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October 1997

**AN EVALUATION OF A NURSE-LED
EAR-CARE SERVICE IN PRIMARY CARE:
BENEFITS AND COST CONSEQUENCES**

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School of Health and Related Research

AN INTRODUCTION TO ScHARR

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- to conduct and promote within the University, Health Services Research (HSR), judged to be excellent both nationally and internationally;
- to deliver the highest standard of teaching in HSR and related subjects;
- to provide research and consultancy services in HSR to clients outside the University, particularly to NHS Trusts and Authorities but also to other public sector bodies and private organisations;
- to be an active and vigorous member of the Trent Institute for Health Services Research.

Professor Ron Akehurst, Director

EXECUTIVE SUMMARY

INTRODUCTION

Ear and hearing problems are seldom life threatening but cause pain, discomfort and embarrassment to many people, and thus affect well-being and quality of life. In recognition of these problems, the Rotherham Primary Ear Care Agency was initiated in 1990 by the Rotherham Health Authorities, and later supported by Trent Region's Clinical Development Fund. The Ear Care Agency defines primary ear care as:

"A local service giving people the opportunity to have equal care for ears, in line with care offered for eyes, teeth and feet."

The agency stresses the importance of patient education, and the giving of preventive advice. The training given to the practice nurses is designed to help them recognise potentially serious ear conditions as well as to treat more minor but still distressing complaints such as otitis externa. Training is also given in basic audiometry. Most practice nurses trained in ear care hold clinics to which patients can return for ear checks at regular intervals. Their practices gradually develop a state of "ear awareness" so that receptionists will offer patients appointments with the nurse rather than the doctor for minor ear conditions, and the increased knowledge of such conditions should lead to fewer patients being referred to hospital unnecessarily.

PURPOSE OF THE RESEARCH

The purpose was to measure outcomes and resource use for patients with ear or hearing related problems treated in general practices where **nurses trained in ear care are available** compared with similar patients treated in a routine way in practices where the **nurses are not trained in ear care**.

LITERATURE REVIEW

A limited literature review was undertaken for this study, relating to the specific areas of common ear problems seen in general practice and the work of practice nurses and their particular contribution to ear care. In addition, methodological literature relating to measurement of ear and hearing-related symptoms, quality of life and patient satisfaction is reported separately, in the relevant chapters.

RESEARCH DESIGN AND METHOD

An **observational design** was chosen because "ear awareness" in the Rotherham practices made them unsuitable for randomising patients between health professionals. Patients with ear or hearing-related problems from eight Rotherham practices were compared with similar patients from nine Barnsley practices. Barnsley was chosen as the control area because of similarity in terms of demography, household composition and distribution, socio-economic factors and employment characteristics. Because the practice receptionists were crucial to the recruitment of patients to the study, an honorarium was offered to participating practices to compensate in a small way for their involvement. In addition, as an incentive (because it is always difficult to recruit control subjects), Barnsley practices were promised a financial contribution towards the cost of ear care training for one nurse per practice at the end of the study.

The protocol was approved by the appropriate **ethical committees and local medical committees**. Permission for access to medical records was granted by the chief executives, consultant ear, nose and throat (ENT) surgeons, audiologists and medical records staff in the relevant hospitals.

Short-term outcomes and resource use were measured for both groups of patients, in an attempt to find out if ear care is better and/or cheaper when provided by specially equipped and educated practice nurses than by GPs who have had only standard educational preparation. General practice and hospital records were used to estimate resource use.

Self-completion questionnaires were given at initial assessment at the practices (Q1), and three weeks later sent by post (Q2), to patients consulting with an ear or hearing problem. Both questionnaires included a health status questionnaire (HSQ-12) to ascertain health

status, as well as questions about severity of problems and symptoms. Questionnaire Two added information about treatment, progress and satisfaction with care, as well as use of over-the-counter medication and travel costs.

The economic analysis followed the cost consequences approach, where analysis of costs and consequences of alternative interventions are presented separately. This allows the decision maker to consider which of the outcomes reported are most important in their own setting and circumstances.

Research questions posed were:

1. How do patient reports of ear-related discomfort or pain vary between the two groups at Q1 and Q2 and in changes reported in the later questionnaire?
2. How do patient reports of their health status and quality of life vary between the two areas between Q1 and Q2?
3. How do hospital ENT and audiological referral rates and patterns vary between the two groups/areas?
4. How do patient perceptions of ear care experienced vary between the two groups?
5. How does resource use vary between the groups?
6. What are the cost implications of the Rotherham Primary Ear Care Service compared with the cost of standard care in Barnsley, in relation to other perceived differences in the experience of the two groups?

RESULTS

949 patients were recruited, with an initial response rate of 83%, and a secondary rate of 67%. Full results were obtained for 438 Rotherham patients (over a 3 month period), and 196 Barnsley patients (over a 6 month period). Characteristics of responders and non-responders were similar for age and sex, and response rates were virtually the same in both areas.

At initial assessment Barnsley patients generally recorded higher levels of discomfort and pain and disruption of normal activities than Rotherham patients. Initially Rotherham patients had higher HSQ-12 dimension scores and hence better self-perceived health. After Q2 there was no statistical evidence of a difference in discomfort and pain reduction between areas after adjusting for differences in the initial levels. Seventeen per cent of Rotherham patients saw only a doctor at their first attendance with an ear or hearing problem, compared with 65% of Barnsley patients. Sixty four per cent of Rotherham patients' ear care (8% Barnsley) was managed by a nurse, and 19% of Rotherham patients (27% Barnsley) saw both doctor and nurse at the first visit.

Overall there was a high level of satisfaction with treatment received, but **satisfaction in Rotherham (91%) was significantly higher than in Barnsley (82%) ($p = 0.0001$)**. Results of the **economic evaluation** indicated that the **total number of GP consultations in Rotherham was lower (average of 0.4 per patient, average cost per patient £6.28) compared to Barnsley (average of 1.4 per patient, average cost per patient £22.53)**. GP consultations in Barnsley produced a greater amount of prescribed drugs per case (6% total costs) compared to Rotherham (1.5%) and there was a **significantly higher use of systemic antibiotics by GPs in Barnsley**. **The average total cost per case was found to be significantly lower when using ear care trained nurses ($p = 0.04$)**.

Some evidence was found for reduction in hospital referral rates in practices with ear care trained nurses, and for more appropriate referrals to audiology, but further work would be needed to substantiate this. Even within Rotherham there were wide differences in the scope of practice and levels of discretion allowed to ear care trained nurses, depending on the GPs' attitudes to expanded roles for nurses.

CONCLUSION

Highly skilled ear care trained nurses have been shown to reduce costs and GP workload by managing care for patients with ear and hearing problems. Nurse-led care also reduces the inappropriate use of systemic antibiotics and probably the number of referrals to ENT. There was no evidence of any detriment to patient care. Patients demonstrated increased awareness of measures to protect the health of their ears and nurses appeared happy to give this service. However, the understanding and support of GPs is needed if the service is to operate to maximum effect. The ear care trained nurse is an example of how expanded nursing roles within general practice can bring benefits to the service and to patients whilst reducing costs.

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INTRODUCTION

Ear and hearing problems are seldom life threatening but cause pain, discomfort and embarrassment to many people, and thus affect well-being and quality of life.^{1,2} In recognition of these problems, the Rotherham Primary Ear Care Agency was initiated in 1990 by the Rotherham Health Authorities, and later supported by Trent Region's Clinical Development Fund. One of the objectives of the agency was to enable more patients to be treated for minor ear problems in primary care settings, thus saving patients the trouble of attending hospital, and freeing consultants' time for patients whose conditions were more serious.³

One of the top priorities of the National Health Service Research and Development Programme (NHS R&D) in relation to the interface between primary and secondary care was "evaluation of treatment by referral versus management in primary care."⁴ Such evaluations are fraught with both methodological and practical problems, and prior to the development of the NHS R&D programme from 1991 onwards, had been neglected in favour of more highly "science-driven" research.⁵ A research proposal to evaluate the work of the Rotherham Primary Ear Care Agency was rejected by the panel assessing bids for the "Primary/Secondary Interface Programme," managed for NHS R&D by NE Thames Regional R&D, and so a modified proposal was put to Trent R&D Directorate because of the Region's earlier financial investment in the Agency. This proposal was funded, and the evaluation began in February 1995 and was completed in May 1996; it covers the most important aspect of the Primary Ear Care Agency's work, the provision of practice nurses trained in ear care. In the study, a group of patients treated in practices with such nurses in Rotherham was compared with similar patients with ear or hearing-related problems in a neighbouring health district (Barnsley) with similar socio-economic characteristics, but without practice nurses trained in ear care.

LITERATURE REVIEW

A limited literature review was undertaken for this study, relating to the specific areas of common ear problems seen in general practice and the work of practice nurses and their particular contribution to ear care. In addition, the methodological literature relating to measurement of ear and hearing-related symptoms, quality of life and patient satisfaction is reported separately, in the relevant chapters.

Common ear problems seen in general practice

Morbidity statistics from general practice⁶ show that disorders of the external ear (ICD 380) are reported more frequently than any other ear condition in adults, although otitis media or Eustachian tube disorder (ICD 381-2) was the most commonly reported ear condition in children. In persons 16 years old and over, the age group considered in the research study, the rate of consultation for disorders of the external ear (ICD 380) was higher than the rate for otitis media, rising to over 1,000 consulting per 10,000 person-years at risk for men aged 75-84 years.

Robertson and Bennett⁷ report that 10% of the population suffer from otitis externa at some time in their life, and that a typical GP with 1,800 patients can expect to see around 16 new cases each year. Since otitis externa frequently recurs for some patients, the 16 new cases probably represent the tip of the iceberg. Jobbins⁸ explains that otitis externa can present as moderate or severe pain, or as chronic itching and discomfort.

Build up of ear wax is probably the most common cause for patients seeking ear care. Sharp et al⁹ report a survey of GPs in the Lothian area of Scotland, where each doctor saw an average of nine patients each month requesting the removal of wax, with a range of 5 to 50 requests per month represented in the survey.

A rigorously conducted survey by the MRC Institute of Hearing Research¹ estimates that about 25% of the adult population (age 17-80 years) have either a unilateral or bilateral hearing impairment, and that 10% of the adult population report bilateral hearing difficulty in a quiet environment. Davis further reports that 13% of people between 51 and 60 years have a hearing loss severe enough to benefit from a hearing aid, but that only 3% of that age group actually have an aid. For older people the need for services is even greater, and Newton et al¹⁰ report

that most people presenting for a hearing aid in their late 60s have experienced problems for at least 10-20 years.

The conditions already mentioned, **otitis externa** (presenting either as painful, itching or discharging ears), **excessive wax** or **hearing impairment**, form the greatest part of the ear-related workload of practice nurses in Rotherham, who have been additionally trained in ear care. Care of patients with long-standing ear disease such as chronic suppurative otitis media and conditions affecting the mastoid cavity is also part of their work (Rodgers, personal communication).

GP and practice nurse knowledge of ear health and care

Much of the literature relating to management of common ear problems in general practice underlines basic principles of examination and treatment which can apply equally to GPs or practice nurses. Inherent in the literature is the observation that undergraduate and postgraduate teaching for doctors in this area is sparse and variable in quality¹¹ and the same would have to be said for nurses. Otoscopic examination, which is taught to practice nurses as part of ear-care training,¹² was found to be problematic to a number of GPs as well as medical students in several centres in England.¹¹ This may explain why in a study of ear wax removal in Scotland,⁹ 8% of 289 GPs referred patients directly to the practice nurse, and 1% to Ear, Nose and Throat (ENT) Outpatients without first examining the patient, and 32% of the GPs did not re-examine the patients after syringing. Difficulty in recognition of ear abnormality by GPs is also reported by Newton et al.¹⁰

A number of authors highlight problems with syringing^{8,9,13} and advocate better use of aural toilet procedures in many cases.^{7-9, 14-18} Another aspect of ear care, usually related to self care by patients, is the common use of cotton-tipped swabs (cotton buds) which causes impaction of wax and sometimes damage to the ear canal.^{15,19} Teaching patients how to care for their ears is an important aspect of ear care nurses' work, which involves good knowledge of predisposing factors particularly for otitis externa.^{7,8,15,20}

Use of medication

A further principle of treatment of common ear conditions which occurs in the literature is choice and route of appropriate medication. Several authors advise on the use of topical

preparations for otitis externa^{7,14,21} and some particularly recommend the use of wicks for this condition.^{7,8,15} Practice nurses trained in ear care become particularly adept at the use of medicated wicks.¹² Bickerton et al¹⁴ report a survey to all (n=401) GPs in an English county, which achieved a 75% response rate. They surveyed GP prescribing habits for discharging ears and found great reluctance to use topical preparations when there is perforation or infection and where ventilation tubes (known colloquially as grommets) are in situ, due to fear of ototoxicity. This is contrary to standard advice in ear textbooks¹⁶ and prescribing manuals (e.g. British National Formulary), which stresses caution only when the oval or round window membranes are perforated, not the tympanic membrane. Bickerton et al¹⁴ point out that chronic ear infection is usually accompanied by fibrosis, so preventing adequate concentration of systemic antibiotics reaching the site. Thus careful aural toilet followed by instillation of topical medication is by far the most effective treatment.^{7,8,15,17} In addition to advice on medication, several authors advise on use of appropriate preparations for softening wax prior to removal, with preference for simple olive oil as the main recommendation.^{9,12,20}

It is clear from the literature quoted so far, that conditions of the outer ear such as excessive wax and otitis externa could be treated more effectively in general practice if both doctors and nurses had greater knowledge and skill in this area. It is also implied that where these conditions contribute to hearing loss, patient problems could be ameliorated to some extent and some hospital referrals could be prevented, or made more appropriately. It is also clear that increasing knowledge for professionals can also be transferred to patients, so that they may take preventive action and achieve better control over chronic ear problems.

In addition to ear problems involving the outer and middle ear, many patients experience irreversibly declining hearing ability or persistent tinnitus, often becoming worse with increasing age.^{1,10} These conditions are not amenable to medical or surgical treatment, but need to be addressed by education, counselling and reassurance, with provision of prosthetic devices such as hearing aids and tinnitus maskers in suitable cases. The role of general practice is to provide appropriate advice and reassurance, and to make appropriate referrals to hospital audiology or ENT services.³ The benefits to the patient from appropriate care in general practice arise from reduced anxiety, better understanding of their problem and the consequential benefits of appropriate onward referral. Greater awareness in general practice of the realisable benefits of hearing aids can lead to onward referral at an earlier age, and hence greater overall benefit to the patient. One way of achieving appropriate onward referral for hearing aids is for audiometry to be carried out at the general practice surgery,¹⁰ thus identifying suitable candidates in a proactive manner.

The review now moves to identification of relevant themes in the literature surrounding practice nurses, their role and work.

Practice nurses and ear care

Probably the most striking change in practice nursing in the last decade has been the exponential rise in numbers of practice nurses. Sheppard²² quotes Department of Health figures for 1984, when there were 2,000 whole time equivalents (WTEs) and 1986, 3,700 WTEs. Atkin et al²³ surveyed all practice nurses listed by FHSAs in 1992, totalling 15,123 nurses, but this figure reduces to 9,500 WTEs because many practice nurses work part time. The reason for this huge expansion is predominantly the demands of the 1990 GP contract²⁴; in order to meet their targets for immunisation and health promotion, GPs need to delegate aspects of their work to practice nurses. They also receive reimbursement for nurses employed to undertake chronic disease surveillance, especially for diabetes and asthma, in addition to existing reimbursement schemes for more routine practice nurse functions. It is doubtful whether expansion of the practice nurse role to include ear care as understood in Rotherham could have taken place at all without this huge increase in numbers of practice nurses.

For many years, ear syringing has been included as an integral part of a "treatment room" nurse's role. Cater and Hawthorn,²⁵ comparing tasks undertaken by treatment room nurses (employed by DHAs to work in health centre treatment rooms and often shared by several practices), attached district nurses (employed by DHAs), and practice nurses (employed by GPs) in Nottinghamshire found that all treatment room nurses, 84% of district nurses and 75% of practice nurses routinely syringed ears. In Hampshire in 1989,²⁶ a survey of 100 GPs reported that 99% routinely delegated ear syringing to their practice nurses; in Glasgow in 1990²⁷ a survey of 131 practice nurses reported that 73% undertook ear syringing. A recent study of practice nursing in Doncaster²⁸ accepted syringing as a traditional treatment room task, but reported that only 76% of Doncaster practice nurses undertook otoscopic examination compared with 81% in the national survey by Atkin et al.²³ However, the latter study also reported that 25% of their respondents wanted further training in this skill, so presumably some were undertaking otoscopic examination whilst not feeling fully competent.

Another group of practice nurse studies report the proportions of nurse time spent in ear syringing. Hibble²⁹ records a mean of 3-6% of nurse time in 22 practices in East Anglia in 1992, Jeffreys et al,³⁰ studying six inner city practice nurses over eight months document that 3-7% of all recorded procedures were ear syringing, and Paxton et al³¹ studying 67 practice

nurses in Scotland in 1991 found that 5-7% of all consultations over a two week period were for ear syringing. Although accepted as the traditional way to remove wax, the dangers of syringing have been reported by Ford and Courteney-Harris,³² Sharp et al⁹ and Rubin et al.³³ These are described as pain or vertigo, cardiac arrest, damage to the tympanic membrane, temporal lobe abscess, wax impaction and pseudomonas ear infection, possibly leading to malignant otitis externa in frail, auto-immune or diabetic patients (adult and child). Despite the frequent mention of ear syringing in surveys, and the two references to otoscopic examination, no other ear care functions (e.g. aural toilet, insertion of wicks) were mentioned in connection with practice nurses except in the Rotherham-based literature.^{3,12,20}

A pilot survey in Hampshire in 1989²⁶ followed by a national survey in 1990³⁴ recorded considerable enthusiasm by GPs for the expansion of the practice nurse role, provided that agreed protocols were followed. However, 98% of the GPs in the national survey in 1990³⁴ believed that patients should be able to refer themselves directly to a nurse. Marsh and Dawes³⁵ report a feasibility study lasting six months in one practice, where a practice nurse received in-service training to diagnose and treat minor illnesses in the GP surgery. Immediate access to the GP was available where the nurse considered it necessary. Fourteen per cent of the almost 700 consultations recorded were for tonsillitis, otitis media and otitis externa. Of these cases, 85% were totally managed by the nurse, (except for the doctor signing prescriptions) and only 21% of the patients needed to be seen again within 2 weeks for the same condition. At no time in this paper was the term "nurse practitioner" used to describe the role. It appears that there is as much a blurring of the distinctions between traditional nursing roles and different levels of expanded practice in practice nursing as in hospital nursing.³⁶ This is confirmed by Atkin and Lunt³⁷ in their national study of practice nurses. They say:

"Practice nursing is characterised by a broad range of work This work is undertaken with varying degrees of responsibility ranging from performing delegated clinical activities requiring competence and skill, to undertaking work requiring independence and judgement and action."

Interestingly, this contrast between delegated activities and independent clinical judgement was highlighted with respect to ear syringing by Cater and Hawthorn²⁵ as long ago as 1988. They used it as an example to test survey respondents' estimation of their levels of responsibility. Nurses were asked to choose which of the following scenarios were nearest to their own practice:

- “ 1. *A patient is referred to you by the general practitioner to have his ears syringed. The general practitioner has diagnosed the problem, prescribed necessary wax softening agents and decided to delegate the ear syringing procedure to you.*

2. *A patient requests (or is directed by the receptionist to you) to have his ears syringed. You obtain a history of his complaint, examine his ears and assess if wax is present, then elicit any contraindications. You recommend softening agents if required. You decide (based on your judgement) that syringing is required and you carry out this procedure without obtaining specific permission because there is agreement that this is delegated to you.”*

Sixty per cent of the practice nurses surveyed said that they always or frequently operated at the level of the second example, whereas only 20% of treatment room nurses and 9% of attached district nurses operated at that level. Almost 40% of the nurses overall wished to extend their role towards that of a nurse practitioner,²⁵ as did a large proportion of practice nurses surveyed by Atkin and Lunt.³⁷

The change in practice nurse roles and responsibilities was recognised in an editorial in BMJ³⁸ entitled, “New opportunities in practice nursing - roles matter more than titles.” The authors state that:

“Many practice nurses are clearly already working as ‘advanced practitioners’ with or without formal qualifications.”

In the context of a brief description of the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) new educational framework for nurses after registration,³⁹ Venning and Roland³⁸ say:

“Are nurses merely an alternative to general practitioners - or is there a range of roles for which they are not only better prepared but also cheaper?”

Redefinition of nursing roles and skills is occurring in many fields of health care including general practice.³⁸ The question to be answered by this study is - **is ear care better and/or cheaper and therefore better value-for-money when provided by specially equipped and**

educated practice nurses in primary health care than by the conventional approach of GPs who have had only the standard existing educational preparation, and may be supported by practice nurses or district nurses with no specialised ear-care training?

BACKGROUND

The service being evaluated

Rotherham Primary Ear Care Agency³ defines primary ear-care as:

“a local service giving people the opportunity to have equal care for ears, in line with the care offered for eyes, teeth and feet.”

The booklet published by the Agency³ continues:

“Prevention of ear-care problems begins with knowledge. Ear-care clinics in general practice enable people to become more aware of how their ears work, how to prevent problems and how to recognise initial signs of recurrence. Nurses are trained to understand and identify ear problems. The service enables more people to be treated locally, leaving extra time for hospital appointments and major problems. The general practitioner can also leave the ear care to the specialist trained nurse, which enables the doctor to have more time to help patients with other problems.”

