirometry and few had a practice nurse. The role of the practice nurse in Australia is less developed than in UK; many have not taken post-registration training in respiratory care and therefore may be less confident in using spirometry

Citation	Goeman <i>et al.</i> 2005 ²⁹⁸
Country	Australia
Setting	Primary care
Dyspnoea/specific condition	Asthma
Application of model/pathway	None reported
Research question/objectives	To ascertain GPs' priorities for achieving optimal outcomes in people with asthma, and the barriers they face in delivering care

Research methods	Data collection: the nominal group technique (highly structured meeting to gain information from experts): 'What do you think is needed to achieve best outcomes in people with asthma?'
Population/sample	GPs ($n = 49$): urban ($n = 34$), rural ($n = 15$)
Recruitment	Invitation and advertisement through the Royal Australian College of General Practitioners and Divisions of General Practice
Main findings relevant to the research question	<p>General</p> <p>Gap between guidelines and GP priorities. 3 + Visit Plan dealt with some issues</p> <p>Specific issues</p> <p>Patient education ranked highest priority for GP groups</p> <p>Continuing medical education was a high priority, particularly in asthma diagnosis and severity (under-over medication)</p> <p>Detecting and diagnosing asthma early and correctly</p> <p>Use of and access to spirometry (expense and confidence in correct use)</p> <p>Lack of time and access limited opportunity for continued education</p> <p>Potential limitations</p> <p>Not reported</p>
Citation	Joo <i>et al.</i> 2013 ¹⁹⁸
Country	USA
Setting	Primary care
Dyspnoea/specific condition	COPD
Application of model/pathway	None reported
Research question/objectives	To identify attitudes and barriers of primary care physicians to performing spirometry for patients with possible COPD
Research methods	Data collection: focus groups
Population/sample	Primary care physicians ($n = 12$)
	Age: mean 40 years. Gender: six female, six male
	Mean time in general practice: 11.9 years
Recruitment	Invitations to all internal medicine primary care physicians from one urban academic medical centre with at least one outpatient clinic per week
Main findings relevant to the research question	<p>General</p> <p>Primary care physicians were not reluctant to use the label patients as having COPD</p> <p>Specific issues</p> <p>Perspective on spirometry use based on whether a pre-existing or new diagnosis</p> <p>Most COPD patients had a pre-existing diagnosis before attending</p> <p>Primary care physicians did not routinely confirm the diagnosis when spirometry had not been used in the initial diagnosis, especially where there were comorbidities</p>

If risk factors for COPD were present (age, smoking, etc.) the diagnosis would not be reinvestigated

Most believed that spirometry was not needed to diagnose COPD as they felt confident in diagnosing from patient history and effects of inhalers. There was a perception that management would not change regardless of spirometry results. There was a lack of confidence/confusion regarding pulmonologist definition of airway disease. Patient-related factors and their lack of willingness to attend for follow-up tests owing to costs and lack of time; transportation and health service insurance issues were also factors

Potential limitations

Primary care physicians from a single academic, urban institution. Therefore, findings may not be generalisable to all primary care physicians

Citation	Khunti <i>et al.</i> 2002 ⁸²
Country	UK
Setting	Primary care
Dyspnoea/specific condition	Heart failure
Application of model/pathway	None reported
Research question/objectives	To explore GPs' accounts of their management of patients with heart failure and identify the perceived obstacles to diagnosis and management
Research methods	Semistructured interviews (individual and group): how GPs diagnose and manage patients with suspected heart failure. Perceived obstacles to diagnosis and management Constant comparison analysis
Population/Sample	GPs (18 practices)
Recruitment	From practices randomised for a larger study
Main findings relevant to the research question	General GPs keen to have access to echocardiography Specific issues Heart failure frequently suspected where patient presents with breathlessness or ankle oedema Reliance on a number of signs and symptoms for diagnosis No systematic method of heart failure diagnosis reported Differing views reported about diagnostic procedures, even within the same GP practice Chest X-ray preferred as easy to arrange and inexpensive. Some diagnosed by trial of diuretics Few reported referring for echocardiography to confirm; many not aware of its usefulness. Those who were aware reported long waiting lists as a barrier A few single-handed practices reported referring to rapid assessment cardiology clinic at the local hospital Other arrangements included requesting a consultant to arrange access

Inadequacy of facilities was a reported barrier to diagnosis, especially echocardiogram, for which there was lack of access owing to not being fund-holders and lack of trust from providers that may perceive the service is not used appropriately

Lack of time was reported as a barrier in dealing with patients suspected to have heart failure. In addition, elderly people took a long time to get dressed and undressed

Diagnostic confusion: difference between respiratory and cardiac origin

Potential limitations

GPs aware that study involved guidelines in management of heart failure; they may have stated socially desirable ideas about heart failure management

