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Patient Electronic Record: Information and Consent (PERIC)

Public attitudes to protection and use of personal health information

July 2002

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Patient Electronic Record: Information and Consent (PERIC)

Public attitudes to protection and use of personal health information

Darren Shickle,	Clinical Senior Lecturer in Public Health Medicine[1]
Jane Carlisle,	Research Associate[1]
Susan Wallace,	Research Associate[1]
Michael Cork,	Clinical Senior Lecturer in dermatology[2]
Deryck Beyleveld,	Professor of Jurisprudence[3]
Ian Bowns,	Senior Research Fellow[1]
Andrew McDonagh,	Consultant Dermatologist & Honorary Clinical Senior Lecturer[4]
Peter Fryers,	Medical Statistician[1]
Rupert Suckling,	Clinical Lecturer in Public Health Medicine[1]
Chris McCabe,	Senior Lecturer in Health Economics[1]
Anne Morgan,	Research Associate[1]

[1]School of Health and Related Research, University of Sheffield, Regent Court, 30 Regent Street, Sheffield, S1 4DA

[2]Division of Genomic Medicine, University of Sheffield, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF

[3] Faculty of Law, University of Sheffield, Crookesmoor Building, Conduit Road, Sheffield S10 1FL

[4] Royal Hallamshire Hospital, Central Sheffield University Hospitals NHS Trust, Glossop Road, Sheffield, S10 2JF

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Chapter 1

Executive Summary

1.1 Summary

Background: The Human Rights Act 1998, the Data Protection Act 1998, the equivalent European Conventions and Directives, and various policies and standards have placed legal and professional requirements to protect health information. These initiatives have occurred at a time when there has been increased recognition of the importance of obtaining information to improve the quality and cost-effectiveness of health care and to monitor and protect the public health. Concerns have been raised about the impact of requirements to obtain consent or provide additional data safeguards on research and public health surveillance activities. The PERIC project was commissioned to address these tensions.

Design: The PERIC project used a combination of methodologies: market research omnibus survey interviews; quantitative interviews with patients and parents of paediatric patients; a self completion postal survey of the public using a conjoint analysis methodology; qualitative interviews with people with learning difficulties, young people and their parents; an evaluation of six information sheets designed to explain to patients how their personal health information is used and five focus groups with members of the public.

Setting 180 sampling points across Great Britain for the market research, North East Derbyshire and Barnsley for other general public surveys, and Sheffield teaching hospitals for research involving patients.

Participants: Members of the general public (including people with learning difficulties and young people), inpatients and outpatients (including young people and their parents).

Results: The public are generally happy for their personal health information to be used when this is in the public interest. People are concerned about who has access to their information rather than what it is used for. The public are content for information to be used by NHS staff, although their responsibilities to maintain confidentiality should be made clearer, potentially with a requirement to sign a contract acknowledging their obligations. Transfer of anonymised data causes least concern, but the use of identifiable data is acceptable if necessary. At present there is a limited understanding of how the NHS uses information, mainly because the public have not had cause to think about the need for information transfer in order to provide health care and to ensure that services are provided cost-effectively to a high standard. The public would like more information about the way in which the NHS uses medical records and, where appropriate, to be informed about specific data transfers or asked for consent. However, they recognise that this is not feasible and, if it is warranted in the public interest, health information should be used.

Conclusions: While the public seem happy to share personal health information, provided that its use can be justified and there are appropriate safeguards, their willingness to provide imputed consent should not be abused for simple convenience. Concerns that human rights and data protection legislation would have detrimental consequences for public health activities and research may be unwarranted.

1.2 Background

The NHS information strategy identifies the importance of data usage in providing quality care for patients. One of the most important proposals within the strategy is to establish an electronic health record, to permit efficient information exchange between caregivers. However, this exchange is in potential conflict with policy and legislation for data protection. The information strategy recognised the need to consult with the public on procedures for data protection and usage. The PERIC project was funded to assess public attitudes to data protection and usage and advise on procedures for seeking consent for access to health information.

1.3 Methods

1.3.1 Quantitative interview study of public attitudes across Great Britain

Interviews were conducted by a market research organisation (RSL-IPSOS) using the initial questions of an omnibus survey. Subjects aged 15 years or over were recruited around 180 sampling points across Great Britain over a two week period in October and November 2000.

Two hundred vignettes were devised with different permutations of the person requesting information (hospital doctor, hospital nurse, GP, practice nurse, GP receptionist, hospital ward receptionist, NHS manager, physiotherapist, researcher, social worker); the reason why information is requested (clinical care, clinical audit, research, financial audit, teaching students, monitoring the performance of doctors, public health infectious disease surveillance); the content of the information (current episode of care, all medical record, all medical record when it contains sensitive information); and the level of personal identification of information required (name and address, medical record number, anonymous).

Subjects were provided with an explanation of why the NHS wants to know about their attitudes to the use of health information. Each interviewee was asked to assess 10 vignettes. After each vignette, subjects were asked "on a scale of 1 to 10 where 1 is very unhappy and 10 is very happy, how happy would you be for this person to use your medical information in this way?"

Simple linear regression models were used to ascertain the relative importance of the demographic characteristics of respondents and of the various elements in the vignettes in determining willingness to consent to access to health information.

1.3.2 Quantitative interview study of patients and parents

Patients and parents of paediatric patients attending the Royal Hallamshire and Sheffield Children's Hospitals were recruited in outpatient clinics or on inpatient wards. Subjects were asked to assess ten of the vignettes used within the National sample. All subjects assessed the same ten vignettes that had been chosen to provide a spectrum of likely responses of happiness to allow access. As with the general public sample, subjects were asked to indicate their 'happiness' using a ten-point scale. In addition, subjects were asked whether they would give consent to their personal data being used in the way described. Demographic information on age, gender, ethnic group and employment status was also

collected. Subjects were also asked to rank their knowledge of the health service against that of an average patient.

1.3.3 Conjoint analysis study of public attitudes

Scenarios were constructed with the same four elements used for the vignettes in the Great Britain general public survey (person, use, content, identifier) plus a level of compensation that could be paid to patients if they allow access to their data. Fewer levels were used within each scenario than for the vignettes, in order to reduce the number of combinations. The number of scenarios was reduced further to 25 through a fractional factorial design. The 300 pair combinations of these 25 scenarios were reduced to 250 by eliminating some pairs for which the general public survey predicted that one choice within the pair would be overwhelmingly preferred to the other. A self-completion postal questionnaire was sent to 1995 members of the public selected from 9 electoral wards in Barnsley and North East Derbyshire. Subjects were asked to make choices between pairs of scenarios. Each subject had either 10 or 12 pairs to assess.

1.3.4 Qualitative study with people with learning difficulties

Subjects were recruited via day centres for people with learning difficulties. Semi-structured interviews were used to explore the attitudes of subjects, firstly to taking responsibility for decisions about medical interventions and, secondly, to their right to privacy by controlling access to their health information. Interviews were recorded and transcribed. A framework analysis was performed.

1.3.5 Qualitative study with young people and their parents

Semi-structured interviews were carried out with young people aged between 14 and 17 years and one of their parents. Consent was obtained from both the young person and their parents. Subjects were recruited in paediatric dermatology and general surgery outpatient clinics and general surgery paediatric wards. Interviews were conducted in subjects' own homes at a later date. The duration of the interviews varied from 20 to 45 minutes. Interviews were recorded and transcribed. Subjects were provided with a range of examples of situations in which they might be required to give consent to a medical procedure, or in which they may have concerns about privacy (e.g. contraception). After the interview each young person was asked if they would be happy for one of their parents to be interviewed, usually the mother. In a few cases, the young person and parent were interviewed together, at their request.

1.3.6 Evaluation of six information sheets designed to inform patients of the way in which personal health information is used and protected

Subjects were recruited from two sources: responders to the conjoint analysis study who had indicated a willingness to participate in further research and inpatients and outpatients attending the Royal Hallamshire Hospital in Sheffield from a range of specialties: dermatology, haematology, rheumatology, gastroenterology, hepatology and general surgery. Six information sheets were evaluated via a self-completion questionnaire: 1. recommended by Caldicott Committee; 2. recommended by Department of Health; 3. used by BUPA; 4. used by local NHS Trust; 5. an expanded version of the Department of Health information sheet; 6. a similar information sheet to version 5, but allowing subjects to give

itemised consent for specific purposes. The content of each was compared. Readability was assessed using the Flesch Reading Ease and Flesch-Kincaid Grade Level scores.

Demographic data were collected on age, gender, ethnic group and employment status. Each subject was asked to read two information sheets. After each sheet, subjects were asked whether they would be willing to give consent to their personal health information being used in the way described. Their understanding of the uses of data that would be permitted by consent was tested by asking whether they thought that four examples of data use seen typically within the NHS were covered by their consent. They were then asked whether they had considered such uses when consent was first sought and with these uses in mind, whether they would still give consent. Subjects were asked to assess the quantity and quality of information contained in each sheet, using a ten point scale where "1= information is too basic, too general, too long, or difficult to understand" and "10 = gives me the kind of information I need to know". The second information sheet was then read and the same questions asked. When they had assessed both sheets, subjects were asked to state which sheet they preferred using a five point scale (strongly prefer or slightly prefer one over another or no preference). Subjects were randomised as to which two sheets they were asked to assess and also the order in which these were read, in case there were systematic preferences for the first or second sheet assessed. Members of the general public sample who were sent the postal version of the questionnaire were also asked to complete the Miller Behavioural Style Scale (MBSS). The MBSS assessed whether people prefer large or small amounts of information. However, this part of the questionnaire was withdrawn following the terrorist attacks in the USA on 11 September, 2001, because some of the questions related to terrorism and mechanical problems on aircrafts.

1.3.7 Qualitative focus groups with the general public

Participants were recruited from respondents to the general public element of information sheet evaluation that indicated that they would be willing to attend a focus group. Five focus groups were conducted. Groups were held during day and evening hours, including the weekend. Subjects were given a £10 gift voucher and travelling expenses in recognition of their contribution to the research. Each group was tape-recorded and the transcripts provided the basis for a framework analysis.

1.4 Results

1.4.1 Quantitative interview study of public attitudes across Great Britain

For almost a third of the vignettes posed, subjects said that they would be very happy to allow access to their health information. Almost a tenth (9.1%) of subjects said that they would be very happy to allow access within all of the vignettes that they were asked to assess. There were however, a significant minority of responses (11.6%) to vignettes where subjects said that they would be very unhappy to allow access. In addition 2.1% of individuals said that they were very unhappy with all of the vignettes presented to them. There were regional differences in response. Older people, individuals from higher social groups and males were more likely to be happy to give access to their health information. The individual requesting information was the most important factor determining willingness to allow access to the health record. Subjects were happier to release data if it was anonymised. The content of the information and the way that it would be used did not

seem to be particularly important, even when the health record contained sensitive information.

1.4.2 Quantitative interview study of patients and parents

184 patients and 90 parents were interviewed. Unlike the general public survey, associations between happiness and age or gender were not seen. However, to permit comparison with the general public survey, direct standardisation was performed against the 1999 Great Britain population, to control for any confounding effect of age or gender. Patients themselves tended to be happier to allow access to personal health information than the parents of paediatric patients, who in turn were happier than people drawn from the general population. There was a strong association between happiness and willingness to consent to access. Patients who perceived themselves to be better informed about the NHS than an average patient tended to be happier and more willing to give consent than those who ranked themselves as having average or below average knowledge.

1.4.3 Conjoint analysis study of public attitudes

621 completed questionnaires were returned plus 54 questionnaires returned because the addressee was deceased or was not resident at that address (overall response rate = 32%). Respondents were most concerned about who looks at the notes, whether sensitive information is contained in the notes, and the extent to which the data subject is identifiable. Subjects were least concerned about their GP having access. Concerns about a health service researcher were not statistically significant when compared to a practice nurse looking at the notes. There was a strong preference for a practice nurse over a health service manager having access to personal health information. The purpose for which medical records are required by the NHS did not appear to be important to the public. The amount of compensation offered did not impact on respondents' decisions to choose a particular scenario. Written comments within a free text section of the questionnaire suggested that the public should not expect payment.

1.4.4 Qualitative interview study with people with learning difficulties

Twenty people with learning difficulties covering a range of ages from 18 to 66 were interviewed. The idea of 'consent' to treatment was new for the sample group and required a full explanation. Some did not understand the explanation, and among those who did there were difficulties associated with deciding what constitutes 'informed' consent among this group of vulnerable people, many of whom simply want to give the 'right' answer. Overall, respondents would not mind anyone having access to what might normally be considered as sensitive information because they assume that everyone with the authority to see their notes acts in their best interests. However, there was some concern about access by certain individuals who were perceived to be untrustworthy. Respondents demonstrated an ability to understand the abstract concept of bullying after repeated education. It is therefore likely that some people with learning difficulties could be involved in decisions about medical interventions and about privacy of their health information.

1.4.5 Qualitative interview study with young people and their parents

Eleven young women and nine young men aged 14-17 were recruited from hospital

inpatients and outpatients. Eighteen parents of these young people were also interviewed. The young people had given little thought to how their health information is used prior to the interview. Young men were less concerned than young women, and younger teenagers were less concerned than older teenagers. Young people with serious conditions were happier than those with little experience of health care for staff to access their health information. Young people with more serious medical conditions preferred to be advised on decisions about their treatment until around age 18, in contrast to teenagers lacking experience of hospital who believed they should make decisions from a much younger age.

1.4.6 Evaluation of six information sheets designed to inform patients of the way in which personal health information is used and protected

Subjects were generally happy to give consent after reading the information sheets. However, many did not think that various uses of their medical records as described to them would have been covered by their consent. Despite this, when asked to reconsider their consent, most would still be happy to give consent. Subjects tended to prefer information sheets that were longer and contained more detail and used simpler language.

1.4.7 Qualitative focus groups with the general public

Thirteen men and 22 women from across the adult age range were recruited comprising employed, part time and retired people. The number of people in the five focus groups varied between five and nine. Participants were surprised at the range of uses of their medical records and expressed initial concern about the range of medical and associated staff with access to their personal data. Ideally patients would like to be asked for consent to the different uses of their health information on a regular basis, especially where named data is involved. However, after discussion of associated issues, and considering the real choice of spending money on a consent procedure, or advising patients about the use of the health information, participants decided that staff time and costs made this impracticable. Patients would like to be asked for their consent to use of their health information; if this is not feasible or practicable they would like to be informed; if this is not practicable they would trust the NHS to do whatever is in the best interests of patients rather than divert money away from health care.

1.5 Conclusions

The general public are generally happy to allow access to their health records. Men, older people and higher socio-economic groups tended to be most content. The survey of patients attending hospital showed that people receiving care were also happy for the NHS to use their personal health information, and were also willing to give consent to do so. There are particular issues relating to consent for use of information within the health records of young people and people with learning difficulties.

The public were most concerned about who has access to their information. Release of the minimum amount of information necessary and in anonymised form was also important. The reason for requesting access was relatively unimportant. This finding was consistent across the various quantitative and qualitative elements of the study. Many of the information sheets that are currently being used to explain to patients how their health information is being used concentrate on the reasons for access rather than who needs to see it. The qualitative research indicated that the public have a very limited understanding

of the roles of people involved in their care, particularly those involved with administrative and support functions. People seemed reassured when the importance of these roles was explained. There were also some concerns that some NHS staff are not sufficiently aware of their obligations to maintain confidentiality.

The NHS may need to make patients more aware of the important role that various categories of staff have in the overall provision of care, and make the contractual obligations of staff more explicit. The information sheets that were evaluated within PERIC were effective in obtaining consent, but failed to ensure that this consent was informed, since many subjects were still oblivious to many of the ways that the NHS uses information. The cost for the NHS of a member of staff explaining all of these potential data flows, or ensuring that written information has been understood, would be prohibitive. However, this does not mean that every effort should not be made to use opportunities to inform patients and to make NHS staff are aware of the implications of even trivial breaches of confidentiality on patient trust. The fact that privacy receives qualified guarantees within the Human Rights Act 1998 may mean that consent must be sought or patients provided with information in all circumstances, even though only a very small proportion of the population are unhappy about allowing access to their personal health information.

Numerous concerns have been raised within the research and public health communities about the implications of the Data Protection Act 1998, the Human Rights Act 1998, court judgements and various professional guidelines based on this legislation and the Common Law. The findings of PERIC would suggest that the public are generally supportive of research, public health surveillance and epidemiology activities that they perceive to be in the public interest. Just because people are happy for the NHS to use their information if it is in the public interest may not mean that they do not want to be asked for consent, or even informed about the way the NHS protects and uses health data. The public inquiries into the Bristol Royal Infirmary and The Royal Liverpool Children's Hospital indicate public concern when patient dignity is not respected. The public do however recognise that where informing or obtaining consent from patients is not feasible, the public interest would require that information should be used, albeit with the minimum quantity of data released preferably in anonymised form.

Chapter 2

The rationale for PERIC (Patient Electronic Record: Information and Consent)

In September 1998, the NHS Executive published "Information for Health: An Information Strategy for the Modern NHS 1998-2005". The purpose of this information strategy is to ensure that information is used to help patients receive the best possible care. The strategy aims to enable NHS professionals to have the information that they need both to provide that care and to play their part in improving the public's health. The strategy also aims to ensure that patients, carers and the public have the information necessary to make decisions about their own treatment and care, and to influence the shape of health services generally. A key element in this strategy is the electronic health record (EHR). The EHR will include information about patient contacts with the GP and primary care team as well as summary information about patient treatment by hospitals and other parts of the NHS. The Information Strategy therefore commits to development of a lifelong electronic health record for every person in the country; round-the-clock on-line access to patient records and information about best clinical practice, for all NHS clinicians; genuinely seamless care for patients through GPs, hospitals and community services sharing information across the NHS information highway; fast and convenient public access to information and care through on-line information services and telemedicine; the effective use of NHS resources by providing health planners and managers with the information they need.

The strategy recognised that "currently there is no agreement on either the content, structure or potential use (for patients, clinicians, public health specialists and planners) of individual personal summary health records. The NHS must consider these issues in the context of developing integrated electronic records in primary care." (paragraph 2.20)

The Strategy recognises that these developments must be made against the need to preserve the confidentiality of patient information which is emphasised as being of 'paramount importance' within the strategy. It was believed that "many patients will appreciate the importance of establishing an EHR to ensure that different healthcare professionals in the primary healthcare team (and under controlled circumstances other healthcare professionals) provide the best care based on a full knowledge of the patient's medical history" (paragraph 2.25). Even so it was recognised that "there are also real concerns about unauthorised access to electronic records" (paragraph 2.24) and that "in exceptional circumstances some patients may not wish for certain aspects of their medical history to be included in their EHR or communicated to other parts of the NHS. Such requests for privacy must be respected" (paragraph 2.26).

PERIC was funded by the Department of Health's Information and Communication Technology Programme and the Information Policy Unit at the NHS Executive to research public attitudes to the use of personal health information and to provide guidance on procedures for seeking informed patient consent to use of their health record for such uses as clinical management, audit and/or research.

`Chapter 3

The legislative and policy framework for consent, privacy and protection of personal health information

The use of personal data relating to the health of individuals is subject to various laws and guidelines. The most important of these are outlined in this chapter, together with some of the events that are shaping the law and policy regarding the use of personal health information.

3.1 Domestic legislation

3.1.1 The Common Law

The Common Law recognises that personal information that patients give to doctors for their treatment is confidential and that the context of the doctor-patient relationship is such that this information is given in confidence. The courts, however, have not been unanimous in the view that they have taken about the scope of this duty. Thus, for example, the view that was taken by Latham J in the *Source Informatics* case[1] was that the nature of the duty of confidence, here, is that it is a duty not to use the information for any purpose other than that for which it was given without the explicit or implied consent of the confider. Consequently, Latham J ruled that where GPs and pharmacists pass information about GPs' prescribing habits to data-base companies for purposes of direct marketing of GPs, unless the patients have given their consent for this, this constitutes a breach of confidentiality even though the information is disclosed only in anonymised (indeed aggregated) form. Even though the information received by the database companies is not personal data, the GPs and pharmacists are using confidential personal data given to them in confidence for an unconsented purpose. This is unlawful unless justified in the public interest or required by law. Since Latham J did not consider the use to be in the public interest, he held that an unlawful breach of confidence was involved. On the other hand the Court of Appeal,[2] in overturning this judgement and holding that no breach of confidentiality is involved in disclosing data in anonymised form to the database companies, held that the duty of confidence is a duty not to use the information in a way that is contrary to the legitimate interests of the confider. Since the Court of Appeal held that the only legitimate interest of the patients in the Source Informatics scenario was in privacy and that this was sufficiently protected by concealment of their identities in the disclosure to the database companies, it follows that no breach of confidence (requiring to be justified by the public interest, etc.) was involved at all. However, while the Court of Appeal judgement overrules that of Latham J in the High Court, it remains arguable that it is not definitive for at least two reasons. First, in reaching its decision, the Court of Appeal relied on the reasoning used by the Federal Court of Australia in a case in which

[1] *R v. Department of Health, Ex Parte Source Informatics Ltd.* [1999] 4 All ER 185. In this case, Source Informatics, a database company planned to obtain information on GP prescribing habits (to sell to pharmaceutical companies for purposes of direct marketing), based on patient prescriptions, in anonymised form from GPs and pharmacists. Source Informatics challenged the lawfulness of Department of Health advice that GPs and pharmacists who co-operated with this scheme would incur legal risks for breach of confidentiality, despite the fact that the information would be anonymised before disclosure, because patients give their personal information for their treatment and other NHS purposes, not for the purposes of direct marketing of pharmacists.

[2] *R v. Department of Health, Ex Parte Source Informatics Ltd.* [2000] 1 All ER 786.

SmithKline and French Laboratories Ltd. claimed that use of information it had provided for licensing of a drug on which its patent had expired could not be used by licensing authorities to assess applications to license generic products without breach of confidence.[3] While Australian judgements have only persuasive force in UK courts, the UK courts can use them to set precedents. However, the reasoning used by the Federal Court was arguably not compatible with that used by the House of Lords on the same facts,[4] because the House of Lords found against SmithKline on the grounds that the breach of confidence that SmithKline complained of was justified by the public interest and statutory duties, whereas the Federal Court found that there was no breach of confidence at all because unconsented use of the confidential information was not unfair to SmithKline. If it is not compatible then the Court of Appeal was bound by the reasoning of the House of Lords, which appears to be more compatible with that of Latham J. Secondly, since the Human Rights Act 1998 came into force (which occurred after the Court of Appeal sat in *Source Informatics),* the courts have taken the view that they are required to interpret the common law compatibly with the European Convention on Human Rights.[5] Since (see below), the interests that Article 8(1) (which grants a right to privacy) of the European Convention on Human Rights protects are much wider than a right to concealment of personal identity, it is arguable that a different interpretation must now be given in any future case.

3.1.2 The Data Protection Act 1998

The Data Protection Act is intended to implement Directive 95/46/EC. The objective of the Directive (the Data Protection Directive) is to protect fundamental rights and freedoms and, in particular, the right to privacy, in relation to the processing of personal data (see Article 1.1), an equivalent adequate level of protection of these rights and freedoms being held to be necessary to permit such data to be transferred from one EU country to another (which is, in turn, necessary for the purposes of the internal market) (see Recitals 7-10). In order to achieve this objective, the Directive requires EU member States to grant those

[3] *Smith Kline and French Laboratories (Australia) Limited and Others v. Secretary, Department of Community Services and Health and Another* [1991] ALR 679 at 691.

[4] *In re Smith Kline & French Laboratories Ltd.* [1989] 2 W.L.R. 397 at 408. SmithKline brought the same action in all the countries in which it had held a patent on the product in question.