This booklet makes it clear that itchy, blocked or uncomfortable ears need not be accepted as unavoidable, and that hearing loss may be helped by regular ear care and appropriate referral. Particular stress is laid on patient education and advice for the prevention of ear problems by the specialist ear-care nurses, who have all received the approved primary ear-care training.

The editor of “ENT News,”⁴¹ describes the benefit to patients of direct access to primary ear care clinics as immediacy of treatment at the first point of contact. He also highlights advantages to doctors - for GPs, the freeing of their time to attend to other problems, and for hospital-based ENT surgeons, twin benefits; first, the ability to concentrate on problems which require their high level of expertise, and second, the facility to refer patients back to well-trained nurses in primary care for regular aural toilet and other follow-up care.

Training in Ear Care

Ear-care training offered to practice nurses through the Agency¹² covers the following topics:

“examination of the ear, aural toilet, use of aural instruments, insertion of dressings, recognition of aural problems and choice of treatment from an approved range of topical medication. Also covered are basic pure tone audiometry, recording and interpretation, as well as advice for people with hearing aids, tinnitus or vertigo. Information on setting up a problem ear-care clinic is an important feature of this course.

The theoretical and practical components of the course relate to the primary care environment, with the emphasis on the community, rather than the hospital setting.”

Pre-registration nurse training covers only very basic information about ear problems and their treatment. The ear-care nurse training consists of three and a half days of training over two months, to include clinical practice in the nurse's own workplace, a practical assessment, an oral examination with an ENT consultant and a written assignment. The training is done by the nurses from the Ear Care Agency supported by consultants from Rotherham District General Hospital (DGH). Training costs £250 and normally 80% of this sum in Rotherham and 70% in Barnsley is reimbursed to the practice by the Health Authorities (but very few Barnsley nurses have been trained). The certificate awarded is the Preventative Ear Care Certificate for Practitioners in the Primary Setting.

One of the aims of the course is that nurses should be able to recognise “a safe and an unsafe ear, as well as a potential otitis externa, so that following removal of ear wax (either by washing or use of instruments, or both) correct preventative advice and treatment can be given.”²⁰

Since the local ENT surgeon has been involved with the training of these nurses a good support network exists. When the consultant sees a patient in hospital who requires regular treatment (e.g. wicks) he can then suggest that this be done in the patient's own practice. Similarly when an ear care nurse sees a patient whom she feels needs immediate attention, the nurse is given direct access to the ENT department to enable appointments to be brought forward or arranged more quickly.

Equipment for ear care in general practice

As the nurse completes the training, she receives a letter to give to the GP with whom she works, advising of her new skills and the course she has completed. The letter informs the GP that each nurse has a list of instruments which she may need in her new role. Practice nurses are referred to as 'she' throughout this report because all the practice nurses in the study were female. Atkin et al's national survey²³ found that 99% of practice nurses were female. They received 12,589 responses from a possible field of 15,123 nurses (83%).

Ear care nurses will require a "Propulse" Ear Syringe (£70) and either a head mirror (£65) or a head light (£20). A basic GP starter set including a fibreoptic auriscope and headlight is available for around £350. Training includes the use of an audiometer (approximately £500) which may be included in equipment needed together with the paper pads to record the results (£2 for 100 sheets). The remainder of the equipment needed is very basic; cotton wool, ribbon gauze, box of tissues, and a large paper roll. Nurses frequently treat by aural toilet and insertion of dressings/wicks. The ointment needed for these dressings/wicks need not be ordered for all patients as the amounts used are small and supplies may be shared between patients. Instruments are sterilised in the normal way.

The service offered to Rotherham patients

Rotherham residents with ear or hearing problems find that on going to their own GP there is a high chance that they can be seen and treated by a nurse trained in ear care. Patients may or may not see the GP first before being seen in either ear care clinics or general nurse clinics. In some practices all nurses are ear care trained but not in others resulting in a variation of work organisation between the selected practices. One practice lost its only ear care trained nurse during the study period and she was not replaced for about 6 weeks.

Some practices hold specific ear care clinics to which patients may self refer; in these practices nurses will organise appointments for courses of treatments and schedule check-up visits for former patients at three or six monthly or yearly intervals. In the practice where the ear-care service began, the appointment times were 20 minutes in length at the start of the service but reduced to 10 minutes by 1995. The aim of the service is that those patients with ear or hearing problems will receive appropriate treatment and advice about their condition, enabling them to better understand their situation. Should the nurse feel that the patient requires a

prescription there is always a GP on the premises, who may or may not examine the patient before signing the prescription recommended by the ear care nurse.

In addition patients have the possibility of calling into the Rotherham Health Advice Shop where an appointment can be made to receive advice from a nurse trained in ear care who will give an ear and hearing check. The ear care nurse will then write to the patient's GP with her findings, with a view to referral to audiology services for a hearing aid or tinnitus management, or to ENT for further investigation and treatment.

The comparison - the service offered to Barnsley patients

In Barnsley, patients with ear or hearing problems will see their GP who will refer them to a practice nurse or district nurse if syringing is necessary. Most nurses in Barnsley will still use the old style syringe and kidney dish. Otherwise patients receive advice or a prescription from the GP. Few nurses or GPs in Barnsley carry out treatments such as insertion of wicks. In this study it was not possible to record treatments received by each individual patient in an accurate way, for reasons explained in the methodology section later. However, it can safely be said that whilst ear-care trained nurses in Rotherham frequently carried out other procedures than syringing e.g. aural toilet, instrumenting ears clear of wax, and inserting wicks, it was very rare to see any record in patient notes of treatments being carried out in Barnsley other than syringing.

Some nurses in Barnsley were already using the "Propulse" syringe, although they may not have been trained to use it, other than reading the guidelines enclosed with it which suggest how it should be used. As we report, these guidelines are being strengthened to include a statement from the firm that "the firm will not be held responsible for the use of the syringe by untrained personnel." There are dangers associated with using the syringe which include not drying the ears and an over-forceful use of the syringe.

A few Barnsley GPs have trained ear-care nurses working in their practices and these practices were excluded from the study. For most residents, ear problems are dealt with by GPs who may have only a small amount of training in ear problems.

"Scanty teaching in otolaryngology has resulted in many general practitioners referring many patients to hospital outpatients departments sooner than they would prefer. A

wider understanding of the history, examination and management of ENT problems may well result in GPs treating more of their patients within the surgery.”¹⁶

It is clear that the Primary Ear Care Agency aims to train nurses to provide a service that is very different from standard practice in most GP surgeries, where a patient with an uncomfortable, blocked ear will receive a routine referral to the practice nurse or district nurse for syringing, with no review or follow-up expected. Where an ear-care trained nurse is available, a full assessment of the problem is made, ear health education is given, treatment offered and given as appropriate, with follow-up and review at regular intervals when necessary. Referral to the GP and/or consultant or hearing clinic is made when needed.

A phrase that is often used in connection with the Primary Ear Care Agency is “ear awareness”. Rodgers²⁰ says:

“Ear problems are still considered of secondary importance by many medical and nursing staff, but in Rotherham we have shown that if priority is given to ear problems communication can be improved, consultant and doctor’s time saved, and patient anxiety relieved..... Proper recognition of ear problems, and effective ear care, can prevent inappropriate referral and treatment.”

That quotation describes ear awareness from the viewpoint of doctors and nurses, but Rodgers¹² also refers to ear awareness for patients:

“Ear clinics in general practice enable people to become more aware of how their ears work, how to prevent problems and how to recognise initial signs of recurrence.”

Rodgers²⁰ demonstrated that the introduction of the ear care service in 1990 initially generated a large number of new attendances at the agency’s first clinic, but that more recently new patient numbers have declined as the backlog of previously unrecognised and untreated conditions has been dealt with (see Appendix 1 for more detail).

To sum up, primary ear care in Rotherham offers patients access to nurses in their own practice who have received training to assess and treat ear conditions within their competence, and to recognise when referral to GP, ENT consultant or audiologist is required. Ear-care

nurses offer advice on preventing ear problems and maintaining ear health, and also offer regular check-ups to patients who need them.

CHOICE OF RESEARCH METHOD AND DESIGN

Primary ear care, being a method used by health professionals to promote health and prevent and treat disease, can be classed as a "health technology". Advice on assessing the effects of such technologies⁴² acknowledges that although randomised controlled trials are the best way to avoid bias between treatment groups, especially when effect is not thought to be very large, such trials are often not possible when looking at technologies applied across a whole area of care, such as the Rotherham primary ear care service. The presence of a practice nurse trained in ear care is thought to make the whole practice "ear aware" and so randomising individual patients between different carers in a practice would not be feasible. Neither would choosing practices in Rotherham without ear care nurses be possible, as there are very few of these, and patients still have access to the central "Health Advice Shop" ear-care nurse.

Inevitably, then, the method chosen was an observational one - to compare patients with ear or hearing-related problems from Rotherham practices with similar patients from Barnsley practices. Barnsley was selected as the control area because of its similarity in terms of demography (age, structure, ethnic mix), household composition and housing distribution, socio-economic factors and employment characteristics, as revealed in the 1981 census⁴³ (local and health authority comparisons for 1991 were not available at the time of study design). "Jamman" scores⁴⁴ for practice populations, indicating socio-economic deprivation, were available for both Barnsley and Rotherham Health Authority areas, and were broadly similar (see below under "practice selection").

Summary of research design

Rotherham and Barnsley practices

Patient-based inquiry

- Questionnaire One (Q1)
- Questionnaire Two (Q2)
(to respondents of Q1, 3 weeks later)

Notes consulted at practice, to cover the 3 month period from the date of issue of Q1.

Staff inquiry to practice nurses

- Questionnaire about time and resources devoted to ear care.
- Telephone survey at end of study period about types of treatment and ear care training.

Rotherham and Barnsley DGH

- Notes of all patients referred during the study were consulted to establish hospital outcomes if the information was not available from GP notes.
- ENT (ear patients only) referral statistics for period of study. One month sample of notes of all patients referred in the month were consulted.

Aims, objectives and research questions for the study

The overall aim of the study is to measure outcomes and resource use for patients with ear or hearing-related problems treated in practices with nurses trained in ear care in Rotherham, comparing them with similar patients treated in a routine way by practices in Barnsley, who do not have nurses trained in ear care.

The short-term nature of the study posed some limitations on what could be achieved. In particular, only short-term health gains could be measured and hence there was only limited ability to examine the benefits to patients with long-term disability arising from irreversible hearing impairment and tinnitus. Such gains would be from advice and reassurance in the short term, with the major gains occurring later when the effects of prosthetic devices became

apparent. In so far as the short-term gains are evaluated here, the analysis is primarily qualitative (see Section 10) and is not tied specifically to the main research design.

Within this framework, the specific objectives are:

Objectives:

1. To compare differences in the proportion of patients aged 16 or over in Rotherham and Barnsley reporting a reduction in pain or discomfort due to their ear or hearing problem on return of their second questionnaire, compared with their reported pain or discomfort stated in their first questionnaire completed three weeks previously (on the day of their consultation at the practice for an ear or hearing problem).
2. To compare differences in responses to a short, quality of life instrument (HSQ 12)⁴⁵⁻⁴⁶ included in the first and second questionnaires, between Rotherham and Barnsley patients.
3. To compare referral rates and patterns for hospital ENT clinics and audiological services between Rotherham and Barnsley practices.
4. To compare patient perceptions of their experience of ear care in the two areas.
5. To estimate the resources used for ear care in the Rotherham and Barnsley practices.
6. To evaluate the relative cost implications of the Primary Ear Care Service as seen in the Rotherham practices studied, compared with the standard care offered in the Barnsley practices studied.

The objectives were operationalised into the following:

Research Questions:

1. How do patient reports of ear-related discomfort or pain vary between the two groups at Q1 and Q2 and in changes reported in the later questionnaire?

2. How do patient reports of their health status and quality of life vary between the two areas at Q1 and Q2?
3. How do hospital ENT and audiological referral rates and patterns vary between the two groups/areas?
4. How do patient perceptions of ear care experienced vary between the two groups?
5. How does resource use vary between the groups?
6. What are the cost implications of the Rotherham Primary Ear Care Service compared with the cost of standard care in Barnsley, in relation to other perceived differences in the experience of the two groups?

Aim of the costing exercise

Increasingly, in the provision of health care, questions relating to resource usage, and more specifically cost-effectiveness, are being posed. The aim of the costing component of this study is to examine the economic implications of two different approaches to dealing with patients presenting with ear problems (initially) to primary care providers.

It should be clearly recognised that this analysis does not constitute evidence relating to the cost-effectiveness of care in the two settings. Cost-effectiveness can only be shown when a ratio showing cost per unit of outcome can be reported. In this project the outcome measures chosen do not possess *both* ordinal and interval properties and are not therefore suitable to generating a cost-effectiveness ratio. **The analysis presented here takes the cost consequences approach**, as described by Drummond.⁴⁷ In this type of analysis a range of costs and consequences of alternative interventions are presented separately. This allows the decision maker to consider which of the outcomes reported are most important in their own setting and circumstances. This approach does demand more careful thought on the part of policy makers who may wish to supplement the evidence presented here with findings from other studies.

METHODOLOGY

Ethical approval, practice selection and access

Ethics committee approval was sought and granted from both Rotherham and Bamsley Health Authorities. Rotherham and Bamsley general practices mostly refer to a single central hospital in each area. Consultants from both hospitals gave their permission for the study team to consult notes of patients referred during the study to the ENT Department. Audiologists in both areas also gave permission for access to audiology notes.

By the beginning of 1995 almost all general practices in Rotherham were covered by a trained ear care nurse. It takes time for newly trained nurses to adapt their working habits and become proficient in their new role and for this reason only practices where the nurse had been trained and carrying out the new role for at least six months were included in the study. Eight such practices were identified and their co-operation was assured. Each practice was offered a sum of money at the rate of one hour per week at receptionist rates for the period of the study to compensate for the receptionist time used in recruitment.

Neighbouring Bamsley has a similar socio-economic mix of population as Rotherham. A few practices in Bamsley already had practice nurses who had completed the additional ear care training and these practices were excluded from the study. After an initial approach six practices agreed to co-operate in the study. Each practice was offered a sum of money at the rate of one hour per week at receptionist rates for the period of the study. Each practice was offered, once the study was completed, that part of the cost of training an ear care nurse which was normally paid for by the practice. Two practices withdrew before data collection could begin leaving only four practices. It was quickly realised that these four practices were not able to supply all the patients needed and that it was necessary to recruit further practices to the study. All 30 practices in Bamsley who had no ear-care trained nurse and had not already been contacted were sent a letter and from these a further six practices were recruited into the study under the same terms as the original four. One of these dropped out in the first week for no known reason. In order to try to keep practices interested as the study progressed all practices received literature about the work done in SCHARR and in the Trent Institute including details of the research support and advice that is available to NHS staff in Trent Region.

The eight Rotherham practices had a median practice population of 7,125 (range 3,142 to 10,800) served by a median of 3.5 GPs (range 1 to 6) per practice. The nine Barnsley practices had a slightly lower median population of 5,591 (range 791 to 8,373), served by a median of 3 GPs (range 1 to 4) per practice.

“Jarman” scores are a measure of socio-economic deprivation.⁴⁴ The higher the positive score, the greater the deprivation. For Rotherham, the median practice Jarman score was +4.5 (range -12.2 to +12.5). For Barnsley, the median practice score was very slightly higher, at +5.0, but representing greater homogeneity, with a range of +3.2 to +10.7.

Questionnaire construction and development

Patients presenting at surgery with ear or hearing problems were to be given a self completion questionnaire which would measure the nature and severity of their problems and health status and allow for general comments at the time of initial consultation, preferably before beginning treatment. Three weeks later those patients completing the initial questionnaire (Q1, Appendix 2) would be invited by post to complete a second questionnaire (Q2, Appendix 3) which would give details of treatment, visits made and current health status as an outcome measure. It was expected that the main effects of treatment would have been experienced by this time.

Self-completion questionnaires (see appendices for Q1 and Q2) were judged to be the only realistic way of gaining information from a large number of patients dispersed throughout 17 practices all over Rotherham and Barnsley attending over a period of several months. Apart from the practicalities of choosing this method, which include staffing and financial implications, other benefits include anonymity for respondents with lack of interview bias, and the opportunity to standardise most responses for ease of analysis whilst including a few open-ended questions to allow further expression of patient opinion.⁴⁸

In the early planning stages of the research project, the intention was to use validated measurement scales such as one or more of the instruments devised by the Medical Research Council's Institute of Hearing Research, for instance, the “Ear Activity Benefit Scale.”⁴⁹ This was possibly to be combined with a health-related quality of life tool such as SF-36, and a visual analogue scale for measurement of pain. However, economic and patient satisfaction measures were also needed, yet the questionnaire had to be capable of completion by the patient whilst waiting to be seen in the practice waiting room!

A compromise was reached by compiling questionnaires 1 and 2 based on health and social problems taken from several of the MRC Hearing Research Institute's instruments, such as discomfort, pain, sleep disturbance, disruption to normal activity, social, family and work life, embarrassment, worry and loss of hearing. Satisfaction with treatment given, and expenditure related to the ear condition were included in just the second questionnaire. Both questionnaires incorporated HSQ 12 (Health Status Questionnaire),⁴⁵⁻⁴⁶ a really abbreviated quality-of-life inventory which has received some validation but is still being developed. As Radosevich and Husnik, of the Health Outcomes Institute say,⁴⁵

"Cost and effect are two major barriers associated with the adoption of outcomes assessment within everyday medical practice. To be successfully implemented, measures of health status must be easy to use, impose little data collection burden upon patients and providers and give interpretable results."

Amongst the applications of HSQ 12 are listed:

"making distinctions in the health status among subgroups of patients"

and

"monitoring changes over time in the health status of patient groups."

Both these applications were appropriate for the ear-care project, therefore HSQ-12 was included. It is a 12 item self-administered questionnaire that profiles eight dimensions of perceived health status: Physical Functioning; Role Limitations Attributable to Physical Health (Role Physical); Bodily Pain; Health Perception; Energy/Fatigue; Social Functioning; Role Limitations Attributable to Mental Health (Role-Mental) and Mental Health. Responses to each item within a dimension are combined to generate a score from 0 (worst health) to 100 (best health).

A number of the questions posed used "Likert"⁵⁰ scales for the answers, because it was felt that they are easily understood by patients, and give more discrimination than "yes/no" answers. By this means, as Fitzpatrick⁵¹ says:

"The respondent is given a greater opportunity to express the precise nature of his or her view. Moreover, the reliability of items increases as the number of response alternatives increases."

A number of recent authors on the topic of patient satisfaction agree that it is common for at least 80% of respondents to express satisfaction with care, particularly if broad, global questions are asked.^{48, 52-54} The same authors stress the necessity for asking specific questions of particular meaning to the patient group concerned, and Thomas and Bond⁵⁵ put in a plea for more qualitative research into patient satisfaction, to *“lead to decisions regarding what to study being determined by patients rather than researchers”* and to *“provide multi-dimensional data which take account of the depth of patient experiences.”*

The recent literature on patient satisfaction also acknowledges that older patients and men generally express more satisfaction, and that dissatisfaction may be linked to patient distress, especially chronic pain, and to waiting a long time to be seen, or having a shorter consultation than was desired.^{51, 53, 56-57}

To summarise the purpose and content of the questionnaires: they were designed to provide outcome measures of health-related quality of life, discomfort, pain, hearing problem, hearing affected, worry/embarrassment, normal activities affected, social or family life affected, sleep affected and other symptoms.

Sample Size

The outcome used for determining sample size was a difference in the proportion of patients in each area reporting a reduction in discomfort or no change in discomfort related to the ear or hearing problem when they return their second questionnaire at three week follow-up, compared with the level of discomfort reported in their first questionnaire. Because of the anticipated difficulty in recruitment in Bamsley due to lack of 'ear awareness', twice as many patients were to be recruited in Rotherham than in Bamsley.

It was judged that a difference between the groups of 10% in the proportion of patients experiencing a reduction or no change in discomfort was practically relevant. So if 70% of patients in one group and 80% of the patients in the other group experience a reduction or no change in discomfort at follow-up; then for an 80% chance of detecting such a 10% difference in proportions as statistically significant at the 5% level, about 660 patients would be needed in total.

If the patients were recruited in the ratio of 2:1 (Rotherham: Barnsley) then 440 patients in Rotherham and 220 patients in Barnsley would need to be recruited and followed-up.

Pilot study

The draft questionnaire was developed and piloted among a group of eight patients attending a Rotherham practice.

The questionnaires were designed to take into account the known difficulties of approaching patients in general practice.⁵⁸ Patients regularly do not take their spectacles with them when they visit the GP and for this reason the font size was kept large. The design was kept simple to encourage as high a response rate as possible.

Some patients were found to be unhappy about completing the form in the surgery and it was necessary to provide the facility to allow the form to be completed at home. In general the shape of the form seemed acceptable and the only alterations made were to draw respondents' attention to the reverse of the questionnaires, which patients had tended to miss out. Once the form had reached an appropriate patient the overall completion was good (7 out of 8) and the response to Q2 at three weeks was high (6 out of 7). The completion of the HSQ-12 was also good (of a possible 156 responses on Q1 and Q2, only 12 were missing) and appeared to present no problems to the respondents. The HSQ-12 was therefore retained in the final version.