Citation	Roberts <i>et al.</i> 2011 ¹⁹⁷
Country	UK
Setting	Primary care and hospital
Dyspnoea/specific condition	Dyspnoea
Application of model/pathway	None reported
Research question/objectives	Underuse of spirometry in primary and secondary care
Research methods	5 × 1-hour focus groups discussing: <ul style="list-style-type: none"> ● general approach to the diagnosis of the breathless patient ● classification of the causes of breathlessness ● methods and investigations used as aids to diagnosis of the breathless patient ● value and accessibility of spirometry, and of its interpretation ● how individuals learnt best about respiratory medicine
Population/sample	Non-specialised trainee doctors ($n = 6$); junior doctors ($n = 8$); senior house officers ($n = 3$); GPWtS in education ($n = 8$); specialist registrar with special interest in respiratory medicine ($n = 6$)
Recruitment	Advertisement on the Student's Union website
Main findings relevant to the research question	<p>General</p> <p>GPs highly aware of the value of spirometry. This may be response to UK NHS GP contract inclusion of accurate COPD diagnosis</p> <p>Specific issues</p> <p>GPs perceived spirometry as a fundamental element of their diagnostic work-up</p> <p>Causes of breathlessness differentiated between urgent and non-urgent</p> <p>Possibility of non-respiratory causes</p> <p>Spirometry cited as an essential diagnostic tool</p> <p>No overt strategy reported for diagnosing COPD</p> <p>More access to spirometry than in the past</p> <p>Importance of bedside teaching and learning within the clinical context</p> <p>Training focused on specific need and retraining was reported as desirable</p> <p>Potential limitations</p> <p>GPs may not have been typical of all in primary care, as all were GPWtS in teaching undergraduates recruited while attending an educational session</p>

Citation	Tod <i>et al.</i> 2008 ²⁹⁹ (from reference list)
Country	UK
Setting	Primary/secondary care interface
Dyspnoea/specific condition	Lung cancer
Application of model/pathway	None reported
Research question/objectives	To identify factors influencing delay in reporting symptoms of lung cancer
Research methods	Data collection: interviews Analysis: framework analysis
Population/sample	Patients diagnosed with lung cancer ($n = 20$) Age range 47–81 years. Gender: 8 female, 12 male
Recruitment	Purposive sampling through a respiratory physician and lung cancer nurse specialists
Main findings relevant to the research question	<p>General</p> <p>Industrial cultural past encouraged stoicism and independence in the community, adding to delays in help-seeking and inequalities in health-care utilisation</p> <p>Specific issues</p> <p>Tendency, especially for non-smokers, to attribute symptoms to other conditions</p> <p>Poor knowledge and awareness of lung cancer symptoms and treatments (available information focus on other cancers)</p> <p>Most lung cancer information smoking related</p> <p>Fear owing to lack of knowledge of treatment/fatalistic beliefs. Fear of death if cancer diagnosed</p> <p>Belief that smoking cessation reduces lung cancer risk to nil, therefore ignoring symptoms</p> <p>Fear of being perceived as a time waster and memories of bad consultation experiences resulted in further delay</p> <p>Expectation that lung cancer diagnosis would incur stigma and blame</p> <p>Stoicism, putting on a brave face, particularly in older generation and men</p> <p>History of poor health-care utilisation in the community</p> <p>Memories of having to pay for care (pre-NHS) meant that consultations only sought if symptoms perceived to be serious. Media messages reinforced this</p> <p>Families facilitated consultation by noticing symptoms and signs and encouraging help-seeking, possibly making appointment for patient</p> <p>Relatives were advocates for patient if symptoms not investigated</p> <p>Potential limitations</p> <p>The sample was limited in terms of ethnicity (not diverse), although this reflects the demographics of the study location</p>