[5] See, e.g., *A Health Authority v X and Ors* (2001) 7 Lloyds Rep Med 349. This judgement, by Munby J., was subsequently upheld by the Court of Appeal in A Health Authority v X and Ors (2001) [2001] EWCA Civ 2014.) In this case a health authority had applied for disclosure of medical records by a GP ('Dr X') and his partners as a result of matters that emerged in the course of care proceedings in respect of patients of that practice. The health authority wished to consider the extent of compliance by Dr X and his partners with their terms of service. Dr X and his partners did not contest the application but sought the court's guidance, having done everything in their power to obtain the appropriate consents from the patients, only two of whom did not consent. Dr X did not dispute that his ultimate obligation was to comply with any court order but asserted that, prior to any order being made, he had to comply with the duty of confidentiality owed to his patients. Munby J found that Dr X and the health authority had similar duties to protect confidentiality of patient records. Confidentiality and respect for the patient's private and family life was guaranteed in Article 8 European Convention on Human Rights. To allow disclosure the Court had to be satisfied that there was a compelling public interest requiring the disclosure. In deciding that in principle that disclosure was necessary within the meaning of Article 8(2) of the Convention, the judge referred to two previous cases considered by the European Court of Human Rights (*Z v Finland* (1997) 25 EHRR 371 and *MS v Sweden* (1997) 28 EHRR 313). However disclosure without consent, which interfered with a patient's rights under Article 8 of the Convention, could only be justified if there were effective and adequate safeguards against abuse; if there was a compelling public interest in the disclosure satisfying the criteria of necessity and proportionality; and disclosure was kept to the minimum amount of information needed. The requirement to justify an interference with a patient's rights under Article 8 of the Convention arose not only when a patient's records passed from his or her doctor to a public authority but also every time the records were transferred from one public authority to another.

who provide personal data ("data subjects") with certain specific rights and to impose specific duties on those who determine the purposes of the processing of personal data (data controllers) and processors of personal data. The Data Protection Act structures these duties and rights under 8 data protection principles.

The first data protection principle (implementing Article 6.1(a) of the Directive) requires personal data to be processed fairly and lawfully. The requirements of fair processing (see Schedule 1 Part II paragraphs 2 and 3, implementing Articles 10 and 11 of the Directive) are that both those who obtain data from the data subject and those who receive personal data from third parties must provide the data subject with at least the identity of the data controller and the data controller's representative (if any), the intended purposes for which the data will be processed, and any other information (for which the Directive, but not the Act provides examples) required for the processing to be fair, unless the data subject already has this information. This information must, according to the Act, be given by those who obtain the information if this is practicable. In other cases, it must be given unless impracticable, would involve disproportionate effort, or is required by law. It should be noted, however, that while this is what the Directive says about other cases (though the Directive refers to impossibility rather than impracticability), Article 10 of the Directive makes no provision for those who obtained the data from the data subject not to provide the information on any grounds. However, it is arguable that Recitals 39-40 of the Directive apply the "other cases" conditions to disclosures/purposes that were not foreseen by those who obtained data from the data subject at the time at which it was obtained. If so, the Directive still does not explicitly permit any failure to provide the "fair processing" information where uses/disclosures were anticipated at the time that the data was being obtained. Consequently, it would seem that compatibility of the Act with the Directive must rest on application of the Article 13(g) provision that Member States may modify Article 10 to protect the data subject or for the rights and freedoms of others. This, however, is questionable because it does not add up, where applicable, to information provision being impracticable. The only plausible alternative is to read the Act as presupposing that it is never impracticable to inform of foreseen/anticipated disclosures/purposes when data is being obtained from the data subject.

In order for health data (as sensitive personal data) to be processed lawfully under the first principle, at least one of the conditions laid down by Schedule 2 (see Article 7 of the Directive) as well as one condition laid down by Schedule 3 (See Article 8 of the Directive) must be met. The conditions in Schedule 2 are (1) with the consent of the data subject; (2) for the purposes of a contract to which the data subject is a party; (3) for the purpose of legal obligations of the data controller (other than those entered into by contract); (4) for the vital interests of the data subject; (5) for the administration of justice, functions under an enactment, Crown, Ministerial or government functions (all of which will also satisfy Schedule 3), or the exercise of public functions in the public interest; or (6) in the legitimate interests of the data controller, provided that this is consistent with the rights of the data subject. However, Article 14(a) of the Directive specifies that the public interest and legitimate interests conditions may not be used without giving the data subject the opportunity to object unless the contrary is specifically laid down by law.

The most applicable conditions in Schedule 3 not already mentioned require the explicit consent of the data subject (which will automatically satisfy the consent condition of Schedule 2); represent the vital interests of the data subject or others, where the data subject cannot give consent, the consent cannot reasonably be obtained, or is unreasonably

withheld; where the data subject has made the data public; for legal proceedings, legal advice, or the exercise of legal rights; for medical purposes by a health professional or a person bound by an equivalent duty of confidentiality; or in circumstances specified in an order of the Secretary of State (in connection with which see The Data Protection (Processing of Sensitive Personal Data) Order 2000, SI 2000 No. 417, which, in particular, lays down a condition for research in the substantial public interest, subject to specified conditions).

The medical purposes condition is, to a degree, controversial, because the Act (Schedule 3.8(2)), specifies medical research as a medical purpose, when the Directive (see Article 8.3) does not do so. It should also be noted that, while neither the Act nor the Directive says so explicitly, at least the conditions of Schedule 3 may not be open alternatives. This is because (see below) the Act must be interpreted consistently with the European Convention on Human Rights on account of the Human Rights Act 1998 (as must the Directive because the values of the Convention are fundamental principles of EC law, violation of which the ECJ has long held would render a Directive invalid),[6] and not to obtain consent for the use of at least sensitive personal data is regarded by the European Court of Human Right as a breach of the Convention Article 8(1) right to privacy. This implies that non-consent conditions can only be used where (and to the extent that) this would be impracticable or inappropriate (e.g., because this would endanger/violate the rights of others or be contrary to national security, etc.)

In addition, lawful processing under the first data protection principle requires any other laws on lawful processing to be complied with which includes, in the UK, the common law on confidentiality.

It should be clear that the obtaining of explicit consent, where practicable and not inappropriate, would enable full compliance with all the requirements of the first data protection principle. For this reason, the Government has rightly indicated that the standard for the NHS should be to seek informed consent for the use of data. However, because this might not be practicable, at least in the short term, other conditions might be applicable, and special provision might need to be made for specific uses (see the Health and Social Care Act 2001 below).

The second data protection principle (implementing Article 6.1(b)) stipulates that personal data should only be obtained for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes. Neither the Act nor the Directive defines "compatibility". However, the Directive specifies that further processing for historical, statistical or scientific purposes shall not be considered incompatible provided appropriate safeguards are put in place. Availing itself of this, section 33 of the Act states that the further processing of data only for research purposes is not to be regarded as incompatible where the "relevant conditions" are met. The "relevant conditions" being that the data are not processed to support measures or decisions with respect to particular individuals, and that the processing is not likely to cause substantial damage or substantial distress to any data subject. If a positive definition of "compatible purposes" is to be constructed then there are three possible routes. One route is to suggest that compatible purposes are those that are implied by the specified purposes as being obviously necessary for them. Another route is to suggest that

[6] See the *Second Nold Case (Case-4/73) [1974] E.C.R. 507.*

compatible purposes are to be viewed as not incompatible purposes, which are to be viewed as those that do not interfere with or conflict with the specified purposes. The third route is to say that purposes are not incompatible provided that they have a substantial public interest justification and are carried out with appropriate safeguards (which is to construct a concept on analogy with the research exemption). Of these the first and third routes would seem to yield fairly uncontroversial results, though the first (which restricts compatible purposes to those for which consent may be implied, might appear overly restrictive). The second, however, would render much processing not incompatible, and is not advisable without sanction by the courts.

The third data protection principle requires that personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed (see Article 6.1(c)). The fourth data protection principle states that data should be accurate and, where necessary, kept up to date (see Article 6.1(d)). To minimise the risk of inappropriate disclosure, the fifth data protection principle requires that personal data should not be kept for longer than is necessary for the purposes for which it was obtained (see Article 5.1(e)). However, there is an exemption for this for further processing, for research only, in Section 33 under the relevant conditions. The sixth data protection principle specifies an obligation to process data in accordance with the specific rights of data subjects (which are the rights to information provision of Articles 10 and 11; the rights to access and rectification, erasure or blocking of Article 12 of the Directive and Sections 7 and 14 of the Act; the rights to object to Article 14 of the Directive and sections 10 and 11 of the Act; the right not to be subjected to automated decision-making of Article 15 of the Directive and section 12 of the Act). The seventh data protection principle (deriving from Article 17 of the Directive) requires that appropriate technical and organisational measures should be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.

The eighth data protection principle (implementing Articles 25 and 26 of the Directive) states that personal data must not be transferred to a country outside the European Economic Area (EEA) unless that country has ensured an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

Member States within the EU are all required to comply with the European Union Directive (95/46/EC) and hence are deemed to provide the necessary level of data protection, and hence transfer to these countries is permissible. The same applies to Norway, Liechtenstein and Iceland, which are members of the EEA and have, as such, undertaken to comply with the Directive.

Currently, the EU recognises only Hungary, Switzerland and Canada outside the EEA as offering adequate protection. For data to be passed to any other country, including the USA, either the data subject must have consented; or the transfer must be necessary for specified contractual interests of the data subject; or for legal interests; or be necessary for the vital interests of the data subject; or be from a register set up to provide information to the public. Alternatively, the data controller must ensure that the persons to whom the data are to be transferred will comply with Directive standards (which can be enforced through a contract). In relation to this, the EU has produced a standards contractual form, and special contractual arrangements known as "the safe harbour agreement" are available to companies within the USA (See Article 26). The Act does not specifically mention contracts for protection or standard contractual arrangements. However, it covers these by

referring to conditions of a kind that the Information Commissioner would recognise, or with the approval of the Information Commissioner (see Schedule 4 of the Act).

While the USA has not yet been recognised as providing adequate protection, various legislative proposals are being considered which might alter the position. This is, however, by no means certain.

Personal records kept for purely domestic purposes are not covered by the Directive. Whereas the Data Protection Directive covers only automated processing and processing of manual records in a relevant filing system, the Act also covers unstructured accessible records, and the Freedom of Information Act 2000 extends this to any personal data held by public bodies. Only the processing of personal data (which is anything that can be done with or to personal data) is covered, Recital 26 of the Directive making it clear that once data has been rendered anonymous the data protection principles no longer apply. However, it is far from clear when data is to be held to have been rendered anonymous for this purpose. To begin with, the Directive defines personal data as "any information relating to an identified or identifiable natural person", who is "one who can be identified, directly or indirectly" by anyone (see Article 2(b) and Recital 26). The Act, on the other hand, regards an identifiable person as one who can be identified directly by anyone or indirectly by the data controller (see section 1). Suppose A, who has obtained data from a patient for purposes X, continues to hold it in a form in which A can identify the patient, but passes it on to B in a form in which B cannot identify the patient for purposes Y that B will determine. It would seem that according to the Directive that the data held by B is still personal data, whereas the Act would seem to imply that it is not. However, the Court of Appeal in *Source Informatics* (see above) declared in *obiter dicta* (which do not set precedents) that the Directive does not hold the data held by B to be covered by the Directive. But, to complicate matters further, Maurice Kay J, in the *Robertson* case,[7] held that where the person who obtains data from the data subject *envisages* it being used for specific purposes, this person is to be regarded as processing the data for these purposes himself or herself. On this basis, if A envisages (let alone knows) that B will process the data for purposes Y, then A is to be regarded as a data controller in the circumstances outlined. Consequently, the data processed by B must be held to be personal data by the Act and the Directive. More specifically, because *Robertson* concerns the Directive's Article 14(b) requirement to provide the data subject with the opportunity to object to the use of data for purposes of direct marketing without having to give reasons, the import of this is that (despite the Court of Appeal's opinion in *Source Informatics* that the Directive does not cover this processing) where GPs and pharmacists obtain data from patients they are required to inform the patients that they intend to pass it on to Source Informatics, who intend to use it for the purposes of direct marketing (on the grounds that it will be handed to Source Informatics in a form in which Source Informatics cannot identify the patients), without informing the patients of this and giving them the right to object, without acting in breach of the fair processing provisions of the Act (per Article 10) and section 11 of the Act (per Article 14(b)). This is important, because (see, e.g., GMC and MRC guidance below) it is widely assumed that the *Source Informatics* case has settled that processing by persons in the position of B is not covered by the Data Protection Act/Directive. In the light of *Robertson,* this must be considered a very unsafe assumption.

[7] *R v (1) Wakefield Metropolitan Council (2) Secretary of State for the Home Department, ex parte Brian Reid Beetson Robertson* [2001] EWHC Admin 915, paragraphs 22 and 23.

3.1.3 The Human Rights Act 1998

This Act gives domestic legislative effect to the European Convention on Human Rights. Section 3 of the Act requires all UK legislation, whenever it was enacted, to be interpreted, if possible, so as to be compatible with Articles 2-12 and 14 of the Convention; and Section 6 requires all public authorities (including the courts) to act compatibly with these rights (unless primary legislation prevents them from doing so).

Article 8(1) of the Convention grants a right to respect for private and family life, home and correspondence. However, this right is not absolute, Article 8(2) stating that

> *there shall be no interference by a public authority with the exercise of this right except such as in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health and morals, or for the protection of the rights and freedoms of others.*

The jurisprudence of the European Court of Human Rights, which the domestic courts must take into account (bearing in mind that individuals may take their cases to the European Court of Human Rights if they do not receive a remedy in the domestic courts for violation of the Convention right) is that to use sensitive personal information (which includes personal health data) without the consent of the person concerned is, by the very nature of the matter, a breach of Article 8(1), which is unlawful unless justified in the terms of Article 8(2). In general terms, the breach must be necessary for a legitimate overriding purpose and must be limited to the extent that is necessary to achieve this purpose. [8]

It should also be noted that the right granted by Article 8(1) is very broad as it protects the individual against:

1. Attacks on his physical or mental integrity or his moral or intellectual freedom.
2. Attacks on his honour and reputation and similar torts.
3. The use of his name, identity or likeness.
4. Being spied upon, watched or harassed.
5. The disclosure of information protected by the duty of professional secrecy.[9]

[8] See, e.g., *MS v Sweden* (1997) 28 EHRR 313.

[9] Jacques Velu, "The European Convention on Human Rights and the Right to Respect for Private Life, the Home and Communications" in A. H. Robertson (ed.), Privacy and Human Rights (Manchester: Manchester University Press, 1973) 12–128 at 92. Indeed, the Commission of the Council of Europe has declared:

> *The scope of the right to respect for private life is such that it secures to the individual a sphere within which he can freely pursue the development and fulfilment of his personality. (Andre Deklerck v. Belgium. Application No. 8307/78 DR21, 116)*

More recently, L. G. Loucaides, "Personality and Privacy Under the European Convention on Human Rights" British Yearbook of International Law LXI (1990) 175–197 at 196, concluded that case law under the European Convention on Human Rights

> *has expounded and upheld the protection of privacy to such a degree that, for all practical purposes, the right of privacy has become a functional equivalent of a right of personality, potentially embracing all those constituent parts of the personality of the individual that are not expressly safeguarded by the European Convention.*

3.1.4 The Health and Social Care Act 2001

Section 60 of the Health and Social Care Act 2001 empowers the Secretary of State to pass regulations that render it lawful to process personal information without consent, even though this is in breach of confidentiality (s.60(2)(c)). Any regulations require the approval of both Houses of Parliament, and are applicable only to cases that are to improve patient care or otherwise in the public interest (s.60(1)) where consent would be reasonably impracticable (s.60(3)). The use of power must be reviewed annually and if a cost-effective alternative has been determined, it must be adopted. The Act does not provide blanket coverage for all purposes. Each and every gathering system will need to apply for inclusion. Section 61 establishes a Patient Information Advisory Group (PIAG) to work up the details of the process and standards to be applied to any possible use of the powers.

Section 60(6) is somewhat puzzling in that it states that, without prejudice to Section 60(2)(c), any regulations must comply with the Data Protection Act 1998. Literally, this means that breaches of confidentiality approved under the regulations will be lawful regardless of what the Data Protection Act says. Now, there is no problem saying that the Data Protection Act will not be breached on account of a breach of confidentiality. However, the Data Protection Act represents the Data Protection Directive and, because EC law is supreme over UK law, the Health and Social Care Act cannot validly breach the Data Protection Directive. So, it must be claimed either that section 60(6) says no more than that actions authorised under section 60(2)(c) will not breach the Data Protection Act on account of breaching confidentiality, or else that these actions are not unlawful on account of not getting consent because the Data Protection Act/Directive does not require consent when these conditions are satisfied. Given what was said above about consent not being required by the European Convention on Human Rights when this would be impracticable, either would be an acceptable interpretation. Section 60(6) should not, however, be taken to imply that there need be no compliance with the fair information provisions. It may be tempting to do so, however, because the Data Protection Act states (see above) that those who obtain information need not comply with information provision if this is impracticable, and it might be held that whenever consent is impracticable information provision is impracticable. As was previously noted, however, it is arguable that this is only consistent with the Directive in cases of unforeseen purposes/disclosures.

3.1.5 The Health Services (Control of Patient Information) Regulations 2002

These are the first regulations passed under section 60 of the Health and Social Care Act 2001. They cover three categories of processing of confidential information

1. Medical purposes related to the diagnosis or treatment of neoplasia (Regulation 2);
2. Communicable diseases and other risks to public health (Regulation 3); and
3. General (Regulation 5), which comprises processing:
   - to enable patients to be less readily identifiable;
   - required for medical research into locations at which medical or conditions or disease may occur;
   - to enable the lawful holder of information to identify and contact patients for the purposes of obtaining consent to participate in medical research, to use the information for research, or to allow the use of tissue or other samples for research;
   - to link, validate quality, and avoid impairment of quality of data;
   - to audit, monitor and analyse provision by the health service for patient care; and

   - to grant access to information for one or more of these purposes (Schedule to the Regulations).

The processing permitted under 1. is very wide and is not confined to data to establish and maintain Cancer Registries (as was thought would be the case at one time). It includes medical research approved by a NHS research ethics committee (Regulation 2(1)(d)). However, the processing may only be undertaken by persons who are individually or as a member of a class approved by the Secretary of State and when authorised by the person who lawfully holds the information (Regulation 2(3)). It is not, however, clear by what process the Secretary of State will approve persons. Regulation 7 specifies various safeguards (including that the person processing must be a health professional or someone owing a similar duty of confidentiality) but this cannot identify the person referred to under Regulation 3.

The processing permitted under (2) covers various specific purposes listed in Regulation 3(1). Processing may be undertaken by the Public Health Laboratory Service, persons employed or engaged for the purposes of the health service, or other persons employed or engaged by a Government Department or other public authority in communicable disease surveillance (Regulation 3(3)). This processing is also subject to Regulation 7.

The processing under (3) may occur, subject to the safeguards of regulation 7, if research, on approval by both the Secretary of State and a NHS research ethics committee (though it is unclear how the Secretary of State will independently issue approval), otherwise on the approval of the Secretary of State alone (with the process again being unclear). However, approved processing under this heading must be registered if it permits the transfer of information between data controllers as understood by the Data Protection Act 1998 (Regulation 6).

The regulations raise a number of questions. For example, they do not appear to be restricted to cases where consent could be said to be genuinely impracticable (e.g., they do not merely permit Cancer Registries to continue using data they already have without consent, but to obtain it prospectively without consent). The role of the research ethics committees is especially unclear. They are presumably involved to make independent public interest judgements. As bodies exercising public functions, indeed statutory ones in this case, they must comply with the law. However, the Department of Health's Guidance to research ethics committees states that they take no responsibility for their decisions in relation to the law. Unless this is changed, it is arguable that they cannot exercise their functions lawfully under the Regulations. And, as already mentioned, it is not entirely clear how necessary approval from the Secretary of State is to be obtained. However, the Regulations only came into force on 1 June 2002, so time and perhaps some legal challenges will no doubt clarify matters in due course.

3.1.6 Other relevant UK legislation

There are a number of Acts that include statutory provisions or obligations for disclosure of information to another, usually specified, person, regardless of any Data Protection Act or Common Law duty of confidentiality that may otherwise exist. Other legislation imposes additional data protection measures within specific areas of health care. In this latter case, it is usually on the basis of a judgement that it is in the public interest to offer additional guarantees to facilitate patients coming forward for treatment. For example, the

NHS (Venereal Diseases) Regulations 1974 and the NHS Trusts (Venereal Diseases) Directions 1991 prevent the disclosure of any identifying information about a patient examined for a sexually transmitted disease (including HIV and AIDS) other than to a medical practitioner (or someone under their direct supervision) in connection with and for the purpose of the treatment of the patient and/or the prevention of the spread of disease.

The Public Health (Control of Disease) Act 1984 and the Public Health (Infectious Diseases) Regulations 1988 place a statutory requirement on medical practitioners to disclose certain information, without obtaining the consent of the patient, if they know or even just suspect that a patient has food poisoning or a notifiable disease. In addition to clinical information about the disease, the practitioner is required to disclose the name, age, sex and address of the current location of the patient. While disclosure is required by the Act and Regulations in the public interest, there is still a requirement to respect privacy and limit disclosure to appropriate individuals only (see for example Section 12 of the 1988 Regulations).

Section 27 of the Health and Safety at Work etc. Act 1974 gives powers to the Health and Safety Commission to obtain any information which the Commission or an enforcing authority acting on behalf of the Commission needs for the discharge of its functions.

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985 (RIDDOR) made under the Health and Safety at Work etc. Act requires statutory notification of industrial accidents and diseases.

Other legislation requiring disclosure is not specific to health information. For example, section 18 of the Prevention of Terrorism Act 1989; and Section 172 of the Road Traffic Act 1988.

3.2 European Convention on Human Rights and Biomedicine[10]

The European Convention on Human Rights and Biomedicine requires respect for the "dignity and integrity of all human beings" (Article 1) and that "the interests and welfare of the human being shall prevail over the sole interest of society or science" (Article 2). Article 5 requires that appropriate information is given to people as to the purpose and nature of a health intervention and that it may only be carried out after free and informed consent is given. Consent may also be freely withdrawn at any time. The Convention also specifies standards for seeking informed consent from minors, people with mental illness and others who are not able to give consent. Other Articles relate to specific areas of biomedicine.

However, the UK has not yet signed or ratified this Convention. Even if it does so, it may not become part of domestic law directly. Its domestic force, therefore, may only be indirect even if it is ratified. For example, it may be implicated in EC Directives, which are binding. It can also be effective in that the EC will not fund medical research which does not comply with the Convention.

[10] Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo, 4.IV.1997

3.3 Guidance

3.3.1 The Caldicott Report[11]

The Caldicott Committee developed six general principles which provided various protections for patient-identifiable information:

1. Justify the purpose(s)
2. Don't use patient-identifiable information unless it is absolutely necessary
3. Use the minimum necessary patient-identifiable information
4. Access to patient-identifiable information should be on a strict need-to-know basis
5. Everyone with access to patient-identifiable information should be aware of their responsibilities
6. Understand and comply with the law

The Committee recommended that someone in each organisation handling patient information should be responsible for ensuring that the organisation complies with legal requirements. The Caldicott Committee also recommended that patients should be provided with an explanation of the NHS policy on data protection.

3.3.2 General Medical Council (GMC) guidelines

In its professional guidance on data protection, the GMC has stated that patients have a right to expect that information about them will be held in confidence by their doctors.[12] The GMC recognises that confidentiality is central to trust between doctors and patients and that, without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care.

The GMC recognises that where patients have consented to treatment, express consent is not usually needed before relevant personal information is shared to enable the treatment to be provided. This is justified because doctors cannot treat patients safely, nor provide the continuity of care, without having relevant information about the patient's condition and medical history. The GMC does, however, require that patients are made aware that personal information about them will be shared within the health care team and, if appropriate, with another organisation or agency providing health or social care and of the reasons for this disclosure. If, however, the patient objects to disclosure, even if required for clinical care, then the GMC states that these wishes should be respected. In cases where it is not practicable to obtain consent, or the patient is not competent to give consent or, exceptionally, in cases where patients withhold consent, the GMC permits personal information to be disclosed in the public interest where the benefits to an individual or to society of the disclosure outweigh the public and the patient's interest in keeping the information confidential.

The GMC recognises that professional organisations and government regulatory bodies which monitor the public health or the safety of medicines or devices, as well as cancer and other registries, rely on information from patients' records for their effectiveness in safeguarding the public health. The GMC states that doctors should co-operate with such

[11] The Caldicott Committee. Report on the review of patient-identifiable information. NHS Executive, December 1997

[12] General Medical Council. Confidentiality: Protecting and Providing Information. London: GMC, 2000.

data collection by providing relevant information wherever possible, as disclosure is unlikely to have personal consequences for the patient. In these circumstances, doctors should still obtain patients' express consent and/or anonymise the record. The GMC believes that the automatic transfer of personal information, whether by electronic or other means, before informing the patient, is unacceptable save in the most exceptional circumstances. Only where it is essential for the purpose may identifiable records be disclosed. Such disclosures must be kept to the minimum necessary for the purpose. In all such cases the GMC require that patients have been told, or have had access to written material informing them of the potential for such disclosure.