Recurrent or New patients

It was expected that it would be possible to find patients who were consulting with new rather than on going problems in order to avoid patient entry to the study in the middle of a treatment. At the pilot stage it was found that patients did not seem to remember when they had last consulted, and also one of the features of the ear care service is that patients regularly come back for check-ups. Thus many patients are recurrent patients. As a result, it was decided that all patients would be included and would receive Q2. The main body of analysis contained all patients, old and new, followed by a separate analysis of new (incident) patients.

Confidentiality and consent

The study design required that patients be asked as they requested an appointment, either at the practice or by telephone, whether they were consulting for an ear or hearing problem. In crowded waiting areas it was thought that patients might not like to be asked publicly the reason for their consultation. A card was therefore produced which the receptionist could show to establish the reason for consultation bearing the words "Do you wish to see a doctor or a nurse for an ear or hearing problem?". In reality practices did not use these cards to any great extent.

Patients were reassured of confidentiality in a letter appended to the questionnaire (Appendix 2). Names of patients were not entered onto questionnaires. Some GPs were anxious about giving the study access to patients notes. For this reason the covering letter stated that by completing the questionnaire patients were concurring with their GP's decision in allowing the study access to surgery held notes. A pre-paid envelope addressed to the study was attached to all questionnaires.

Conventionally, patient notes are available for research provided that confidentiality and anonymity are preserved.⁵⁹⁻⁶⁰

Eligibility

The protocol required that all patients in the study would be over 16 years in age and would have presented at the surgery with an ear, ear-related or hearing problem. Receptionists were to establish this eligibility when patients phoned, made an appointment or presented at surgery. Those who qualified for inclusion into the study would complete Q1 before they saw either the GP or the practice nurse.

Data collection

Practices were provided with pens and clip boards to enable patients to complete the questionnaires easily. An ear care poster and a poster acknowledging the practice's help in the study were given to each practice for display in the surgery. Small handbills were left lying in the practices for the public to take telling them of the study. Questionnaires were consecutively numbered and receptionists were required to log eligible patients' names and

addresses onto a master sheet to enable the Q2 to be mailed out after three weeks. It was recognised that the role of the receptionist was central to the success of the study and for this reason a payment of one hour a week at receptionists rates for the duration of the study was offered to each practice. Questionnaires were issued by practices commencing June 1995 and finishing mid October in Rotherham and in Barnsley from June 1995 to the second week in December 1995.

Patients who took Q1 home for completion, but did not return them, were not sent any reminders, as the form was supposed to represent the position on the day of consultation. Three weeks later Q2, including a letter, was mailed to all those who had returned a Q1 (Appendix 3). Reminder Q2s with an appropriate letter were sent out two weeks from the date of sending the initial Q2 to non responders. Those who still did not reply were contacted by telephone where possible and encouraged to return the completed form. Thus the date of completion of Q2 may be up to six weeks from the date of Q1.

Data collection from patients' notes

The notes of all patients who had completed the initial questionnaire Q1 were consulted in each practice, at least three months after the date when the Q1 was first issued. Not all notes were available, some patients having left the practice or died or their notes were currently in use. Patients who had refused a Q1 were excluded. Information collected included date of birth, sex, whether they had consulted in the previous year with either a GP or practice nurse for an ear or hearing problem, all visits they had made to the GP or the practice nurse during the three months from the date of Q1, for ear or hearing problems. All drugs on prescription were noted and any referrals to the ENT or Audiology services during the three months or in the year previous to the date of Q1 were recorded.

Rotherham ear-care nurses use a bright green treatment card which is kept in patient notes. Details of all consultations and referrals were recorded. These cards were well completed by the nurses and included details of drugs the nurse had suggested that the GP prescribe.

It was not so easy to collect information from patients' notes completed by GPs due to unclear writing, and local variations in making entries.

Some practices in Barnsley did not use their own practice nurse to syringe ears but referred patients to the District Nursing Service. The district nurses did not have access to patient notes and so no record was made in the notes to indicate that the syringing had taken place. The assumption was made for data collecting purposes that where a GP had indicated in the notes that a patient was to be referred for syringing, that they

- a) had been referred and
- b) that the ears were syringed.

It will be appreciated that no further information could be deduced about the condition found in the ear following syringing nor any action taken by the DN recorded. It is not known whether the DNs ever advised the patients to return to see their GPs for advice, treatment or suggested prescriptions.

Practice nurse/district nurse questionnaire

Early in the study, one ear-trained nurse in each Rotherham practice and one practice nurse or district nurse in each Barnsley practice was asked to complete a questionnaire to indicate the number of minutes spent on various procedures; removal of ear wax, treatment of Otitis Externa and counselling regarding hearing problems, on a first and subsequent visit.

Telephone survey to practice nurses

A short telephone interview was carried out with four ear-care trained practice nurses and three non-ear care trained practice or district nurses, at the end of the data collection period, to ascertain views on treatments carried out and training received (Appendix 4).

Hospital referrals

When a patient had been referred to the Audiology Service or the ENT department during the three months following the Q1, any information that was available was collected from letters in the patient notes. Where it was thought that the information from the hospital might be incomplete the hospital notes were consulted.

Both Barnsley DGH and Rotherham DGH supplied numbers of all referrals from the selected practices to ENT for six months from June to December 1995, to enable a rate of referral per

population practice to be established. All cases were looked at for the month of September in Rotherham and for October in Bamsley to enable us to compare the number of cases in the study with the total who were eligible for inclusion.

RECRUITMENT PROBLEMS AND SOLUTIONS

Difficulties experienced in data collection

Patients did not always arrive at the surgery early enough to complete the form before their appointment. Some practices were extremely busy and not all receptionists had time to establish whether patients should be included in the study, or remembered to hand out Q1. Patients did not always hear the question accurately and it was later found that they may have said they had a problem in general rather than that they were consulting on that day with a relevant problem (these patients were later excluded from the study). Some GPs were not happy that patients would be asked by receptionists why they were consulting and felt it was better that they themselves asked patients whom they had just seen about an ear or hearing problem, to collect a questionnaire from the receptionist on their way out, other GPs were prepared to hand out the Q1s themselves. On some occasions this resulted in no patient name being recorded. It frequently meant that the questionnaire was taken home for completion with the result that there may have been a diminution of response. Moreover as practices lost interest in the study more forms were taken home. Wherever possible it was recorded whether the questionnaire was completed in the surgery or taken home. In practices where patients normally self-referred directly to an ear clinic then it was found to be preferable that the ear-care nurses handed out the questionnaires, even if it meant completion after treatment. However this method, if not backed up by receptionists asking patients at the desk or GPs asking patients following consultations, resulted in the loss of some patients to the study.

Particular problems of recruiting patients into the study were encountered in Barnsley as is often true in control areas of studies. The Barnsley practices and their GPs had not been involved in the setting up of the Ear Care Agency and had no experience of working with ear care trained nurses, resulting in no ear awareness in the practices by the staff or the patients. There were no designated ear clinics. There were no ear-trained nurses to encourage participation and do the work of the study. In Rotherham, although it had been acknowledged that the commitment of receptionists was needed for the study to succeed, it was the direct involvement of the practice nurses in distributing the questionnaires which achieved the more complete coverage. Additional letters were written to all GPs in Barnsley reminding them of their practice commitment to the study, because of low recruitment figures.

No patient should ever receive two Q1s but as time passed, recurrent patients who visited regularly reappeared and it was increasingly difficult to recruit new patients to the study. During the data collection period it became more and more difficult to keep the practice staff interested in the study, even though all practices were visited by a researcher each week and kept informed about the study. This was particularly the case in Bamsley.

Loss of patients to the study

As a result of these difficulties the authors acknowledge that patients have been lost to the study in the following circumstances:-

1. When receptionists failed to ask all ear patients when booking appointments.
2. When doctors failed to ask appropriate patients to collect a form, or failed to give out a form.
3. When only those attending a clinic were included and not those consulting directly with the GP.
4. When receptionists or doctors forgot to record a patient's name. These patients had to then be excluded from the study as they could not be contacted for Q2.
5. Patients who have said they had an ear problem to the receptionist but then did not mention it to the GP during the consultation have been excluded from the study as they were not consulting on that day with an appropriate problem.

Diminution of effect

The advantage to the study of receptionist handing out the Q1 before treatment was to get a baseline position when the symptoms of pain, discomfort etc. were at their maximum. It can be appreciated that this was not achieved uniformly or completely due to the difficulties of working in seventeen practices that all wanted to adapt the process to suit their own circumstances. This lack of uniformity underlines the pragmatic nature of this study.

Non-responders to Q2

In order to measure outcome both a Q1 and a Q2 was needed. When there was no response after a 2nd Q2, patients were telephoned whenever possible to either encourage them to send in the completed form or to establish why they had not completed it. As a result patients reported that some had received the form incorrectly as they were under 16 or they had not

consulted on that day with an ear or hearing problem. Others felt that the form did not apply to them and gave reasons such as " I don't have an ear problem - I only need ear syringing occasionally" This view was particularly found in Bamsley. Some patients had been away or were ill, while others said they were not interested in filling in the form and could not see how it could be useful.

Exclusions

Patients were excluded if:-

- no name was available
- patient notes were unavailable
- patient was aged under 16
- patient notes showed no record of ear problem on or around date of issue of Q1, or patients informed us they had not consulted with an ear or hearing problem.

Of the 1072 first Questionnaires (Q1s) issued to patients over 16, seventeen were excluded because no name was recorded. A further 27 were excluded because the patient notes were not available due to the patient having died, left the practice or the notes being currently in use. Seventy-nine were excluded because there was no sign in the patient notes that they consulted on that day with an ear or hearing related problem. This left 949 eligible patients.

Dispute between one of the practices and Rotherham Health

One practice was dropped from the study when they stopped operating their ear care service. This happened because, as fund-holders, they felt that money from secondary care should be redirected to primary care if tasks which formerly were done in hospital were now being done in general practice.

STATISTICAL METHODS

Parametric statistical tests assume the data originate from a known statistical distribution. We used non-parametric statistical tests which avoided any distributional assumptions; for continuous measurements (e.g. age, number of GP visits) Mann-Whitney tests of significance were used. For categorical measurements (e.g. sex, diagnosis), Chi-squared tests were used.

For the HSQ-12 dimension scores, the summary measure of health gain after treatment calculated for every patient was the difference between the follow-up score (from Q2) and the initial score (from Q1). A large positive value in these scores represents a large health gain.

Mean summary responses were calculated and 95% Confidence Intervals (CI) for the mean difference were calculated by bootstrap methods.⁶¹ Bootstrap methods work by resampling from the observed data and thus make no distributional assumptions.

Parametric analysis of covariance methods⁶² were used to compare the changes in HSQ-12 dimension scores from Q1 to Q2 between areas, taking into account any differences in the initial (at Q1) HSQ-12 dimension scores. This assumes that the HSQ-12 dimension scores are continuous measurements and are normally distributed.

Similarly, for the categorical outcomes measured at 3 weeks in Q2, (e.g. pain, discomfort etc.) log-linear modelling⁶³ was used to look for associations between area and outcome at Q2, after adjusting for differences in the initial level at Q1.

Data management and analysis

The questionnaire data were entered into a computer using 'Epi-Info' software. The patient data were entered onto an Access data base and transferred to SPSS and Excel for analysis.

Nature and source of cost evidence

The perspective taken in this analysis is both, an NHS and a societal one in that the range of costs considered takes into account both those falling to the NHS in primary and secondary care settings, and also the costs that fall to patients when using the services reported here.

Evidence relating to the quantities of resources used in the two care settings was gathered from a number of sources. Patient notes from both primary and secondary care were accessed in order to gather information. In addition self-reported details were obtained from patient questionnaires.

The cost figures used in calculating the final cost per case evidence came from a variety of sources. The cost of GP consultations and consultations with practice nurses were both taken from figures previously published by the Personal Social Services Research Unit.⁶⁴ Time estimates relating to practice nurse consultation were based on a questionnaire given to practice nurses in several Rotherham and Bamsley practices and an average consultation time calculated.

The cost per consultation with trained ear-care nurses (ECNs) in Rotherham was more problematic. The time spent in each consultation was calculated in the same manner as in Bamsley. The cost per consultation in Rotherham had to reflect training costs (initial and annual update), equipment costs and that proportion of the Ear Care Agencies (ECA) budget which could be directly attributed to supporting the care of patients at practice level. Both costs were calculated on a per patient seen basis, the first one on the basis of the average number of patients per year an ECN sees (based on data supplied by the ECA on a sample of 8 practices). ECA costs were broken down to a cost per practice basis and then broken down to cost per patient seen by taking a sample of how many ear-care patients were seen annually in each of the 8 practices sampled.

In sum the costs of training, equipment, ECA support, came to a total of £1.38 (out of a base case cost per consultation of £6.88) or 20% of the cost per each ECN patient consultation.

Secondary care costs (Audiology and ENT outpatient visits) were taken directly from prices quoted to GP fundholders by the two provider units in Rotherham and Bamsley. Drug prices were taken from the British National Formulary (BNF) and Monthly Index of Medical Specialties

(MIMS). Costs which accrued to patients in the form of travel to the various facilities, the cost of any alternative non-NHS treatment and the cost of over the counter preparations, were assessed by patients directly and taken from answers supplied in the patient questionnaires.

Mean costs per patient in the two groups were compared by a re-randomisation test procedure.⁶¹ Mean cost differences were calculated and 95% confidence intervals (CI) produced by bootstrap methods.

RESULTS

1. Response Rates

Response to questionnaires

Despite extending the number of control practices and the data collection period in Barnsley, it was not possible to recruit and follow-up the required target of 660 patients. In all **949** patients were eligible and invited to participate in the study during the recruitment period. **Seven hundred and ninety patients** agreed to participate in the study and **responded by returning the first questionnaire (initial response rate of 83%)**. One hundred and fifty six of these were lost at the 3 week follow-up and failed to return the 2nd questionnaire, a **secondary response rate of 80%** (Table 1.0). This left **634** patients available for assessment, (438 in Rotherham and 196 in Barnsley), only slightly short of the numbers proposed in the initial sample size. Response rates were very close between the areas at Q1, and identical at Q2.

Table 1.0: Response to Questionnaires

	Total n = 949 %		Barnsley n = 299 %		Rotherham n = 650 %	
<i>Eligible</i>	100		100		100	
<i>Failed to return Q1</i>	16.8		18.1		16.2	
<i>Returned Q1</i>	83.2		81.9		83.8	
		n = 790		n = 245		n = 545
<i>Failed to return Q2</i>	16.4	19.7	16.4	20.0	16.5	19.6
<i>Returned Q2</i>	66.8	80.3	65.6	80.0	67.4	80.4

2. Comparison of characteristics of responders with non-responders

The median age of responders was 54 years, and 47% were female. Fifty-three percent had previously visited the practice in the previous 12 months with an ear or hearing-related problem.

Our sample of responders did not appear to differ from the non-responders in terms of age, sex, or whether they were new cases (Table 2.1).

Table 2.1: Comparison of the characteristics of Q1 Responders with Q1 Non-Responders

		Responders (max. n = 790)	Non-Responders (max. n = 159)	p value
Area	<i>% Bamsley</i>	31.0	34.0	0.46
Sex	<i>% Female</i>	47.4	42.1	0.23
New or Recurrent Ear Patient	<i>% New</i>	53.1	60.8	0.08
Age in Years	<i>Median (IQR)</i>	54 (38 - 67)	51 (37 - 64)	0.17*

IQR: Interquartile range.

Recurrent Patient: Evidence that they visited practice in previous 12 months with an ear or hearing-related problem.

*P-values are for chi-squared tests, except * Mann-Whitney tests.*

After completion of Q1, 156 patients dropped out and did not return the second questionnaire (Q2). There is some evidence to suggest that these patients were more likely to be male, younger and new (incident) cases (Table 2.2).

Table 2.2: Comparison of the characteristics of Q2 responders with Q2 non-responders

		Failed to return Q2	Returned Q2	p
		<i>max. n = 156</i>	<i>max. n = 634</i>	
Area	<i>% Rotherham</i>	68.6	69.1	0.90
Sex	<i>% Female</i>	39.7	49.3	0.03
New or Recurrent Ear Patient	<i>% New</i>	61.5	51.0	0.02
Previous Referral in 12 months before 1st Questionnaire Issued	<i>% Yes</i>	3.2	4.2	0.59
Current referral after 1st Questionnaire Issued	<i>% Yes</i>	5.1	7.3	0.34
Age in Years	<i>Median (IQR)</i>	41 (28.5 - 65)	57 (41 - 69)	0.0001*
No. of Visits to GP in 3 months after 1st Questionnaire	<i>Median (IQR)</i>	1.0 (0.0 - 1.0)	1.0 (0.0 - 1.0)	0.04 *

*P-values are for chi-squared tests, except * Mann-Whitney tests.*

Those failing to return Q2 did not appear to differ with respect to initial diagnosis (Table 2.3) and discomfort (Table 2.4), although the non-responders were likely be experiencing greater pain (Table 2.5) and more sleepless nights (Table 2.6).

Table 2.3: Comparison of Q2 responders with Q2 non-responders: initial diagnosis at Q1

	Failed to return Q2 (n = 156)	Returned Q2 (n = 634)
	(%)	(%)
Wax	42.9	49.8
Otitis Externa	7.1	8.8
Hearing	9.6	7.7
Itchy	5.8	4.6
Pain	4.5	6.3
Discharge	1.3	3.3
Other	25.0	18.1
Not Known	3.8	1.3

Chi-squared test = 12.83 on 7 degrees of freedom (df), p = 0.08.

Table 2.4: How much discomfort in the last week, including today, from ear or hearing-related problem by Q2 returned status

	Failed to return Q2 (n = 151)	Returned Q2 (n = 618)
	(%)	(%)
None	7.3	10.8
Slight	18.5	24.1
Moderate	41.1	39.0
Severe	27.2	22.2
Extreme	6.0	3.7

Chi-squared test = 5.95 on 4 df, p = 0.20.

Table 2.5: How much pain in the last week, including today, from ear or hearing-related problem by Q2 returned status

	Failed to Return Q2 (n = 149)	Returned Q2 (n = 610)
	(%)	(%)
None	33.6	45.4
Slight	16.1	20.5
Moderate	30.2	20.2
Severe	15.4	12.1
Extreme	4.7	1.8

Chi-squared test = 15.78 on 4 df, p = 0.003.

Table 2.6: Other hearing problems by Q2 returned status

	Failed to return Q2 % Yes	Returned Q2 % Yes	p value
Normally have a hearing problem	54.1	58.7	0.31
Hearing affected by ear or hearing problem today	69.4	66.3	0.47
Current ear or hearing problem causes worry or embarrassment	47.6	49.8	0.62
Current ear or hearing problem affected normal activities in last week	40.0	34.6	0.21
Current ear or hearing problem affects social or family life	36.2	39.6	0.45
Current ear or hearing problem affects sleep	41.5	30.7	0.01

P values are for Chi-squared tests.

Finally, there is no suggestion that those lost to follow-up had different HSQ-12 dimension scores (Table 2.7).

Table 2.7: Initial (at Q1) HSQ-12 dimension scores by Q2 returned status

HSQ-12	Failed to return Q2		Returned Q2		p
	n	Median (IQR)	n	Median (IQR)	
Physical Functioning	134	100 (50 - 100)	579	83 (50 - 100)	0.32
Role Physical	149	65 (25 - 100)	609	65 (25 - 100)	0.68
Bodily Pain	144	85 (45 - 100)	611	85 (45 - 100)	0.66
Health Perception	150	60 (25 - 85)	614	60 (60 - 85)	0.92
Energy/ Fatigue	147	60 (20 - 80)	605	60 (40 - 80)	0.89
Social Functioning	145	100 (75 - 100)	609	100 (75 - 100)	0.87
Role-Mental	145	100 (65 - 100)	603	100 (65 - 100)	0.90
Mental Health	147	60 (47 - 80)	602	67 (47 - 80)	0.10

p: Mann-Whitney Test Statistic *p* value.

3. Responders: Completion Rates of items in Q1 and Q2

The completion rates of items in the first questionnaire was good for most questions (Table 3.1) and did not appear to differ by area. The proportions of missing data from dimensions of the HSQ-12 were 3% to 11% of all possible data items.

Table 3.1: Percentage of responders who omitted questions from Q1 by area

Question Number	Total % Missing n = 790	Barnsley % Missing n = 245	Rotherham % Missing n = 545
<i>Initial</i>	6.4	6.9	6.3
1	2.7	4.1	2.1
2	3.9	4.9	3.5
3	4.3	5.7	3.7
4	4.8	3.3	5.6
5	6.2	5.3	6.7
6	3.0	2.8	3.2
7	3.8	1.6	4.8
8	4.2	4.5	4.1
9	3.3	5.3	4.3
10a	9.9	9.0	10.3
b	9.6	8.6	10.1
c	9.9	6.9	11.2
11	4.0	2.4	4.8
12	5.3	4.5	5.7
13	4.6	4.1	4.8
14	4.4	2.8	5.2
15a	5.6	6.5	5.2
b	4.8	5.7	4.5
c	5.3	5.3	5.4
d	5.2	5.7	5.0

As the percentage of omitted responses was similar in the two areas, completion rates for Q2 were not analysed separately.

Completion rates of identical questions were generally found to improve at follow-up (Table 3.2).