Citation	Walters <i>et al.</i> 2008, ³⁰¹ Walters <i>et al.</i> 2005 ³⁰⁰ (from reference list)
Country	Australia
Setting	Primary care
Dyspnoea/specific condition	COPD
Application of model/pathway	None reported
Research question/objectives	To investigate attitudes influencing the diagnosis of COPD among doctors and patients with COPD in primary care
Research methods	Data collection: interviews and focus groups
Population/sample	GPs ($n = 19$) Patients ($n = 14$): interviews only Age: mean = 67 years. Gender: nine female, five male
Recruitment	By letter: participants from two Tasmanian GP practices
Main findings relevant to the research question	<p>General</p> <p>Delay in diagnosis by GPs may be intentional due to poor prognosis and perception that patients are unwilling to receive a diagnosis. This could lead to lack of spirometry use by GPs</p> <p>Specific issues</p> <p>COPD was rarely named; the terms emphysema and asthma were used. Emphysema was regarded by GPs as a term more familiar to patients than COPD</p> <p>Diagnosis rarely given directly, often attached to asthma</p> <p>Diagnosis could vary over short periods of time</p> <p>Patients used terms interchangeably to describe their symptoms</p> <p>GPs also noted changes in language used by respiratory teams over time, which was confusing and difficult to explain to patients</p> <p>COPD was considered in presence of risk factors, especially smoking</p> <p>Reluctance to label the condition given the consequences for the patient (serious, potentially terminal)</p> <p>Delay in diagnosis as no advantage perceived by GP, even after several visits. However, treatment often initiated prior to diagnosis. Patient may come to know the diagnosis from elsewhere (e.g. pharmacist)</p> <p>Patients expressed frustration at not having a diagnosis and may seek information elsewhere (e.g. internet, or remain poorly informed)</p> <p>Delay in diagnosis could result in losing opportunity to discuss smoking cessation. However, GPs were dubious whether or not diagnosis would affect smoking behaviour</p> <p>Potential limitations</p> <p>May not have identified the entire COPD population in the practices</p>

Survey data extractions

Citation	Boffin <i>et al.</i> 2006 ³⁰³
Country	Belgium
Setting	Primary care
Dyspnoea/specific condition	COPD/asthma
Research question/objectives	To describe the use of spirometers by Flemish GPs, characteristics of their spirometry practice, training needs and preferences, and attitudes towards office spirometry

Research methods	Data collection: telephone survey Analysis: SPSS – chi-squared and ANOVA
Population/sample	197 GPs
Recruitment	Random selection from database
Main findings relevant to review question	General: response rate was 81%. Just over one-third of GPs had access to a spirometer, and peak flow meters were used to assess lung function Specific issues More than half of GPs had never used a spirometer. < 20% had ever used one Spirometer use had ceased because of the time it takes, which impacts on consultation times, or lack of knowledge and skill Most spirometers were obtained from a pharmaceutical company Peak flow meters were used by over half the GPs GPs agreed that training was needed by GPs ready to perform spirometry A minority agreed that GPs should be able to access centres where they could manage the spirometry test themselves One-third of the GPs and all those using spirometry were guided by an educational session, mainly organised by spirometry providers Potential limitations: absence of data on GP referrals for spirometry in specialist settings

SPSS, Statistical Product and Service Solutions.

Citation	Bolton <i>et al.</i> 2005 ³⁰⁴
Country	UK
Setting	Primary care
Dyspnoea/specific condition	COPD
Research question/objectives	To determine the availability, staff training, use and interpretation of results of spirometry in 72% of general practices in Wales
Research methods	Data collection: questionnaire Availability of spirometry; access to local lung function without consultant physician referral; confidence in use (including calibration); interpretation of results; the type and length of training, the number of their registered COPD patients investigated with spirometry Lung function tested using spirometers by experienced users and interpreters Analysis: SPSS – chi-squared test and Mann–Whitney <i>U</i> -test
Population/sample	Practitioners at 227 general practices 125 patients from two practices where diagnosis had been made without spirometry The response rate was 61.6%, 227 of the 371 practices contacted. Each practice was asked the size of the population they covered. From 214 practices reporting, the estimated population served was 1,415,647 individuals
Recruitment	Randomly selected practices were sent a questionnaire. Patients were drawn from two Cardiff practices
Main findings relevant to review question	General Response rate: 61.6%. Increase in access to and use of spirometers is promising and probably reflects a response to guidelines as well as pressure for GPs to undertake a greater role in COPD diagnosis. Most spirometry was performed by practice nurses, which may reflect in the confidence and training levels reported

Specific issues

The majority of practices (187) owned a spirometer and most of these (160) used one

Of the remaining 27 practices, 11 had never used a spirometer, 12 had recently acquired one (four no response)

Over half of practices carrying out spirometry were confident and one-third reported satisfaction with their result interpretations

Nearly half of practices reported limited/no confidence

Over one-third of practices used a spirometer to diagnose COPD in all suspected cases

Where spirometry was carried out, the practice nurse either did so alone or shared with the GP in the majority of practices (145/160)

Use of spirometry was associated with confidence in its use ($p < 0.001$)

Use of spirometer and confidence in its use was positively associated with higher median time in training (range 1 hour to 6 hours; $p < 0.001$). Confidence in interpretation of results was also associated with higher median hours of training (range 0.6–4 hours; $p < 0.001$). No details available on training content or access

Provision of spirometry training varied, including specific spirometry courses, hospital based, pharmaceutical company based, and one-to-one tuition

A higher median confirmation of COPD was evident in practices reporting greater confidence in use and interpretation ($p = 0.155$) than in those reporting lower confidence

Three practices without a spirometer had access to hospital facilities to assess lung function

Potential limitations

None reported

SPSS, Statistical Product and Service Solutions.