3.3.3 The House of Lords Select Committee on Science and Technology[13]

In evidence on behalf of the GMC to the House of Lords Select Committee on Science and Technology, Professor Hilary Thomas claimed that the GMC guidelines on cancer registries had been misinterpreted and that it was not their intention that all patients had to sign consent forms or receive long explanation. However, the GMC believed that patients had a right to know the information was being used, and that it was feasible to identify suitable opportunities to provide this explanation. The House of Lords Select Committee recommended that the GMC should clarify its guidelines accordingly as a matter of urgency.

The House of Lords Select Committee was concerned that there were several ways in which the Data Protection Act 1998 could seriously inhibit legitimate medical research. The Committee suggested that the requirement to use personal data for only specified purposes might be difficult because it may be impossible to foresee the full extent of future uses of data. Arguably, this fails to take account of the fact that the Directive (see Recitals 39 and 40), expressly permit disclosures for unforeseen purposes without informing the data subject if this would be impossible or involve a disproportionate effort. Whatever caveats (see above) there might be about the Data Protection Act's implementation of the Directive's Article 10 these do not extend to Schedule 1, Part II, Paragraph 2(1) of the Data Protection Act's specification that those who obtain data from the data subject do not have to inform of the purposes of processing, etc., where this would be impracticable, *if* impracticability refers to unforeseeability.

The Select Committee distinguished between data collected for a specific purpose directly either from patients or participants in research projects and use of existing data for purposes other than those for which they were originally obtained. The primary collection and use of data would always require individual consents, unless there was a statutory requirement. However, the Select Committee thought that different considerations applied to the secondary use of data because the passage of data may make it impossible or impracticable to obtain individual consent, and public interest may mean that it will be essential to achieve as near full coverage of the population as possible.

The House of Lords report also recommended that the Government establish a Medical Data Panel to provide a single, clear process for approving projects involving the secondary uses of NHS and medical research data.

[13] House of Lords Select Committee on Science and Technology. Human Genetic Databases: Challenges and Opportunities. Fourth Report 2000/2001 Session.

The Select Committee suggested that there was a duty for people to participate in research and that it should be "pointed out that ... the medical treatment that all receive is based on studies carried out on very many earlier patients and that the request is for them to provide similar help for future generations".

3.3.4 Medical Research Council (MRC) guidelines

The MRC has produced guidelines on the use of personal information in medical research that researchers supported by the MRC are expected to follow as a condition of funding.[14] The general principles underlying the guidelines are consistent with those in the Data Protection Act, NHS policies and other professional guidance. For example, the importance of confidentiality; provision of information on how data will be used; explicit informed consent wherever practicable; and anonymisation as far as is possible. The MRC guidelines contain a number of research scenarios that are offered as examples of how their ethical and legal principles translate into practice.

The MRC recognises that situations arise in which medical research questions can only be answered using personal medical information, but where it is not feasible to seek consent. Based on ethical and legal advice, the MRC believes that, in some circumstances, it would be justifiable to use personal information, and disclose it to a limited number of other people, without consent.

The MRC specified principles governing research using information without consent. Hospitals and practices involved in the research must develop procedures for making patients aware that their information may sometimes be used for research, and explaining the reasons and safeguards. When consent is impracticable, confidential information can only be disclosed without consent if the likely benefits to society outweigh the implications of loss of confidentiality. It would also only be permissible if there is no intention to feed back information to the individuals involved or take decisions that affect them and there are no practicable alternatives of equal effectiveness. The infringement of confidentiality should be kept to a minimum.

In guidelines relating to the use of human tissues and biological samples in research,[15] the MRC has recommended that biological material donated for research be treated as gifts or donations, although gifts with conditions attached, so underlining the altruistic motivation for participation in research. The MRC guidelines required that donors understand what the sample is to be used for (including research that cannot be foreseen) and how the results of the research might impact on their interests. A two-part consent process was recommended, the donor being first asked to consent to the specific experiment(s) already planned, and then to give consent for storage and future use for other research. The MRC suggested that unless the sample was to be anonymised, it would not be acceptable to seek unconditional blanket consent, for example using terms such as "all biological or medical research". It was recommended that future research should be explained in terms of the types of studies that could be investigated, and the possible impact of the research on them personally.

[14] Medical Research Council. Personal Information in Medical Research. London: MRC, 2000
[15] Medical Research Council. Human tissue and biological samples for use in research: Operational and Ethical Guidelines. London: MRC, 2001.

As the NHS moves towards seeking explicit consent for use of personal health information the two-part consent approach could be adopted: firstly for use of information for clinical care, and secondly for other potential uses. For the same reasons given in the MRC guidelines on tissue sample, unconditional blanket consent for any NHS use of health information may not be adequate, and patients would require more detail about potential secondary uses.

3.4 Events driving policy

3.4.1 Public Inquiries at the Bristol Royal Infirmary[16] [17] and The Royal Liverpool Children's Hospital[18]

The development of these various professional guidelines has been in part driven by the need to comply with legislation. However, public outcry following disclosure of lack of professional respect for patient dignity has also been very influential. Two of the more high profile of these scandals resulted in the establishment of Public Inquiries. A Public Inquiry was established in June 1998 to consider the paediatric cardiac service provided at the Bristol Royal Infirmary, following disclosure of mortality rates significantly in excess of the national average and concerns about competency of staff performing these operations. The Royal Liverpool Children's Inquiry was established in December 1999 to investigate concerns relating to the removal, retention and disposal of human tissue, including organs of the body, from children following post mortems performed at the Royal Liverpool Children's Hospital.

The prevailing view in the medical and scientific community, as perceived by the Bristol Inquiry, was that the taking and using human material were important for medical development, research and education and hence was sufficient justification in itself. The Panel thought that the medical-scientific community did not appreciate that there might be ethical and legal issues which needed to be addressed. The fact that the public were unaware of this standard practice was unacknowledged or ignored. The Bristol Inquiry believed that obtaining consent should be seen as a process, and not just the signing of a form. The Bristol Inquiry was told by a wide cross-section of patient groups that "there is still an image of patients as passive recipients *for* whom rather than *by* whom decisions are made". The Report stated that "a relationship based on respect will only flourish if there is a foundation of honesty in the exchanges between patient (or parent) and professional".

The Bristol Report recognised that information should be given in a variety of forms (written, oral, audio-visual); it should be given in stages and reinforced over time; and tailored to the needs, circumstances and wishes of the individual. The Liverpool Inquiry was critical of the consent forms that they reviewed and stated that "none of the forms we have seen provide the basis for clinicians to obtain fully informed consent and properly to set out and record the decision. Clear information language is essential. It appears that the

[16] The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary. Interim Report: Removal and retention of human material (chair: Professor Ian Kennedy). May 2000

[17] Learning from Bristol: The report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 -1995 (Chairman: Professor Ian Kennedy) Command Paper: CM 5207. London: The Stationery Office, 2001

[18] The Royal Liverpool Children's Inquiry Report. (Chairman: Mr Michael Redfern QC). London: Department of Health, 2001

more official the form, the less efficient it is in practice." The Liverpool panel was concerned about the wording of the Human Tissue Act 1961, and the Panel recommended that the Act "be amended to provide a test of fully informed consent". There were particular criticisms of the medical profession's interpretation of 'reasonable enquiry' and what should be considered 'practicable'.

The Bristol Panel recognised that pressures of time are a factor inhibiting good communication and that there is a relationship between the time to communicate and the resources available to the NHS. The Liverpool Inquiry recognised that its proposed consent process would be longer than that currently used, but did not address the cost of this additional time commitment. Both the Bristol and Liverpool Inquiries recommended that health professionals receive training on how to seek fully informed consent.

Chapter 4

Public and patient attitudes to the use of their health information: a review of the literature.

4.1 Summary

Objectives: To critically review the findings from published studies examining the attitudes of both patients and the general public to the use of their health information.

Design: A review of published English language literature from 1966 until February 2002

Data sources: 110 studies were identified by searching electronic databases (Medline 1966 to 2002/02, CINAHL 1982-2002/02, and Embase 1980-2002/02). These were rated and 26 met the inclusion criteria. Subsequent hand searching found an additional 18 relevant papers.

Main outcome measures: Attitudes to who has access to health information, the purpose for which access is needed, the sensitivity of the health information and knowledge of individual rights surrounding health information.

Results: Public attitudes to the use of their own health information are related to their attitudes to confidentiality and privacy, together with their attitudes towards, and expectations of, healthcare and non-healthcare professionals who might access their information. These attitudes may vary depending on the sensitivity of the information, the mechanism of recording this information, the healthcare setting and the potential uses to which their information may be put.

Conclusions: Although there is no evidence from the published literature as to which of these factors the public perceive to be the most important, public attitudes are different to professional attitudes to patient information, which may be a cause for conflict. In many cases the public may not even have considered the issues surrounding their health information.

4.2 Background

Data protection legislation and professional guidelines in a number of countries have been criticised by researchers and epidemiologists who claim that there will be disastrous consequences for epidemiological activities such as cancer registration[19] and communicable disease surveillance. There is an expectation that if the public are asked to give consent, then they will either explicitly refuse or not respond to requests for consent. As a consequence this would introduce significant volunteer bias into databases, and limit the utility for public health purposes. The Data Protection Act 1998, does limit the requirement to obtain consent or to inform data subjects according to what is 'practicable', 'reasonable' or requires 'disproportionate effort'. Empirical evidence of adverse consequences and the difficulties involved in approaching patients would be required to justify use of personal data without seeking consent or giving data subjects an opportunity

[19] *Health Authority v X, 2001.*

to object. The aim of this paper is to review the literature to assess public attitudes to privacy and use of personal health information.

4.3 Search strategy

The following electronic databases were searched: Medline 1966 to 2002/02, CINAHL 1982-2002/02, and Embase 1980-2002/02. Searches were restricted to English language papers, and the keywords used were: "attitude", and "health information" or "medical records", and "public" or "patient", and "privacy" or "confidentiality".

110 references were found and their titles and abstracts reviewed to identify 26 suitable papers. Hand searching, searching of grey literature and canvassing of expert opinion identified a further 18 papers so in total 44 papers were reviewed. Papers were included only if they reported original research that explored public or patient attitudes to the use of, or limits to, the use of their own health information. Theoretical discussion papers were excluded. In view of the small number of original research papers found all papers were reviewed irrespective of sample size or methodology. A qualitative analysis of the studies was undertaken.

4.4 Results

Public attitudes to the use of their own health information are related to their attitudes to confidentiality and privacy, together with their attitudes towards and expectations of healthcare and non-healthcare professionals who might access their information. These attitudes may vary depending on the sensitivity of the information, the mechanism of recording this information, the healthcare setting and the potential uses to which their information may be put. There is no evidence from the published literature as to which of these factors the public perceive to be the most important.

4.4.1 Knowledge of rights, privacy and confidentiality

Constitutional rights, including rights to privacy are a key concern to 85% of Americans[20] and much of the literature on public attitudes to data protection has been conducted in the USA. Thirty percent of Americans were termed 'privacy fundamentalists', those people who place high value on privacy and 55% 'privacy pragmatists', who were able to trade off privacy for other goods.[21] The Internet has highlighted differences between individual attitudes to health information compared to other information. 54% of Internet users have shared information and yet of those defined as health seekers only 21% have provided an e-mail address, 17% a name or other identifying information, because 80% want to obtain

[20] Gostin L, Turek-Brezina J, Powers M, Kozloff R, Faden R, Steinauer D. Privacy and security of health care information in a new health care system. JAMA 1993;270(20):2787-2493.
[21] Equifax-Harris. Equifax-Harris Mid decade consumer privacy survey 1995. New York: Louis Harris and associates, 1995. In Detmer D. Your privacy or your health – will medical privacy legislation stop quality health care. Int J Qual Health Care 2000;12:1-3.

health information anonymously.[22] Individuals were particularly concerned if their health insurers found out about their online health activities.[23]

Although 89% of American High School pupils could correctly identify the 'principle' of confidentiality this was simply identifying the correct definition of the word 'confidential' from four alternative definitions without any assessment of ability to use the principle correctly.[24] A third of the pupils were aware of a right to confidentiality for specific health issues, but at least half of the pupils admitted they did not know of their rights. In the UK 92% of teenagers agreed with the definition of confidentiality as 'what you tell your doctor should not be discussed with other people without you knowing'.[25] Although only two thirds believed this is what their GP did, this had no effect on their consultation behaviour.

Among American physicians, 53% reported discussing confidentiality with their adolescent patients, 21% discussed confidentiality with all their young patients whilst 11% did not discuss it at all.[26] Female doctors were more likely to discuss confidentiality than their male counterparts.

It is not only adolescents that struggle with confidentiality. Psychiatric patients in Oregon valued medical confidentiality highly but lacked adequate information as to their rights.[27] They were much more likely to approve release of information for medical purposes than non-medical purposes. Only a third of patients had an accurate knowledge of who had access to their records, many thought erroneously that only doctors and nurses had access, and fewer still knew of any legal protections of confidentiality. Many felt that the release of health information was mandatory prior to receiving health care and almost all patients felt the release of health information was mandatory for non-medical purposes and only a third signed for the release of information without any sense of coercion. Parents also struggle, with only 22% of Minnesota parents knowing their parental rights and responsibilities when it came to access to information and medical records of their children.[28]

4.4.2 Health professional groups and need to know

Public attitudes towards who should have access to their health information is closely linked with the 'need to know' of the individual and the perceived extent to which that

[22] Pew Internet and Life Project. The Online Health Care Revolution: How the Web helps Americans take better care of themselves. Pew Internet and Life Project 2000. http://www.pewinternet.org/reports/toc.asp?Report=26 (last accessed 24 April 2002).
[23] California Health Care Foundation. Ethics Survey of Consumer Attitudes about Health Web Sites (2nd Edition) California Health Care Foundation 2000. http://www.chcf.org/topics/view.cfm?itemID=12493 (last accessed 24 April 2002).
[24] Cheng T, Savageau J, Sattler A, DeWitt T. Confidentiality in Health Care: a survey of knowledge, perceptions and attitudes among high school pupils. JAMA 1993;269(11):1404-7.
[25] Churchill R, Allen J, Denman S, Williams D, Fielding K, Von Fragstein M. Do the attitudes and beliefs of young teenagers towards general practice influence actual consulting behaviour? Br J Gen Pract 2000;50: 953-7.
[26] Ford C, Millstein S. Delivery of Confidentiality Assurances to Adolescents by primary care physicians. Arch Pediatr Adolesc Med 1997;151:505-509.
[27] Kinzie J, Holmes J, Arent J. Patients' release of medical records: involuntary, uninformed consent. Hospital and Community Psychiatry 1985;36:843-7.
[28] Cutler E, Bateman M, Wollan P, Simmons P. Parental knowledge and attitudes of Minnesota Laws concerning adolescent medical care. Pediatrics 1999;103(3):582-587.

individual is bound by confidentiality.[29] In one UK general practice all the 39 patients interviewed agreed that all the doctors in the practice should have some degree of access to their medical records, but only their usual GP should have unlimited access. A minority felt that other primary care staff (nurses and midwives) should have no access whatsoever, because they were not perceived to be bound by confidentiality to the same extent as doctors. In some cases it was felt that the doctor should decide whether or not the nurse was responsible enough to have access to the records.

A larger UK study involving 1,000 patients replicated these findings.[30] Over 94% of respondents thought their usual doctor had access and 98% felt they should have access to all their medical records. These figures were lower (76% and 84%) for other doctors in the practice. However when it came to other staff less than half (43%) thought the practice nurse had access to their records and even fewer 34% believed that they should have access to all their notes with 40% feeling that access to part of the record would be acceptable. Again patients were less enthusiastic at other professional members of the primary health care team (district nurse, health visitor, midwife, physiotherapist and occupational therapist) having access to their records. 12-14% of individuals thought they currently had access to their notes with 11-20% agreeing that they should have access to all their records, and 22-37% agreeing access to part of their record. 75% of men believed that the midwife does not and should not have access to their medical records. Receptionists were felt to have more access than they should, but medical secretaries were perceived to have had special training and therefore were bound by the same professional rules of conduct as 'medical' staff.[29]

Australian chemists were perceived by adolescents to raise particular concerns over their ability to maintain confidentiality where sexual health information and condoms are involved.[31] These concerns may arise from the small communities that the chemists in this study were working in, where chemist staff may be family friends or relatives, rather than anything intrinsic to chemists. In Belgium, worries about confidentiality breaches to parents were also cited as a reason for teenagers delaying attending a doctor for contraceptive advice.[32] 25% of American high school pupils would forgo healthcare for this reason.[24]

4.4.3 Doctors and non-clinicians

This compares with experience in South Australia where 85% of 3,000 people asked reported that they were confident or very confident that doctors and hospitals were responsible data custodians, but almost 10% were not very or not at all confident in their ability.[33] South Australian patients were less likely share their patient held record

[29] Carmen D, Britten N. Confidentiality of medical records: the patient's perspective. Br J Gen Pract 1995;45:485-488.
[30] Wardman L, Rout J, Ormiston P, Nagle J, Munshi S, Kirby A et al. Patient's knowledge and expectations of confidentiality in primary health care: a quantitative study. Br J Gen Pract 2000;50:901-902.
[31] Warr D, Hillier L. 'That's the problem with living in a small town': privacy and sexual health issues for young rural people. Aust J Rural Health 1997;5:132-139.
[32] Peremans L, Hermann I, Avonts D, Van Royen P, Denekens J. Contraceptive knowledge and expectations by adolescents: an explanation by focus groups. Patient Education and Counseling 2000;40:133-140.
[33] Mulligan E. Confidentiality in health records: evidence of current performance from a population survey in South Australia. Med J Aust 2001;174:637-640.

information with non-clinicians.[34] Doctors are thought to protect personal information (and therefore confidentiality) better than other non-clinical professional groups i.e. the insurance industry, banks, the government, the news media or any other institution.[35] However, of the 2,131 Americans surveyed, 17% thought that doctors and 23% thought that hospitals should be doing more to protect the confidentiality of their information.

4.4.4 Expectations of patients

3,540 patients from 8 European countries (UK, Norway, Sweden, Denmark, The Netherlands, Germany, Portugal and Israel) were asked about their priorities with regard to general practice. Between 77- 91% of patients in the countries surveyed felt that a GP should be able to guarantee confidentiality of information of all his patients.[36] The doctor-patient relationship may also be threatened by questioning the doctor, which may arise from issues of privacy or confidentiality.[29,37]

The perceived level of anonymity is important for patients e.g. sperm donors,[38] but also for the perceived content of the health record. [29] In many cases confidentiality is maintained by 'indifference to anonymous patients' and may account for the public being less worried about their information in hospital than in general practice, since general practice records tend to carry much more personal and social information.[29] Many of those concerned about the content of the information were not concerned by who has access to it, providing factual rather than subjective information was recorded.[29] However, Siegler demonstrated in a university-affiliated teaching hospital in the US that at least 25, and up to 100, health care professionals and administrative staff had access to a patient's medical record.[39] If the public were aware of the large number of people who have access to their information they might be more concerned about both access and content.

Patients have different expectations of confidentiality than 'house staff' and medical students. Patients have either a stricter definition of confidentiality than medical staff or they expect a tighter adherence to the principle.[40] When 108 patient-reported confidentiality breaches were investigated 48 were legally defensible breaches i.e. information passed from one treating practitioner to another without patient authorisation, 32 were legally indefensible disclosures and 28 disclosures could not be analysed. [15] Of those who had suffered a breach, legitimate of not, 58 believed that direct harm to them had resulted from the breach including embarrassment, arguments, and loss of trust in medical services.

[34] Liaw ST. Patient and general practitioner perceptions of patient-held health records. Fam Pract 1993;10(4):406-415.
[35] News and Notes. Most people think doctors do a good job of protecting the privacy of their records. Hospital and Community Psychiatry 1979; 30(12):860-1.
[36] Grol R, Wensig M, Mainz J, Ferreira P, Hearnsahw H, Hjortdahl et al. Patients priorities with respect to general practice care: an international comparison. Fam Pract 1999;16:4-11.
[37] Ornstein S, Bearden A. Patient perspectives on computer-based medical records. J Fam Pract 1994;38(6):606-10.
[38] Robinson J, Forman R, Clark A, Egan D, Chapman M, Barlow D. Attitudes of donors and recipients to gamete donation. Hum Reprod 1991;6(2):307-9.
[39] Siegler M. Confidentiality in medicine – a decrepit concept. N Engl J Med 1982;307:1518-21.
[40] Weiss BD. Confidentiality expectations of patients, physicians and medical students. JAMA 1982;247:2695-2697.

4.4.5 Content of records and sensitivity of information

Most patients think that the decision as to what health information was recorded rested with the doctor.[29] There is a perceived need for negotiated entries over sensitive issues as 11% of respondents in a US Louis and Harris Associates survey thought that doctors' questions were too personal.[35] This perception may arise because doctors are asking very personal questions (e.g. about relationships) which are not perceived as necessary for clinical care or because patients do not appreciate how personal information may be used in their care or the care of other people. Sensitive information is more likely to be disclosed if confidentiality is assured. [41]

Sexual health issues seem to be a particular concern. Of 102 self identified gay, lesbian and bisexual individuals aged between 18-23, two thirds never discussed sexual orientation with health care providers, less than half remembered being informed about confidentiality but those who did remember being informed were three times as likely to have discussed issues of sexual orientation.[42] Of those who had not been informed over 70% said they would discuss issues to do with sexuality if informed.

The information may be so sensitive that patients feel unable to give information to their usual health care provider, may seek health care from other providers or give false information. Whereas 86% of high school pupils in the USA would seek health care from their family physicians for physical illnesses, this fell to 57% for care related to pregnancy, HIV or substance misuse because they felt their doctors were unable to maintain confidentiality. [24] Of men at high risk from HIV, 63% would not test if name based reporting were required.[43] If the benefits of name based testing were explained this was reduced to 50%. However, even of those who were tested 42% would give a false name. In Germany, Kochen found in his sample of over 400 individuals diagnosed with HIV that although for the majority (91%) of individuals the GP was aware of their HIV status, over a third of patients did not routinely inform other doctors or medical staff about their status.[44] Individuals had more confidence in specialist centres than general practices to maintain confidentiality and this was related to the level of anonymity and confidence in the medical practitioner. In Uganda, confidentiality breeches are a major concern for women considering voluntary counselling and testing for HIV.[45] In Maryland USA, 50% of blood donors indicated they would provide less accurate medical and personal information if the blood donating agency were required to divulge previously confidential information.[46]

[41] Ford C. Millstein S, Halpern-Felsher B, Irwin C. Influence of physician confidentiality assurances on adolescent's willingness to disclose information and seek future health care: a randomised controlled trial. JAMA 1997;278(12):1029-1034.
[42] Allen L, Glicken A, Beach R, Naylor K. Adolescent health care experience of gay, lesbian, and bisexual young adults. J Adolesc Health 1998;23:212-220.
[43] Woods W, Dilley J, Lihatsh T, Sabatino, J, Adler B, Rianldi J. Name-based reporting of HIV-positive test results as a deterrent to testing. Am J Public Health 1999;89:1097-1100.
[44] Kochen M, Hasford J, Jäger H, Zippel S, L'Age M, Rosendahl C, et al. How do patients with HIV perceive their general practitioners? BMJ 1991;303:1365-8.
[45] Pool R, Nyanzi S, Whitworth J. Attitudes to voluntary counselling and testing for HIV among pregnant women in rural south-west Uganda. AIDS Care 2001;13(5):605-615.
[46] Banks H, Williams A, Nass C, Gimble J. Changes in intention to donate blood under hypothetical condition of reduced confidentiality. Transfusion 1993;33:671-674.

There has only been limited research on the acceptability of communicable disease contact tracing for the index patient, the contact and the staff involved. Cowan et al.[47] summarised the research by suggesting that acceptability seemed determined by two factors: maintenance of confidentiality and availability of treatment. For example, Cowan et al. quoted a U.S. study[48] of 25 women with HIV infection, which found that 68% were willing to disclose the names of their sexual partners to the Health Department if confidentiality was assured. In practice, however, only 24% of the women in the study had informed partners that they had had prior to their HIV diagnosis and 52% had told partners subsequent to diagnosis. Another U.S. study with 132 partners of HIV infected patients used an anonymous, self-completion questionnaire to assess their attitudes to being told by the public health department that they were at risk. Most (87%) thought that the public health department were correct in disclosing their exposure risk and 97% thought that notification should continue. Pavia et al.[49] noted that partner notification was less successful in white men who have sex with men, compared with other groups. They concluded that this may be due to distrust of public health authorities and that homosexual and bisexual men preferred to notify partners without the involvement of public health workers. Fenton et al.[50] surveyed senior consultants in 59 genitourinary medicine clinics in England. There was concern that partner notification, if handled inappropriately, could lead to identification and ostracisation of individuals from their communities. Although 77% of consultants stated that HIV partner notification had become an accepted part of their clinic's practice, all respondents thought that there were factors which hindered this process. The most common limiting factor (mentioned by 73%) was health care worker's concerns about the unacceptability of HIV partner notification to patients.