Table 3.2: Percentage of responders who missed questions from Q2 (n = 634)

Question Number	% Missing	Question Number	% Missing
1 (1)	1.6	15 (13)	2.8
2 (2)	2.1	16 (14)	3.0
3 (3)	2.1	17a (15a)	4.9
4 (4)	6.2	17b (15b)	5.0
5 (5)	3.2	17c (15c)	4.9
6 (6)	4.7	17d (15d)	4.4
7	9.3	18	5.0
8	10.6	19	5.0
9 (7)	5.5	20	3.0
10 (8)	2.8	21	3.3
11 (9)	2.4	22	6.6
12a (10a)	4.6	23	7.0
12b (10b)	5.7	24	6.0
12c (10c)	4.7	25	5.7
13 (11)	3.0	26	7.1
14 (12)	3.3	27	3.5

The question number in parenthesis is the equivalent question on the 1st Questionnaire.

4. Comparison of characteristics of patients at Q1 in the two areas

Seven hundred and ninety patients responded to the first stage of the study (245 Barnsley, 545 Rotherham). Using data from GP records, the patients in the two areas were found to be similar with respect to age, sex, previous and current referrals. There was evidence that Barnsley patients were more likely to be new cases, 64% compared with 48%, (Chi-squared test = 18.81 on 1 df, $p = 0.0001$), and were more likely to have returned to consult the GP in the 3 months after Q1 (Table 4.1).

Table 4.1: Comparison of characteristics of Barnsley & Rotherham patients at Q1 (from records)

		Barnsley <i>max. n = 245</i>	Rotherham <i>max. n = 545</i>	p
Sex	% Female	46.1	48.0	0.63
New or Recurrent Ear Patient	% New	63.6	47.5	0.0001
Previous Referral in 12 months before 1st Questionnaire Issued	% Yes	3.1	5.8	0.07
Current referral after 1st Questionnaire Issued	% Yes	8.6	6.1	0.20
Age in Years	<i>Median (IQR)</i>	54 (37 - 65)	55 (38 - 68)	0.29 *
No. of Visits to GP in 3 months after 1st Questionnaire	<i>Median (IQR)</i>	1.0 (1.0 - 1.0)	0.0 (0.0 - 1.0)	0.0001*

Recurrent Patient: Evidence from records that they visited practice in previous 12 months with an ear or hearing-related problem.

*P-values are for chi-squared tests, except * Mann-Whitney tests.*

The following tables are an analysis of all cases, but when the same analysis is repeated on new cases only, the results were almost identical (see Sections 6 and 7).

There was evidence of differences in the proportions of patients in the various diagnostic/symptomatic categories (Table 4.2). It was not possible to separate symptoms and diagnoses in any meaningful way, for patients presenting with ear-related problems. GPs tended to use a more restricted vocabulary than nurses in their records, with a slightly greater likelihood of recording a diagnosis such as otitis externa (OE) rather than a symptom (e.g. "itchy"). This may possibly account for differences in Table 4.2 of initial diagnosis.

Table 4.2: Comparison between Barnsley & Rotherham patients: initial diagnosis at Q1 (from records)

	Barnsley (n = 245)	Rotherham (n = 545)
	(%)	(%)
Wax	43.7	50.6
Otitis Externa	12.7	6.6
Hearing	5.3	9.4
Itchy	1.2	6.4
Pain	11.4	3.5
Discharge	1.2	3.7
Other	20.4	19.1
Not Known	4.1	0.7

Chi-squared test = 54.13 on 7 df, p = 0.0001.

The higher proportion of notes of Barnsley patients which recorded pain (Table 4.2) is reflected in their questionnaires (Tables 4.3 and 4.4). There is a clear trend for Barnsley patients to report having a greater degree of discomfort and more severe pain than Rotherham patients.

Table 4.3: At Q1, how much discomfort in the last week, including today, from ear or hearing-related problem

	Barnsley (n = 235)	Rotherham (n = 534)
	(%)	(%)
None	6.0	12.0
Slight	19.1	24.7
Moderate	37.4	40.3
Severe	30.6	20.0
Extreme	6.8	3.0

Chi-squared test = 21.95 on 4 df, p = 0.0002 and chi-squared test for linear association 20.51 on 1 df, p = 0.0001.

Table 4.4: At Q1, how much pain in the last week, including today, from ear or hearing-related problem

	Barnsley (n = 233)	Rotherham (n = 526)
	(%)	(%)
None	32.6	47.7
Slight	18.9	20.0
Moderate	26.6	20.2
Severe	18.5	10.3
Extreme	3.4	1.9

Chi-squared test = 21.75 on 4 df, p = 0.0002 and chi-squared test for linear association = 21.40 on 1 df, p = 0.0001.

Tables 4.5 and 4.6 show that the everyday life of Barnsley patients is affected by their ear or hearing-related problems to a greater extent than the life of Rotherham patients, particularly with respect to worry and embarrassment, social and family life, and sleep.

Table 4.5: At Q1, effect of ear or hearing problems on life

	Barnsley % Yes (min n = 231)	Rotherham % Yes (min n = 509)	p value
Normally have a hearing problem	52.8	60.0	0.07
Hearing affected by ear or hearing problem today	69.6	65.6	0.28
Current ear or hearing problem causes worry or embarrassment	56.5	46.2	0.009
Current ear or hearing problem affected normal activities in last week	45.0	31.4	0.0003
Current ear or hearing problem affects social or family life	46.9	35.3	0.002
Current ear or hearing problem affects sleep	45.3	27.2	0.0001

P values are for Chi-squared tests.

Table 4.6: Of those affected at Q1, severity of effect of ear or hearing problems on life

		Barnsley (%)	Rotherham (%)	p
Severity of Hearing problem	<i>slight</i>	26.1	39.4	
	<i>moderate</i>	49.6	47.2	
	<i>severe</i>	24.4	13.4	0.005
Hearing affected	<i>slight</i>	28.7	37.8	
	<i>moderate</i>	47.7	46.7	
	<i>severe</i>	23.8	15.5	0.03
Worry or embarrassment	<i>a little</i>	27.5	39.1	
	<i>some</i>	44.3	38.6	
	<i>a lot</i>	28.2	22.3	0.08
Normal Activities affected	<i>a little</i>	25.2	31.7	
	<i>some</i>	54.2	47.7	
	<i>a lot</i>	20.6	20.7	0.47
Social or Family Life affected	<i>a little</i>	25.0	30.6	
	<i>some</i>	43.8	44.8	
	<i>a lot</i>	31.3	24.6	0.38
Sleep affected	<i>a little</i>	28.3	36.9	
	<i>some</i>	39.6	39.3	
	<i>a lot</i>	32.1	32.1	0.29

P values are for Chi-squared tests.

Finally, Table 4.7 shows the HSQ-12 dimension scores at initial assessment. There is evidence of differences on all eight of the dimensions with the Rotherham patients having the higher dimension scores and hence the better self-perceived health status. There is also some evidence of ceiling effects of the HSQ instrument with Rotherham patients at the top of the 0-100 dimension scale.

Table 4.7: At Q1, HSQ-12 dimension scores by area

HSQ-12	Barnsley		Rotherham		p
	n	Median (IQR)	n	Median (IQR)	
Physical Functioning	225	83 (33 - 100)	488	100 (50 - 100)	0.03
Role Physical	239	65 (25 - 100)	519	100 (25 - 100)	0.001
Bodily Pain	238	65 (45 - 100)	517	85 (65 - 100)	0.0001
Health Perception	242	60 (25 - 85)	522	60 (60 - 85)	0.002
Energy/ Fatigue	231	40 (20 - 80)	521	60 (40 - 80)	0.04
Social Functioning	235	75 (50 - 100)	519	100 (75 - 100)	0.004
Role-Mental	234	65 (45 - 100)	514	100 (65 - 100)	0.001
Mental Health	231	60 (47 - 80)	518	72 (53 - 87)	0.0004

p: Mann-Whitney Test Statistic *p* value.

5. Q1 and Q2 Comparison of differences between areas in recorded changes and outcomes

The data suggests (Table 5.1) that patients in Rotherham did slightly better in terms of reduction in discomfort at Q2 than patients in Barnsley after adjusting for differences in the initial level of discomfort. However this was not statistically reliable for discomfort (Chi-squared = 19.33 on 12 df, $p = 0.08$).

Similarly (Table 5.2) there is no statistically significant difference between Barnsley and Rotherham with respect to pain reduction at Q2 (Chi-squared = 12.86 on 12 df, $p = 0.40$), after adjusting for differences in the initial level of pain.

Table 5.1: *Discomfort related to ear or hearing problem at Q2 by area and initial level of discomfort at Q1*

Level of Discomfort at Q1	Area	n	Level of Discomfort at Q2 (row %)			
			None	Slight	Moderate	Severe
None	Barnsley	12	67	25	8	0
	Rotherham	55	91	6	4	0
Slight	B	37	51	46	0	3
	R	109	62	29	8	1
Moderate	B	69	36	42	13	9
	R	168	44	36	13	8
Severe	B	68	28	22	37	13
	R	90	39	29	22	10

Chi-squared = 19.33 on 12 df, $p=0.08$, providing only weak evidence of any difference between Barnsley and Rotherham in the proportions of patients experiencing different levels of discomfort at Q2, given their initial level of discomfort recorded at Q1.

Shaded cells indicate patients showing a reduction (improvement) in discomfort at Q2 relative to their initial level of discomfort at Q1.

Table 5.2 Pain related to ear or hearing problem at Q2 by area and initial level of pain at Q1

Level of Pain at Q1	Area	n	Level of Pain at Q2 (row %)			
			None	Slight	Moderate	Severe
None	Barnsley	61	84	15	2	0
	Rotherham	210	96	3	1	0
Slight	B	37	58	22	8	3
	R	86	69	21	8	2
Moderate	B	48	58	25	13	4
	R	73	63	16	16	4
Severe	B	38	40	26	21	13
	R	46	54	22	15	9

Chi-squared = 12.86 on 12 df, p=0.40

Shaded cells indicate patients showing a reduction (improvement) in pain at Q2 relative to their initial level of pain at Q1.

Table 5.3 shows the effect of the ear or hearing problem in various aspects of life at Q2 by area and initial status at Q1. Only for normal activities affected by ear or hearing problem is there any evidence of differing outcomes at Q2 between Barnsley and Rotherham patients after adjusting for initial status.

Table 5.3 Effect of ear or hearing problems on quality of life at Q2 by area and initial status at Q1

a) Normally have an ear or hearing problem

Normally have a hearing problem at Q1	Area	n	Normally have a hearing problem at Q2 (row %) at Q2	
			No	Yes
No	Barnsley	82	82	18
	Rotherham	167	89	11
Yes	B	102	19	81
	R	247	26	74

Chi-squared = 4.33 on 2 df, p=0.15

b) Hearing affected by ear or hearing problems

Hearing affected at Q1	Area	n	Hearing affected at Q2 (row %)	
			No	Yes
No	Barnsley	56	73	27
	Rotherham	136	77	24
Yes	B	128	46	54
	R	254	50	50

Chi-squared = 0.74 on 2 df, p=0.65

c) Worry or embarrassment from ear or hearing problem

Worry or embarrassment at Q1	Area	n	Worry or embarrassment at Q2 (row %)	
			No	Yes
No	Barnsley	73	95	5
	Rotherham	216	90	10
Yes	B	109	32	68
	R	182	36	64

Chi-squared = 1.75 on 2 df, p=0.45

d) Normal activities affected by ear or hearing problem

Normal activities affected at Q1	Area	n	Normal activities affected at Q2 (row %)	
			No	Yes
No	Barnsley	101	88	12
	Rotherham	287	94	6
Yes	B	86	76	25
	R	115	61	40

Chi-squared = 9.32 on 2 df, p=0.01

e) Social or family life affected by ear or hearing problem

Social life affected at Q1	Area	n	Social or family life affected at Q2 (row %)	
			No	Yes
No	Barnsley	95	76	24
	Rotherham	259	85	15
Yes	B	86	38	62
	R	147	45	55

Chi-squared = 5.07 on 2 df, p=0.08

f) Sleep affected by ear or hearing problem

Sleep affected at Q1	Area	n	Sleep affected at Q2 (row %)	
			No	Yes
No	Barnsley	107	90	10
	Rotherham	304	91	9
Yes	B	79	49	51
	R	102	61	39

Chi-squared = 2.40 on 2 df, p=0.30

Shaded cells indicate patients showing an improvement in quality of life at Q2 relative to their initial level.

The mean health gains as measured by the HSQ-12 were small, less than 7 points, (on a 0 - 100 scale) in both areas (Table 5.4). However, in no health dimension was there a significant difference between Barnsley and Rotherham patients in health gain over 3 weeks, even after adjustment for the higher initial health status of Rotherham patients at Q1.

Table 5.4: Summary HSQ-12 dimension scores from initial assessment to follow-up by area

HSQ-12	Barnsley		Rotherham		Mean Difference (95% CI)	p
	n	Mean Change (SD)	n	Mean Change (SD)		
Physical Functioning	172	-1.6 (26.6)	384	-0.8 (21.4)	0.8 (-3.5 to 5.3)	0.54
Role Physical	185	5.9 (32.7)	409	1.3 (29.2)	-4.5 (-9.8 to 1.1)	0.21
Bodily Pain	185	6.2 (27.8)	408	2.9 (21.5)	-3.3 (-8.0 to 0.9)	0.07
Health Perception	188	-1.8 (20.5)	411	1.0 (19.2)	2.8 (-0.6 to 6.2)	0.15
Energy/Fatigue	177	2.2 (26.8)	403	2.2 (25.1)	0.0 (-4.9 to 4.8)	0.98
Social Functioning	183	-0.1 (31.4)	412	2.6 (23.9)	2.7 (-2.2 to 7.9)	0.18
Role-Mental	180	1.9 (30.8)	410	1.8 (26.9)	-0.1 (-5.1 to 5.1)	0.90
Mental Health	177	0.2 (21.2)	401	0.3 (19.5)	0.1 (-3.6 to 3.8)	0.98

A positive mean change indicates a health improvement from initial assessment. Similarly a positive mean difference indicates Rotherham has a larger health gain than Barnsley, and a negative mean difference that Barnsley has the greater gain.

p: Mann-Whitney Test Statistic p value.

95% CI for the mean difference calculated using bootstrap methods.

P values for differences in mean health change at Q2 between areas, adjusted for initial health status dimension scores at Q1: physical functioning p = 0.72; role physical p = 0.10; bodily pain p = 0.22; health perception p = 0.10; energy/fatigue p = 0.96; social functioning p = 0.27; role mental p = 0.97; mental health p = 0.84.

At the initial surgery appointment for the ear or hearing-related problem Bamsley patients were more likely to see the doctor (Table 5.5) and Rotherham patients the nurse. Similarly Bamsley patients were more likely to be asked to come back and see the doctor and to receive a prescription (Table 5.6), whereas Rotherham patients were more likely to be asked to come back and see the nurse. Bamsley patients more frequently had to take time off from unpaid activities because of their ear or hearing problem, whereas there were similar proportions in both groups who had had time off paid employment (Table 5.6).

Table 5.5: Who patient saw at initial surgery appointment 3 weeks ago for ear or hearing problem, from Q2

	Barnsley (n = 191)	Rotherham (n = 422)
	(%)	(%)
Doctor	65.4	16.6
Nurse	7.9	64.0
Both	26.7	19.4

Chi-squared test = 191.0 on 2 df, p = 0.0001.

Table 5.6: Time-off, purchases, consultations, prescriptions and appointments, from Q2

	Barnsley % Yes (min n = 189)	Rotherham % Yes (min n = 395)	p value
Time off from paid employment for current ear or hearing problem	4.4	6.3	0.37
Time off from unpaid activities for current ear or hearing problem	8.9	3.4	0.005
Purchased anything to treat the problem	20.9	21.2	0.95
Consulted anyone else outside the NHS for whose services you had to pay	4.2	3.6	0.73
Asked to come back and see Doctor	31.3	15.1	0.0001
Asked to come back and see nurse	26.9	59.8	0.0001
Received a prescription for ear problem	56.8	25.5	0.0001
Visited Hospital about ear problem in last 3 weeks	7.4	6.8	0.78
Waiting for an appointment at ENT	12.5	13.1	0.84

P values are for chi-squared tests.

Around half of both groups of patients are likely to travel to the surgery by car (Table 5.7).

Table 5.7: How patient normally travels to surgery, from Q2

	Barnsley (n = 189)	Rotherham (n = 426)
	(%)	(%)
Walk	39.7	34.0
Car < 5 miles	50.8	54.0
Car > 5 miles	0.5	1.9
Bus < 5 miles	7.4	9.2
Bus > 5 miles	1.6	0.9

Chi-squared test = 4.00 on 4 df, p = 0.41.

The overall level of satisfaction with treatment received for the problem is high (Table 5.8) in both areas, although Rotherham patients appear to have a greater level of satisfaction.

Table 5.8: Satisfaction with treatment received for problem, from Q2

	Barnsley (n = 189)	Rotherham (n = 423)
	(%)	(%)
Extremely Dissatisfied	4.2	4.0
Dissatisfied	13.8	5.0
Satisfied	44.4	37.6
Very Satisfied	37.6	53.4

Chi-squared test = 21.48 on 3 df, p = 0.0001 and chi-squared test for linear association = 20.62 on 1 df, p = 0.0003.

6. Comparison of characteristics of new patients at Q1 in the two areas

Analysis of new incident cases only (i.e. there was no evidence from the patient notes that they had visited the practice in the previous twelve months prior to Q1 with an ear or hearing-related problem).

Significantly more Barnsley patients (63.6%) were new (incident) cases (Chi-squared test = 18.8 on 1 df, $p = 0.0001$) compared with 47.5% of Rotherham patients.

Tables 6.1 to 6.6 show the characteristics of this subgroup of new patients at initial assessment (Q1). The patients in the two areas were similar with respect to age, sex and current referrals (Table 6.1). There was evidence that new Barnsley patients returned to see their GP more often in the 3 months after Q1.

Table 6.1: Comparison of characteristics of Barnsley & Rotherham new patients from records, at Q1

		Barnsley <i>max. n = 156</i>	Rotherham <i>max. n = 259</i>	p
Sex	% Female	45.5	44.0	0.76
Current referral after 1st Questionnaire Issued	% Yes	6.4	5.4	0.68
Age in Years	Median (IQR)	52 (35 - 63)	54 (35 - 67)	0.40 *
No. of Visits to GP in 3 months after 1st Questionnaire	Median (IQR)	1 (1 - 1)	0 (0 - 1)	0.0001*

*P-values are for chi-squared tests, except * Mann-Whitney tests.*

There were significant differences in the proportions of patients in the various diagnostic/symptomatic categories.

Table 6.2: Comparison between Barnsley & Rotherham patients: initial diagnosis at Q1 (from records) - new cases only

	Barnsley (n = 156)	Rotherham (n = 259)
	(%)	(%)
Wax	46.8	54.4
Otitis Externa	12.8	3.9
Hearing	5.1	13.9
Itchy	1.9	4.2
Pain	11.5	3.9
Discharge	0.0	1.9
Other	19.2	16.6
Not Known	2.6	1.2

Chi-squared test = 33.57 on 7 df, p = 0.0002.

The higher proportion of recording of pain in the notes of Barnsley patients (Table 6.2) is reflected in their questionnaires (Tables 6.3 and 6.4). There is a clear trend for Barnsley patients to report having more severe pain and discomfort. Table 6.5 also show that a greater proportion of the Barnsley patients' hearing or ear-related problems were causing worry, affecting normal activities and social life and sleep.

Table 6.3: At Q1, how much discomfort in the last week, including today, from ear or hearing-related problem: new cases only

	Barnsley (n = 154)	Rotherham (n = 253)
	(%)	(%)
None	5.8	13.0
Slight	21.4	27.3
Moderate	40.3	36.0
Severe	28.6	22.5
Extreme	3.9	1.2

Chi-squared test = 11.17 on 4 df, $p = 0.02$ and chi-squared test for linear association = 9.87 on 1 df, $p = 0.002$.

Table 6.4: At Q1, how much pain in the last week, including today, from ear or hearing-relating problem: new cases only

	Barnsley (n = 152)	Rotherham (n = 250)
	(%)	(%)
None	32.2	49.6
Slight	17.1	20.4
Moderate	30.9	18.4
Severe	18.4	10.8
Extreme	1.3	0.8

Chi-squared test = 17.82 on 4 df, $p = 0.001$ and chi-squared test for linear association = 15.95 on 1 df, $p = 0.0001$.

Table 6.5: At Q1, effect of ear or hearing problems on life: new cases only

	Barnsley (min n = 149) % Yes	Rotherham (min n = 244) % Yes	p value
Normally have a hearing problem	47.4	56.8	0.07
Hearing affected by ear or hearing problem today	68.0	67.3	0.90
Current ear or hearing problem causes worry or embarrassment	51.3	40.2	0.03
Current ear or hearing problem affected normal activities in last week	43.4	28.4	0.002
Current ear or hearing problem affects social or family life	44.8	33.5	0.02
Current ear or hearing problem affects sleep	42.3	24.8	0.0003

P values are for chi-squared tests.

Finally, Table 6.6 shows the HSQ-12 dimension scores at initial assessment. There is evidence of differences on four out of eight of the dimensions (Role Physical, Bodily Pain, Role Mental and Mental Health), with the Rotherham patients having the higher dimension scores and hence the better self perceived health status. (There were less differences between the Barnsley and Rotherham new patients that when new and old patients were considered together - Table 4.7.)