Citation	Caramori <i>et al.</i> 2005 ³⁰⁵ (from reference lists)
Country	Italy
Setting	Primary care
Dyspnoea/specific condition	COPD
Research question/objectives	To investigate the degree of use of spirometry to establish the diagnosis of COPD in Italy
Research methods	Data collection: questionnaire Analysis: statistical package (Qubisoft)
Population/sample	General practices
Recruitment	A total of 2424 questionnaires were analysed after eliminating one questionnaire that was incomplete
Main findings relevant to review question	General Response rate: 2474/2475 (almost 100%). Only a small minority of COPD cases are diagnosed by GPs in Italy. There may be need for specific educational programmes targeted at GPs in Italy Specific issues Most GPs felt that COPD prevalence in Italy had increased over 10 years Most GPs reported that COPD symptoms are better controlled owing to early diagnosis and availability of effective treatments

Main symptoms assessed for diagnosis of COPD were persistent cough, expectoration and exercise dyspnoea

Spirometry was used to confirm the diagnosis by 69.8% of GPs

Just fewer than half of GPs reported to be able to diagnose COPD independently

Reasons for underuse of spirometry include lack of access to lung function laboratories, or the perception that spirometry is unnecessary

Potential limitations: retrospective epidemiological study

Citation	Halpin <i>et al.</i> 2007 ³⁰⁶
Country	UK
Setting	Primary care
Dyspnoea/specific condition	COPD
Research question/objectives	To assess the confidence of HCPs in diagnosing and managing COPD
Research methods	Data collection: telephone interview (questionnaire); case scenarios Analysis: Mann–Whitney <i>U</i> -test, Kruskal–Wallis test and chi-squared test
Population/sample	2001: 60 practice nurses; 46 GPs 2005: 61 practice nurses; 39 GPs All nurses ran respiratory clinics
Recruitment	Practices telephoned at random
Main findings relevant to review question	<p>General</p> <p>Response rate not reported. The majority of GPs and practice nurses were aware of guidelines which may be reflected in the increase in GP confidence in COPD diagnosis. No comparable increase was evident for practice nurses</p> <p>Specific issues</p> <p>Between 2001 and 2005, there were no significant differences reported in number of COPD patients seen per week or frequency of respiratory clinics, nurse qualifications or experience</p> <p>Most nurses were aware of national guidelines by 2005, especially those provided by NICE. Awareness of guidelines was associated with greater confidence in diagnosing COPD</p> <p>Confidence of GPs in diagnosing COPD was higher in 2005 than in 2001, although practice nurses expressed less confidence and no change between 2001 and 2005</p> <p>80% of GPs and 70% of practice nurses reported being confident in differentiating between COPD and asthma in 2005</p> <p>Most participants reported that spirometry was an essential tool in diagnosis and less than one-third reported that referral was essential, although this had risen by 10% from 2001</p> <p>Spirometer access increased from 78% of practices in 2001 to 95% in 2005</p> <p>GPs reported higher confidence than practice nurses in interpreting spirometry results, having increased significantly from 2005, although no similar increase was evident for practice nurses</p> <p>Potential limitations</p> <p>Possible selection bias (all practices confirmed that they saw patients with COPD). However, practices were chosen at random. Using case scenarios as a way of assessing diagnostic strategies</p>

Citation	Kaminsky <i>et al.</i> 2005 ¹⁹¹ (from reference list)
Country	USA
Setting	Primary care
Dyspnoea/specific condition	COPD
Research question/objectives	To assess primary care physicians' knowledge and use of office spirometry for the detection of COPD
Research methods	Data collection: mailed questionnaire to assess the size and location of the practice as well as characteristics of the practice and prevalence/management of patients with COPD Workshop: slide presentation followed by 30 minutes' hands-on use of a spirometer. Daily log of spirometry use and costs Analysis: descriptive statistics; Fisher's exact test for associations
Population/sample	General practices $n = 29$
Recruitment	Contact with all primary care medical groups associated with the local Area Health Education Centre
Main findings relevant to review question	General Response rate: 51%. Confidence in interpreting spirometry results increased following workshop Specific issues Main reasons for not performing spirometry following the workshops: <ul style="list-style-type: none"> ● lack of time ● lack of familiarity with testing ● uncertainty in interpreting test results ● patient reluctance Potential limitations Only half of the target population responded to the survey, despite attempts to maximise return. The population may not be representative of the primary care community. Main data collection tool had not undergone validation with the same population. Primary outcome measure of success was number of spirometry tests performed in a relatively short time frame. Sources for data were subject to recording and classification error. Tests were not stratified by underlying diagnosis, indication or repeated tests on the same subjects

A decorative graphic consisting of numerous thin, parallel green lines that curve from the left side of the page towards the right, creating a sense of movement and depth.

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