4.4.6 Use of health information

The public may be happy about their information being used for research in general terms, with 77% of a Health Maintenance Organisation (HMO) membership agreeing to the use of their information in this way.[51] Most of those who agreed were highly educated and predominantly white and felt that participation in research had a positive effect on their health care. However, the subject area for research is crucial. When study specific consent was required for an epilepsy study using medical records the rates of consent fell to 19%,[52] as opposed to in excess of 90% where study-specific consent was not required.[53] Refusal rates were highest in patients with mental health concerns, trauma or eye care and among women aged 39 or older.

[47] Cowan FM, French R, Johnson AM. The role and effectiveness of partner notification in STD control: a review. Genitourinary Medicine 1996; 72(4): 247-252.
[48] Chervenak JL, Weiss SH. Sexual partner notification: attitude and actions of HIV-infected women. Presented at V International Conference on AIDS, Montreal, June 8, 1989, Abstract Th.D.P.4.p 759.
[49] Pavia AT, Benyo M, Niler L, Risk I. Partner notification for control of HIV: results after 2 years of a statewide program in Utah. American Journal of Public Health 1993; 83: 1418-1424.
[50] Fenton KA, Copas A, Johnson AM, French R, Petruckevitch A, Adler MW. HIV partner notification policy and practice within GUM clinics in England: where are we now? Genitourinary Medicine 1997; 73(1): 49-53.
[51] Purdy S, Finkelstein J, Fletcher R, Christiansen C, Inui T. Patient participation in research in the managed care environment: key perceptions of members in an HMO. J Gen Intern Med 2000;15:492-5.
[52] McCarthy D, Shatin D, Drinkard C, Kleinman J, Gardner J. Medical records and privacy: empirical effects of legislation. Health Serv Res 1999;34(1):417-425.
[53] Yawn B, Yawn R, Geier G, Xia Z, Jacobsen S. The impact of requiring patient authorization for use of data in medical records research. J Fam Pract. 1998;47(5):361-365.

Health information is used as part of physician peer-review. 64% of 648 patients surveyed disapproved of their records being read by outside physicians without their permission, as there was no attempt to seek individual patient consent or to anonymise the records prior to the review.[54] Yet when asked about an audit of their medical records the same percentage (64%) agreed. [55] Agreement to be audited varied markedly and depended on the physician involved, and individuals with 'intimate' diagnoses (e.g. gynaecological diagnoses and examinations) were more likely to consent to a review of their records than those with less 'intimate' diagnoses (tonsillitis and hypertension).

Over 20% of Swedish patients found it difficult to decline being involved in medical student teaching. [56] Yet in New Zealand 73-96% of members of the public were strongly in favour of taking part in medical student teaching depending on the medical setting.[57] The percentage who would agree fell if the setting were a sexually transmitted disease clinic. Almost all the women and a third of the men would expect to be told about teaching involvement at booking if they were receiving care from the private sector. In the UK consent to have a medical student at the consultation was more likely to be granted for less sensitive consultations, but also when there was only to be limited discussion between the doctor and the student once the patient had left the room.[58]

Cancer registries use information for public health monitoring. A natural experiment of white middle aged women in the US found that enrolment rates for a clinical trial were no different if information from a cancer registry was used to identify women compared with an indirect approach via a physician.[59] Only 2 of 351 women approached directly complained about the approach, while 2 potential subjects of the 65 women approached indirectly felt pressurised to participate because the approach came through their physician.

4.4.7 Electronic records

Computerised methods of recording information are felt to present a much greater threat to privacy and confidentiality than written records.[29] Although many of the issues are the same for paper and electronic records the public appear to be more engaged with the electronic debate.

4.4.8 Areas where confidentiality may be unwittingly breached

Although confidentiality is valued highly by patients, Luke suggested that it may be foregone for the sake of improved quality of care as the majority of parents of children on a paediatric ward were happy for their children's notes to be kept at the end of their beds,

[54] Dodek D, Dodek A. From Hippocrates to facsimile: protecting patient confidentiality is more difficult and more important than ever before. CMAJ 1997;156(6):847-852.
[55] Neuhaus E, Lyons T, Payne B. Patient responses to request for written permission to review medical records. Am J Public Health 1976;66(11):1090-2.
[56] Westbeg K, Lynøe N, Lalos A, Löfgren M, Sandlund M. Getting informed consent from patients to take part in the clinical training of students: randomised trial of two strategies. BMJ 2001;323:488.
[57] Grant V. Patient involvement in clinical teaching. J Med Ethics 1994;20:244-250.
[58] O'Flynn N, Spencer J, Jones R. Consent and confidentiality in teaching in general practice: survey of patient's views on the presence of students. BMJ 1997;315:1142.
[59] Sugarman J, Regan K, Parker B, Bluman L, Schildkraut J. Ethical ramifications of alternative means of recruiting research participant from cancer registries. Cancer 1999;86(4):647-651.

despite the fact that the issue of confidentiality was not specifically raised. [60] There are other potential breeches of confidentiality that patients might not realise, including the overhearing of patient specific information on ward rounds or in elevators.[61,62] A minority of parents (10 out of 24) had concerns over confidentiality within a paediatric grand round.[63] Publication of identifiable information in medical journals has in the past caused distress to individuals.[64]

4.5 Discussion

The search strategy employed found relatively few original research papers. Moreover, the majority of the research is from America and applying these findings to the UK is difficult and exacerbated by the fact that American Health Maintenance Organisations rely on health information for billing information. Other drawbacks of the research are that many of the studies are small and non-response rates are high, and non-responders may have markedly different attitudes to health information than responders. The majority of excluded literature focussed on the doctor's role in disclosing confidential information to third parties, together with hypothetical attitudes taken by the public to their health information. There has been an increase in published literature on public attitudes to health information in recent years through issues surrounding HIV and, in part, the emergence of electronic methods of information recording, which has brought this issue to greater prominence.[65] Obvious gaps in the research remain, particularly concerning the effects of age, gender and social group on public attitudes. The debate has also been restricted to the attitudes to those with more traditional roles in healthcare, such as doctors and nurses as opposed to the role of public health practitioners, managers and those with close partnerships with the NHS.

4.6 Conclusion

Public attitudes to the use of their own health information are related to attitudes to confidentiality and privacy, together with their attitudes towards and expectations of healthcare and non-healthcare professionals who might access their information. Attitudes vary depending on the sensitivity of the information, the mechanism of recording this information, the healthcare setting and the potential uses to which the information may be put. However there is no evidence from the published literature as to which of these factors the public perceive to be the most important. Public attitudes to their health information may be different to professional attitudes to patient information, which may be a cause for conflict. In many cases the public may not even have considered the issues surrounding their health information.

[60] Luke S, Gallagher A, Lloyd B. Staff and family attitudes to keeping joint medical and nursing notes at the foot of the bed: questionnaire survey. BMJ 1999;319:735.
[61] Rylance G. Privacy, dignity and confidentiality: interview study with structured questionnaire. BMJ 1999;318:301.
[62] Ubel P, Zell M, Miller D, Fischer G, Peters-Stefani D, Arnold R. Elevator talk: observational study of inappropriate comments in a public space. Am J Med 1995;99(2):190-194.
[63] Birtwistle L, Houghton J, Rostil H. A review of a surgical ward round in a large teaching hospital: does it achieve it's aims? Med Edu 2000; 34: 398-403.
[64] Smith R. The importance of patient's consent of publication. BMJ 1996; 313: 16.
[65] Whetten-Goldstein K, Nguyen T, Sugarman J. So much for keeping secrets: the importance of considering patients' perspectives on maintaining confidentiality. AIDS Care 2001;12(4):457-466.

Chapter 5

What do the general public think about the use of their personal health information?

A quantitative survey of adults across Great Britain

5.1 Summary

Objectives: To assess public attitudes to protection and use of personal health information by the NHS.

Design: Subjects were asked during an interview to assess a selection of 10 out of 200 vignettes. Each vignette contained four elements: a category of individual; access to some or all of the health record; specified purpose; and level of patient identifier. Subjects were asked to say how happy they would be to allow access to their health record in the circumstances described. Linear regression was performed to analyse the main determinants of happiness to allow access to personal information.

Setting: 180 sampling points across Great Britain.

Participants: 3921 members of the public aged 15 years or over.

Results: The public were generally happy to provide access to health information. For almost a third of vignettes, subjects said that they would be very happy to allow access to their health information. 9.1% of subjects said that they would be very happy to allow access within all of the vignettes that they were asked to assess. There was however, a significant minority of responses (11.6%) to vignettes where subjects said that they would be very unhappy to allow access. In addition 2.1% of individuals said that they were very unhappy with all of the vignettes presented to them. Individuals from higher social groups, older people and males were more likely to be happy about access to their health information. The individual requesting information was the most important factor determining permission to access health information. Subjects were happier to release anonymised rather than personally identifiable data.

Content of the information to be released did not seem to be particularly important, even when the health record contained sensitive information. With the exception of teaching students, the use of the information was not an important determinant of consent.

Conclusions: Despite a high level of support for use of health information in most circumstances, this does not mean that patients do not want to be asked for consent, nor that the views of the small minority can be ignored.

5.2 Background

The aim of the UK health information strategy[66] is to ensure that information is used to help patients receive the best possible care. The data required are usually anonymised and aggregated, but sometimes personal identifying information is also needed. The strategy aims to enable NHS professionals to have the information that they need both to provide that care and to play their part in improving the public's health. The Strategy, however, recognises that these developments must be made against the need to preserve the confidentiality of patient information which is emphasised as being of 'paramount importance' within the strategy. There is an expectation within the Strategy that many patients would appreciate the importance of good information systems in order to provide high quality health care. However, the literature review (chapter 4) found very little quality research, especially performed within the UK, on public opinion on this subject. This research was commissioned to assess whether the public were indeed happy to allow the NHS to use their personal health information; and to identify the characteristics of individuals least happy to allow access to health information; and the contexts of information use that cause most concern within the public.

5.3 Methods

Two hundred vignettes were devised with different permutations of person requesting information; reason why information is requested; content of the information; and level of personal identification of information required:

Person requesting information: a doctor in the hospital; a nurse in the hospital; your GP; a practice nurse working with your GP; a receptionist working in your local GP clinic; a hospital ward receptionist; a NHS manager; a physiotherapist; a researcher; a social worker employed by the local council.
Reason information requested: as part of the health care that you are receiving; in order to monitor the quality of care that patients like you are receiving; as part of a research project on a new medical treatment; in order to monitor that NHS money is being appropriately spent; to use during teaching of students; in order to assess the performance of doctors; in order improve the public health by monitoring spread of a flu epidemic.
Content of the information: information only about your current health problem; all your past medical history; all your past medical history including a problem that you consider to be particularly sensitive.
Level of identification: contain your name and address; only have your medical record number, they would have no information about your name or address; be totally anonymous and would have no information to link the record to you.

While 630 combinations of vignettes are feasible, some were eliminated because they were unlikely to occur in practice. For example, it was assumed that name would be required for clinical care; receptionists would need name and address and/or medical record numbers; NHS managers or researchers would not be involved in clinical care. The vignettes were structured as in the following example: "*A doctor in the hospital* [person] would like access to your notes which contain *information only about your current health problem*

[66] NHS Executive. Information for Health. NHS Executive, 1998.

[content] *as part of the health care that you are receiving* [role]. The information about you would contain *your name and address* [identification]."

Interviews were conducted by a market research organisation (RSL-IPSOS) as the initial questions of an omnibus survey. Subjects aged 15 years or over were recruited around 180 sampling points across Great Britain over a two week period.

Subjects were provided with an explanation for why the NHS wants to know about their attitudes to the use of health information. Each interviewee was asked to assess 10 vignettes. After each vignette, subjects were asked "on a scale of 1 to 10 where 1 is very unhappy and 10 is very happy, how happy would you be for this person to use your medical information in this way?" If subjects asked for further explanation of any element within the vignette the interviewer had written descriptions for each permutation. To optimise the quality of the sample, the order of questions within each block of ten was partially rotated within the interviews

Data were analysed using SPSS for windows version 9.0. Mann-Whitney and Kruskal Wallis tests were used to analyse differences between demographic groups. Simple linear regression models were used to ascertain the relative importance of the demographic characteristics of respondents and of the various elements in the vignettes in determining willingness to consent to access to health information. The model was then validated by comparing each predicted response with the actual average response for that vignette. From this an overall estimate of the accuracy of the model could be calculated to give a Root Mean Square Error (RMSE) value.

5.4 Results

3921 adults aged 15 years or over from 180 sampling points across Great Britain were interviewed (table 5.1). There were no statistically significant differences between the age profile of the sample and that for England and Wales as a whole.

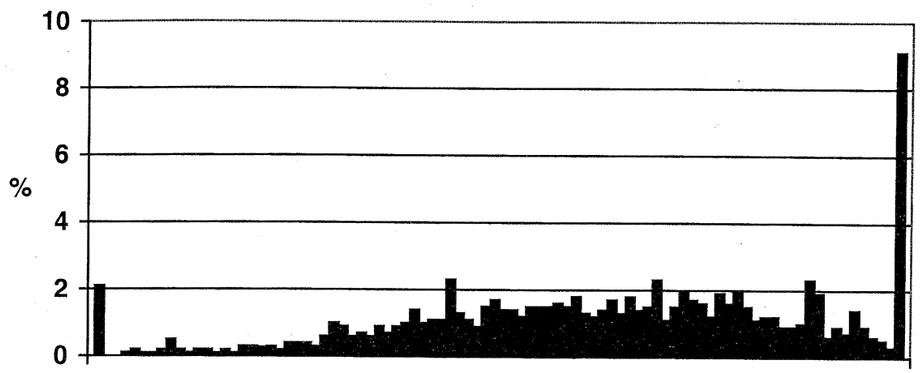
Between 171 and 202 responses were obtained for each vignette. In total there were 38,700 separate vignette assessments. Almost a third of all these responses (31.6%) were '10' i.e. the subject was very happy to consent to release in that particular circumstance (figure 5.1). Conversely, 11.6% of assessments attracted a score of '1' i.e. the subject was very unhappy. However, some subjects (9.1%) tended to be very happy with every vignette posed (i.e. total aggregate of 100), while others (2.1%) were very unhappy about access to their health information, whatever the circumstances (total aggregate of 10) (figure 5.2).

Table 5.1: Demographic characteristics of subjects

	n	%
SEX		
Male	1721	43.9
Female	2200	56.1
AGE		
15 - 17	142	3.6
18 - 24	467	11.9
25 - 34	742	18.9
35 - 44	730	18.6
45 - 54	580	14.8
55 - 59	237	6.0
60 - 64	275	7.0
65+	748	19.1
SOCIAL GRADE		
A	56	1.4
B	644	16.4
C1	876	22.3
C2	995	25.4
D	735	18.7
E	615	15.7
TOTAL	**3921**	**100.0**

Figure 5.1: Distribution of scores for vignettes

Figure 5.2: Distribution of the sum of all ten responses by individual subjects to the ten vignettes that they were asked to assess



Males tended to be happier to allow access in health information than females (Mann-Whitney test: $p<0.001$) and older people tended to be happier than younger people (Kruskal Wallis test: $X^2=78.5$, d.f.=7, $p<0.001$) (table 5.2). People who were parents or guardians were less happy to allow access to their own health record than those without children (Mann-Whitney test: $p<0.001$) (table 5.2).

People from higher social groups were significantly happier to allow access to their health information than other social groups (Kruskal Wallis test: $X^2 = 20.12$, df = 5, p = 0.001) (table 5.2). There was also a statistically significant positive association between income and willingness to allow access (Kruskal Wallis test: $X^2= 26.272$, d.f. = 14, p = 0.024) (table 5.2). People who left school at age 13 or 14 were the happiest to allow access to personal health information. People who left school at 16 were less happy to allow access than those who had attended higher education (table 2). While these differences were statistically significant (Kruskal Wallis test: $X^2= 42.034$, d.f., 4, $p<0.001$) there may be a cohort effect, as only older people could have left school at the age of 13 or 14.

There were statistically significant differences between respondents from different regions of Great Britain (Kruskal Wallis test: $X^2 = 78.717$, d.f.= 10, $p<0.001$) (table 5.2).

People with an ethnic origin from India or Pakistan were significantly happier to allow access to health information than people with white (Mann-Whitney: p=0.006) or black (Mann-Whitney: p=0.016) ethnic origins (table 5.3). White people tended to be happier to allow release of health information than black people, but this difference was not statistically significant (Mann-Whitney: p=0.554).

Table 5.2: Association between demographic characteristics of subjects and the sum of the responses to the ten vignettes assessed

	Mean	n	Standard	Median
ALL PERSONS	**67.76**	**3824**	**21.95**	**70.0**
GENDER				
Male	69.24	1686	22.22	71.0
Female	66.59	2138	21.66	68.0
AGE				
15 - 17	65.99	139	20.31	65.0
18 - 24	64.09	440	20.72	65.0
25 - 34	66.74	725	20.90	68.0
35 - 44	65.86	715	21.66	67.0
45 - 54	66.10	566	23.24	69.0
55 - 59	71.14	230	20.85	75.0
60 - 64	69.43	270	23.30	71.0
65+	72.72	739	22.12	76.0
REGION				
North	69.79	464	20.19	72.0
North West	66.41	160	22.71	69.0
Yorkshire &	67.30	281	20.99	67.0
West Midlands	64.04	375	22.89	65.0
East Midlands	67.38	387	18.12	67.0
East Anglia	64.94	322	25.43	68.0
South West	74.64	297	20.66	80.0
South East	70.12	615	21.15	73.0
Greater London	69.97	342	22.21	72.0
Wales	64.35	273	23.81	64.0
Scotland	63.00	308	22.40	64.0
SOCIAL GRADE				
A	71.14	56	26.33	80.0
B	70.61	638	21.41	73.0
C1	66.67	843	21.72	69.0
C2	67.23	980	21.87	68.0
D	66.86	711	21.62	68.0
E	67.88	596	22.67	71.0

Two simple linear regressions were constructed to assess the most important demographic (table 5.3) and vignette characteristics (table 5.4) determining subject willingness to allow access to their health information.

The simple linear regression model predicted statistically significant higher 'happiness scores' for males, higher social groups, older people, South Asian ethnic origin and certain regions of Great Britain.

Table 5.3: Model predicting effect of demographic characteristics of subject on total happiness score given for ten vignettes assessed

	Unstandardised Coefficients (B)	Standard. Error	p
Constant = Age 65+, Terminal education	**89.27**	**2.83**	**<0.01**
GENDER			
Female	-2.56	0.73	<0.01
AGE			
15-24	-7.39	1.55	<0.01
25-34	-4.85	1.49	<0.01
35-44	-5.95	1.46	<0.01
45-54	-6.02	1.33	<0.01
55-64	-2.18	1.34	<0.11
REGION			
North	-4.74	1.60	<0.01
North west	-8.76	2.12	<0.01
Yorkshire and Humberside	-6.92	1.80	<0.01
West Midlands	-10.89	1.69	<0.01
East Midlands	-7.14	1.69	<0.01
East Anglia	-9.86	1.75	<0.01
South East	-5.25	1.54	<0.01
London	-5.65	1.75	<0.01
Wales	-10.15	1.81	<0.01
Scotland	-11.83	1.76	<0.01
SOCIAL GROUP			
A	-0.95	3.02	0.75
C1	-3.15	1.22	0.01
C2	-3.07	1.23	0.01
D	-2.76	1.31	0.04
E	-2.42	1.40	0.08
ETHNIC ORIGIN			
White	-5.03	2.06	0.01
Black	-4.90	3.28	0.14
Other	-7.73	4.49	0.09
TERMINAL EDUCATION AGE			
15	-0.88	1.27	0.49
16	-2.06	1.20	0.09
17-18	-1.36	1.43	0.34
19+	-0.43	1.49	0.77
MARITAL STATUS			
Single	-0.57	1.11	0.61
Widowed/ divorced/ separated	-0.50	1.01	0.62
PARENTAL STATUS			
Children	-0.01	1.01	0.99

Table 5.4: Model predicting effect of various elements in vignettes on happiness to give access to health information

	Unstandardised Coefficients (B)	Standard. Error	p
Constant = GP, Clinical care, Current episode, Anonymous	**9.777**	**0.132**	**<0.001**
PERSON			
Hospital doctor	-0.896	0.137	<0.001
Hospital nurse	-1.629	0.141	<0.001
Practice nurse	-1.422	0.143	<0.001
GP receptionist	-3.554	0.155	<0.001
Hospital receptionist	-3.183	0.153	<0.001
Manager	-2.130	0.141	<0.001
Physiotherapist	-1.593	0.177	<0.001
Researcher	-2.362	0.140	<0.001
Social Worker	-3.804	0.177	<0.001
PURPOSE			
Clinical Audit	-0.245	0.070	0.001
Research Project	-0.326	0.072	<0.001
Financial Audit	-0.579	0.068	<0.001
Teaching	-1.348	0.107	<0.001
Monitoring Doctors	-0.317	0.072	<0.001
Public Health	-0.329	0.069	<0.001
CONTENT			
Past History	-0.226	0.038	<0.001
Sensitive History	-0.477	0.038	<0.001
IDENTIFIERS			
Name & Address	-1.353	0.041	<0.001
Medical Record No	-0.320	0.042	<0.001

The greatest demographic influence on happiness with access to data was region of residence. Age, gender and social group were also important predictors of happiness to allow access. The simple linear regression model predicted that the permutation of elements that would cause least concern would be a GP asking for anonymised information about the current health problem in order to provide care for a patient (predicted score 9.777). This permutation was not included within the 200 vignettes because health information required for clinical care would need to include some form of patient identification. The combination with the lowest predicted mean score (3.045) was a GP receptionist wanting access to notes containing name and address and the full past medical history including sensitive information to use during teaching of students. This vignette was not used either because a GP receptionist would not be directly involved in the teaching of students.

The individual requesting information was the most important factor determining willingness to allow access to the health record. Subjects were happier to release anonymised data. Content of the information to be released did not seem to be particularly

important, even when the health record contained sensitive information. Similarly, with the exception of teaching students, the use of the information was not an important determinant of consent.

The model assumed that each element was independent of every other. However, this may not be the case since a patient may be worried about a GP receptionist having access to their notes for teaching students but not concerned about a GP using their health information for teaching. The model was tested by comparing the predicted mean score with the actual value for the 200 vignettes used and calculating the squared error. The Root Mean Square Error (RMSE) value comparing each predicted response with the actual average response for that vignette was 0.26 for all the records in the study.

Eighty-five percent of the predicted mean scores were within 5% of the observed value. The model did not show any systematic tendency to underestimate or overestimate the predicted mean score. Nor was there any pattern to the characteristics of the vignettes with the greatest differences between the observed and predicted score.

5.5 Discussion

This research indicates that the general public are on the whole happy to provide access to their health information. For almost a third of vignettes, subjects said that they would be very happy to allow access to their health information (score of '10'). These less controversial vignettes represent the most common scenarios for use of health information by the health care system. However, in almost a tenth of vignettes, subjects said that they would be very unhappy to allow access. Some of these situations included use of health information by particular health professionals that would be considered to be core to the provision of quality health services.

As part of a survey of 975 adults aged 16 or over from across Great Britain conducted for the Information Commissioner, [67] 96% of the sample saw protecting people's personal information as very or quite important. It was more likely to be regarded as important by women, 35-54 year olds and those in social grades C2DE. Financial and medical information, along with home address were the types of information that caused most concern. 73% of adults were either very or quite concerned about the amount of information that is kept by organisations nowadays about the individual. These findings are compatible with the PERIC research, which also showed greater concern amongst women, younger people and lower social groups.