Table 6.6: At Q1, HSQ-12 dimension scores by area: new cases only

HSQ-12	Barnsley		Rotherham		p
	n	Median (IQR)	n	Median (IQR)	
Physical Functioning	144	83 (50 - 100)	231	83 (50 - 100)	0.86
Role Physical	153	65 (25 - 100)	250	100 (65 - 100)	0.01
Bodily Pain	155	65 (45 - 85)	247	85 (45 - 100)	0.0001
Health Perception	155	60 (20 - 85)	250	60 (60 - 85)	0.16
Energy/ Fatigue	152	40 (40 - 80)	248	60 (40 - 80)	0.86
Social Functioning	152	100 (75 - 100)	248	100 (75 - 100)	0.13
Role-Mental	153	65 (45 - 100)	244	100 (65 - 100)	0.02
Mental Health	152	60 (47 - 80)	248	73 (53 - 87)	0.008

p: Mann-Whitney Test Statistic p value.

7. Q1 and Q2: Comparison of differences between areas in recorded changes and outcomes; new cases only

At the three week follow-up (Q2) there is no reliable evidence (Tables 7.1 and 7.2) of differences in outcomes (reductions in discomfort and pain) between the two areas after adjusting for the initial level of discomfort and pain.

Table 7.1: Discomfort related to ear or hearing problem at Q2 by area and initial level of discomfort at Q1, new cases only

Level of Discomfort at Q1	Area	n	Level of Discomfort at Q2 (row %)			
			None	Slight	Moderate	Severe
None	Barnsley	9	78	11	11	0
	Rotherham	28	96	0	4	0
Slight	B	26	46	50	0	4
	R	54	70	20	9	0
Moderate	B	47	47	36	9	9
	R	65	57	28	12	3
Severe	B	37	35	30	30	5
	R	41	44	27	22	7

Chi-squared = 20.41 on 12 df, p=0.07

Shaded cells indicate patients showing a reduction (improvement) in discomfort at Q2 relative to their initial level of discomfort.

Table 7.2 Pain related to ear or hearing problem at Q2 by area and critical level of pain at Q1, new cases only

Level of Pain at Q1	Area	n	Level of Pain at Q2 (row %)			
			None	Slight	Moderate	Severe
None	Barnsley	40	88	12	0	0
	Rotherham	102	95	4	1	0
Slight	B	21	83	10	5	3
	R	40	62	24	10	5
Moderate	B	37	63	19	14	5
	R	24	67	17	17	0
Severe	B	20	50	30	10	10
	R	19	47	32	21	0

Chi-squared = 12.54 on 12 df, p=0.40

Shaded cells indicate patients showing a reduction (improvement) in pain at Q2 relative to their initial level of pain.

The mean health gains as measured by the HSQ-12 were small, less than 5 points, (on a 0 - 100 scale) in both areas (Table 7.3) in six of the eight dimensions. However, in only two health

dimensions (Role Physical and Bodily Pain) was there evidence of a difference in health gain between Barnsley and Rotherham new patients. After adjustment for the higher perceived initial health status of Rotherham patients at Q1, only the difference in the Role Physical dimension was statistically reliable.

Table 7.3: Summary HSQ-12 dimension scores from initial assessment to follow-up by area - new cases only

HSQ-12	Barnsley		Rotherham		Mean Difference (95 % CI)	p
	n	Mean Change (SD)	n	Mean Change (SD)		
Physical Functioning	107	-1.6 (25.8)	167	0.6 (24.2)	2.2 (-3.8 to 8.4)	0.50
Role Physical	118	7.9 (32.7)	182	-2.5 (26.3)	-10.4 (-17.5 to -3.4)	0.01
Bodily Pain	119	7.9 (30.1)	180	1.8 (22.7)	-6.0 (-12.4 to 0.5)	0.006
Health Perception	119	-0.4 (20.3)	182	-0.3 (18.8)	0.1 (-4.6 to 4.7)	0.86
Energy/Fatigue	117	2.6 (25.7)	178	1.9 (28.7)	-0.7 (-6.7 to 6.0)	0.79
Social Functioning	118	1.5 (32.2)	182	2.9 (20.7)	1.4 (-5.2 to 7.8)	0.60
Role-Mental	117	4.8 (31.60)	180	0.3 (24.5)	-4.5 (-11.4 to 2.0)	0.09
Mental Health	117	2.0 (21.0)	179	-0.8 (20.3)	-2.8 (-7.5 to 2.1)	0.30

A positive mean change indicates a health improvement or gain from initial assessment. Similarly a positive mean difference indicates Rotherham has a larger health gain than Barnsley, and a negative mean difference indicates that Barnsley has the greater gain. p: Mann-Whitney Test Statistic p value.

95% CI for the mean difference calculated using bootstrap methods.

P values for differences in mean health change at Q2 between areas, adjusted for initial health status dimension scores at Q1: physical functioning p = 0.47; role physical p = 0.003; bodily pain p = 0.06; health perception p = 0.94; energy/fatigue p = 0.84; social functioning p = 0.66; role mental p = 0.17; mental health p = 0.36.

Summary of results of analyses of Q1 and Q2

1. There were 949 eligible patients; 790 returned Q1 (initial response rate = 83%) and of these, 634 returned Q2 (secondary response rate = 80%). Of the final 634 patients, 438 were in Rotherham and 196 in Barnsley. (The original target was 440 and 220 respectively.)
2. Characteristics of non-responders to Q1 were similar to responders, whereas non-responders to Q2 were more likely to be younger, male and new cases, reporting more pain and loss of sleep at Q1 than responders.
3. Completion rates of individual questions were high, (90% - 97% at initial assessment (Q1) and 89% - 97% at 3 week follow-up (Q2)).
4. There is evidence that at initial assessment (Q1) Barnsley patients generally had more severe pain and discomfort from the ear or hearing-related problem. Barnsley patients also reported that their condition had affected normal activities, social life and sleep to a greater extent than Rotherham patients.
5. At initial assessment there is evidence of differences on all eight of the dimensions with the Rotherham patients having the higher dimension scores and hence better health.
6. At the three week follow-up (Q2) patients in Rotherham show a slightly greater, though not statistically significant, reduction in discomfort after adjusting for differences in the initial level of discomfort. Similarly, there was no statistical evidence of a difference between Barnsley and Rotherham patients in pain reduction from Q1 and Q2 after adjusting for differences in the initial level of pain. Looking at the effect of ear or hearing problems on various aspects of life between Q1 and Q2, it is only in the area of normal activities being affected that there is any evidence of differing outcomes between Barnsley and Rotherham after adjusting for initial status, with Rotherham showing a greater improvement.
7. There was no evidence of differences in any of the changes in HSQ-12 dimension scores between Barnsley and Rotherham patients over the three weeks between Q1 and Q2, even after adjustment for the higher initial health status of Rotherham patients. There was improvement in both areas for some of the health dimensions.

8. Overall, there was a high level of satisfaction with treatment received, but satisfaction in Rotherham was significantly higher than in Barnsley (82% Barnsley, 91% Rotherham) (Chi-squared test $\chi^2 = 21.48$ on 3 df, $p = 0.0001$).
9. The analysis of new (incident) patients only shows that significantly more Barnsley patients (63.6%) were new cases, compared with 47.5% of Rotherham patients (Chi-squared test = 18.81 on 1 df, $p = 0.0001$). This reflects the guiding principle for ear-care nurses to recall patients for regular check-ups. As in the preceding analysis, Barnsley patients reported more discomfort, pain and affects on quality of life at Q1. However, at Q2, after adjustment for initial status, there was no reliable statistical evidence of differences in these outcome measures, with the exception of role physical on the HSQ-12.

8. Results from the economic evaluation

The results presented below are based on data gathered relating to 438 patients treated in Rotherham and 196 treated in Barnsley (i.e. those who returned Q2).

It can be seen in Table 8.1 that the composition of primary care costs differs markedly in the two settings. **In Rotherham, where trained ear-care nurses are used, the total number of GP consultations and hence total costs was lower.** In Rotherham there was a total of 172 GP consultations (average of 0.4 per patient) making up 18% of total costs (average cost per patient = £6.28). This compares with a total of 276 visits to GPs in Barnsley (average 1.4 per patient) which accounted for 50% of total costs (average cost per patient £22.53). Thus it appears that the availability of practice nurses trained in ear-care helped to reduce the demands placed on GP time. This translated into cost savings as the time of nurses trained in ear care (ECNs) is valued at less than that of GPs.

The situation with regard to consultations with ECNs in Rotherham and practice nurses (PN) in Barnsley followed a different pattern. In Rotherham the number of visits to the ECN per patient was 2.02 compared with 0.62 visits per patient to a PN in Barnsley. Consequently the contribution to total costs of care by ECNs was higher (35%) than that of PNs (7%). However, this did not offset significantly the cost savings found in Rotherham due to the use of ECN time in excess of GP time.

The greater number of GP consultations in Barnsley appears to have produced a greater amount of prescribed drugs per case, making up 6% of total costs, compared with only 1.5% in Rotherham. One interesting feature of prescribing in Barnsley was the amount of systemic antibiotics prescribed. **In Barnsley there was a total of 36 prescriptions for systemic antibiotics against 26 prescriptions in Rotherham (p=0.0001).** Previous work^{7,8,14,15,17} has suggested that the use of these drugs is often inappropriate for the condition(s) being treated and this drug use therefore represents wasted resources.

Table 8.1: Comparison of costs for Rotherham and Barnsley patients

Category	Costs £ (% of total)		Average Cost £ per 100 study patients	
	Rotherham (n=438)	Barnsley (n=196)	Rotherham	Barnsley
PN visits*	-	585.60 (6.6)		299
ECN visits**	5455.84 (34.9)	-	1245	
GP visits	2752.00 (17.6)	4416.00 (49.9)	628	2253
Drugs GP	233.61 (1.5)	528.32 (5.9)	53	270
Drugs PN	175.59 (1.1)	3.85 (0.0)	40	2
Audiology OP	189.90 (1.2)	228.00 (2.6)	43	135
ENT OP	2957.78 (18.9)	1175.00 (13.2)	675	695
Hospital drugs	19.23 (0.1)	22.65 (0.3)	6	11
Alternative non-NHS care	300.00 (1.9)	250.00 (2.8)	68	148
Patient travel	89.50 (0.6)	52.50 (0.6)	20	31
OTC medicines	3450.50 (22.1)	1626.50 (18.3)	788	830
Total cost for all patients	£15 624.00	£8 888.42		
Average cost per patient	£35.67	£45.35		
Range	£0.50 - £604.24	£4.80 - £490.30		
Difference in average cost per case (95% CI)	£-9.68 (£-19.86 to £1.16)			

PN= practice nurse; ECN = ear care nurse; OP = outpatient clinics secondary care; OTC = over the counter medicines

* Cost based on an average consultation time of 12 minutes

** Cost based on an average consultation time of 13.5 minutes with initial nurse training costs being defrayed over 5 years and initial start equipment being depreciated over three years

Taken together the costs of primary care consultations (ECN/PN plus GP) did not differ markedly between the two settings (53% in Rotherham versus 56% in Barnsley), although this changes to 55% of the total in Rotherham compared to 62% of the total in Barnsley when drugs prescribed in primary care are added. However, the components of total primary care costs are markedly different in the two settings.

The total costs of secondary care were again remarkably similar; in Rotherham these costs accounted for just over 20% of the total as compared to 16% in Barnsley. Similarly the impact on total costs of hospital-prescribed drugs, patient travel and over-the-counter medicines purchased by patients was very similar in the two settings.

Looking at the figures in their totality (taking NHS and societal costs together) **average total cost per case was significantly lower in the setting that used specially trained practice nurses to treat patients reporting with ear problems.** The average total cost per case was found to be £9.68 less in Rotherham (95% CI -£19.68 to -£1.16, $p = 0.04$).

If NHS costs only are considered, by excluding non-NHS care, over-the-counter medicines and patient travel, the total for NHS costs for Barnsley patients ($n=196$) was £6,959.42, and for Rotherham ($n=438$) £11,783.95. This gives a cost per patient of £35.51 for Barnsley patients, and £26.90 for Rotherham.

Sensitivity analysis

In calculating costs it is often necessary to make assumptions and also to gather data in ways which may produce only rough estimates of the true situation. In this analysis the above applies to the way in which the cost per PN and ECN consultation was calculated. In order to deal with these uncertainties it is usual to carry out sensitivity analysis. This is a way of asking 'what if' type questions, allowing the reader to see what effect the varying of assumptions makes to the final cost outcomes.

The base case analysis assumed an average consultation time of 13.5 minutes in Rotherham and 12 minutes in Barnsley. It may be that the estimated times given for the various treatments were over or under-stated. In particular it has been suggested that the average time for ECN consultations may be somewhat lower than the 13.5 minutes used in the base case analysis (Rodgers 1996). Table 8.2 below presents the results of varying the average time per PN/ECN

consultation. If the time taken per ECN consultation was to be lowered to 9 minutes the average total cost per case falls to £32.51, some 8% lower than the base case estimate. This gives a statistically significant difference in average total cost per case between Rotherham and Barnsley of £12.84 (95% CI -£22.48 to -£4.37) when compared to the base case figure used in the Barnsley analysis.

If we examine a different case and assume that the true average time spent by practice nurses with patients in Barnsley was only 8 minutes, then comparing this to the base case in Rotherham reduces the difference in average total cost per case to -£11.84 (95% CI -£18.65 to -£0.23). Thus even in this scenario a significant cost difference exists between the two settings.

Table 8.2

Average Practice nurse consultation time	Average total cost per case £	
	Rotherham	Barnsley
33% lower (Roth. = 9 mins, Barns. = 8 mins)	32.51	44.35
Base case	35.67	45.35
33% higher (Roth. = 18 mins, Barns = 16 mins)	38.84	46.34

We also examined some of the other assumptions made when calculating the cost per ECN consultation. The base case analysis assumed that a trained ECN would stay in post 5 years, if this was reduced to two years the average total cost per case increases to £36.44 (from £35.67). With respect to equipment, in the base case we depreciated the initial equipment cost over three years, if this increased to five years then the average total cost per case decreases to £35.50. The original analysis assumed that part of the Ear Care Agency budget was attributable to providing back-up to practices. If this element was removed altogether then the average total cost per case decreases to £34.76. From this limited one-way sensitivity analysis it can be seen that the actual average total cost per case is not highly sensitive to changes in the three parameters outlined here. The total cost per case is far more sensitive to the changes hypothesised in consultation times.

Key points of economic analysis

- It appears that the cost of treating patients with a range of ear problems is significantly lower in Rotherham where trained ear care nurses are used.
- Sensitivity analysis carried out shows that the results are fairly robust when looking at the way true costs per consultation with PNs and ECNs may vary.
- The cost savings appear to stem from a direct substitution of ECN time for GP time in Rotherham. In Barnsley the average cost per case of consultations with a GP was £22.53 compared to £6.28 in Rotherham.
- Further evidence is needed to clarify the situation regarding any differential effect that may exist in the outcomes of patients treated by ECNs, and on the effect of the possibility of higher GP consultation figures for Rotherham.

9. Hospital Referrals

Numbers of all-age referrals to Rotherham and Barnsley ENT consultants from the study practices for the year 1995 were supplied by the respective hospital information departments (these referrals cover all ENT conditions, not just ear problems). These figures showed that the **approximate all-age local referral rate from Barnsley study practices was 19.3 per 1000 practice population, almost double that of the Rotherham study practices at 10.1 local referrals per 1000 practice population.** This is a difference of 9.2 referrals per year (95% CI 7.7 to 10.7) per 1000 practice population.

Such differences in referral rate are not reflected in the study's findings reported above. Tables 4.1 and 6.1 show no evidence of differences between the two areas in current hospital referrals as revealed in patient records. Table 5.6 reveals no difference in patient reported referral rates either.

One month in each hospital was looked at in more detail, September in Rotherham, and October in Barnsley, months when all practices in each area were contributing to the study.

Barnsley hospital referrals

Table 9.1: Analysis of those aged 16+ referred from the 9 practices to Barnsley ENT in October 1995

(approximate total practices' population is 50,000)

Patients referred for nose/throat problems	13	(38%)
Patients referred for ear problems	10	(28%)
Notes not available (therefore specific problem not known)	7	(20%)
Patients who did not attend appointments	4	(11%)
Patients who cancelled appointments	1	(3%)
Total	35	

Study of the hospital case notes for the 10 patients known to be referred for an ear problem in October 1995 produced the following analysis:

Table 9.2: Analysis of Barnsley ear referrals

To be admitted for surgical intervention	2
Found to be suitable for a hearing aid	2
To be further assessed in 6 months for a hearing aid	2
Seen at first appointment with the following result:	
a) Hearing impaired, not suitable for hearing aid	1
b) Wax present, hearing impaired, does not want hearing aid	1
c) Wax present, intermittent Eustachian tube dysfunction, prescribed Flixonase	1
d) Resolved otitis externa, prescribed Otomise spray	1
Total	10

In theory, all these patients should have been entered into the study by the Barnsley practices, but in actuality only six of them were known to have been entered. The fact that at least 4 patients in Barnsley should have been entered into the study and were not, in one month alone, demonstrates the difficulties in patient recruitment in that area. This difference in missing cases of 4 out of 10 in Barnsley to 14 out of 20 in Rotherham is not statistically significant (Chi-squared = 1.41 on 1 df, $p = 0.25$). Of the 12 other referrals where either the notes were not available or patients had not attended appointments, the names of 4 were recognised as research participants and so presumably had been referred for ear problems. It was not possible to say whether the remaining 8 were referred for ear or nose or throat problems. Another cause for concern is the high percentage (11%) of patients failing to attend hospital ENT appointments.

Rotherham hospital referrals

Table 9.3: *Analysis of those aged 16+ referred to Rotherham ENT by 8 practices in September 1995 (approximate total practices' population is 57,000)*

Patients referred for nose/throat problems	11	(34%)
Patients referred for ear problems	21	(66%)
Notes not available	Nil	
Patients who did not attend (after repeat appointments)	Nil	
Patients who cancelled	Nil	
Total	32	

Study of the hospital case notes for the 21 patients known to be referred for an ear problem in September 1995 produced the following analysis:

Table 9.4: *Analysis of Rotherham ear referrals*

Found to be suitable for hearing aid	2
Found not to need hearing aid	1
To be assessed in one year for hearing aid	1
On list for surgical intervention	2
Had surgical intervention	2
Patients treated and discharged	5
Patients still receiving treatment	8
Total	21

In theory, all 21 patients should have been entered into the study by the Rotherham practices, but in actuality only 6 were study participants. As one other was from the practice who had by September dropped out of our study the actual shortfall is 14 patients. This figure gives rise to concern that in practices where reliance was placed on allowing ECNs to recruit patients into the study as they attended the ear-care clinics, patients attending the doctors have been missed, including some patients needing hospital referral.

It is notable that no patients eventually failed to attend Rotherham hospital clinics, although some needed more than one appointment. Over the six years (1990-1995 inclusive) that the

specialist ear care clinic has been held in the Ear Care Agency's base practice, the mean rate of non-attendance for appointments is low, at 1.5%.

10. Analysis of patient-generated qualitative data

Both Q1 and Q2 contained some open-ended questions as well as those requiring structured response. In Q1, question 5 gave opportunity for the patient to explain their worry or embarrassment about their ear or hearing problem, and question 15 provided further space for comments. In Q2, question 5 was repeated, and question 27 invited observations on the treatment received in general, and specifically at the GP surgery or at the hospital.

a) Patients' perceptions of ear and hearing problems

The responses to question 5 were analysed thematically; the greatest volume of response centred on the worry and embarrassment caused by deafness, affecting social and family life, work, personal confidence and the practicalities of everyday life. Fears were expressed for the future, with the prospect of deterioration in hearing ability; a number of patients reported that the use of a hearing aid often raised as many problems as it solved. Other topics raised by patients were the difficulties of living with tinnitus, the irritation and pain of recurrent otitis externa, and the embarrassment of chronic aural discharge. Appendix 5 quotes patient responses on the themes already mentioned, given in answer to question 5 on both questionnaires (Q1 and Q2).

b) Patients' views on the service provided

Table 5.8 has already demonstrated the high levels of satisfaction with treatment received, with 91% in Rotherham and 82% in Barnsley either satisfied or very satisfied. The qualitative comments in section 27 of Q2 illuminate the area of satisfaction, and are reported first for Rotherham, and then for Barnsley.

Rotherham patients' views of the service

Rotherham patients made comments about the ear care trained nurses, even though the questions on Q1 and Q2 did not differentiate between doctor and nurse at the surgery. This demonstrates that patients recognised that a different service was being provided.

"I feel very fortunate to have ear care specialists to hand at my surgery."

"The ear care nurse I saw seemed very skilled and ensured I had no pain whilst she was dealing with my ears of wax."

The availability of the service was noted

"They are willing to see me very quickly in emergencies"

and patients appreciated the follow up system

"my problems are merely irritation and wax build-up. Whilst this condition no longer troubles/disrupts my life, prior to my transfer to Rotherham the situation was very different. My former doctor's efforts with drops and 'bicycle pump' syringe served to aggravate the situation rather than improve it. Symptoms included severe irritation, pain, headaches, dizzy spells, loss of sleep. I now attend the clinic regularly, usually every four months. The treatment from [named nurses] has been superb."

"I think the new ear care initiatives in Rotherham are very good and very reassuring."

Other comments were made which did not specifically mention the ear care service or ear care trained nurses but still reflected the nature of the service:

"Very helpful and successful treatment."

"Very polite, professional and efficient service."

"Excellent."

Patients commented on the care received from the practice nurses

"Practice nurses have a good understanding and are generally very helpful."

One patient contrasted the GP and the nurses: *"Doctor not interested, nurse very concerned."*

Treatments mentioned which nurses gave were:

"To have an ointment 'painted' in my ears to relieve the severe itching."

"To put cream on gauze and put it in my ears."

"She cleans my ears out very well. I have both my ears syringed every 3 months."