[67] http://www.dataprotection.gov.uk/ar2001/download/datasub.pdf (last accessed 3 August 2001)

Public attitudes to who should have access to their health information is closely linked with the 'need to know' of the individual and the perceived extent to which that individual is bound by confidentiality. In a study of 39 patients in one UK general practice[68] all the patients interviewed agreed that all the doctors in the practice should have some degree of access to their medical records, but not all those interviewed wanted all the doctors to have completely free access to their records, particularly if they were not directly involved in that patient's care. When it came to other primary care staff, nurses and midwives, a minority of interviewees felt that they should have no access whatsoever, otherwise limited access could be granted. The level of access was related to the perceived extent to which nurses are bound by confidentiality. The majority of interviewees felt that administrative staff did not need access routinely, but might require access on a need to know basis. Liaw showed that Australian patients were less inclined to share their information with non-clinicians.[69] This again implies that the public has a greater regard for the medical profession's ability to protect their privacy than other professional groups. These findings are consistent with the research report here, which showed that doctors were trusted more than nurses and physiotherapists, who in turn were trusted more than non-clinicians.

In general, the public may be less worried about their information in hospital than in general practice. This is not because hospitals look after their information any better than general practices but that whilst in hospital, patients may feel like a face in the crowd. To this should be added the fact that general practice records tend to carry much more personal and social information than hospital based records. Many of those concerned about the content of the information were not concerned by who has access to it.

Confidentiality is valued highly by patients. However, patients may be willing to forgo confidentiality for the sake of improved quality of care.[70,71] Health information is used as part of physician peer-review,[72] but 64% of 648 patients surveyed disapproved of their records being read by outside physicians without their permission. An earlier study by Neuhaus showed that 64% of patients agreed to have their records audited.[73] Surveys of the general public have shown the public to be less happy with the use of their medical information for research. In a Harris Equifax poll only 18% considered the use of patient records for medical research without prior consent acceptable and 39% found it somewhat acceptable.[74] Happiness was increased if the information was not personally identifiable, but a third still found it unacceptable to use non-identifiable information without prior patient consent.

[68] Carmen D, Britten N. Confidentiality of medical records: the patient's perspective. British Journal of General Practice 1995; 45: 485-488.
[69] Liaw ST. Patient and general practitioner perceptions of patient-held health records. Family Practice 1993; 10(4): 406-415.
[70] Luke S, Gallagher A, Lloyd B. Staff and family attitudes to keeping joint medical and nursing notes at the foot of the bed: questionnaire survey. BMJ 1999; 319: 735.
[71] Patno K. Young, P. Dickerman J. Parental attitudes about confidentiality in a pediatric oncology clinic. Pediatrics 1988; 81: 296-300.
[72] Dodek D, Dodek A. From Hippocrates to facsimile: protecting patient confidentiality is more difficult and more important than ever before. CMAJ 1997; 156(6): 847-852.
[73] Neuhaus E, Lyons T, Payne B. Patient responses to request for written permission to review medical records. AJPH 1976; 66(11): 1090-2.
[74] Equifax-Harris. Equifax-Harris Mid decade consumer privacy survey 1995. New York: Louis Harris and associates, 1995. In Detmer D. Your privacy or your health – will medical privacy legislation stop quality health care. International Journal for Quality in Health care 2000;12: 1-3.

The subjects in the research reported in this chapter were asked whether they would be happy with their personal information being used in the way described. The legal imperative is that the data subject provides consent (whether this is explicit or implicit), although it is obviously desirable for them to be happy to give consent. If consent had been used as an outcome measure it would only be possible to divide people into those who consent and those who do not. It was felt more desirable to use a ten point 'happiness scale' to obtain a better understanding of the variation in strength of opinion.

Even though people are happy to allow access to their personal health information this does not mean that they do not want to be asked to give consent, or to be informed about the way their information is being used. The Public Inquiries into the Bristol Royal Infirmary and Royal Liverpool Children's Hospital demonstrated the scale of public anger at not properly respecting research subjects.

There is also a distinction between consent and informed consent. The interviewers had additional text to describe terms in vignettes if subjects asked for clarification. However, it is likely that many - if not most - members of the public have a poor understanding of the roles of various health professionals and of the various ways in which the health care system uses data. For example, many subjects may have been reluctant to allow a social worker to have access to their records because they perceive social workers as being involved with cases of child abuse and they may not have considered their role in planning patient discharge. It is conceivable that many of the people that were unhappy with specific vignettes would consent to access if provided with appropriate explanations and reassurances. However, it is also conceivable that some of those who were very happy, would withhold consent if they were better informed about the way their health information was protected (or not as the case may be) and used.

UK legislation and European directives provide data protection rights for health and other forms of personal information. The Human Rights Act 1998 and European Convention of Human Rights specify rights to privacy. Thus even if the vast majority of the public were happy to allow access and would relinquish the right to be asked, it may still necessary to ask for consent to prevent infringing the human rights of individuals who did want to be asked to give consent or given the opportunity to object. The Founding Fathers of the USA were concerned about the 'tyranny of the majority' where the rights of the few were infringed by decisions of the majority, even if these were made following a democratic due process. However, there is the contrary danger of the 'tyranny of the minority' if the complexity of obtaining explicit consent means there are significant opportunity costs for other uses of scarce health care resources.

The PERIC study asks individuals to respond to hypothetical scenarios. People may be much more reluctant to allow access to their medical record if they are patients with real and potentially very sensitive information to be protected. HIV patients when asymptomatic appear happy for information to be shared, however, they are much more protective of information when symptomatic.[75,76] More research is required to demonstrate

[75] Carretero M, Chiswick A, Catalan J. whose health is it? The views of injecting drug users with HIV infection and their professional carers. AIDS care 1998; 10: 323-8.
[76] Catalan J, Brener N, Andrews H, Day A, Cullum S, Hooker M, Gazzard B. Whose health is it? Views about decision making and information seeking from people with HIV infection and their professional carers. AIDS care 1994; 6: 349-56.

whether or not seeking explicit consent is practical. Further research is needed on the boundaries of implied consent and when the NHS can depend on imputed consent: i.e. an individual would consent if asked.

Chapter 6

What do patients think about the use of their personal health information?

A quantitative survey of patients and parents of paediatric patients in Sheffield

6.1 Summary

Objectives: To assess whether patients have different attitudes to the use of health information than members of the general public and to study the relationship between happiness to allow access and willingness to provide consent.

Design: Patients and parents of paediatric patients attending the Royal Hallamshire and Sheffield Children's Hospitals were recruited in outpatient clinics or on inpatient wards. Subjects were asked to assess ten of the vignettes used within the national sample. All subjects assessed the same ten vignettes that had been chosen to provide a spectrum of likely responses of happiness to allow access. As with the general public sample, subjects were asked to indicate their 'happiness' using a ten point scale. In addition, subjects were asked whether they would give consent to their personal data being used in the way described. Demographic information on age, gender, ethnic group and employment status was also collected. Subjects were also asked to rank their knowledge of the health service against that of an average patient.

Setting: Out-patient clinics and hospital wards in two teaching hospitals

Participants: 184 patients and 90 parents of paediatric patients

Results: In contrast to the general public survey, associations between happiness and age or gender were not seen. However, to permit comparison with the general public survey, direct standardisation was performed against the 1999 Great Britain population, to control for any confounding effect of age or gender. Patients tended to be happier to allow access to personal health information than the parents of paediatric patients, who in turn were happier than people drawn from the general population. There was a strong association between happiness and willingness to consent to access. Patients who perceived themselves to be better informed about the NHS than an average patient tended to be happier and more willing to give consent than those who ranked themselves as having average or below average knowledge.

Conclusions: Patients, especially those with more knowledge of the NHS, were even more happy to allow access to their health information than people interviewed within the general public study. They were also willing to provide consent. This may be because they felt more obligation to continue a tradition of patients participating in activities to improve the quality of health care. They may also have had more opportunities to form a judgement that the NHS protects and uses personal health information appropriately.

6.2 Background

The survey across Great Britain (chapter 5) indicated that the general public were generally happy to allow access to their personal health information. However, the questions asked were hypothetical and so may have lacked relevance for some people. Virtually all the subjects in the general public survey will be registered with a general practitioner and hence will be NHS patients. By chance, some of the sample will have had more serious health problems requiring secondary care, but questions about personal health experience were not included within the general public survey. It was therefore not possible to study how contact with the NHS influenced attitudes to health privacy. A separate study was therefore performed with patients to explore this question.

Members of the general public were asked in the survey whether they were happy to allow access, but legally what matters is that they give consent, either explicit or implicit. This element of the study therefore examined whether patients would give consent, as well as whether they would be happy to do so. While it would have been desirable to compare the national general public data with patients also drawn from across Great Britain, the mean sum happiness score for the public sampled in Yorkshire and the Humber (67.30) was similar to the national mean (67.76) (table 5.2).

6.3 Methods

Patients were approached in outpatient clinics or on the wards in two large teaching hospitals (Royal Hallamshire Hospital and Sheffield Children's Hospital). They were receiving care from a number of specialties (dermatology, haematology, rheumatology, general surgery, urology, gastroenterology, hepatology, genito-urinary medicine, paediatric surgery). The initial approach was made by a nurse involved with the patient's care, before being formally asked for consent by a researcher (JC, SW).

Basic demographic information was collected on age, gender, employment status, and ethnic group. The location of recruitment (speciality and in/out patient status) was also recorded. As in the general public survey, each patient was asked to assess ten vignettes, with each vignette containing different variables within four categories: a health professional who would have access; a use for the information; a level of anonymity or identification; scope of the content of information to be released. In the general public study, interviewees were asked to assess ten out of 200 vignettes. However, all patients and parents were given the same ten vignettes to assess. These vignettes were chosen on the basis of the findings of the general public survey to provide a range of positive or negative responses and degrees of consensus. Following each vignette, subjects were asked whether they would be happy to allow access using the same ten point scale as the general public survey (1= very unhappy, 10 = very happy). They were also asked whether they would consent to their health record being used in the way described. Amount of contact with the NHS was gauged by asking subjects to rate their knowledge of the NHS compared with that of an average patient, using a five point scale: a lot, or a little less, the same, or a lot or a little more, than an average patient.

For each of the ten vignettes, the responses of parents and patients were compared to assessments of the same vignettes from the general public survey.

Data were analysed using SPSS version 10. Direct standardisation was performed using Great Britain population data for 1999 to allow for any confounding effect of age and gender. Statistical significance was measured using chi squared test and chi squared for linear trend. A receiver operating characteristic (ROC) curve was drawn to show the relationship between happiness and willingness to consent.

Ethics approval was provided by South Sheffield Local Research Ethics Committee (reference number: SS/00/298).

6.4 Results

Interviews were conducted with 184 patients and 90 parents of paediatric patients. The results of these interviews were compared with data from 1731 people who had answered one or more of these ten selected vignettes within the general public survey.

There were more females in the patient sample (58.7%) than the general public sample (55.6%) although this difference was not statistically significant. There were, however, significantly more females in the parent sample (76.7%). The patient group were, on average, significantly older than the general public group, who in turn were significantly older than the parent sample (table 6.1).

Table 6.1: Age profile of patient, parent and public samples

Age	Patient	Parent	Public
	n (%)	n (%)	n (%)
15 - 24	19 (10.3)	7 (7.8)	275 (15.9)
25 - 34	20 (10.9)	31 (34.4)	317 (18.3)
35 - 44	28 (15.2)	41 (45.6)	327 (18.9)
45-54	35 (19.0)	11 (12.2)	266 (15.4)
55 - 64	37 (20.1)		228 (13.2)
65 and over	45 (24.5)		318 (18.4)
Total	184 (100.0)	90 (100.0)	1731 (100.0)

There were no significant gender (table 6.2) or age (table 6.3) associations with happiness to allow access to health information and willingness to give consent.

Table 6.2: Association between gender and happiness to consent to access to health information

	Male		Female		Total	
Happiness	n	%	n	%	n	%
1	68	8.9	103	9.5	171	9.3
2	18	2.4	14	1.3	32	1.7
3	9	1.2	27	2.5	36	2.0
4	10	1.3	26	2.4	36	2.0
5	23	3.0	65	6.0	88	4.8
6	20	2.6	41	3.8	61	3.3
7	24	3.2	50	4.6	74	4.0
8	52	6.8	90	8.3	142	7.7
9	13	1.7	37	3.4	50	2.7
10	523	68.8	627	58.1	1150	62.5
Consent						
Yes	671	88.3	941	87.1	1612	87.6
No	89	11.7	139	12.9	228	12.4
Total	760	100.0	1080	100.0	1840	100.0

Table 6.3: Association between age and happiness to consent to access to health information

	15 - 24		25 - 34		35 - 44		45-54		55 - 64		65 and over		Total	
Happiness	n	%	n	%	n	%	n	%	n	%	n	%	n	%
1	20	10.5	27	13.5	22	7.9	46	13.1	33	8.9	23	5.1	171	9.3
2	6	3.2	2	1.0	16	5.7	4	1.1	4	1.1	0	0.0	32	1.7
3	4	2.1	5	2.5	8	2.9	7	2.0	6	1.6	6	1.3	36	2.0
4	5	2.6	2	1.0	8	2.9	10	2.9	7	1.9	4	0.9	36	2.0
5	11	5.8	19	9.5	17	6.1	15	4.3	18	4.9	8	1.8	88	4.8
6	10	5.3	5	2.5	14	5.0	15	4.3	10	2.7	7	1.6	61	3.3
7	11	5.8	9	4.5	15	5.4	15	4.3	12	3.2	12	2.7	74	4.0
8	13	6.8	8	4.0	30	10.7	28	8.0	23	6.2	40	8.9	142	7.7
9	9	4.7	6	3.0	13	4.6	13	3.7	1	0.3	8	1.8	50	2.7
10	101	53.2	117	58.5	137	48.9	197	56.3	256	69.2	342	76.0	1150	62.5
Consent														
Yes	162	85.3	166	83.0	238	85.0	301	86.0	326	88.1	419	93.1	1612	87.6
No	28	14.7	34	17.0	42	15.0	49	14.0	44	11.9	31	6.9	228	12.4
Total	190	100.0	200	100.0	280	100.0	350	100.0	370	100.0	450	100.0	1840	100.0

When standardised to allow for any confounding effects of age and gender, patients were consistently happier to allow access to personal health information than people within the general public survey (table 6.4).

Table 6.4: Responses of patients and public to vignettes (directly standardised to 1999 Great Britain population)

Vignette		n	1	2	3	4	5	6	7	8	9	10
1	Patient	184	0.000	0.000	0.003	0.004	0.016	0.000	0.033	0.070	0.017	0.858
	Public	201	0.050	0.011	0.017	0.011	0.051	0.037	0.034	0.109	0.108	0.571
2	Patient	184	0.007	0.006	0.004	0.003	0.031	0.010	0.044	0.059	0.047	0.790
	Public	178	0.056	0.010	0.038	0.009	0.098	0.036	0.113	0.170	0.100	0.371
3	Patient	184	0.047	0.000	0.023	0.028	0.041	0.043	0.097	0.052	0.049	0.621
	Public	191	0.073	0.015	0.038	0.046	0.124	0.046	0.126	0.144	0.075	0.314
4	Patient	184	0.074	0.007	0.033	0.022	0.055	0.024	0.029	0.066	0.027	0.664
	Public	187	0.084	0.026	0.047	0.032	0.103	0.053	0.113	0.125	0.060	0.356
5	Patient	184	0.064	0.011	0.004	0.006	0.028	0.040	0.037	0.119	0.042	0.650
	Public	203	0.118	0.068	0.028	0.028	0.159	0.025	0.060	0.102	0.102	0.309
6	Patient	184	0.110	0.017	0.042	0.004	0.081	0.050	0.094	0.078	0.000	0.524
	Public	197	0.126	0.082	0.061	0.058	0.144	0.034	0.077	0.079	0.055	0.285
7	Patient	184	0.080	0.022	0.011	0.013	0.056	0.034	0.041	0.082	0.049	0.611
	Public	202	0.086	0.011	0.028	0.023	0.087	0.086	0.053	0.164	0.146	0.315
8	Patient	184	0.064	0.029	0.018	0.047	0.080	0.021	0.020	0.083	0.039	0.598
	Public	193	0.154	0.048	0.058	0.027	0.087	0.051	0.095	0.105	0.071	0.303
9	Patient	184	0.130	0.037	0.019	0.031	0.072	0.038	0.025	0.087	0.041	0.521
	public	189	0.218	0.091	0.058	0.079	0.090	0.051	0.073	0.086	0.067	0.188
10	patient	184	0.352	0.060	0.044	0.042	0.052	0.066	0.033	0.040	0.010	0.300
	public	189	0.363	0.101	0.055	0.088	0.107	0.032	0.048	0.052	0.040	0.114

The oldest parent in the sample was in the 45-54 year old age group. The responses of parents were therefore compared with patients and public aged 54 or under. Direct standardisation was performed against the 1999 Great Britain population aged 15-54 years. Parents of paediatric patients were happier to allow access to their children's health records than the general public sample, but the parents were more reluctant than the adult patients (table 6.5).

Table 6.5: Responses of parents of paediatric patients, adult patients and general public to vignettes (directly standardised to 1999 Great Britain population aged 15-54 years)

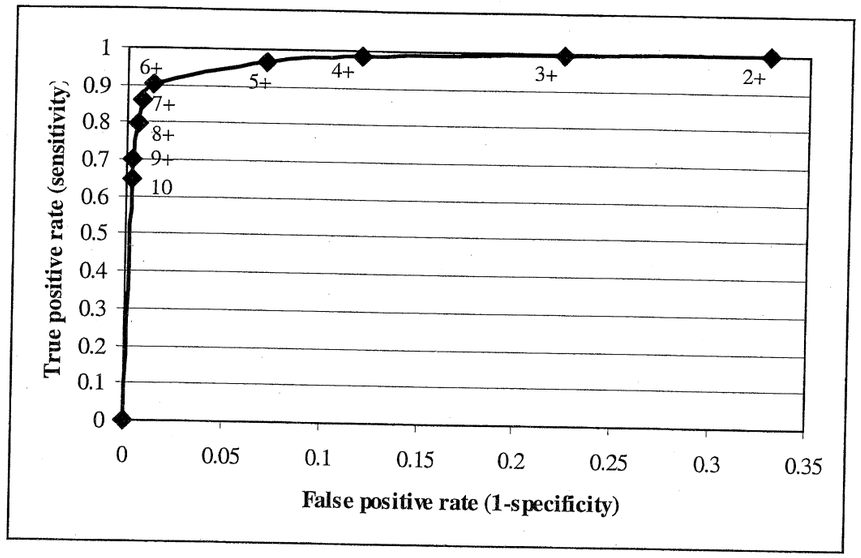
	Number of assessments	1	2	3	4	5	6	7	8	9	10
Parent	900	0.140	0.020	0.018	0.018	0.091	0.037	0.069	0.079	0.059	0.468
Patient	1020	0.106	0.026	0.022	0.023	0.062	0.038	0.053	0.071	0.041	0.556
Public	1315	0.144	0.046	0.046	0.042	0.116	0.044	0.087	0.112	0.078	0.285

Patients who indicated that they were willing to give consent for their personal health information to be used in the way described within a vignette also tended to be happy with the decision to allow access (table 6.6, figure 6.1).

Table 6.6: Relationship between consent and happiness with allowing access to personal health information

Vignette	Willing to Consent	Level of happiness to allow access to health record										Total
		1	2	3	4	5	6	7	8	9	10	
1	Yes				1	7	3	6	23	14	218	272
	No		1	1								2
2	Yes			1	1	8	5	12	23	18	198	266
	No	4	1		1	2						8
3	Yes			3	3	14	13	26	23	11	160	253
	No	16	1		2	2						21
4	Yes			1	7	16	8	15	23	14	161	245
	No	18	3	7		1						29
5	Yes		1	2	2	13	15	11	34	14	158	250
	No	17	2	1	2	2						24
6	Yes	1	3	3	2	23	17	20	22	3	132	226
	No	33	3	6		4	1	1				48
7	Yes			2	2	19	8	20	28	12	157	248
	No	19	3	1	2	1						26
8	Yes		1	2	7	20	10	10	22	10	147	229
	No	24	10	6	2	3						45
9	Yes		4	4	5	18	12	14	25	12	122	216
	No	40	5	6	1	4	1		1			58
10	Yes	2	4	5	5	16	13	10	12	6	77	150
	No	87	12	12	9	3					1	124
Total	Yes	3	13	23	35	154	104	144	235	114	1530	2355
	No	258	41	40	19	22	2	1	1	0	1	385

Figure 6.1: Receiver operating characteristic (ROC) curve for 'happiness score' and consent



Patients who thought that they had a lot or a little more knowledge of the NHS than the average patient were significantly more likely to be happy about allowing access to their personal health information than those who thought that they had average knowledge (Chi Square for linear trend = 20.153, p=0.0001). There were no statistically significant differences between those who thought that they had average knowledge compared with those who perceived themselves as having a little or a lot less knowledge of the NHS. Patients who perceived themselves as having more knowledge about the NHS compared with an average patient were significantly more likely to say that they would be willing to consent to their information being used in the ways described (X^2=23.78, d.f.=4, p<0.0001) (table 6.7).

Table 6.7: Relationship between willingness to give consent and knowledge about the NHS

Consent	Self perception of own knowledge of the Health Service compared with an average patient					
	A lot less	A little less	Same as average patient	A little more	A lot more	Total
Yes	56	193	1199	538	369	2355
No	14	37	231	72	31	385
	70	230	1430	610	400	2740

6.5 Discussion

The null hypothesis prior to conducting the study with patients was that there would be no difference between the attitudes of patients and the general population. Indeed an alternate hypothesis could be constructed whereby patients would be more concerned about privacy because by definition they have a condition of sufficient seriousness to warrant hospital care. In contrast many members of the general public, especially younger males, may have had little contact with the NHS and hence may have limited, non-sensitive information within their medical record.

Although there were significant associations between age and gender with happiness to allow access to personal health information within the general public study, these associations were not seen in the patient sample. As the median age of people within the patient sample was older than that for the general public survey, then an older patient population would be expected to be more willing to allow access to health information. However, when the data were standardised to control for any confounding effect of age, those people known to be current NHS patients were typically more willing to allow access than those in the general population, whose contact with the NHS was unknown.

The parent sample was predominantly female and from the younger age groups. The general public survey suggests that this group would be most concerned about privacy, albeit they were being asked about access to their child's health record. However, the standardised data showed that the parents were also happier to allow access than the general public, which may be because they considered that a young child would not be concerned about sensitive information in their record.

Individuals with a medical condition requiring attention in secondary care are also more likely to have had contact with health professionals. On the basis of these experiences, patients could form the view that health professionals are very trustworthy and hence patients may be reassured that their health information would not be abused. Alternatively, patients may have observed examples of indiscretion and hence be more concerned about privacy. However, the study showed that patients who perceived themselves as knowing more about the NHS, perhaps through repeated episodes of care or employment in the NHS, were more likely to give consent to use of their medical information. The association between 'happiness' and age or gender found in the general public survey was not seen in the patient sample. Of course, older people will have accumulated more episodes of care over time and this experience and knowledge of the NHS may have been a confounding factor in the general public survey, although a cohort effect is still likely. However, women tend to have more contact with the NHS than men (e.g. consultations for contraception, pregnancy, taking children to see the GP) but they were less likely than men to be happy to allow access in the general public survey.

As the House of Lords Science and Technology Select Committee[77] has pointed out, the quality of care that patients receive has depended on previous cohorts of patients participating in research. Patients may therefore be more motivated to altruistically 'donate' information. Alternatively they may feel 'coerced' to do so, as they were asked about willingness to consent while attending hospital.

[77] House of Lords Select Committee on Science and Technology. Human Genetic Databases: Challenges and Opportunities. Fourth Report 2000/2001 Session.

The general public survey asked about happiness to allow access to health information. The strong correlation between happiness and consent suggests that the vast majority of people would be willing to give consent if asked, albeit the question would still have been hypothetical and people may respond differently if their health information was actually going to be used in the ways described in the vignette as a consequence of their answer. As the vignettes that caused least concern were the more typical uses of information within the NHS, seeking informed consent should not result in significant volunteer bias as has been suggested.[78,79,80] Of course, whether the NHS has the resources to seek informed consent in every patient contact is another issue.

[78] Statement by the U.K. Association of Cancer Registries (UKACR) on the General Medical Council (GMC) Guidance on Confidentiality. BMJ 2000; 321: 854.
[79] Kmietowicz Z. Registries will have to apply for right to collect patients' data without consent". BMJ 2001; 322: 1199.
[80] Helliwell T. Need for patient consent for cancer registration creates logistical nightmare. BMJ 2001; 322: 730

Chapter 7

A survey using Conjoint Analysis

7.1 Summary

Objectives: To use the conjoint analysis methodology to assess public attitudes to use of personal health information.