"For a hearing test."

Frequent mention was made of future appointments

"I was advised to inhale for a few weeks, then return and see the nurse at the surgery."

"Regular checks prevent my problem from recurring."

"Treatment and follow up I have received from the nurses has been excellent. I would have no hesitation in contacting them immediately if the problem recurred."

"I visit when the problem recurs about every 6 months."

Nurses provided information to the patients

"Very thorough, good explanation and I felt I had been listened to."

"Explains what causes the [problem] and preventions are."

"Explaining what was happening and giving me advice on how to prevent its recurrence."

as did the doctor

"My doctor always explains exactly what the problem is."

Additional care was provided by nurses:

"On my first visit to the doctors regarding my ear, I was made to feel guilty taking up his time as I am sure he thought it was just ear wax and not an infection (as it was). I am pleased to say the nurse showed me more compassion."

Not all treatment was successful.

"The treatment does not seem to be working."

"I would like to know what is causing the problem as it keeps coming back."

"[GP] He's been treating me with antibiotics for the last 3 years and he tells me it's an infection. Sometimes it hardly bothers me as I have come to live with it. I suffer ear ache all times, itching and noises in my ear."

Patients were able to compare the treatment from the practice nurses with that of the doctor.

"Practice nurses have a good understanding, are generally very helpful." and from the same person: "GPs tend not to be as knowledgeable as the practice nurses,"

a view which reinforces comments made in the practice nurse interviews.

In addition, patients were

"pleased that I did not have to bother the doctor with what I perceived as a minor problem."

Barnsley patients' views of the service

Some Barnsley patients appreciated the service provided by both doctors and nurses, and many comments were made reflecting good care received.

"The treatments I have been given are usually 100% effective."

"The doctors and staff are very courteous and helpful."

"I have received first class treatment from the GP and the district nurse who attended me when she visited the surgery to remove wax."

Not all patients expect ear problems to be alleviated and the comments made by some patients reflect this:

"The trouble seems to be excess wax. It is many years since I had them syringed."

"The doctor and nurse did the best they could to alleviate the problem."

"The drops helped but the ailment cannot be cured."

There were patients who felt that the treatment they had received had not worked.

"I have received treatment for my ears for the past 18 months and they are no better now than when I started."

"I am still the same. I will probably go back to the doctors and see if anything else can be done. I was given some antibiotics but I still get an itching feeling and a buzzing noise, especially at night."

"...fitted with a hearing aid, but I am thinking about buying one as the NH one really hurts my ear, that is, when I have saved up for one."

"The tablets I have had have not worked."

"I had my ear syringed but that was not the problem. What came out was white flaky bits and it has not stopped me itching."

Patients would have liked more information:

"Although I believe the doctor performed as any GP would do in prescribing antibiotics and ear drops, I still do not know what the actual cause of the infection is. Also the doctor said it may resolve into a chronic condition if untreated. I still do not know whether I should visit the doctor at the end of this second course of treatment."

Some patients had immediate access to treatment

"It was wonderful to attend surgery and have the ear syringed there and then."

But some patients found they had to attend a number of times before any improvements were made.

"The first doctor had no idea, the second doctor was a little better, the nurse was better than the two doctors."

"One doctor gave me tablets. He said I had an ear infection. One week later I felt worse so I saw another doctor. He said my ears were blocked so he gave me drops then. Another week later I had them syringed. I had to suffer for nearly 3 weeks from going to see the doctor."

"The ear still feels as 'blocked up' as before the treatment began. I have made another appointment and have had to wait one week before being able to see the same practitioner."

"From being unwell to seeing the doctor was 8 days."

Generally the comments made by Bamsley patients show a lot of goodwill by doctors and nurses in the care they provide for patients. Patients go on to report that not all treatments were successful. Unlike Rotherham patients, Bamsley patients did not report being asked to return to the surgery for regular check-ups.

11. The views of the practice nurses

Telephone interviews were carried out in March and April 1996 with an opportunity sample of 4 Rotherham practice nurses trained in ear care, and 4 Bamsley nurses without the training (see Appendix 4 for questions asked).

a) Rotherham nurses' views on the new ear care role

Initially, two of the nurses were not enthusiastic about going on the course, the other two being enthusiastic but apprehensive. Afterwards all valued the course and had no criticisms to make.

"It helps to develop your skills and knowledge."

"I learnt a lot from it."

"It's a must before you do any treatment of ears."

One nurse stressed:

"the difference now is that we have more or less an open line to an expert instead of going the long way round to get patients' help. We tend to try outpatients first, but I wouldn't draw back from phoning him [the ENT consultant] direct if needed. I would also speak direct to Rosemary Rodgers."

"I couldn't tell a good ear from a bad ear ear care training gave us the confidence."

The ear care trained nurses arranged clinics so that:

"We are there to meet the needs of patients, not to make them come when we want. If they have a problem which needs early treatment, they are put in on the day."

The training has improved communication with patients.

"Now I know what I am looking at."

"I feel more confident in being able to cope, rather than referring everything to the doctors. I feel more able to answer the patients' questions."

The extended nursing skills were mentioned.

"I don't just syringe now - I do dressings as well."

However, not all nurses were able to use all the new skills because of restrictions at the practice. One said:

"[the GP] does not think we should do audiograms here,"

although the nurse had done these in her previous practice.

The Rotherham nurses saw the effect of ear care training on the GP's work as a way to

"release him to do other things. Ear care nurses treat 95% of all ears in our practice"

and

"helps the GP workload;"

"the GP knows he can rely on us to see patients with confidence and to decide what's required and then get him to sign."

The balance of knowledge was changing -

"5 years ago the GP knew most, but now I have pulled up quite a lot and he will say 'well, what do you think?' but in the end of course they have the final say."

"The old-fashioned way was to treat ears with antibiotics, but now they know they [the GPs] do not need to treat with antibiotics. It is the practice nurses that have taught the GPs this."

Where the new system works well, GPs have complete trust in the nurses' ability -

"They are quite happy to let us see every ear care patient that comes in."

Not all GPs are happy with the new knowledge of the practice nurses.

"There is a feeling against the nurses that they can do ear care. As a result of the ear care training, I feel that compared to some GPs in terms of knowledge, we are better. We know how to examine ears properly and in the past, if we found things and we have referred them to the doctor, they sometimes come back - 'oh no there's nothing there,' but it's turned out that there has been. We've been right and they've been wrong."

All four Rotherham ear care nurses thought that patient care had improved:

"they have more or less open access,"

"the nurse gives the patient longer, I can also do other things"

"the ones on regular dressings find it easier to come to the surgery rather than trailing to the hospital."

b) A comparison of treatments carried out by the two groups of nurses

Most marked was the range of treatments mentioned by the ear care nurses, compared to the non ear-care trained nurses. All were asked how they would treat patients with hearing problems, itchy ears or pain. All Rotherham nurses trained in ear care began by stressing their individualised approach:

"Taking a history and doing an examination."

"Each patient is different."

"Discuss their needs and what we can do for them."

"You try and meet the patient's needs."

By comparison, when asked under what circumstances Barnsley practice nurses saw patients with ear problems,

"I don't make any decisions."

"Under no circumstances."

"They have to see the doctor. I don't make any decisions about ears." "If it's not purely wax, we refer them to the GP."

"Always refer to the doctor because we don't know anything about ears apart from ear wax."

"We'll have a look in, but generally it's syringing."

A Barnsley district nurse said that, in the week before syringing, softening agents were used:

"I prefer the GP or pharmacist to recommend which softening agent to use."

Rotherham nurses did syringe ears, but it was only part of the ear care treatment. They used the Propulse syringe:

"It's easier on the thumbs"

"I like the Propulse,"

but there was some disagreement about whether all patients liked it. According to one nurse,

"they find it noisy and because they can feel the end of the nozzle that goes in the ear, they describe this as pain."

Rotherham nurses felt their attitude to syringing ears had changed since training:

"well now you take a full history.... it's important, you know what you are going to syringe and then you check the ear afterwards for inflammation and discharge and treat accordingly."

"I was always frightened in case I perforated the ear drum. This was partly because I hadn't been trained properly. I was just told, this is what you do, get on with it."

"I couldn't use a head lamp before, and now I wouldn't do any syringing without a lamp."

Two Bamsley nurses were using the Propulse syringe having been shown how to use it by a doctor or another practice nurse.

Rotherham practice nurses record treatments both in patients notes and on ear care cards, so that complete records are available. In Bamsley practice nurses may write a note but where the district nursing service provides the syringing service, the nurse said *"we don't know the patient and we don't know the history. We have our own paperwork which we fill out, and when the patient is discharged, the notes get sent up to the stores."*

c) The nurses' views of the future

Rotherham ear-care nurses saw ear care as:

"part and parcel of the job of a practice nurse,"

"every nurse should do this training and in the future I think it ought to carry on, if for nothing else, to keep abreast and keep open the channel we have got now."

Bamsley nurses recognised that there were ear or hearing problems among patients:

"I think that older people just put up with it and with hearing problems people just suffer it really."

One Bamsley non-ear care trained nurse thought ear care training would benefit patients:

"it's easier going to a specialist trained nurse with a problem, rather than a GP. I find GPs don't know a great deal about specialist things."

As part of the research programme some of these nurses are now to receive ear care training and are looking forward to the course:

"there must be more for nurses to do to ears than just syringe them."

"I think it's a good idea [the course] because then you will know what you're looking at."

Nurses in the district nursing service are without ear care support:

"it would be nice to have a nurse that I could ring and say 'oh I have come across this today. What do you suggest?'"

DISCUSSION

The primary focus of discussion is the results themselves. Where appropriate, methodological issues will be raised in the context of interpretation of the results. Each time the discussion reaches one of the six research questions posed alongside the study's objectives, that question will be highlighted for ease of identification.

First, however, we discuss the **recruitment levels and response rates** in the two areas and at different stages of the study. A target of 660 patients was set (440 in Rotherham, 220 in Bamsley) in order to detect a statistically significant difference between the two groups in their responses to both questionnaires. In the event, 634 patients persevered through both stages of inquiry, from a total of 949 who were eligible, an overall response rate of 67%, 790 (83%) returned Q1, and 156 of these failed to return Q2, giving a secondary response rate of 80% (Table 1). Given the difficulties of carrying out research in the busy environment of general practice, we found this level of response acceptable.

Keeping both doctors and staff interested in the research was a problem, particularly in the control area. Rotherham practices already knew about ear care but perhaps more effort could have been made to generate an interest in the Bamsley practices. However, there is a fine line between encouraging practice staff to follow the research protocol in their recruitment of patients, and being so rigid that staff then refuse to cooperate. We believe that our acceptance of some variations in recruitment methods gave the best participation in the circumstances, and ensured that almost all practices continued in the study through to its completion. The number of patients in the study eventually reached almost to the level planned, by extending the data collecting period in Bamsley. It is not thought likely that the nature of the patients would have changed during this extended period.

What can be said about the patients who were lost to the study? It was only at the close of the study, when hospital referrals were being investigated, that we realised that recruitment in Rotherham was failing to capture a number of patients who had seen only the GP. Patients who self referred to the ear clinics were recruited in large numbers because the nurses were thorough in recording all patients. However, we acknowledge that where the clinics were less developed, it is likely that some patients were lost amongst those consulting the doctor, when they failed to mention the reason for their visit to the receptionist or the doctor failed to enter them into the study. In Bamsley everyone had to be caught on their initial contact at reception

or with the GP; some of those patients too are likely to have been lost to the study. It would appear that in both settings it is patients consulting the GP who have been lost, but more markedly in Rotherham.

The pragmatic nature of the study is apparent when the nature of the service offered is considered. Ear care trained nurses are not all working in identical environments. They have responded to the demands of individual practices and particular GPs. The size of the practice influences its organisation and the structure of clinics. Some GPs are more "ear-aware" than others, some are more aware of the Rotherham ear-care service and all GPs operate as individuals in their own practices. Despite our attempts to standardise recruitment practices, we cannot say that the samples of patients in the two areas were drawn in exactly the same way, or that patients lost to the study were necessarily alike in the two areas.

Once the study was underway, high completion rates achieved for Q1 and Q2 suggests that patients found the layout and content acceptable. The responders did not differ markedly from the non-responders although more younger men (who were also new cases) failed to complete Q2, a finding in line with other studies⁶⁵ (Tables 2.1 to 2.7, and 3.1 and 3.2).

We now discuss **characteristics of patients in the two areas** as reported in Q1 and in their GP records. Bamsley patients (n=245) and Rotherham patients (n=545) were similar with respect to age, sex and previous and current referrals to hospital ENT clinics (Table 4.1). However, a higher proportion of Bamsley patients (64%) had not visited their GP practice for an ear or hearing problem in the previous 12 months, compared with 48% of Rotherham patients. This is not surprising, given the "ear-awareness" in Rotherham practices, where most patients know that even minor ear problems will be given attention. Bamsley patients were significantly more likely than Rotherham patients to have paid a return visit to the GP in the three months after Q1; this applies to the analysis of all patients (Table 4.1) and to the analysis of new (incident) cases only (Table 6.1). Bamsley patients' recorded diagnosis or presenting symptom from records (Table 4.2 for all patients, and 6.2 for new cases) revealed greater proportions of more acute conditions, such as otitis externa, or pain, than Rotherham patients. Bamsley patients also reported a greater level of discomfort and pain at initial assessment (Tables 4.3 and 4.4). In addition, Bamsley patients experienced greater disruption of their everyday lives because of their ear or hearing problems (Table 4.5) and expressed poorer health status (Table 4.7) than Rotherham patients.

The poorer aural health of Bamsley patients may partly be explained by the undoubted loss to the study of some patients seen only by the GPs in Rotherham who may have had more severe symptoms. However, given the reported similarity between the two areas in terms of socio-economic status and "Jarman scores" we suggest that at least some of the difference in the ear or hearing related morbidity between the two areas may be due to the availability of practice nurses trained in ear care in the Rotherham practices in recent years. Not only will recurring conditions like excessive wax or otitis externa be kept in check so that they do not reach an acutely painful state very often, but patients will be better educated in self-care for their ears so that they take preventive action when necessary, and feel less anxious about their aural health.

We may now attempt to answer the first research question - how do patient reports of ear-related discomfort or pain vary between the two groups at Q1 and Q2 and in changes reported at the later questionnaire?

We have already noted that there is a clear trend for Bamsley patients to report higher levels of discomfort and pain at Q1 than Rotherham patients (Tables 4.3, 4.4 and 6.3, 6.4). Tables 5.1 and 5.2 reveal that in the weeks between Q1 and Q2 patients in both areas reported a reduction in discomfort, with Rotherham appearing to do slightly but not statistically reliably better, after adjusting for differences in the initial level of discomfort. There was no statistical evidence of any difference in reduction in pain at Q2 from Q1 between Bamsley and Rotherham, after adjusting for differences in the initial level of discomfort.

Analysis of changes in discomfort and pain reduction was carried out on all cases in the study and also on new or incident cases only with almost identical results.

So the answer to the first research question is that Bamsley patients reported more discomfort and pain than Rotherham patients, whether they are new or recurrent cases. Both areas show a reduction in discomfort and relief of pain by Q2, with only a slight suggestion that Rotherham patients did better than Bamsley patients in reduction of discomfort and no evidence of difference in pain reduction.

The second question is - how do patient reports of their health status and quality of life vary between the two areas between Q1 and Q2?

At Q1 (Table 4.7) the analysis of HSQ-12 scores for all patients reveals there is evidence of differences on all eight of the dimensions with the Rotherham patients having the higher dimension score and hence the better self-perceived health status. Some Rotherham patients already had HSQ-12 scores totalling 100 at Q1, giving no opportunity for improvement (the ceiling effect) at Q2. In the weeks between Q1 and Q2 most patients in both groups recorded slight health gains, less than 7 points (on a 0-100 scale) (Table 5.4). However, in no dimension was there a significant difference between Bamsley and Rotherham patients between Q1 and Q2, irrespective of the higher perceived health status of Rotherham patients at Q1.

The answer to this question is therefore that the initial health status of Rotherham patients is greater than Bamsley patients. While health gains were made by both groups, on no dimension was the gain significantly different between groups. However, because of the observed ceiling effects on the HSQ-12, there is some doubt in the authors' minds about the sensitivity of the HSQ-12 instrument to detect changes in quality of life after treatment for ear or hearing problems. This may possibly explain the non-differential health gains experienced by both areas.

It was clear from patients' comments when given opportunity through open-ended questions that many factors influenced their response to HSQ-12; amongst these were particularly stressful events such as the death of a spouse or son or daughter, recent illness within the family and more major personal illnesses.

Before moving to consider further research questions, it is necessary to discuss briefly other aspects of ear care revealed in the analysis of results. **Great differences in patterns of care between Bamsley and Rotherham practices were revealed in Tables 5.5 and 5.6, although the possibility that more doctor-consulting patients were missed in Rotherham than in Bamsley, as shown in the hospital referral data, leads to some caution in interpreting these figures.** In Bamsley, 65% of patients saw a doctor only at the initial surgery appointment, and 27% saw both doctor and nurse, leaving only 8% seen by a nurse only. By contrast, in Rotherham only 17% of patients saw a doctor only, 19% saw doctor and nurse, and 64% saw a nurse only. Following the initial visit, 57% of Bamsley patients received a prescription, 31% were asked to see a doctor again, and 27% to return to see a nurse. Again in contrast, only 26% of

Rotherham patients received a prescription, 15% were asked to return to see a doctor, and 60% to return to see a nurse. These details have economic significance, but are interesting in their own right. Bamsley GPs' use of systemic antibiotics was much greater than that of the Rotherham GPs. The literature quoted earlier^{7,8,14,15,17} has shown that using antibiotics in this way may often be inappropriate. It also appears that a high proportion of patients in Rotherham were considered suitable by the practice nurses to be managed solely by them. This was reflected in the study by Marsh and Dawes³⁵ reported in the literature review, where 85% of patients with minor illnesses were managed by nurses, and in an even more recent study⁶⁶ where a practice nurse managed 95% of 343 patients presenting at a minor illness surgery held every weekday over a four month period.

Whilst patient satisfaction was high in Bamsley (82%) it was even higher in Rotherham (91%). Clearly the patients did not feel deprived in any way by neither seeing a doctor nor receiving a prescription. The topic of patient satisfaction will be revisited later.

We turn next to research question three - how do hospital ENT and audiological referral rates and patterns vary between the two groups/areas?

From the data supplied by the Hospital Information Departments for the seventeen participating practices there was strong evidence of a difference in all-age referral rates to ENT during 1995, of 19.3 per 1000 practice population in Bamsley compared to 10.1 per 1000 practice population in Rotherham. However, the selected month's (September in Rotherham, October in Bamsley) data analysis did not reflect Rotherham's lower figures although adjustments for age make comparison difficult. Given the similarity of the two areas the lower referral rate in Rotherham may be partly explained by the care given to all age patients by the ear-care trained nurses.

Of particular importance is the high DNA (Did Not Attend) rate found in Bamsley DGH (11%) and a zero rate in Rotherham. Furthermore the DNA rate found in the Ear Care Agency's base clinic run by ear-care trained nurses was 1.5% over a 6 year period, demonstrating that local treatment by known nurses produces good attendance rates.

It would be beneficial to monitor the effects of ear-care trained nurses on hospital referrals over a much longer period. Little can be said about referral patterns for the patients who entered the study via the seventeen participating practices because the time period was too short for

complete follow up of all referrals, the numbers entered into the study were small, and patients were omitted who should have been included in the study.

Our conclusion must be that there is some evidence of reduced referral rates in those practices using ear-care trained nurses but further more rigorous work is needed.

Research question four asks how patient perceptions of ear care vary between the two groups.

We have already referred to the differences in satisfaction recorded in Table 5.8, where 82% of Bamsley patients were either satisfied or very satisfied with treatment received, compared with 91% in Rotherham. In the methodology section we stated that satisfaction rates of 80% are quite commonly achieved^{48, 52-54} so the Bamsley rate is not as unusual as that for Rotherham. It was also noted that older patients and men generally express more satisfaction - in our study the median age of patients was 54 years (which was similar in the two areas) and more than half (52.6%) were male - again similar between areas.

Section 10b of the results reports the qualitative responses of both Rotherham and Bamsley patients, demonstrating high levels of goodwill towards staff in both areas, and appreciation of the service given. However, Rotherham patients often contrasted the knowledge and helpfulness of practice nurses trained in ear care compared to the more routine attention of doctors. They also demonstrated their own understanding of their ear condition, which had resulted from the educational activities of the nurses. Bamsley patients expressed general levels of satisfaction, but also some frustration with having to wait for treatment, or with treatments not working. The literature had revealed that chronic pain and waiting a long time to be seen are often associated with lower rates of satisfaction^{51,53,56-7} so this may explain the lower rates for Bamsley.

The qualitative responses (see Appendix 11) revealed that many patients experienced hearing impairment or tinnitus, and described the disability and handicap that resulted. The high prevalence of such conditions in the general population is well known.¹ The research design did not allow the long term benefits of ear care to be evaluated, but it might be expected that a limited short-term effect could be observed from reduced anxiety in the Rotherham patients. This might be apparent in the HQ12 responses. There was some evidence of this revealed in Tables 4.7 and 6.6, where Rotherham patients are shown to have better mental health.

So in answer to question four, Rotherham patients returned a higher rate of satisfaction with care than did Barnsley patients, and also demonstrated greater "ear-awareness".