Design: Scenarios were constructed using the same four elements as the vignettes within the Great Britain general public survey (person, use, content, identifier) plus a level of compensation that could be paid to patients if they allow access to their data. Fewer levels were used within each scenario than for the vignettes, in order to reduce the number of combinations. The number of scenarios was reduced further to 25 through a fractional factorial design. The 300 pair combinations of these 25 scenarios was reduced to 250 by eliminating some pairs where the general public survey predicted that one choice within the pair would be overwhelmingly preferred to the other. A self-completion postal questionnaire was sent to people identified from electoral rolls. Subjects were asked to make choices between either ten or 12 pairs of scenarios.

Setting: Nine electoral wards in Barnsley and North East Derbyshire selected to provide a range of socio-economic deprivation.

Participants: 1995 members of the general public.

Results: 621 completed questionnaires were returned plus 54 questionnaires returned because the addressee was deceased or was no longer resident at that address (overall response rate = 32%). The respondents were most concerned about who has access to the notes, whether sensitive information is contained in the notes, or the extent to which the data subject is identifiable. Subjects were least concerned about their GP having access. Concerns about a health service researcher were not statistically significant when compared to a practice nurse looking at the notes. There was a strong preference for a practice nurse over a health service manager having access to personal health information. The purpose for which medical records are required by the NHS did not appear to be important to the public. The amount of compensation offered did not impact on respondents' decisions to choose a particular scenario. Written comments within a free text section of the questionnaire suggested that the public should not expect payment.

Conclusions: This survey using the conjoint analysis methodology confirmed the main findings of the national general public survey which used linear regression analysis of responses to vignettes.

7.2 Background

Conjoint analysis is a technique that measures the strength of individuals' preferences for different attributes of a good or service and determines whether people are willing to exchange an improvement in one attribute for a reduction in another. Previously used in market research, it is becoming a widely used research tool for evaluating health care.[81,82,83,84,85,86] Conjoint analysis questions require respondents to make choices between a series of pairs of scenarios. In so doing, it is possible to infer how individuals make trade-offs between different attribute levels.

Conjoint analysis was therefore used to assess the relative importance of attributes relevant to patients' consent for access to their medical record.

7.3 Methods

7.3.1 Choosing attributes for study

In a conjoint analysis, respondents are presented with hypothetical scenarios comprising different levels of key attributes of a service, and are asked to choose between them. The key attributes are often derived from literature reviews, group interviews or from a pre-defined policy question. In this study, key attributes were based on the results of the general public survey (chapter 5). In addition to the four key attributes used within the vignettes for the general public study (who has access to the notes; why they would have access to the notes; how the patient would be identified; what type of medical history would be available), a fifth variable of compensation offered to patients was included within the hypothetical scenarios. Compensation was included here, but not in the original vignettes, in order to elicit the public's willingness to accept monetary payment for use of their medical records.

Fewer levels were used for each attribute than within the general public study in order to have a feasible number of permutations to use. The attributes and levels presented in table 7.1 give rise to 240 ($2^2 \times 3^1 \times 4^1 \times 5^1$) possible scenarios. The number of scenarios was reduced further to 25 through the use of computer software[87] which identified a fractional factorial design sufficient to estimate a simple additive effect that assumes no interaction between the attributes.

Ideally all 25 options would be compared with each other. This would require 300 pairwise choices to be included in the questionnaire(s). One means of reducing the number of

[81] Vick S, Scott A. Agency in health care. Examining patients' preferences for attributes of the doctor-patient relationship. Journal of Health Economics 1998; 17: 587-605
[82] Ryan M, Hughes J. Using conjoint analysis to assess women's preferences for miscarriage management. Health Economics 1997; 6: 261-273
[83] Van der Pol M, Cairns J. Establishing patient preferences for blood transfusion support: an application of conjoint analysis. Journal of Health Services Research & Policy 1998:;3: 70-76
[84] Farrar S, Ryan M, Ross D, Ludbrook A. Using discrete choice modelling in priority setting: an application to clinical service developments. Social Science & Medicine 2000; 50: 63-75
[85] Morgan A, Shackley P, Pickin M, Brazier J. Quantifying patient preferences for out-of-hours primary care. Journal of Health Services Research & Policy 2000; 5: 214-218
[86] Shackley P, Slack R, Michaels J. Vascular patients' preferences for local treatment: an application of conjoint analysis. Journal of Health Services Research & Policy (In press)
[87] SPSS for Windows Version 10. SPSS Inc. Chicago, Illinois

scenarios is to remove dominant and dominated options. That is, options which are obviously superior or inferior on all attribute levels. It was evident from the results of the general public study that in some pairwise comparisons one scenario would be dominant. For example, all other things being equal, a scenario that included a doctor having access to patient notes would be preferred to the comparator scenario.

Table 7.1: Attributes and associated levels included in the conjoint analysis

Attributes	Levels
Who sees your notes:	GP Practice nurse Health service manager Health service researcher
Why they want to see your notes:	Clinical audit Research Public health
What information does the person have access to:	Past medical history (excludes sensitive history) Sensitive medical history
How you are identified in your notes:	Name and address Medical record number
How much you will be paid:	None £5 £10 £15 £20

After removing those pairs of scenarios where one scenario was considered dominant, 250 pairwise choices remained. All 250 pairwise choices were then split between 21 versions of the questionnaire: 20 questionnaires included 12 choices and one included 10 choices.* The questionnaire asked respondents to "imagine that you are an NHS patient whose medical history is of interest to health service staff or researchers, for a single specific purpose." An example of a pairwise choice from the questionnaire is shown in figure 7.1. Respondents were given the option of ticking both boxes if they did not have a preference for either. A space was provided for comments from the respondent on any aspect of the questionnaire or the issue.

7.3.2 Sample selection

The appropriate sample size for conjoint analysis studies has yet to be resolved. Previous studies have used samples of between 40 and 200 and have been able to estimate sufficiently robust models.[81,82,83,84,85,86] A sample size of n=1995 ensured that each version of the 21 questionnaires would be received by an equal number of individuals: n=95 for each version of the questionnaire.

* Due to an oversight in the matrix that was used to list all possible combinations of scenarios, duplicate questions were accidentally included in the final 250 pairwise choices. Where the question was duplicated within a specific questionnaire the duplicate was removed randomly. The remaining duplicated questions were randomly spread over the remaining questionnaires. The result is that the final study design, although inefficient, was not biased.

Figure 7.1: Example of a pairwise choice presented to respondents in the questionnaire

Which situation would you prefer? *(please tick box below)*

	Situation A	**Situation B**
Who sees your notes:	Your GP	Practice nurse
Why they want to see your notes:	For clinical audit	
What information does the person have access to:	All your medical history but no sensitive information	All your medical history including sensitive information
How you are identified in your notes:	Name and address	
How much you will be paid:	Nothing	£10
	Prefer A ☐	**Prefer B** ☐

Please tick one or both boxes

The Department of the Environment, Transport and the Regions Indices of Deprivation 2000 are measures of deprivation for every ward and local authority area in England. These combine a number of indicators covering a range of domains (income, employment, health, deprivation and disability, education skills and training, housing, and geographical access to services) into a single deprivation score for each area. Nine wards in the Barnsley and North East Derbyshire local authority areas were selected according to their Index of Multiple Deprivation 2000 score, in order to reflect the range of wards for England as a whole. The combined population for the nine wards (or part thereof) used within the sampling frame was 9858. Names and addresses were obtained from the local authorities. One thousand nine hundred and ninety five individuals were selected by a stratified systematic sampling approach.

Subjects were sent one of 21 variants of the questionnaire by post, with a covering letter and a freepost reply envelope. Subjects were told that respondents would be entered into a prize draw for a £50 gift voucher. A pilot questionnaire was given to a convenience sample of adults to ensure that the purpose of the exercise and the questions were understood.

7.3.3 Analysis

A multi-variate regression model was estimated, in which each attribute contributed to an overall preference score. The weights estimated for each level of each attribute (or coefficient) indicated its contribution to the respondent's choice between hypothetical consultations A and B or both. The standard errors in the model were adjusted to take account of multiple observations per respondent.

7.4 Results

7.4.1 Response rates

A total of 1995 questionnaires were sent out. 621 completed questionnaires were returned (535 first mailing, 86 second mailing). The response rate was 31%. In addition, there were 54 questionnaires returned because the addressee was deceased (25) or no longer resident at that address (29). Thus the overall response rate was 32% after excluding questionnaires known not to have reached their target recipient.

The median age group was 45 to 54 years and the majority of respondents were female (59%). The distribution of returned questionnaires by version varied from 41 for version 15, to 21 for version 19. Individual socio-economic data were not collected. However the area of residence provides an indication of the socio-economic status of respondents. The response rate was highest from least deprived wards, although this difference was not significant.

7.4.2 Respondents' comments included within questionnaire

Of the 621 respondents, 162 chose to add a written comment at the end of the questionnaire. In a majority of these cases (111 or 18% of the total responses), the respondent gave their opinion on the important issues raised. Other comments related to the difficulty in forming opinions, apologies for late return of questionnaire etc.. Some people commented on several issues. The following issues were found to be prominent (in descending order based on number of responses): payment, who has access to notes, inclusion of sensitive history, and patient consent to view notes.

<u>Payment</u>
Almost one third of the respondents who returned comments (31) referred to financial compensation. Most of them did not understand why they were being asked about payment for medical information. There were strong feelings that people should not expect payment; it would be a burden to the NHS and take money away from patient care. The general consensus was:

> *"I could not understand what payments had to do with medical research."*

<u>Who should access medical record information</u>
This question elicited the next greatest number of responses (18). From these comments it was clear that people acknowledge that GPs should obviously have full access to medical notes. They are less enthusiastic about practice nurses reviewing their notes and even less enthusiastic when faced with health service managers or researchers reviewing their notes. There was a hierarchy, clearly spelled out by one comment:

> *"GP or nurse can see all data, researchers can see data without name and address and managers shouldn't need to see them at all."*

<u>Sensitive information</u>
Fourteen respondents commented on how the sensitivity of the information would affect their willingness to allow access. As with the previous two concerns, they wanted only their GP to be aware of any sensitive medical information. Again if this information is to

be used for research purposes, the name and address must be removed. However, this can be contentious. For example, one respondent states that:

"I would prefer sensitive information to be used only in research and public health where applicable and outside of the practice I would prefer to be known by a number."

Others felt that sensitive information should never be released:

"I would stress that under no circumstances would I want sensitive information to be available to anyone other than my own GP, although I appreciate research is very necessary."

Another respondent confirmed the fear of misuse of data:

"I would be unhappy having my sensitive information leave the surgery with my name and address on it, as I wouldn't trust it not to fall into the wrong hands."

Whether the wrong hands is receptionist who gossips or an insurance company is not clear.

Consent and confidentiality

Eleven of the respondents wrote that they firmly felt that they should be approached for their consent to use their records for research purposes. Before they would give consent, respondents felt that researchers must abide by the rules of confidentiality. As one respondent put it:

"If managers and researchers abided by the rules of confidentiality it would be okay, but if not they shouldn't have records."

Identifiable records

These respondents (10) agreed that if their medical information is to be used for research purposes, that only their medical number was used rather than full name and address. As one respondent stated:

"I have no objections to records being used to assist in helping improve services or research as long as the individual is not identified by name and address."

In contrast to these respondents, a significant group (18 responses) were quite happy for all their medical information to be used by whoever needed it, if it would help the public good. There was a general belief by these people that research would benefit patients and they were happy to help. One typical comment was:

"I have no preference regarding who would be able to look at my medical records because if they help other people it can only be a positive way forward."

Of course there was also a very small number of people (3) who just didn't care who did or did not see their notes. The remaining comments touched on miscellaneous issues and did not fit into any of the preceding categories.

7.4.3 Model results

Results from a multinomial logit regression analysis are shown in table 7.2. In this analysis the dependent variable takes one of three values: that is, 1 when scenario A is chosen, 0 when scenario B is chosen, and 2 when both boxes are ticked. The latter occurs when the respondent is indifferent and cannot choose between the scenarios. To perform this analysis the coefficients for one of the values 0,1, or 2 must be set to zero. This category then becomes the one with which each of the other categories is compared. So, if the value 0 (Scenario B) is chosen as the comparator, as it has been here, then two tables are produced: the first compares preferences for A over B and the second compares preferences for choosing to tick both boxes over choosing scenario B alone. Table 7.2 gives details of the former: that is, the factors influencing respondents' choice of A over B.

Table 7.2: Results from the multinomial logit regression analysis

Variable	First model		Final model		
(Number of obs = 6868)	Coefficient	Std Error	Coefficient	Std Error	Relative risk
Who looks at notes:					
GP[a]	1.00*	0.08	0.97*	0.08	2.64
Health service manager[b]	-0.53*	0.09	-0.53*	0.08	0.59
Health service researcher[c]	0.02	0.09			
Purpose of looking at notes:					
For research[d]	-0.01	0.06			
For public health[e]	0.11	0.08			
Notes do not include sensitive history[f]	0.34*	0.07	0.34*	0.07	1.40
You are identified by name and address[g]	-0.53*	0.07	-0.50*	0.07	0.60
Amount of money payment [h]	0.00	0.01			

[a] Who looks at your notes: 1= GP 0=not a GP
[b] 1=Health service manager 0=Not health service manager
[c] 1=Health service researcher 0= Not health service researcher
Reference category is practice nurse
[d] Purpose of looking at your notes: 1=For research 0=Not research
[e] 1=For public health 0= Not for public health
Reference category is audit
[f] 1=Notes do not include sensitive history
0=Notes include sensitive history
[g] 1=You are identified by your name and address
0=Identified by medical record no.
[h] Amount of money payment = £0, £5, £10, £15, £20
* p<0.05

The results show that having a health service researcher look at your notes, the purpose for which notes are read, and money payments were not statistically significant. Those variables were removed from the final model which is shown in columns 4 and 5. For "Who looks at your notes" practice nurse does not appear in the table because it is the baseline against which the other health service workers are compared. The positive coefficient for GP indicates that individuals are more likely to prefer a situation where the doctor looks at their notes. Least popular is the situation where a health service manager

looks at notes: that is, where the sign on the coefficient is negative. Similarly the negative sign on name and address indicates that people prefer that a medical record number is used to identify them on notes. The positive sign on the variable for exclusion of sensitive medical history implies that individuals would prefer any sensitive information in their notes to be removed before their notes were used.

The relative importance of the attributes can be measured by examining the relative size of the coefficients in the table. The most important thing for the respondents is that a GP should look at their notes rather than any of the other three health service workers. The second strongest preference is that they be identified by a medical record number rather than their name and address. Next in importance is their distaste for a health service manager looking at their notes, followed by their dislike of sensitive medical history being included in their notes.

The exponentiated value of a coefficient is the relative risk ratio for a one unit change in the corresponding variable. Therefore, this implies that individuals would be more than 2½ times more likely to prefer scenario A to scenario B if a GP were going to look at their notes compared to a practice nurse. Furthermore, they would be half as likely to choose scenario A over scenario B if a health service manager were going to look at their notes compared to a practice nurse.

By including only those levels and attributes that are statistically significant: who looks at your notes; inclusion of sensitive information in the notes; and how you are identified, eleven different scenarios can be produced. These eleven scenarios are shown in table 7.3 in order of strength of preference.

The scenario most likely to be chosen is one where the GP looks at medical notes that do not include any sensitive history and where the patient is identified by a medical record number. Since the probability of choosing this scenario is high (0.56) the probability of being indifferent: that is, of ticking both A and B, is relatively low (0.14). This table allows examination of how individuals are prepared to trade between attributes. For example, from table 7.2 it is understood that, all other things being equal, individuals would prefer a practice nurse to look at their notes rather than a health service manager. However, if sensitive medical history is excluded from the notes and a patient is identified by only a medical record number (scenario 7) then that scenario will be preferred to one where a practice nurse has access to sensitive history and name and address of the patient. Also, in scenarios 4 and 5 both GP and practice nurse have access to sensitive history. However, individuals' preferences for a GP are so strong compared to a practice nurse that they would tolerate a GP having access to their name and address rather than choose a practice nurse who has limited information on the identity of the patient.

Table 7.3: Ranking of scenarios based on respondents' preferences

Scenario	Who sees notes	What information	How you are identified	Probability of choosing this scenario	Probability of choosing A and B
1	GP	no sensitive medical history	medical number.	0.56	0.14
2	GP	no sensitive medical history	name and address	0.46	0.23
3	Practice nurse	no sensitive medical history	medical number.	0.40	0.29
4	GP	sensitive history	name and address	0.39	0.28
5	Practice nurse	sensitive history	medical number.	0.33	0.33
6	Practice nurse	no sensitive medical history	name and address	0.32	0.37
7	Health service manager	no sensitive medical history	medical number.	0.31	0.37
8	Practice nurse	sensitive history	name and address	0.26	0.41
9	Health service manager	sensitive history	medical number.	0.25	0.41
10	Health service manager	no sensitive medical history	name and address	0.24	0.44
11	Health service manager	sensitive history	name and address	0.19	0.48

7.5 Discussion

The results of the conjoint analysis study are consistent with the main finding of the general public study: i.e. when the NHS wants access to patients' notes for whatever purpose, of most concern to the public is who looks at the notes, whether sensitive information is contained in the notes and how the patient is identified. It was expected that, all other things being equal, when a GP had access to patient notes this scenario would be preferred to scenarios where other health service staff would have access: this is a similar result to that of the regression analysis in the general public study.

However, the results showed that access by a health service researcher was not statistically significant when compared to a practice nurse. This indicates that when practice nurse and health service researcher were presented in a pairwise choice, respondents did not base their decision to choose A or B on this attribute. They did, however, express a strong preference for practice nurse over health service manager. The results from the general public study showed that when a health service researcher or health service manager had access to notes the level of the public's dissatisfaction was similar. This might be explained by differences in the perceived role of "health service manager" and "health service researcher". Although a brief description of each was given in the questionnaire,

most people would be more aware of the role of a practice nurse or a GP on a day to day basis.

The purpose for which medical records are required by the NHS did not appear to be important to the public. This is a similar finding to the general public study where that variable was also found not to be statistically significant. The amount of compensation offered did not impact on respondents' decisions to choose a particular scenario. It may be that the amounts offered, and the differences between them, were not sufficiently large to affect choice of scenario. It is more likely, however, given the written comments on the questionnaires, that the public had strong feelings that people should not expect payment: a typical response was that "It would be a burden to the NHS and take money away from patient care".

The results presented here should be viewed with some caution. It is generally accepted that a good response rate in health services research is one of 75% or above.[88] For conjoint analysis postal questionnaires however, response rates are generally much lower: ranging from 33% to 65%.[82,85,86] This might reflect the greater complexity of such instruments. The response rate was just over 30% which probably relates to the complexity of the questions. This compares with a response rate of over 60% to a previous conjoint analysis postal survey in the Sheffield area. The previous study, however, used a self selected sample, and the hypothetical topic they were asked to consider related to out-of-hours primary care, which is a subject to which the public can more easily relate than the one presented here. Although, by their nature, conjoint questions are complex the advantage of this type of survey is that it yields a number of observations per respondent: in this case approximately twelve observations per respondent. This results in a relatively large data set despite the low response rate.

The technique adds to methodology used in the general public study since it provides information about the relative importance of the different attributes. It also appears to have theoretical validity in that the negative and positive signs on the coefficients in the conjoint analysis study were what would have been expected for most of the attributes, based on the results from the general public study.

[88] Bowling A. Research Methods in Health: investigating health and health services. 1997 Open University Press, Buckingham

Chapter 8

Attitudes of young people to various uses of their health information

8.1 Summary

Objectives: To investigate the views of young people aged 14-17 on confidentiality around personal health information and when they should take responsibility for their own health care decisions.

Design: Semi-structured interviews were used for this exploratory qualitative study. Transcripts of tape recorded interviews provide the basis for a framework analysis.

Setting: Recruitment conducted in paediatric dermatology and general surgery out-patient clinics and general surgery paediatric wards. Interviews were conducted in subjects' own homes.

Participants: Eleven young women and nine young men aged 14-17 were recruited from hospital inpatients and outpatients. Eighteen parents of these young people were also interviewed.

Results: The young people had given little thought to how their health information is used prior to the interview. Young men were less concerned than young women, and younger teenagers were less concerned than older teenagers. Young people with serious conditions were more happy than those with little experience of health care for staff to access their health information. Young people with more serious medical conditions preferred to be advised on decisions about their treatment until around age 18, in contrast to teenagers lacking experience of hospital who believed they should make decisions from a much younger age.

Conclusions: Young people who have some experience of hospital health care services demonstrate greater trust in health care staff than those with little experience as hospital patients.

8.2 Background

The 1989 United Nations Convention on the Rights of the Child establishes quasi-legal rights in which in every action concerning a child, the best interests of that child should be considered (Article 3). The Convention protects a child's freedom to form his or her own views (article 12) of expression (article 13), thought, conscience, religion (article 14), and access to information (article 17). It also requires States to protect the child from interference with privacy (article 16). The United Nations Convention recognised the special role that parents have in the upbringing of a child (article 18).

Depending on the nature and importance of a question on which a decision is required, children should be included in the decision making process. The amount of influence or control that a child has will increase with age and their capacity to make autonomous choice. In health care, the age at which children can make decisions without their parents'

consent is unclear. However, children will have rights to confidentiality, and they will increasingly attain the capacity to exercise these rights as they get older. This will include the right to restrict parental access to their personal health information. Within the survey of patients and parents (chapter 6), parents were happy to allow access to their child's health record, although many of these children were very young. In this paper, the views of older children with more developed privacy needs were assessed, together with those of their parents.

8.3 Methods

The aim of this research was to explore the attitudes of young people to their right to privacy to control access to their health information, and to taking responsibility for decisions about medical interventions. It has been recognised that qualitative methods enable young people to express themselves more easily than completing questionnaires.[89]

Qualitative interviews were carried out, using a topic guide, with young people aged between 14 and 17 years and one of their parents. The duration of the interviews varied from 20 to 45 minutes. Interviews were recorded and transcribed.

Because of the general lack of knowledge of medical records the researcher provided the young people with a range of examples of situations in which they might be required to give consent to a medical procedure, or in which they may have concerns about privacy. This enabled a fruitful discussion which would not otherwise have been possible, as pilot interviews had demonstrated that young people were unable to visualise imaginary situations in which they might be asked for consent.

Nursing staff asked parents of young inpatients and outpatients aged from 14 to 17 if they were happy for a researcher to approach them to explain about the study. Parents were then asked for permission to approach their children. Young people who agreed to participate in the study were interviewed in their own homes at a later date.

Great care was taken with this group, who should be considered as vulnerable because of their youth, to ensure that they felt free to end the interview at any time, and felt no pressure to answer questions they found embarrassing or preferred not to answer for any reason. In addition, the researcher explained that very few people could spontaneously discuss the medical record, as no one had given it any thought until the researcher asked them. Thus feelings of inadequacy because of lack of knowledge about the topic and any sense that the interview represented a 'test' or that they were expected to know details of medical records was minimised.

Before discussing each new topic the young person was asked what they understood by some of the terms used. For example 'medical record', and 'best practice' were suggested and those who demonstrated little understanding were given a simplified explanation. The subject of contraception was always discussed in terms of a third party so that the young people did not feel uncomfortable, or feel concern that their own relationships were being discussed.

[89] Woodfield T. Involving children in clinical audit. Paediatric Nursing 2001; 13(3): 12-16.

After the interview each young person was asked if they would be happy for one of their parents to be interviewed, usually the mother. In a few cases, the young person and parent were interviewed together, at their request.

Ethics approval was provided by South Sheffield Local Research Ethics Committee (reference number: SS/00/298).

8.4 Results

The sample included 9 males (six age 14, one age 15, one age 16 and one age 17 years) and 11 females (2 age 14, four age 15, four age 16 and 1 age 17 years). Ten young people were recruited when attending dermatology or surgical outpatients clinic (eight females, two males) and ten on a general surgery ward (three females, seven males) at the Sheffield Children's Hospital. The sample ranged from young people who had experienced a single acute event once in the year prior to the interview to those with long term and/or life threatening conditions. Eighteen parents were interviewed: 16 mothers and 2 fathers.