Research questions five and six are connected, and deal with the economic aspects of the study. **Research question 5 asks how does resource use vary between the groups?**

It appears that the availability of practice nurses trained in ear-care helped to reduce demands on GP time (Rotherham average of 0.4 consultations per patient with GP, compared to Barnsley average 1.4 consultations per patient). GP consultations which produced a prescription were doubled in Barnsley (57%) compared to Rotherham (26%). Further, the Barnsley prescribing patterns showed a significantly higher use of systemic antibiotics than did the Rotherham pattern.

Research question 6 asks what are the cost implications of the Rotherham Primary Ear Care Service in relation to standard care, and the perceived differences in outcome and experience between the groups?

From our findings it appears that the cost of treating patients with a range of ear problems is significantly lower in Rotherham where trained ear-care nurses are used. The extra costs associated with the provision of ECNs as opposed to ordinary practice nurses has been taken into account. Some assumptions have been made in this analysis regarding how the training and other costs affect the cost per patient seen by ECNs. However, the sensitivity analysis carried out shows that the results are fairly robust when looking at the way true costs per consultation with PNs and ECNs may vary.

Because the possibility that doctor consultation rates in Rotherham may be higher than demonstrated in the study was only revealed at the end of this project, further research in this area is needed. Further perusal of notes in the GP practices in the study might make this point clearer.

Because of the short period over which we followed this cohort of patients, few have progressed to the stage where they have been subject to hospital inpatient procedures.

The answer to question 6 is that although the average total cost per patient in both settings may be somewhat understated, it does appear that the use of ECNs produces

cost savings in the primary care aspect of the management of patients with minor ear problems. These cost savings appear to stem from a direct substitution of ECN time for GP time in Rotherham. In Barnsley the average cost per case of GP consultations was £22.53 compared to £6.28 in Rotherham. If ECNs can treat this group of patients at least as effectively as GPs then this shift of professional responsibility from doctor to nurse makes sense.

Advantages to general practice of the ear-care service

The literature suggests that using practice nurses frees GP time for other activities. The study found that where ear-care clinics are well developed, practice nurses and patients recognised that this was the case. Patient perceptions reported in Section 10 of the research found advantages in being seen by a nurse, while the nurses showed that they certainly recognised that it was an opportunity for them to discuss health needs with the patients.

Not all practices were found to provide ear care in the same way, and although the evaluation of the ear care service has covered eight practices with well established ear-trained nurses, the actual provision in the practices was quite varied. The attitudes and expectations of the GP or GPs in the practice are central to decisions about the way services are run in a practice. This was outside the study and has not been explored. There is however a huge difference between the model where GPs were willing to hand over all ear patients to the nurse for the initial contact (nurses calling the GP in for second opinions and prescriptions), and a more conventional one of initial consultation with the GP, where patients are referred to the ECN once the diagnosis had been made and the GP has decided on a course of treatment which the nurse then carried out. This model does not give the nurses a nurse practitioner role but simply one of a nurse with extended skills which have been recognised by the GP. Similarly ear-care nurses are trained to carry out tuning fork tests and audiometry but these skills are not used in all practices, thus wasting training. During the three months of the study duration in Rotherham, 18 referrals were made to audiology from practices with ear-care trained nurses. As a result, 15 hearing aids were issued. Therefore we conclude that referrals to audiology were appropriate. Training has been offered to GPs in South Yorkshire by the Ear Care Agency in conjunction with the Community Medical Executive (CME) to demonstrate how they can get the most out of their ear-care trained nurses. There has been only a low take up of this offer.

The ENT consultant from the local hospital conducts the oral examination for practice nurses on the ear-care course and has been involved from the start in the development of the Ear Care Agency. It is the hope of the agency that referrals to secondary care would be reduced through early treatment at a practice level. The study has demonstrated that all-age referrals in Bamsley are almost double those in Rotherham in 1995 (19.3 per 1000 practice population compared to 10.1 per 1000 practice population). A number of examples came to light during the data collecting where the hospital ENT department referred patients back to primary care for a course of treatment which recognised the skills of the ear care trained nurses, thus saving hospital time, and making it easier for patients for travelling and convenience. For example:

"I have discharged her from the clinic with the advice to attend your Aural Care Nurse periodically for checking and cleaning of the mastoid cavity. We should be happy to see her again if she runs into difficulties"

Letter from staff surgeon to GP

Practice nurses in Bamsley did not possess these skills. Equally there were occasions when patients were not referred back from hospital care to the GP for treatment which the ear-care trained nurse could have carried out. During the study one of the Rotherham practices ceased ear care activities since they felt that money had not followed patients; where patients were being treated in primary care who would previously have been referred to secondary care, the practices were saving the hospital expense. This topic is outside the scope of the study and has not been addressed.

It is noteworthy that in another region, the West Midlands, the NHS Executive has provided funds for two practice nurses, originally trained by the Rotherham Ear Care Agency, to extend their ear-care scheme to other nurses, including health visitors.^{67,68}

CONCLUSIONS

The authors are aware that the pragmatic nature of the study makes interpretation of the results difficult. The Ear Care Agency has been in operation for five years, covering most practices in Rotherham. The eight practices involved in the study have all had long established ear care services but were widely different in the day-to-day ear care arrangements offered to patients. Practices ranged from a highly developed nurse practitioner role of running specified clinics with open access, to a GP dominated service, where the trained nurse was called in to carry out limited procedures only after a GP consultation.

Similarly in Bamsley, the practices, though without formal ear care services, varied in the use of the practice nurses or district nurses, and the relationship between these nurses and their GPs.

Within this wide variation of settings we believe we have carried out a study which allows us to make some clear statements about the nature and effect of the Rotherham ear care service.

Bamsley patients did show lower health status at the initial approach and more disruption was caused to their everyday lives by their ear or hearing problem, borne out not only in the statistics but in the freely made general responses at the end of Q1. The "ear awareness" among Rotherham patients, in terms of education about ears and ear problems and the value placed on the availability of expert advice and treatment in practices was readily recognisable.

The treatment received in both areas resulted in only small improvements in health status as shown by the HSQ-12. Perhaps this was not a suitable instrument with which to measure health gains resulting from ear or hearing treatment. However, it can be said that treatment by ear-care nurses does not appear to disadvantage patients in health status terms, and patients do at least as well as when treated by GPs.

A major finding of the study, which substantiates claims made by ear-care nurses, is that they can and do substitute their time for GP time in patient management and this substitution shows considerable savings. Ear care nurses' use of topical preparations are in accord with recommended practice compared with the dispensing of systemic antibiotics by Bamsley GPs.

Nursing is undergoing change at this time and the extended skills of the ear-care nurses demonstrate how a practitioner role can be beneficial to patients. Nurses respond to this

challenge in their work; they showed doubts about the new service at the start but once trained and carrying out their new role found it to be stimulating and relevant to the needs of patients.

Our first conclusion is that:

1) The ear-care service in Rotherham shows cost savings to the NHS, provides service benefits to the public and increases the skills of practice nurses.

The ear-care service under development in Rotherham calls into question the role of the practice nurse as an assistant to the GP. For ear care to be totally effective, nurses must have autonomy to operate their own clinics and recall their own patients, they must recognise ear problems and be confident to treat them. They need supportive, informed GPs who provide suitable premises, correct equipment and who will work with them to ensure that patients receive appropriate treatment and referral when necessary. Ear-care nurses need a local support system backed up by the local ENT consultants to provide regular updating of their knowledge and treatment skills.

Our second conclusion is that:

2) To be fully effective, the ear-care service must extend its influence to include GPs, so that they fully understand the work of the service, the principles of treatment and the potential of the service to improve patient care.

Less can be said about the interface between primary and secondary care from this study. The ear-care service claims to reduce referrals to secondary care and this would appear to be the case, looking at hospital information service figures. This is an important area and more work needs to be done. If more care can be moved to local areas, patients will benefit and savings will be made.

Our third conclusion is that:

3) Further consideration should be given to the interface between primary and secondary care so that patient movement between sectors is as efficient as possible.

POSSIBILITIES FOR FUTURE RESEARCH

1. The outcomes for patients treated by ear-care nurses compared to those treated by GPs

This study looked at overall outcomes from a number of practices using ear-care nurses. Treatment patterns varied within practices and many patients were seen by GPs at some point in their treatment. This study has shown a high level of satisfaction with the service provided by the practice nurses but has failed to show any treatment differences apart from a greater pain reduction in Barnsley. It is suggested that patients who receive treatment from ear-care trained nurses will have better long term outcomes than patients consulting with non-specialist GPs.

The proposal is to contact patients who participated in this study to look at the long term effects of treatment in the two settings.

2. Long-term care of patients by ear-care trained nurses reduces referrals to secondary care

Evidence from the Stag Medical Practice has shown that while referrals will initially rise following the introduction of an ear care service, in the longer term they will fall as cases of long-term ear disease are recognised and dealt with by the nurses. Through education nurses will prevent conditions from developing so that there is no need for specialist referral.

The proposal is for a longitudinal study which would approach hospital ENT departments to generate lists of all ear referrals from general practices, both with and without ear-care trained nurses, over a period of a number of years. Changes in the referral pattern should be detectable.

3. Can audiologists do clinical ear care?

Some patients arrive at the audiology department with ears blocked by wax. Before hearing tests can be carried out they have to be referred back to the practice or ENT Department for removal of wax. It is suggested that audiologists should be trained to remove wax by the use of syringe and instruments, saving patients time and distress and reducing the need for this further referral. This is in line with developments in ear care in the USA.⁶⁹

It is proposed that some audiologists be trained to remove wax and recognise ear problems. An RCT would be conducted to allocate patients into two treatment groups. Patients would be followed through to establish how the extended skills affect their treatment. The impact on the audiology service would also be assessed. Consideration might be given to a third arm of the trial where audiology patients are seen by an ear-care trained nurse before audiological tests are carried out.

ACKNOWLEDGEMENTS

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The authors wish to acknowledge the help given to this study by GPs, nurses, practice managers and receptionists in the seventeen practices involved in the study in the Rotherham and Bamsley areas and from the Rotherham Ear Care Agency staff. We thank them all for their cooperation and participation. We are especially grateful, of course, to the patients who responded so magnificently to our questionnaires.

We also wish to thank the consultant ENT surgeons and the heads of audiology at both Rotherham and Bamsley hospitals, as well as the information and medical records staff, for their cooperation and help. We valued the contribution of Mrs J Charlesworth of Rotherham and Dr L Hodgson of Bamsley in facilitating the study.

Professor Charlie Brooker of SCHARR and Ms Debbie Wild (formerly health economist at SCHARR and now manager at Fordingbridge Hospital, Hampshire) gave valuable advice in the early stages of this study.

Professor Jon Nicholl, MCRU, SCHARR gave valued support, particularly to the statistics at all stages of the study.

Last, but not least, we give our thanks for clerical help to Sally Coleman, Lois Read, Andrea Shippam, and Chris Todd. We are most grateful to Jane Durell for her sterling work in typing the final report.

NOTE ON AUTHORSHIP

The research team consisted of:

Project leader: Dr Susan Read, Senior Lecturer (Research) in the Acute and Critical Care Department of Sheffield University School of Nursing and Midwifery. Formerly Research Fellow in the nursing section at SCHARR.

Project Manager: Margaret Fall, Research Associate, SCHARR.

Health Economist: Mark Deverill, SCHARR

Statistician: Stephen Walters, SCHARR

The steering group consisted of:

Professor Philip Milner, now Chair in Public Health Medicine at the University of Bath, formerly Director of Public Health, Rotherham Health Authorities.

Professor Mark Lutman, now Chair in Hearing Research at the Institute of Sound and Vibration Research, University of Southampton, formerly Senior Lecturer at the Medical Research Council Institute of Hearing Research, Nottingham.

Rosemary Rodgers, Director of the Primary Ear Care Agency, Rotherham Health Authority.

The steering group members made a substantial contribution at the design stage of the project, gave advice throughout the life of the project, and were involved in interpreting the results and making significant comments on the final report, which they fully endorse.

For these reasons, the authorship belongs jointly to the research team and the steering group members.

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Appendix 1

The work of the Rotherham Primary Ear Care Agency began in 1990 when Rosemary Rodgers, a nurse with hospital ENT experience, joined the Rotherham Health Authority. Following a local survey which established that 64% of a convenience sample of 300 elderly nursing home residents in Rotherham were presently experiencing some kind of ear or hearing problem, a nurse-led ear care clinic was set up in a practice catering for 11,000 patients. By 1993, one in five visits to the practice nurse in the original practice was for ear care. In 1990 Rosemary Rodgers set up training courses in ear care for practice nurses from any GP surgeries in Rotherham Health Authority. A local ENT consultant assisted in developing the course, which is now open for nurses to come from around the UK and elsewhere. In 1994, Rodgers¹² reported that for minor ear problems, referrals to Ear, Nose and Throat (ENT) outpatients from practices with an ear care trained nurse had almost halved in the three years since the Agency began.

As well as providing ear care training for practice nurses from almost all Rotherham practices, the Ear Care Agency publishes educational leaflets for the public and for health professionals, and maintains an input to the Health Advice Centre open to the general public. It aims to ensure access to ear care for all the population of Rotherham, including ethnic minorities, people who are housebound or disabled, and patients in various forms of long term care. The Ear Care Agency also promotes "Deaf Awareness" and "Sympathetic Hearing Scheme" courses to improve access and communication between the hearing, and hearing impaired communities.

A demonstration is given by Rodgers²⁰ of how "ear awareness" for patients and practice staff has affected numbers attending for ear care by practice nurses in one large practice (11,000 patients). Figure 1 shows that in 1989, before the introduction of the new service, a total of 409 patients attended for ear advice or treatment. After introduction of the service, the number of ear care consultations increased, but gradually those new patients have dropped from over 500 to 266 by 1994, as the backlog of patients with previously unrecognised and untreated ear problems was dealt with in the intervening years.

Figure 1: Total number of consultations for ear problems, and the total number of new ear patients seen at the base practice of 11,00 patients

Year	Total no. of consultations by practice nurses	Total no. of ear care consultations	Total no. of new ear patients seen
1989	No figures available	409	13
1990	6,930	1,243	523
1991	10,695	1,844	535
1992	10,870	1,906	443
1993	11,887	1,989	344
1994	11,327	1,896	266
1995	11,704	1,798	239
Totals	63,031	11,085	2,363

Appendix 2



The University of Sheffield

SCHARR

Sheffield Centre for Health and Related Research

Director: R L Akehurst
Professor of Health Economics

Regent Court
30 Regent Street
Sheffield
S1 4DA
Tele: (0114) 282 5454/5
Fax: (0114) 272 4095

Dear Patient

EVALUATION OF EAR CARE IN GENERAL PRACTICE

Your Doctor's practice has agreed to collaborate in a study of Ear Care. This study is currently being carried out in Rotherham and Barnsley Health Authorities, and has been funded by Trent Regional Health Authority. The purpose of this study is to compare different ways of helping people with ear problems who attend General Practice.

You have been given this letter and a questionnaire because you have come to the surgery today with an ear or hearing problem for which you are seeking advice or treatment.

I would be most grateful if you would please complete the questionnaire for me and place it in the envelope provided. If you complete it here you may leave it with the receptionist or if you complete it at home you should put it in the post. The envelope is addressed and does not need a stamp.

Everything you tell us will be treated confidentially and will not be used in any way which will identify you, your Doctor or the Practice Nurse. Your GP has agreed that by completing the questionnaire you will also be giving permission for us to consult surgery held notes about your problem.

If you wish to make any enquiries about this study please contact Mrs Margaret Fall (Tel 0114 272 2515 or 0114 282 5209).

Thanking you in anticipation of your help.

Mrs Margaret Fall
Research Associate

CONFIDENTIAL

Rotherham 1 Barnsley 2



Practice Number

0 9

Patient Number

0 2 2

University of Sheffield



Sheffield Centre for Health and Related Research (SCHARR)

EVALUATION OF EAR CARE SERVICE IN GENERAL PRACTICE

**THANK YOU FOR AGREEING TO HELP US.
PLEASE ANSWER THE QUESTIONS CAREFULLY.
THERE ARE QUESTIONS ON BOTH SIDES OF EACH
PAGE.**

Please start on Page 2

Have you been to the surgery for an ear or hearing problem in the last 3 months

please tick Yes
No

1. How much **discomfort** have you had in the LAST WEEK, including today, from your *ear or hearing problem*?

(**discomfort** includes itching, ringing, buzzing and fullness)

none slight moderate severe extreme

2. How much **pain** have you had in the LAST WEEK, including today, from your *ear or hearing problem*?

none slight moderate severe extreme

3. Do you think you **normally have a hearing problem**?
(If you use a hearing aid please answer as if you were not wearing it)

No (if no go to Q4)
Yes

a) Would you describe your hearing problem as

slight moderate severe

b) Does your normal hearing problem affect you in any of the following situations?
Please tick all that apply

Watching TV At work

Listening to the radio In social situations

Answering the phone In the street

4. When you arrived at the surgery today with your ear or hearing problem

Was your hearing affected?

No (if no go to Q5)
Yes

If yes, how much was it affected?

slightly moderately severely

5. Does your current ear or hearing problem cause you any worry or embarrassment?

No (if no go to Q6)
Yes

If yes

a) Please explain your worry or embarrassment?

.....
.....
.....

b) How much worry or embarrassment does it cause you?

a little
some
a lot?

6. **During the last week** has your current ear or hearing problem affected your normal activities?

No (if no go to Q7)
Yes

If yes, how much has it affected your normal activities

a little
some
a lot

7. Is your current ear or hearing problem affecting your social or family life?

No (if no go to Q8)
Yes

If yes a) how much has it affected you?

a little
some
a lot

8. Is your current ear or hearing problem affecting your sleep?

No (if no go to Q9)
Yes

If yes a) how much has it affected your sleep?

a little
some
a lot

The following questions are about your general health

9. In general, would you say your health is:

(tick one)

- Excellent.....
- Very good.....
- Good.....
- Fair.....
- Poor.....

10. The following items are about activities that you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

ACTIVITIES	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Lifting or carrying groceries	1	2	3
b. Climbing several flights of stairs	1	2	3
c. Walking half a mile	1	2	3

11. During the **past week**, how much difficulty did you have doing your work or other regular daily activities **as a result of your physical health?**

(please circle one number)

- None at all 1
- A little bit 2
- Some 3
- Quite a bit 4
- Could not do daily work 5

12. During the **past week**, to what extent have you accomplished less than you would like in your work or other daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)? *(please circle one number)*

Not at all.....1
Slightly.....2
Moderately3
Quite a bit4
Extremely5

13. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

(please circle one number)

Not at all.....1
Slightly.....2
Moderately.....3
Quite a bit4
Extremely5

14. How much bodily pain have you had during the **past week**?

(please circle one number)

None.....1
Very mild2
Mild.....3
Moderate4
Severe.....5
Very severe6

15. These questions are about how you feel and how things have been with you during the **past week**. For each question, please give the one answer that comes closest to the way you have been feeling.

(circle one number on each line)

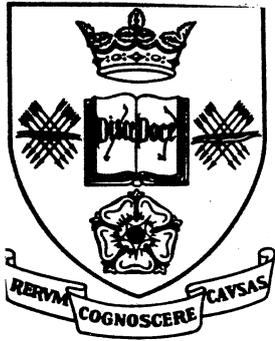
How much of the time during the past week:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	1	2	3	4	5	6
b. Did you have a lot of energy?	1	2	3	4	5	6
c. Have you felt down-hearted and low?	1	2	3	4	5	6
d. Have you been a happy person?	1	2	3	4	5	6

Please feel free to use this space for any comments you may wish to make.

Please now put your questionnaire into the envelope and give it to the receptionist, or if you are at home please post it to us. It does not need a stamp.

**Thank you very much for helping us
by answering these questions**

Appendix 3



The University of Sheffield

SCHARR

Sheffield Centre for Health and Related Research

Director: R L Akehurst
Professor of Health Economics

Regent Court
30 Regent Street
Sheffield
S1 4DA
Tele: (0114) 282 5454/5
Fax: (0114) 272 4095

EVALUATION OF EAR CARE IN GENERAL PRACTICE

Three weeks ago you visited your General Practice as you had a problem related to your ears or your hearing. You very kindly filled in a questionnaire for us about how you were feeling. I am interested to learn what has happened to you since this time.

I would be most grateful if you could complete the enclosed questionnaire and return it to me, using the freepost envelope provided. You do not need to add a stamp.

Your answers now and those of three weeks ago will enable us to establish how your treatment has progressed. Studies like this are of great importance to the workings of the National Health Service and the research team really are grateful when people like you help us by answering our questions. You are assured once again that anything you tell us will be treated confidentially and not used in any way that will identify you, your GP, or your Practice Nurse.

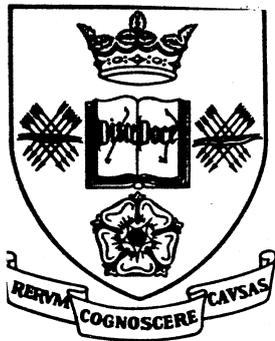
If you have any queries about the study please write to or telephone Mrs Margaret Fall (0114 272 2515 or 0114 282 5209).

Thank you again for your help.

Yours sincerely

Mrs Margaret Fall
Research Associate

Appendix 3



The University of Sheffield

SCHARR

Sheffield Centre for Health and Related Research

Director: R L Akehurst
Professor of Health Economics

Regent Court
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Tele: (0114) 282 5454/5
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EVALUATION OF EAR CARE IN GENERAL PRACTICE

Three weeks ago you visited your General Practice as you had a problem related to your ears or your hearing. You very kindly filled in a questionnaire for us about how you were feeling. I am interested to learn what has happened to you since this time.