8.4.1 Issues associated with consent

The young people were asked about taking responsibility for decisions for a range of medical interventions. When the concept of withholding consent to a treatment was initially suggested the primary spontaneous response was surprise and disbelief that anyone would refuse treatment recommended by their doctor. However, there was a recognition that some interventions had uncertain outcomes. After consideration of the benefits and disadvantages of various examples proposed, and in the light of their own growing maturity, the young people in the study believed that they should, increasingly with age, have a right to make their own decisions.

Experience of being seriously ill appears to be influential in differentiating between those young people who wish to assert their independence and those who are happy to comply with medical interventions because they trust doctors. Young people who had had extensive contact with the NHS suggested much higher ages for consent than those who had fewer or less serious illness episodes.

8.4.2 Age of responsibility for giving consent

Once young people had recognised that their growing independence incorporated increasing responsibility for making decisions about their own lives, including medical interventions, two main views emerged regarding an appropriate age. One view, held mostly by young women in the study, was to perceive their current age as the point at which they should take responsibility for making decisions about consent to treatment.

The legal age of majority, that is 18 years, was perceived to be the defining age by a substantial, mostly male and younger, group. Several young males explained that they felt it was impossible to say when they should take responsibility, as they could not imagine how they would feel when they were two or three years older, and how their approach to independence might develop. Increased maturity was simply uncharted territory which they could not envisage:

"I don't how I would feel when I'm 17." (14 year old male inpatient)

One young patient with lifelong episodic experience as an inpatient demonstrated confidence tempered by an awareness of his limitations:

> *"'It depends on the seriousness of the situation and how responsible the young person is. I personally could make the decision that a treatment is not right for me, having rationally thought it through that I don't want this operation. But then I'm not completely sure that I could, may not be as responsible as I think. In a year's time I definitely would." (14 year old male inpatient)*

Three main elements emerged as influential in forming young people's opinions on the age at which they should take responsibility for decisions about medical interventions. Firstly, they recognised that the rate at which young people mature varies. They therefore thought it was not possible to designate a single chronological age as right for making such important decisions. One young patient considering the question described the problem:

> *"A young person could make the decision about whether or not to have a serious operation at about 15. But it's difficult because some people are more mature than others, and some could probably understand better at age 14 than others who are about 17." (15 year old female inpatient)*

Exceptionally, one girl in the study thought that:

> *"..people are still immature in their teens, but would have the maturity to make decisions when they reached their 20s." (14 year old female outpatient)*

The second element involved the seriousness of the medical intervention. Interventions with serious implications were perceived to require more mature decision making processes than minor interventions. Young people therefore generally thought there should be an older age limit for making decisions about serious or life threatening situations. Similarly, the age for taking responsibility for making the decision about whether or not to participate in the trial of a new drug was seen to depend on the seriousness of both the disease and any possible consequences.

The third element comprised a young person's personal experience of serious illness. Those young people who had experienced life threatening or long term conditions during which they had spent long periods as an inpatient, involving protracted and complex contacts with doctors in the hospital, could not imagine refusing treatment. They trusted their doctors and therefore wanted to accept their doctors' advice about undergoing a medical procedure. They assumed that the doctor always acted in the best interests of the patient, and that, as the professionals:

> *"I would always do as the doctors say because they are the experts and therefore know what is best." (15 year old female inpatient)*

Another 15 year old female inpatient who, similarly, would not refuse treatment and always accepted procedures suggested by the doctor, nevertheless believed that she should, as a matter of principle, have the right currently to make those decisions. A female inpatient, whose condition was less serious, thought that a young person should be able to say 'no' to treatment at any age, and certainly from early teens. Another young person with limited outpatient only experience said that:

> *"You can't force that kind of thing on a person if they really didn't want it. You can't strap them down."(16 year old female outpatient)*

The youngest age at which any young person felt they might decide to refuse treatment for a trivial condition was 12, suggested by a female outpatient responding to the example of having stitches for a minor cut in an Accident and Emergency department. For a serious operation one male outpatient thought the decision should lie with the young person from age 7 to 10, and another thought that, while it depended on the seriousness of the situation, a young person should have the right to refuse a serious operation from age 13.

Younger teenagers were likely to be more compliant than older ones. The male inpatient group appeared to be particularly compliant in allowing doctors and parents to take responsibility for consenting to treatment. It is recognised that boys mature at a later age than girls, and young men's lesser maturity may constitute another reason for their compliance. Young people who were accustomed to being dependent on medical staff and parents because they had been ill for long periods in hospital or at home were more likely to be compliant than young people who had not been dependent in this way.

8.4.3 Awareness of the medical record

None of the young people in the study had given any thought to the content or purpose of their medical record prior to the interview. Many had little awareness of what information the NHS collects and stores about patients. Subjects were prompted by asking whether they had seen their doctor writing anything while they were in a consultation. This led to suggestions that their record contained their presenting condition, or details of the treatment received, or that it was a record of their visits to the hospital. Several young people agreed that they would expect the record to contain details of their condition and subsequent treatment:

> *"how I'm progressing...what kind of pills I'm taking." (14 year old male)*

Nevertheless, some young people had previously given some thought to NHS systems. Those with greater experience of the NHS, and especially young patients who had experienced ongoing contact over several years, demonstrated more awareness of the happenings that related to themselves. One exceptionally articulate young man responded:

> *"I have a very comprehensive idea of the NHS. Since I was a baby I've been admitted and to outpatients in hospital over a hundred times if it is something serious I go straight to the hospital because they have my history there and can treat me quicker...[medical record provides] full information of what happens to you medically." (14 year old male)*

None of the young people in the sample suggested any information that they thought should not be held in their medical record.

8.4.4 Disclosure to parents

While young people understood the concept of privacy they had not thought of it in connection with restricting parental access to medical records. Young women appeared to

be more concerned than young men to preserve their privacy in relation to parental access to their medical records. They tended to suggest 15 or 16 as the age from which they would like their records to be confidential between themselves and their doctors. Male inpatients were the most inclined to allow parental access to their record until age 18, as the legal age of adulthood. Some young male inpatients talked about parents' 'right to know.' It may be that the compliance expressed by young men was a function of their greater dependence on parental care as the majority of them had been inpatients and so, suffered more serious illness which is likely to foster feelings of dependence rather than independence.

The majority of young people in the study were firm in their view that contraception and sexual behaviour were areas of their lives that they would wish to keep private from their parents. Concerns associated with confidentiality in consultations about contraception were seen to pose a problem and it was suggested that a young person might go elsewhere for contraceptive advice if they thought their consultation with the GP was not in confidence. Overall young people in the study felt that a young person has a right to confidentiality with their doctor, some from the age of 11. Others felt that parents have a right to know about their child's request for contraception up to age 15. There was a view that, as sex is illegal below the age of 16, it is important for the doctor not to disclose the confidence so that the child is not criminalised. A few young people, however, saw under age sex as an illegal activity that a doctor should report to a parent. Conflict was perceived between the dual needs of privacy and independence for young people, balanced with the need for parental protection. Most young people in the study saw negotiation and discussion as the most satisfactory way out of the dilemma.

Drug misuse was seen as a difficult area for doctors wanting to maintain confidentiality with young patients, because the use of illegal substances was perceived to be a serious risk behaviour which, generally, a doctor should disclose to parents. A clear distinction was drawn between consultations with doctors for contraception, which was associated with what the young people in the study saw as a healthy and natural behaviour, and problems for which young people themselves were seen to be responsible, such as using illegal drugs or, sometimes, eating disorders. Illegal drug use was condemned as being a choice, and so not subject to the normal rules of confidentiality because it is an illegal behaviour.

Overall it was thought that a young person's permission should be sought before parents could gain access their health record. While the young people thought that their own parents always did what was in the best interests of their child, some acknowledged that not all parents are benevolent, and that different relationships and circumstances called for different responses. It was also felt that a doctor should first tell a young person of an intention to disclose a confidence to parents and in some cases, such as where there were difficult relations between parents and children, should comply with the young person's wish for confidentiality. There was a common view that the best resolution in very serious situations would be for the doctor to encourage a young person to tell the parents themselves.

Some young people, while they were eager to establish independence from parental decision making, nevertheless pondered whether they had the necessary information and experience. A number of young patients with extensive NHS contact liked to discuss difficult treatments with both doctors and parents and tended to feel that they were better informed than their parents about the major implications associated with their condition.

They nevertheless preferred to reach a consensus on, especially, serious medical intervention. Others, however, considered their parents' limited medical knowledge meant that a young person and their doctor should be the only people involved in the decision.

8.4.5 Views of parents

In contrast to the young people, parents who were interviewed were unanimous in their wish to be involved in every decision relating to medical interventions involving their children. Several parents, and a few children, described the importance of full discussion between parents and children. Parents talked about 'the right to be included' in decisions about treatment. They did at the same time, however, perceive that the locus of consent should depend on the maturity of a young person and on the seriousness of their condition.

Ideas changed and developed as some parents were talking, and thinking for the first time, about privacy and their children's medical records. While they talked about a parent's 'right to know' especially in relation to behaviours such as using illegal drugs, they equally recognised that a young person's consultations about contraception should probably be private from around the age of 16.

Parents perceived 18 as a minimum, rather than a maximum, age at which their children should take responsibility for making decisions about medical interventions. The common view was that as long as the young person was still living at home there should be no age limit on parental involvement, to well above 18 years. Parental responses to the age at which a young person might take responsibility for completing a straightforward questionnaire ranged from no lower limit to 15 years of age; more than one parent was concerned that a young person should be responsible enough to make sure they answered all questions correctly.

Parents in the study acknowledged that not all parents are supportive of their teenage children. It was also suggested that the doctor's approach to parents was dependent on the size of the community. For example, in a small village where people knew each other the doctor is more likely to know how helpful particular parents would be. In a town, where people tend to be anonymous, the doctor is less likely to know the dynamics of each family. Individual personal relationships between parents and their children were also perceived as various and doctors should take these into account when deciding if they should disclose the confidence of a young person.

8.5 Discussion

Harris has argued that "the traditional distinction between adults and children, which incapacitates children because of their supposed incapacities, does not in fact distinguish adults and children. It may distinguish the competent from the incompetent, but if full political status is to be granted only to the competent, then a large and significant proportion of children must be granted full political status and a very great number of adults must be disenfranchised."[90] Findings from the present study, in which chronological age was perceived to be less important than individual maturity in relation to giving or withholding consent to a medical procedure, support this argument.

[90] Harris J. The political status of children. In: Graham K (ed.). Contemporary Political Philosophy: Radical Studies. Cambridge: Cambridge University Press, 1982: 35-55.

The judgement as to whether a child is competent to consent may be dependant on what is at stake for the child. Gaylin[91] suggested that if the risks associated with a medical intervention are low and the benefits are high, then greater weight should be given to the preferences of the child. Young people in the present study perceived the seriousness of the medical intervention, and of possible implications or adverse effects, to be a major issue associated with consent. Thus young people who had experienced prolonged or serious conditions were more likely to leave decisions about treatment to their doctors because they had learned to trust their doctors' judgement. Young people's own experiences of doctors, nurses and others involved in their care appeared to provide them with a knowledge base from which to consider their parents' opinions, and the ability of NHS staff to use information wisely.

Overall young people in the study saw discussion with doctors and parents as the best means of reaching a decision about serious medical intervention. This evidence is supported by Bell[92] who, similarly, found that "relationships and processes which embody supportive and companionable interactions are more likely to offer opportunities for representation and participation than those which are dominant and submissive." McGrath's[93] work, with children suffering from acute lymphoblastic leukaemia, where "the experience of undergoing such extensive treatments affects not only the child, but the entire family" demonstrates further the necessity of family involvement. Doctors have, however, been recommended to check that young patients agree with the view given by their parents[1] to ensure that the wishes of the young person are taken into account in medical interventions. There is a view that the power for decision making in relation to medical interventions has gone from the parents not to the children but to the doctors.[94]

While the views of the young people in the study varied regarding an appropriate age at which a young person should be able to give consent to a medical intervention, the views of professionals can cover a wider range. The opinions of staff working in family support and child protection services fell into two distinct groupings when asked at what age a child should be allowed to refuse medical treatment.[95] Irrespective of their jobs and roles one group gave age 5 to 6, while the other group advocated age 16 to 18. The social workers in this study were characterised by differentiating children *making* decisions as opposed to children *being involved in* the decision making process.

Legally, a child still cannot withhold consent which a parent has given.[96] It is accepted that the concept of informed consent in young people below the age of 18 requires legal clarification.

Young patients in the study considered confidentiality to be an equally important issue. This finding is supported by an evaluation of three projects providing contraceptive and pregnancy counselling organised by the Department of Health in 1986 which demonstrated

[91] Gaylin W. The Competence of Children: No Longer All or None. Hastings Center Report 1982; 12: 33-38.
[92] Bell M. Promoting children's rights through the use of relationship Child and Family Social Work 2002; 7: 1-11.
[93] McGrath P. Findings on the impact of treatment for childhood acute lymphoblastic leukaemia on family relationships Child and Family Social Work 2001; 6: 229-237.
[94] Drake C. Informed consent? A child's right to autonomy Journal of Child Health Care 2001; 5(3): 101-104.
[95] Shemmings D. Professionals' attitudes to children's participation in decision-making: dichotomous accounts and doctrinal contests Child and Family Social Work 2000; 5: 235-243.
[96] Davies M. Textbook on Medical Law 1996; London: Blackstone Press Ltd.

that "the most important characteristic of the service offered should be an awareness of the key issue of confidentiality. This is of paramount importance to young people."[97]

Some young people demonstrated their unwillingness to ask the doctor about sensitive conditions because of concern about confidentiality.[98] A study of high school pupils in the US showed that while 86% would normally seek health care from the family doctor 25% would forgo health care because of concerns over a breach of confidentiality. The percentage of young people seeing the family doctor for care related to pregnancy, HIV or substance misuse fell to 57%.[99] Young people in Australia were also unhappy about possible breaches of confidentiality associated with information on sexual health among pharmacists in their small community.[100]

In an attempt to discover typical practises associated with confidentiality between doctors and their young patients, Ford and Millstein found that 53% of doctors in California reported discussing confidentiality with patients aged 15-18.[101] Gillick, however, was concerned that underage sex would be a negative likely outcome of confidentiality between doctors and young patients in consultations.[102] However, a relationship has been found between keeping secrets from their parents and the development of adolescent emotional autonomy.[103] Although the concept of confidentiality in relation to their health information is not one that young people have necessarily thought about or understand, it appears to play a part in their seeking help or advice from their doctors.

Young men in the study were less concerned than young women to keep medical records confidential. This reflects research on adults within the general public survey (chapter 5), which has demonstrated that males are significantly more happy to allow access to health information than females.

Much of the children's rights literature in the UK relates to children in the care of the local authority - 'looked after children',[104] and children with disabilities. The wider population of children tends not to perceive that they are a part of the children's rights debate. An initiative in County Durham 'Investing in Children'[105] aims to introduce children in the area to participation into the debate as described in the United Nations Convention on the Rights of the Child.

[97] Allen I. Family Planning and Pregnancy Counselling Projects for Young People. 1991; London: Policy Research Institute.
[98] Ford C, Millstein S, Halpern-Felsher B, Irwin C. Influence of Physician Confidentiality Assurances on Adolescents' Willingness to disclose Information and Seek Future Health Care: a randomized controlled trial. JAMA 1997; 278(12): 1029-1034.
[99] Cheng T, Savageau J, Sattler A, DeWitt T. Confidentiality in Health Care: a survey of knowledge, perceptions and attitudes among high school pupils. JAMA 1993; 269(11): 1414-1417.
[100] Warr D, Hillier L. 'That's the problem with living in a small town': privacy and sexual health issues for young rural people. Australian Journal of Rural Health 1997; 5: 132-139
[101] Ford C, Millstein S. Delivery of Confidentiality Assurances to Adolescents by primary care physicians. Arch Pediatr Adolesc Med. 1997; 151: 505-509.
[102] Gillick V. Confidentiality, Contraception and Young People. BMJ 1994; 308(6924): 342-343.
[103] Finkenauer C, Engels R, Meeus W. Keeping Secrets from Parents: advantages and disadvantages of secrecy in adolescence. Journal of Youth and Adolescence 2002; 31(2): 123-136.
[104] Munro E. Empowering looked after children Child and Family Social Work 2001: 6: 129-137.
[105] Cairns L. Investing in children: learning how to promote the rights of all children Children and Society 2001; 15: 347-360.

Chapter 9

Attitudes of people with learning difficulties to various uses of their health information

9.1 Summary

Objectives: To explore the attitudes of people with learning difficulties, firstly to taking responsibility for decisions about medical interventions and, secondly, to their right to privacy by controlling access to their health information.

Design: Semi-structured interviews were used for this exploratory qualitative study. Transcripts of tape recorded interviews provide the basis for a framework analysis.

Setting: Three day care centres in North and South Yorkshire

Participants: Twenty people with learning difficulties covering a range of ages from 18 to 66 were recruited in day centres.

Results: The idea of 'consent' to treatment was new for the sample group and required a full explanation. Some did not understand the explanation, and among those who did there were difficulties associated with deciding what constitutes 'informed' consent among this group of vulnerable people, many of whom simply want to give the 'right' answer. Overall, respondents would not mind anyone having access to what might normally be considered as sensitive information because they assume that everyone with the authority to see their notes acts in their best interests. However, there was some concern about access by certain individuals who were perceived to be untrustworthy.

Conclusions: Respondents demonstrated an ability to understand the abstract concept of bullying after repeated education. It is therefore likely that some people with learning difficulties could be involved in decisions about medical interventions and about privacy of their health information.

9.2 Background

While a role for people with physical disabilities is emerging in the research community[106] the position of people with learning difficulties remains problematic.[107] There is however increasing recognition of the importance of recognising the rights of people with learning difficulties within health care. The White Paper, "Valuing People", enshrined principles of rights, choice and independence for people with learning disabilities .[108] The perceptions of people with learning difficulties were sought in semi-structured interviews as one element of the research, and provided a useful basis for further work with a group whose views are not always included in policy-making decisions.

[106] Oliver M, Barnes C. All we are Saying is Give Disabled Researchers a Chance. Disability and Society 1997; 12(5): 811-813
[107] Richardson M. Involving people in the analysis. Journal of Learning Disabilities 2002; 6(1): 50-60.
[108] Department of Health. Valuing People: A New Strategy for Learning Disability for the 21st Century. London: Department of Health, 2001

9.3 Methods

Managers of two Mencap day centres and one independent day centre, all located within North and South Yorkshire, were approached with a request to carry out interviews with clients. The managers agreed to ask clients if they would be willing to participate in the study. The remit for the sample group, provided by the day centre managers, was clients with 'mild to moderate difficulties who are at the top end of the ability range.' A majority of women fell into this more able group at each centre which inevitably resulted in a gender imbalance between the numbers of men and women available for interview, although the centre managers reported a fairly even distribution of male and female clients attending the centres. The sample of 20 included everyone from the three centres who fitted the description and expressed a willingness to be interviewed.

Interviews were carried out with a sample of 20 men and women with learning difficulties to explore their attitudes to decisions about medical interventions and their right to privacy to control access to their health information.

Qualitative interviews were carried out using a topic guide. Great care was taken in the interviews with this group of vulnerable people to ensure that they felt free to end the interview at any time, and felt no obligation to answer questions they found difficult. Because of vastly different levels of ability the interviewer (JC) was flexible in the way topics were presented to each respondent, and some topics were not covered with people who appeared not to understand them. The duration of the interviews varied from 10 minutes to half an hour.

A range of terms, concepts and situations were explored at the start of each new topic in this phase to derive some objective measure of the level of understanding of these study participants. These included, for example, knowledge of their own age, of the term 'secret' to assess how well respondents in this group might understand the concept of confidentiality, and 'computer' to enable a discussion of electronic record storage. Various ways of describing 'vaccination' were used to explain the kind of information which might go to form the medical record. The subject of relationships and partners was always introduced with great care so that respondents did not feel there were any expectations associated with relationships.

9.4 Results

The gender and age range of people with whom interviews were achieved are described in Table 9.1. The names of the study sample have been changed to preserve their anonymity. Details of the cognitive and social abilities of some of the sample were limited because of their restricted communication skills or lack of memory. All respondents could say who they lived with, but a few did not know how old they were (centre mangers provided information on age). The main life circumstances of respondents (for example whether or not they lived alone, had a partner, or were in paid or unpaid employment) provided a rudimentary measure of the level of cognitive ability.

Table 9.1: Characteristics of the sample

Case	Name (anonymised)	Age	Lives with	Employment status
1	Frances	31	parents	never worked
2	Gaynor	36	parents	never worked
3	Jackie	40	carers/residents	never worked
4	Helen	38	parents	never worked
5	Adam	30	parents	never worked
6	Donna	27	parents	never worked
7	Dennis	37	alone (la tenant)	in paid employment
8	Cathy	25	with husband	worked previously
9	Olive	64	with sister	worked previously
10	Amy	18	with parents	never worked
11	Brenda	23	with parents	never worked
12	Rob	61	alone	worked previously
13	Mary	51	boy friend (7 years)	never worked
14	Noreen	56	foster parents (16 years)	never worked
15	Pamela	66	foster parents	never worked
16	Mathew	50	with mother	never worked
17	Thomas	61	alone	never worked
18	Linda	42	with mother	never worked
19	Harold	42	aunt	worked previously
20	Elaine	28	parents	never worked

Although a number of interviewees said they had a boy or girl friend probing uncovered that the majority only saw their 'partner' at the day centre, and they had no apparent knowledge of sexual relationships. A few people in this study did have a full sexual relationship with a partner, and their views are discussed below.

Some of the sample continued to improve skills such as writing, reading, and spelling, and several had attended a computer course. A substantial minority of respondents had difficulties with verbal communication, and with understanding some of the concepts raised in the interviews, especially where this involved a hypothetical situation. Explanation of the term 'vaccination' had no meaning for a number of respondents.

Only three members of the sample group, all male, were householders. Two of the women were in stable relationships and living with their partners. The remainder of the sample lived either with their parents or in shared housing with carers or foster parents.

Several of the sample were described as capable of paid employment by the centre managers, although only the most able person in the sample group (Dennis), was in employment which paid enough to take him above the benefit level (he continued to receive disability living allowance). Dennis worked 5 mornings a week as a kitchen assistant at the day centre for which he was paid £213 monthly (£49.15 weekly in 2001). He paid full rent on a local authority house. Other respondents did not work for a variety of reasons. Day centre managers described the main influences on employment status as parental protectiveness and a lack of funding, for example for fares and/or for a companion to accompany vulnerable adults to and from a place of work.

Several of the sample group from one centre spent weekday afternoons working as volunteers on a shopping scheme for the elderly. The scheme, which was run by the day centre, involved collecting shopping lists from older people in their own homes, going to the supermarket, getting the shopping requirements for each older person, and delivering the shopping and the bill to them. The day centre had an arrangement with the supermarket to pay for the shopping after it was delivered to the customers, and provided a minibus and driver for transporting helpers and shopping. It is likely that clients on this scheme would have been capable of paid work.

Two clients from another centre in this study (Harold and Elaine), had attended a work training conference, and Harold regularly travelled by tram independently. Another (Jackie) worked one day a week at an Oxfam shop. Otherwise respondents spent weekdays at the day centres or at home.

The sample was not selected from a health service setting, and some therefore had experienced only limited contact with health professionals. Almost all the sample reported visiting the doctor, although a few could not remember whether or not they had had any contact with health services. The majority of respondents were accompanied by a parent, legal guardian or carer on all their visits to a doctor. One woman, who lived with her husband (Cathy), was accompanied by a carer. However two other women, one of whom was in a relationship (Mary), visited the doctor alone and both understood the rationale for the medical record. Two of the three male householders (Dennis, Rob) also visited their doctors unaccompanied, but the third, although he lived alone (Thomas,), was always accompanied either by his sister or his key worker because he said, of being "unable to explain myself."

9.4.1 Issues of consent

Day centre managers described parents and carers as often paternalistic toward people with learning difficulties. Parents tended to perceive their adult children as being in need of special protection partly as a result of their disability, but also because of the fear of verbal and physical bullying. Their concerns were confirmed in the interviews as several respondents tended to give what they believed to be the 'right' answer in order to please, by agreeing to everything suggested by the interviewer, even when this led to conflicting responses and a lack of internal consistency.

The idea that they might refuse any treatment offered to them by a doctor and agreed by a parent or carer was received as a completely new concept by almost everyone in this element of the study. It was taken for granted that doctors, parents and carers always and only acted in the best interests of themselves as the patient. It therefore never occurred to them to question decisions made by doctors and parents in relation either to taking medication or undergoing surgical procedures.