I would be most grateful if you could complete the enclosed questionnaire and return it to me, using the freepost envelope provided. You do not need to add a stamp.

Your answers now and those of three weeks ago will enable us to establish how your treatment has progressed. Studies like this are of great importance to the workings of the National Health Service and the research team really are grateful when people like you help us by answering our questions. You are assured once again that anything you tell us will be treated confidentially and not used in any way that will identify you, your GP, or your Practice Nurse.

If you have any queries about the study please write to or telephone Mrs Margaret Fall (0114 272 2515 or 0114 282 5209).

Thank you again for your help.

Yours sincerely

Mrs Margaret Fall
Research Associate

CONFIDENTIAL

Rotherham 1 Barnsley 2

Practice Number

Patient Number

University of Sheffield



Sheffield Centre for Health and Related Research

EVALUATION OF EAR CARE SERVICES IN GENERAL PRACTICE

You visited the surgery with an ear or hearing problem on / / 1995 and kindly completed a form for us.

Would you please tell us how you have been since then by turning over the page and answering the questions by putting ticks in the appropriate boxes.

1. How much **discomfort** have you had in the LAST WEEK, including today, from your *ear or hearing problem* ?

(discomfort includes itching and fullness)

None	slight	moderate	severe	extreme discomfort
<input type="checkbox"/>				

2. How much **pain** have you had in the LAST WEEK including today, from your *ear or hearing problem* ?

None	slight	moderate	severe	extreme pain
<input type="checkbox"/>				

3. Do you think you normally have a **hearing problem** ?
(If you use a hearing aid, please answer as if you were not wearing it)

No (If no go to Q4)

Yes **If yes:**

a) Would you describe your hearing problem as

slight	moderate	severe
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

b) Does your normal hearing problem affect you in any of the following situations ? *Please tick all that apply.*

Watching TV	<input type="checkbox"/>	At work	<input type="checkbox"/>
Listening to the radio	<input type="checkbox"/>	In social situations	<input type="checkbox"/>
Answering the phone	<input type="checkbox"/>	In the street	<input type="checkbox"/>

4. Is your **hearing** affected by the *ear or hearing problem* you visited the surgery with three weeks ago ?

No (If no go to Q5)

Yes **If yes**, how much is it affected?

slightly

moderately

severely

5. Does your current *ear or hearing problem* cause you any **worry or embarrassment** ?

No (If no go to Q6)

Yes **If Yes**

a) Please explain your worry or embarrassment:
.....
.....
.....

b) How much worry or embarrassment does it cause you ?

a little

some

a lot

6. **During the last week, has your ear or hearing problem affected your normal activities ?**

No (If no go to Q7)

Yes

If yes, how much has it affected your normal activities?

a little

some

a lot

7. **If you undertake paid employment have you had to take time off for this current ear or hearing problem?**

No (If no go to Q8)

Yes

I do not undertake paid employment (go to Q8)

If YES:

a) How many days

1-3 days

4-7 days

8-13 days

more than 2 weeks

still off work

b) Did you lose income as a result of these days off ?

No

Yes

8. Many people undertake **other activities** which are **unpaid** e.g. child care, housewife/husband, hobbies etc. Have you had to take time off from these activities for this current *ear or hearing problem*?

No (If no go to Q9)

Yes

If YES

a) How many days

1-3 days

4-7 days

8-13 days

more than 2 weeks

b) Did you incur additional expenditure as a result of these days off?

No

Yes

9. Has your *ear or hearing problem* affected your **social or family life**?

No (If no go to Q10)

Yes

If YES, how much has it affected you?

a little

some

a lot

10. Is your current *ear or hearing problem* affecting your sleep ?

No (If no go to Q11)

Yes

If yes, how much has it affected your sleep ?

a little

some

a lot

11. In general, would you say your health is:

(tick one)

Excellent

Very good

Good

Fair

Poor

12. The following questions are about activities that you might do during a typical day. Does your health limit you in these activities ? If so, how much ?

(please circle one number on each line)

ACTIVITIES	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Lifting or carrying groceries	1	2	3
b. Climbing several flights of stairs	1	2	3
c. Walking half a mile	1	2	3

13. During the **past week**, how much difficulty did you have doing your work or other regular daily activities as a **result of your physical health**?

(please circle one number)

- None at all 1
- A little bit..... 2
- Some 3
- Quite a bit 4
- Could not do daily work 5

14. During the **past week**, to what extent have you accomplished less than you would like in your work or other daily activities as a **result of any emotional problems** (such as feeling depressed or anxious)?

(please circle one number)

- Not at all 1
- Slightly 2
- Moderately 3
- Quite a bit 4
- Extremely 5

15. During the **past week**, to what extent has your physical health or emotional problems **interfered with your normal social activities** with family, friends, neighbours or groups ?

(please circle one number)

- Not at all..... 1
- Slightly 2
- Moderately 3
- Quite a bit 4
- Extremely 5

16. How much **bodily pain** have you had during the **past week** ?

(please circle one number)

- None 1
- Very mild 2
- Mild 3
- Moderate 4
- Severe 5
- Very severe 6

17. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling.

(please circle one number on each line)

How much of the time during the past 4 weeks:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	1	2	3	4	5	6
b. Did you have a lot of energy	1	2	3	4	5	6
c. Have you felt down-hearted and low?	1	2	3	4	5	6
d. Have you been a happy person?	1	2	3	4	5	6

Would you think about all the time since you first realised you had your current ear or hearing problem.

18. In this time, have you purchased anything to try to treat the problem yourself ?

No (If no go to Q19)

Yes If yes:

a) What did you buy ?

b) How much did it cost ?

19. In this time, have you consulted anyone else outside the NHS for whose services you had to pay ?

No (If no go to Q20)

Yes If yes:

a) Who did you visit ?

b) What did they do ?

give advice	<input type="checkbox"/>
give a prescription	<input type="checkbox"/>
give treatment	<input type="checkbox"/>

other (please specify)

c) How much did they charge ?

20. Please tick to show how you normally get to the surgery ?
(include if brought by someone)

I usually walk to the surgery

I come by car less than 5 miles

I come by car more than 5 miles

I come by bus less than 5 miles Cost: £.....

I come by bus more than 5 miles Cost: £.....

Three weeks ago you were in the surgery with an ear or hearing problem

21. Who did you see about your problem ?

- A doctor
- A nurse
- Both

22. Were you asked to come back to see the doctor ?

- No (If no go to Q23)
- Yes

If YES:

How many times have you been back to see the doctor about this problem in the last three weeks ?

- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| None | 1 | 2 | 3 | 4+ times |
| <input type="checkbox"/> |

23. Were you asked to come back to see the nurse ?

- No (If no go to Q24)
- Yes

If YES:

How many times have you been to see the nurse about this problem in the last three weeks ?

- | | | | | |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| None | 1 | 2 | 3 | 4+ times |
| <input type="checkbox"/> |

24. When you came three weeks ago or at any time since, have you received a prescription for your ear problem ?

No (If no go to Q25)
Yes

If yes, how much did it cost you ? No cost
£.....

25. Have you visited hospital about **this ear problem** in the last three weeks ? (Do not include visits made for repair of equipment such as hearing aids)

No (If no go to Q26)
Yes **If yes:**

a) Which hospital did you visit ?

Rotherham General Hospital

Barnsley General Hospital

Other (please state)

b) Which department did you visit ?

Accident & Emergency or Casualty Department

ENT / Hearing Department

Other

c) How many visits did you make to the hospital ?

Please state number:

d) How much did it cost you each time you visited the hospital ?
.....

26. Are you waiting for an appointment for the ENT Department
- in Rotherham General Hospital ? Yes No
- in Barnsley General Hospital ? Yes No
- in a Sheffield Hospital ? Yes No

Looking back since you first visited your surgery with your ear or hearing problem:

27. How **satisfied** are you with the treatment you have received for your problem ?

extremely dissatisfied	dissatisfied	satisfied	very satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please add any comments about the treatment you have received:

a) In general

b) In the surgery

c) In the hospital

Thank you once again for taking the time to complete this questionnaire. Please put it in the envelope provided and post it to us. You do not need to use a stamp.

Appendix 4

TELEPHONE QUESTIONNAIRE TO EAR-CARE AND NON-EAR CARE PRACTICE NURSES

- 1 How long have you worked in this practice?
- 2 What are your qualifications? (if not ear-care trained go to q.16)
- 3 Did you do your ear care training while working in this practice?
- 4 Were you happy with the training?
- 5 Who decided you should attend?
- 6 Were you enthusiastic about the idea of ear care training at the beginning?
- 7 Do you think it is a good idea now?
- 8 What differences has it made to your working practice?
- 9 What differences do you think it makes to the way that the doctor works in your practice?
- 10 What differences do you think that it makes for the patients?
- 11 Could the ear care service be improved in this practice?
- 12 Clinically do you have any worries about the ear care service?
- 13 How would you manage patients with
 - a) hearing problems audio tympanometer syringe
 - b) itchy ears syringe toilet wicks
 - c) pain in their ear? syringe wicks prescription via GP
- 12 Has your attitude to syringing ears changed since your ear care training?
- 13 How does ear care fit into your work as a P.N.?
- 14 Do you specialise in anything else?
- 15 Any other comments?
- 16 Under what circumstances do you see patients with ear problems? Where do you see them?
- 17 What procedures do you carry out on patients with ear problems?

18 How would you manage patients with

- a) hearing problems audio tympanogram syringe
- b) itchy ears syringe toilet wicks
- c) pain in their ear? syringe wicks prescription via GP

19 When a GP asks you to see a patient do you feel part of a team treating the patient?

20 How do you report back your findings to the GP?

21 The research group found it difficult to find patients with ear problems in Barnsley who were attending their GP. Can you make any suggestions as to why this should be?

22 You will have heard about the ear care service in Rotherham? Do you have any comments to make?

23 Would you like to be trained in ear care?

24 Any other comments?

Appendix 5

THE PATIENT'S STORY

In both Q1 and Q2 patients were asked, *"does your current hearing or ear problem cause you any worry or embarrassment?"* Those answering 'YES' were asked to explain further. The unsolicited and unstructured comments made by patients in both Rotherham and Barnsley have been used to write these paragraphs. They demonstrate that, although ear and hearing problems are rarely life threatening, they cause much worry, embarrassment and unnecessary suffering.

Hearing difficulties

The fundamental problem can be stated as *"(I)..... cannot hear what people say and am unable to lip read."*

Patients experience trouble *"catching conversations"* *"in busy or noisy surroundings"* and *"... not being able to join in a normal conversation,"* *"because I can't hear what people are saying to me."* Talking meant *"asking people to repeat all the time,"* *"sometimes two or three times before I pick up what has been said"* and *"speaking louder than normal,"* *"and you end up hoping that you have said yes and no in the right place or answering yes or no to questions I have not heard properly."* A frequent worry was the need to ask *"people to repeat things,"* but this *"can make people impatient and annoyed,"* or cause humour *"someone may say 'watch out' and I hear 'one trout'."* A related problem was that *"(I) often keep to the same subject when other people have changed the subject, particularly in the car."*

Problems with hearing affect family life. *"I cannot always hear what my husband said to me, especially if I am in another room or there is background noise."* Difficulties are experienced *"when someone is on my deaf side"* or *"when two people are talking at once my mind goes a blank"*. The *"TV is rather loud...the rest of the family want it down"* *".....the TV can be heard half way up the road so I am told"*. Families do help *"I have to keep asking my wife what is said"* When the patient is also the carer there are problems as *"(I).....cannot hear wife (disabled) properly if called 80% of the time."*

Difficulties occur with relationships *"I am having more worry as regarding understanding people. I even have a lot of trouble understanding my wife which is making my ordinary run of life very difficult."* *"My husband has to repeat himself two or three times, it's the same when we are in company."* Curtailment of social life meant *"not going to bingo"* or following hobbies *"I cannot always hear wild bird calls/songs that others can with me".* *"If there is music on I cannot hear people talking."*

The use of the telephone is difficult - *"quietly spoken people...become very difficult to listen to especially with any background noise around."* Answering the telephone is difficult but solved for one person by *"(I)prefer to let the answer phone do the job then be able to listen 2 or 3 times."*

At work deafness causes problems. *"....I totally rely on my hearing aid, it is essential for me to carry out my work."* *"Communications with customers are difficult"* *"I deal with a lot of telephone enquires and have a lot of problem hearing people;"* *"working on a switchboard is difficult".* One person said *"I am constantly giving inappropriate answers because I've misheard the question. I lack confidence at work because of this."* For some the situation causes serious concern: *"I worry that I will mishear some information and make a mistake at work."* *"(I) am worried that if this problem persists I will be unable to continue as a musician."* *"I have started a new job as a study officer in a fairly noisy factory. I have difficulty conversing with the operators I am studying ... professionally it affects my effectiveness...socially it's just an irritant."* *"I lecture, and for a fortnight have been unable to respond well to students in large lecture theatre,"* and *"missing some of what is said in meetings."* *"At college I find it difficult when listening to tapes in language lessons; I am much slower than everyone else."*

Deafness diminishes the person, *"I do not feel whole"* or *"I used to feel embarrassed if people knew I was deaf. I am more confident now but still don't like people to know I wear an aid."* One reported *"feeling of helplessness and isolation,"* and wrote on their two questionnaires (completed at least 3 weeks apart and without any prompts) that not hearing what people say *"makes one feel foolish".* Being deaf is to be the *"butt of jokes;"* *"loss of hearing causes ridicule."* *"....I get so frustrated;"* *"some people look at you as though you are daft as well as deaf."* *"They treat you like a fool, is this person stupid"* or *"they think I am a snob or I am stuck up."* *"I think people can tell".* *"(I) won't always ask people to repeat*

what they said;" "in having to say pardon so many times particularly on the phone."
"People think I don't listen to them." "I feel a social outcast. I cannot join in any conversation without making a fool of myself by answering wrongly or not at all."
"It's awful having people shout at you because your hearing is impaired. I have always been deaf in one ear all my life, but when the hearing deteriorated in the other it was bad".

There are problems for the deaf as "(I) can't judge how loud I am speaking (and) don't seem to be able to sing properly;" "I tend to talk very loudly."

Hearing problems affect everyday life. "I live alone and sometimes do not hear the phone or door bell." I have "difficulty hearing the alarm clock." "I intend to learn to dive and being unable to 'clear' my ears prohibits me from even starting." "(I) worry most about driving, crossing the road, can't hear people on the phone." "Shops etc. have little patience in helping you," "...having to wear ear plugs to go socialise at night," "not being able to follow the questions in quiz nights and not hearing numbers at bingo."

Comments were made about hearing aids. "If I turn my hearing aid up it makes a buzzing noise and I can't hear what people say to me." "When in a crowded room or club I have to turn my aid down then I can't hear who I am talking to." "I have two hidden hearing aids but I frequently cannot hear what others say." "I am worried that I may need a hearing aid." "I could not get used to the over ear part of the aid and have since bought a pop in type. I must persevere more." "An inner aid is not possible so ... have obtained hearing specs." Having a hearing aid does not solve all problems - "even wearing my aid I cannot catch all of a conversation." "I get mixed up with words when I don't wear my hearing aid and I don't wear it often as it hurts my ear after a time." And there is a stigma attached to the aid - "not wishing people to know I wear an aid." Others said "since I got the hearing aid about 30 years ago, my hearing has got worse" and "I worry that it will never be solved."

A few comments were made on the prospect of deafness and fears for the future. "I have only good hearing in one ear in which I wear an aid; if I get problems, hard wax etc., I worry I might not be able to hear at all." There is a worry that, "as I get older it will get worse" or "become permanent;" "I worry about deafness and

infection.” “I worry that until I lose my hearing completely that I will keep having problems with my balance which is very severe at the moment.” “I am very worried about falling.”

For some deafness compounds other problems. *“As well as a moderate hearing problem I also have language difficulties which makes it hard for me to communicate”. “A great deal of the time the deafness causes me to be miserable and gives rise to panic attacks”. When deafness comes it causes worries: “I don’t normally have any hearing problems and since my eyesight isn’t good I rely on hearing what I can’t see.”*

Problems with tinnitus

Patients experience sounds: *“My left ear seems to have hissing noise,” “echoing;” “I am concerned about the slight ‘buzzing’ in my head on my right side. I thought that if the wax in the ear was removed that the buzzing would cease, but it hasn’t.” “My worry is just the ringing and itching sensation.”* More unusual sounds were heard - *“noises in the ear at night e.g. cows mooing, cats etc.,” “ringing noises when relaxing” or “whistling noisesit wears you down with your nerves” and “picking up a lot of background noise.”* One patient describes it as *“a banging noise in the right ear and buzzing noise in the left but banging now and again.” “When I am sat quietly or reading, I can hear my pulse beating, a bump, bump, all the time which is very distracting.” “As I suffer from tinnitus (sic) as well as deafness I find it difficult when I am in company with other people.”*

Other ear-related problems

One patient said they had *“severe head pain and vomiting “ due to Menière’s Disease. Other patients reported “severe headaches and dizziness,” or “the pain developed relatively quickly and with the pain my ears became blocked making hearing very difficult.”* Pain is experienced *“on take off and landing in aeroplanes” or “after flying it is painful for 3/4 days.” “My right ear hurts sometimes when I lie on that ear in bed”. “It stops sleep and is sometimes very painful.”* Some patients worry *“because I have started having dizzy spells and feeling nausea”. “I go dizzy if out anywhere”. Dizziness*

when looking after children caused one lady to say *"I was worried about them if I fainted."*

A different kind of worry comes with the *"constant itching - you want to pick it - I'm unable to stop thinking about the itching."* *"...I cannot help scratching them, which is not a very attractive habit!"* *"At times the itching is so severe one tends to try and ease it by rubbing the ear itself."* *"Whatever action one takes to ease this situation is very obvious to all present."* Discharge is embarrassing and many mentioned the smell. *"I have a discharge from my ear and it smells;"* *"I have discharge odour"* or it *"runs down my face without me knowing it"* or *"my ears weep a lot"*. There is embarrassment because of *"having to wipe my ears if they are running;"* *"sometimes in company my ear starts to discharge and itch and it makes me very uncomfortable."* Others reported *"loads of wax and dry wax,"* *"I suffer from excema in my ear and this weeps and scabs over,"* *"I cannot lay on it, also it seems swollen inside the ear."*

Patients in Bamsley mentioned many of the same frustrations and embarrassments as those in Rotherham, but they made fewer comments which showed an understanding of the nature of the problem and the treatment which had been received. Bamsley patients did not appear to know what to do about their problem and gave no examples of support in dealing with ear problems. *"The build up of ear wax seems to be uncontrolled by my cleaning habits."* *"I've had a few times where I've had my ears syringed (sic) and it just comes back."* *"I have cotton wool in my ear all the time."*

Rotherham patients drew attention to the need to maintain regular treatment. *"I need to attend surgery approximately every six months to undergo preventative ear care" and this can cause worry* *"because I keep having to go to the clinic for wax,"* *"I worry that this over a period of time could affect my hearing"*. One explained their deafness as due to a build up of wax which occurs two or three times a year. For one the treatment was not a total success: *"Whatever treatment I am given seems to have a short term cure, then the itching problem recurs."* The treatment may cause worry - *"oil drops smell unpleasant "* or *"there has been no improvement in my hearing at all."*

The recurrent nature of ear problems in Bamsley causes worry. *"Every few weeks I need attention and nothing clears up my problem."* *"I am getting ear infections at*

least every 2 months. This has been going on for the past 2 years.” “It may get worse and apparently there is no hope of a ‘cure’.” “Nobody seems to know what is causing the problem and I have had it on and off for many years now.” Others have hopes that treatment will bring improvements “(I)..have had an ear infection which left me totally deaf, after anti-biotics my hearing improved a little. I had drops in for 2 weeks and am now waiting for my ear being unblocked (cleaned out), hoping my hearing will improve then.....” Patients worry that their problems will develop further; “I am worried about slight infection developing into something more severe so it is best to get it checked out”. One patient asks “Could this infection have an effect on the quality of hearing in that ear ?”

Those experiencing ear problems for the first time have a fear of deafness *“I thought I might go deff (sic). When both ears become affected then worry is caused.” “(I am) deaf in right, ear failing in left ear awaiting hearing test.”*

Patients worry about their problems and treatment. *“I cannot understand why I still feel a little pressure in my left ear.” “No embarrassment but it is slightly worrying that my hearing/ears problem continues to recur even after treatment” and one said “(I) worry that there might be some underlying cause for it.”* Even when help is available this can be a cause of worry: *“I feel a bit worried now when I have to have them syringed as they feel tender inside.” “I’m wondering what’s the matter within the ear?”*

A Barnsley patient expressed hopes *“I have had hearing problems for years and wish I could do something about it.”*

Rotherham patients were more likely to understand their ear problems and their management but still had worries. *“I find it difficult to keep my ears dry when I wash my hair and I know that if they get wet the problem will come back.”* Some patients understood their problem. *“The Doctor says I have narrow channels and make a lot of wax; it is hard wax on the ear drum and makes me go deaf.” “My problem is due to wax trouble.”*

The worry and embarrassment caused by ear problems can clearly be seen from these comments. People with ear problems often do not seem to be treated with

understanding by families or the public. Nor do they always understand their problems or treatment. Patients worry about managing their daily living, and coping in the future. They fear straining relations with family, friends and work colleagues.

Generally the comments made by Bamsley patients show a lot of goodwill by doctors and nurses in the care they provide for patients. Patients go on to report that not all treatments were successful. Patients did not report being asked to return to the surgery for regular check ups.