Women in the study appeared to be especially compliant. One, for example (Gaynor), said she would have whatever treatment her parents wanted her to have. Similarly another, (Olive) said she would undergo any treatment suggested by her doctor if her sister was in agreement. A third woman described her doctor, herself and her parents as jointly agreeing to a hysterectomy (as contraception) after she started a first relationship with her partner at age 44 (Mary). It is not possible to make a judgement about how well informed Mary was

before agreeing to major surgery, but it is plausible that a woman aged 44 would not want a first baby.

Contradictory responses demonstrate the compliant attitude of some respondents. One man, for example, had had an operation because his mother and doctor agreed that he should (Mathew). He said he had not wanted the operation and that he would not have another, but then said that he would consent to further surgery if his mother said he should. A woman, likewise, had an operation for a ganglion on her hand at her mother's suggestion, but said that if she did not want an operation she should be able to make that decision (Jackie). She also thought she would make her own decision about trying new treatment, but then said she would probably follow her mother's wishes.

Predictably, the views of the few men and women in the sample who demonstrated an understanding of the concept of autonomy were the most interesting and relevant for this study. They initially described 18 as the age at which young people should decide themselves about whether or not to undergo a medical procedure, because they knew this to be the legal age of adult status.

Eighteen was thought to be the appropriate age to take responsibility for consent to a medical intervention by Dennis. His appendix had been removed as an emergency operation at age 28 and he had signed his own consent form. He thought that parents should be present in the Accident & Emergency department with young people up to age 15 or 16, but may have altered this view if given more time for reflection.

Several women in the study perceived 16 as the age when they could take some responsibility for decisions about their medical treatment. One initially gave 18 as the age when she could make such decisions but after probing thought she should be included in the decision making process from age 16 if the treatment had long term consequences (Frances). When given an example of treatment with damaging side effects and uncertain outcome, another too thought she should be able to decide from age 16 whether or not to receive treatment (Brenda). Respondents could not always say what they would think if their doctor or parents suggested an operation because they could not imagine themselves in this situation.

Decisions about future treatment could, however, be influenced by painful or otherwise negative experiences. One man, for example, had not wanted an operation on his leg because he disliked needles, and the first operation had been unsuccessful which meant he had to have another at a second hospital (Rob).

A small number of people from the sample appeared to understand the concept of informed consent. Others may have developed a greater understanding if it had been the subject of special sessions at the Day Centre, as bullying had been. As a result of the special sessions all the clients interviewed at this Centre had a good understanding of 'bullying', as well as knowing how they should respond to bullies. It is likely that careful explanation and discussion of informed consent would have similar positive effects on their understanding of a concept which was new to them.

9.4.2 Awareness of medical record

Before exploring their views it was important to establish each respondent's level of

understanding in relation to the medical record so that the discussion would have some meaning, or the interviewer would assess whether a meaningful discussion was possible.

None of the people interviewed understood the term medical record, but several expressed familiarity with the term 'notes', and recognised that when they visit the doctor the notes he or she writes relate to themselves. The importance of recognising terminology was demonstrated thus:

"I know about medical notes, they're paper, but I don't know what a record is." (Mary)

Several respondents thought that the term 'medical record' simply meant their doctor, probably because they heard the word 'medical', and related it directly to ailments. Thus when asked for an explanation of medical notes, the following responses were given:

"Had leg operation" (Mathew)
"When you go to hospital." (Noreen)
"Like when you have a bad stomach" (Gaynor)

Several other women, however, showed no understanding at all in relation to the term medical notes.

Understanding of the concept and rationale for the medical record was demonstrated by others. A number of respondents were able to describe a rationale for medical records by describing the notes as a record of their problem and treatment:

"If you're taken poorly he (doctor) writes down if you've got flu or an upset tummy." (Cathy)
"Is it to look back and see what you have had?" (Rob)

When asked about knowledge of the medical record the most able of the respondents commented:

"No I don't think I've seen it. Haven't been this year [to the doctor] except for sciatica, and had a blood test. I've been to see the practice nurse and had a tetanus jab." (Dennis)

9.4.3 Privacy

The majority of people interviewed said they were happy for anyone to have access to their notes. Privacy was a concept which many of the respondents found particularly difficult to understand. The idea of *who* should have access to the record meant more to those respondents who differentiated between the various people in their lives and is discussed below.

Only Dennis among the men could think of anything he would not want to be accessible to any person who might need to see his notes. Dennis, however, did not want anyone apart from his doctor and selected workers at the day centre to see sensitive material because of the highly personal nature of the information, even if no identifier is attached. (He was, at the same time, interested enough to ask how he could see his own record on his next visit

to the practice). Similarly most women, whether or not they had seen their doctor about contraception, were happy for people in the medical profession to see their health information because they perceived everyone to be acting in their best interests. Knowledge about who might have access to their medical records was limited. For example Helen thought her doctor and nurses had access to the record, but no other people. Mathew thought only the doctor saw his notes, not the nurse, but said he would be happy for anyone to have access to his notes. Mary, who had had a hysterectomy as a contraceptive, was happy for anyone to see anything in her record including information about sexually transmitted disease.

In contrast, and after prompting, respondents who considered information which they perceived to be sensitive, relating for example to a sexual problem, did not want certain staff to have access to their medical notes. Dennis, who was in a developing relationship with a partner, thought at first that everything in his medical notes should be freely accessible to anyone. He had had a sexual relationship with a former girl friend, and was aware of sexually transmitted diseases. He would not mind his own support worker seeing this part of his record, or any medical related professional, but said he would not want the GP receptionist to have access, because he was afraid that she would talk about his problem to other people: 'You don't know what would go on.'

Individual staff were differentiated by willingness to allow access to notes by this sample group. One woman, for example, was happy for her social worker and trainee doctors to see her notes but stressed that she did not want the practice nurse to have access to them (Frances). Probing brought out that she particularly disliked the nurse. Similarly, another thought that doctors and carers had access to notes, and was happy about this, except in the case of particular carers that she disliked (Jackie).

People with learning difficulties generally agreed that they were happy for professionals to have access to their medical records, including information about a sensitive problem, in order to improve public health, for research, and for training new doctors. The level of identification of individual notes was poorly understood and so was not seen to be an issue.

9.4.4 Mode of storage

A substantial proportion of the sample had been on a computer course, with the result that there was good comprehension of the question about whether they would prefer their medical records to be stored on paper or on computer.

After a brief explanation from the interviewer the overall preference was for computer storage, although few respondents could support their choice with a reason. Several of the sample appeared to view computers as having a high value because they were perceived to be tools for able people. Jackie, for example, preferred her notes to be stored electronically, although she could not say why, but explained that her doctor currently wrote into a computer.

One person commented that papers are more likely to be lost than electronically held information:

"If you've got papers, sometimes they might lose the papers." (Rob)

9.5 Discussion

Initially all the study sample were happy for anyone to access their medical records, as they saw everyone as safeguarding the best interests of themselves as vulnerable. Presumably this was a stance encouraged by carers and guardians so that caring was made easier by compliance with the wishes of themselves and medical staff. It has been suggested that 'It is difficult to discuss autonomy, dignity or privacy as anything other than principles, toward which clients and carers may aspire'.[109]The dichotomy between protection and autonomy will remain an issue in relation to people with learning difficulties and, as Malin and Wilmot found,[109] there emerges a tendency to err on the side of protection.

Some of the sample group appeared to be happy for their carers to give consent to a suggested medical intervention but conflicting responses and a lack of internal consistency demonstrated that they had not made a considered judgement. The issue of *informed* consent is particularly difficult to define or to assess in these circumstances. It is, in any case, hardly possible to apply the issue of informed consent to people whose memory does not allow them recall of any past experiences on which to base a decision, and members of the sample who fall into this group are not discussed.

However, previous research has found that examples of inappropriate medical intervention[110] demonstrate the importance of including people with learning difficulties in the decision making process as far as possible. It became clear in the course of the interviews for the present study that not all people in the sample were capable of understanding certain concepts such as privacy and consent, and will always need a carer to make decisions for them.

An expressed wish by some respondents to see their medical record lends support to the view that it may be a lack of knowledge rather than an inability to consider the issues which influenced respondents' comments in the interviews. Williams and Robinson[111] described how, in a study to assess the amount of control people with learning difficulties had over their community care assessments, that: "people are enabled to understand about their rights [and].. this means regular contact, over a period of time, by someone who can get to know the person with learning disabilities and listen to their views as they develop."

It is likely that unfamiliar terminology as well as new concepts placed the sample at a disadvantage in discussing the issues put to them. It is also possible that the understanding of some people in the sample exceeded their ability to express thoughts verbally, and caution should be taken before dismissing this group of people as unable to have a view on concepts which are new to them such as privacy and consent. Disability research has already recognised that "A prerequisite to effective involvement and choice is information."[112]

[109] Malin N, Wilmot S. Ethical Advisory Group. Journal of Learning Disabilities 2000; 4(3): 117-226.
[110] Hart S. Spotlight on consent. Learning Disability Practice 2001; 4(4): 14-17.
[111] Williams V, Robinson C. Tick this, tick that. Journal of Learning Disabilities 2000; 4(4): 296-305.
[112] Preston-Shoot M. 'Messages from disability research for law, policy and practice' p. 272, in Cooper J. (ed.) Law, Rights and Disability, 2000. London and Philadelphia: Jessica Kingsley Publishers

Some thought should be given to the effect of personal relationships between practice staff and patients and between carers and patients who have particular concerns about certain individuals accessing their health information.

The shopping scheme, although unpaid, was reported by those respondents involved to give them a sense of self esteem. Their appreciation of being trusted to perform what they perceived to be a responsible task indicates that they would benefit from trust in relation to more personal matters such as involvement in decisions about medical interventions as well as the opportunity to exercise some control over paternalistic oversight by parents and carers.

People who are unusually dependent on others, from their most important to the most trivial needs, do not easily think independently partly, perhaps, out of habit but also because they do not wish to incur disapproval from a needed source of support. Compliance emerged as a typical trait among this group of respondents, and one which compounds the difficulties associated with the issue of informed consent for people with learning difficulties. Person centred care would enable people with learning difficulties to contribute their input to decisions about consent to medical interventions as well as exercising some control over who has access to their health information and encouraging a greater sense of autonomy.[113]

Although no view on the level of identification associated with medical notes was provided in these interviews this may become an issue for people with learning difficulties if, as with privacy and consent, the concept is clearly and carefully explained to them.

[113] Parley F. Person-centred outcomes. Journal of Learning Disabilities 2001; 5(4): 299-308.

Chapter 10

How do the public think that they should be informed about the use of personal health information?

An evaluation of patient information sheets

10.1 Summary

Objective: To evaluate various information sheets designed to explain to patients how their personal health information is used.

Design: Six information sheets were evaluated: 1. recommended by Caldicott Committee; 2. recommended by Department of Health; 3. used by BUPA; 4. used by local NHS Trust; 5. an expanded version of the Department of Health information sheet; 6. a similar information sheet to version 5, but where subjects could give itemised consent for specific uses. Each subject was asked to read two out of the six information sheets. After each sheet, subjects were asked to complete a self-administered questionnaire.

Setting: Community, and a teaching hospital (dermatology, haematology, rheumatology, gastroenterology, hepatology and general surgery).

Participants: Members of the general public, in-patients and outpatients.

Main outcome measures: Willingness to give consent, understanding uses of data that would be permitted by consent, assessment of quantity and quality of information, Miller Behavioural Style Scale.

Results: Subjects were generally happy to give consent after reading the information sheets. However, many did not think that various uses of their medical records as described to them would have been covered by their consent. Despite this, when asked to reconsider their consent, most would still be happy to give consent. Subjects tended to prefer information sheets that were longer and contained more detail and used simpler language.

Conclusions: While patients were willing to give consent for their health information to be used in the ways described, this consent may not be informed. Further work will be required to develop and evaluate cost-effective approaches of complying with data protection legislation.

10.2 Background

The European Directive (95/46/EC)[114] provided protection for individuals with regard to the processing of personal data and on the free movement of such data. The Data Protection Act 1998 introduced the measures necessary for the UK to comply with this Directive. Article 10 of the European Directive specifies the information that should be given to the data subject. These 'fair processing provisions' are covered within the first of the eight principles of data protection laid out in The Data Protection Act, 1998. The First Principle (Schedule 1, Part II, Paragraphs 1-4) specifies that personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless the following information has been supplied or made readily available to data subjects:

- The identity of the data controller or their representative (i.e. those who determine the manner in which processing is carried out);
- The purpose(s) for which the data subject's personal data is or are intended to be processed; and
- Any other information which in the circumstances should be given to the data subject to ensure that processing is conducted fairly.

The first Principle also requires that at least one of the conditions in Schedule 2 is met and in the case of sensitive personal data (which would include health information) at least one of the conditions in Schedule 3 is also met. The UK Government has made it clear that the standard for the NHS should be to seek informed consent for use of data, although they recognise that this would be difficult to achieve in all circumstances in the short term. If the NHS was to obtain informed consent, then both Schedules 2 and 3 would be satisfied, as would the fair processing provisions of the first data protection principle.

The UK General Medical Council (GMC) [115] have required that patients are made aware that personal information about them will be shared within the health care team and, if appropriate, with another organisation providing health or social care, and of the reasons for this disclosure. The GMC also recognised that information about patients is required for purposes such as epidemiology, public health safety, administration of health services, education and training, clinical audit, and research. Even so, in all such cases the GMC requires that patients have access to written material informing them of such processing, as required within the Data Protection Act 1998, and are given the opportunity to object.

Similar rights to disclosure about the use of health information exist outside Europe. For example, in the USA, patients have rights to understand and control how their health information is used.[116] Health care providers and planners are required to give patients a clear written explanation of how they can use, keep, and disclose their health information.

Hitherto, health care providers have not routinely or explicitly explained to patients about the way they protect and use personal health information. Efforts will need to be made to devise procedures in order to comply with these various legislation and regulations. This paper addresses the content that could be included within this information by evaluating

[114] The Official Journal of the European Communities of 23 November 1995 No L. 281 p. 31.
[115] General Medical Council. Confidentiality: Protecting and Providing Information. 2000
[116] National Standards to Protect the Privacy of Personal Health Information. Washington D.C.: Health and Human Services, 2001

various information sheets of differing length and complexity that have been devised for this purpose.

10.3 Methods

Each subject was asked to assess two out of six information sheets being evaluated:

- 'Caldicott': Modified from an information sheet commended by the Caldicott Committee used by Fischer Medical Centre, Skipton.[117]
- 'DoH': Recommended by the Department of Health.[118]
- 'BUPA': Text approved by the Information Commissioner used by BUPA, a private health care organisation.[119]
- 'Trust': Currently used by a local NHS Trust.
- 'Sheffield': Version of Department of Health information sheet modified in light of qualitative pilot work.
- 'Itemised': Version of Department of Health information sheet modified in light of qualitative pilot work, with opportunities for patients to give selective consent to specific uses of health information.

Subjects included members of the general public and patients attending the Royal Hallamshire Hospital, Sheffield. Outpatients and inpatients were recruited from a range of specialties: dermatology, haematology, rheumatology, gastroenterology, hepatology and general surgery. Suitable patients were approached by nursing staff to ask whether they would be willing to be interviewed, before being formally consented by a researcher (JC or SW) and asked to complete a questionnaire. Questionnaires were also sent by post to members of the public who had previously agreed to participate in further research when responding to the conjoint analysis survey (chapter 7). Subjects from this earlier survey had been randomly selected from the electoral rolls for North East Derbyshire and Barnsley local authorities living in wards chosen to provide a range of socio-economic deprivation. A reminder questionnaire was sent to non-responders.

Background information was collected on age; gender; ethnic group; marital status, and employment status. Subjects were asked to read an information sheet and to decide whether or not they would give hypothetical consent for their information being used as described. Subjects were then asked whether four examples of uses of health information would be covered by the hypothetical consent they had just given, whether they had thought about their health information being used in these ways when giving consent and with these uses in mind, would they still give consent. Subjects were asked to appraise the information sheet on a ten point scale where "1= information is too basic, too general, too long, or difficult to understand" and "10 = gives me the kind of information I need to know". The second information sheet was then read and the same questions asked. When they had assessed both sheets, subjects were asked to state which sheet they preferred using a five point scale (strongly prefer or slightly prefer one over another or whether they had no preference). Subjects were randomised as to which two sheets they were asked to

[117] The Caldicott Committee. Report on the review of patient-identifiable information Leeds: NHS Executive, December 1997. Appendix 10. (see http://www.doh.gov.uk/confiden/app10.htm – accessed March 2002)
[118] Department of Health.. The Protection and Use of Patient Information: Guidance from the Department of Health. London: Department of Health, 1996.
(http://www.doh.gov.uk/ipu/confiden/protect/pguid6.htm – accessed March 2002)
[119] Hinde S, Warren V. BUPA wants to ensure systematic transfer of data. BMJ 2001;322:730

assess and also the order in which they were read, in case there were systematic preferences for the first or second sheet assessed.

The first mailing of the postal questionnaire included questions for the Miller Behavioural Style Scale (MBSS)[120,121] to identify information seekers (monitors) and distractors (blunters). This scale asks the individual to imagine four stress-evoking scenes that are similar in context to the stress that someone may be under when entering hospital (potential mechanical problems on an aeroplane, being taken hostage by terrorists, concerns about being made redundant, visiting a dentist). Each scene is followed by eight statements that represent different ways of dealing with the situation. Four of the statements are of a monitoring or information-seeking variety and four are of a blunting or information-avoiding variety. The total monitoring and total blunting scores were obtained by summing the number of monitoring or blunting responses that the subject indicated across the four situations. Previous research with primary care patients showed the monitoring sub-scale to be more strongly associated with health behaviours than the blunting sub-scale.[122] High monitors are people with scores above the median monitoring score, low monitors are below the median score. Following terrorism in the USA on 11 September 2001, it was decided to withdraw the MBSS from the subsequent questionnaires that were distributed because asking people about problems on aeroplanes and terrorist hostages may have caused offence.

A required sample size was calculated based on the ability to detect a true difference of 0.7 in the mean rating on a ten point scale between any two information sheets (using the standard deviation of 2.45 within a pilot sample, α=0.05; β=0.8).

The readability of the information sheets was assessed using readability scores (calculated using Word 2000) based on the average number of syllables per word and words per sentence. The Flesch Reading Ease score rates text on a 100-point scale; the higher the score, the easier it is to understand the document. For most standard documents, the target score should be approximately 60 to 70. The Flesch-Kincaid Grade Level score rates text on a U.S. grade-school level. For example, a score of 8.0 means that an eighth grader can understand the document. For most standard documents, the target score should be approximately 7.0 to 8.0.

Data were analysed using SPSS for windows version 10.0. Mann-Whitney and Kruskal-Wallis tests were used to analyse differences between information sheets.

Respondents were entered into a £50 gift voucher prize draw.

Ethics approval was obtained from the South Sheffield Local Research Ethic Committee (reference number: SS/00/178).

[120] Miller SM. Monitoring and Blunting: Validation of a Questionnaire to Assess Styles of Information Seeking Under Threat. Journal of Personality and Social Psychology 1987; 52(2): 345-353.
[121] Miller SM, Leinbach A, Brody DS. Coping Style in Hypertensive Patients: Nature and Consequences. Journal of Consulting and Clinical Psychology 1989; 57(3): 333-337.
[122] Miller SM, Brody DS, Summerton J. Styles of coping with threat: Implications for health. Journal of Personality and Social Psychology 1988; 54: 142-148.

10.4 Results

The information sheets varied in length, readability (table 10.1) and content (table 10.2).

Table 10.1: Length and readability scores of information sheets

	Caldicott	Sheffield	Itemised	DoH	Trust	BUPA
Words	866	596	704	477	276	120
Paragraphs	24	25	36	22	8	6
Sentences	44	14	20	18	11	6
Sentences per paragraph	2.3	2.0	1.6	1.6	1.5	1
Words per sentence	18.9	20.1	18.1	18.3	23.3	20
Pages (in 14 point font)	3	1.75	3	1.6	1	0.5
Passive sentences	31%	28%	45%	27%	27%	16%
Flesch Reading Ease score	50.2	49.8	59.2	53.9	54.0	35.6
Flesch-Kincaid Grade Level score	10.9	11.3	9.4	10.2	11.5	12.0

Postal self completion questionnaires were returned by 313 (70%) of the 450 members of the public who were sent a questionnaire. Questionnaires were also completed by 113 inpatients and 200 outpatients. Of the 626 subjects 39.7% were male and 60.3% were female. The average age was 50.3 years. 74.5% were married, 12.4% single, and 13.2% were widowed, divorced or separated. 42.1% were in full-time employment, 7.4% worked part-time, 7.2% self-employed, 30.9% were retired, 1.5% were students, 7.4% disabled, 3.6% were unemployed or not working for some other reason. Virtually all subjects (98.7%) were of white ethnic origin.

Most subjects were willing to give consent to the first information sheet they were asked to read: Sheffield 94.1%; Trust 94.0%, Caldicott 93.1%; Itemised 92.8%; DoH 92.6%; BUPA 90.0%. The percentages consenting overall for each sheet was lower for some sheets if read by subjects after they had had an opportunity to read an alternative sheet (table 10.3).

When posed with uses of health information, many subjects did not think that the hypothetical consent that they had just given covered that use. For example, only 42% of people who read the BUPA sheet thought that if they had signed a consent form, then they would have permitted a receptionist to look at their notes when she files test results (table 10.3). Many people had not considered such examples of information use when they were asked to give consent (range: 26.1% for Sheffield sheet; 43.0% for BUPA sheet). When people were given an opportunity to rethink whether they would consent, most people were still willing to give consent, although there was larger withdrawal of consents for those sheets that had been less effective initially at informing subjects about ways in which information would be used. For example consent for the BUPA sheet fell from 86.7% to 74.7% (table 10.3).

Table 10.2: Content of information sheets

Subject	Caldicott	Sheffield /Itemised	DoH	Trust	BUPA
Rationale for record	✓	✓	✓	✓	
Content of health record	✓				
Contact person for questions	✓	✓	✓		
Anonymised where possible		✓	✓	✓	✓
Contractual obligation of staff	✓	✓			✓
Legal protections	✓	✓	✓	✓	✓
Consent needed for disclosure	✓				
Right of access to own notes	✓	✓			
Disclosure required by courts	✓	✓	✓		
Public health	✓	✓	✓	✓	
Planning, managing, finance	✓	✓	✓	✓	✓
Investigating complaints		✓	✓		
Clinical audit/governance		✓	✓		✓
Clinical care/ treatment	✓	✓	✓	✓	
Training/ education	✓	✓	✓	✓	
Research		✓	✓		✓
Immunisation	✓				
Screening	✓				
Cancer registries		✓			✓
Infectious diseases/PHLS	✓	✓			✓
Doctors/nurses	✓	✓			
Therapists	✓				
Receptionists/Secretaries	✓	✓			
Social services	✓	✓			
Benefits agency	✓				
Insurance	✓				
Sharing with family/friends	✓				

Within the 'Itemised' sheet, subjects were asked to indicate whether they would give separate consent for five different uses of personal health information. Virtually everyone (97.8%) consented to use of information as part of the health care that they received e.g. using their past medical history to make a diagnosis or choose treatments, to arrange appointments, filing, and planning discharge from hospital. Many (92.4%) would permit their information to be used for public health functions e.g. cancer registries and surveillance of communicable disease. The use of data that received the lowest proportion (87.4%) giving consent was for managing and planning the NHS, e.g. clinical audit, financial audit, measuring hospital activity, health needs assessment, investigating complaints. A high percentage (96.7%) would allow access to their notes, x-rays and test results if it helped train and educate staff. 85.6% consented to their notes being searched to identify patients with a particular illness to contact them to see if they would be willing to participate in research evaluating a new treatment.

Table 10.3: Informed consent given following information sheet

Would you consent to your information being used as described in this Information Sheet?												
	Caldicott		Sheffield		Itemised		DoH		Trust		BUPA	
yes	182	94.8%	179	91.3%	171	91.4%	174	89.7%	184	92.5%	170	86.7%
no	10	5.2%	17	8.7%	16	8.6%	20	10.3%	15	7.5%	26	13.3%
Do you think you have agreed to the uses described below by the consent that you have just given?												
A receptionist working in your local GP clinic looks at your notes* which contain information about an episode of mental illness in the past, and your name and address, when she files test results in your notes												
	Caldicott		Sheffield		Itemised		DoH		Trust		BUPA	
yes	119	60.4%	135	67.8%	121	62.1%	102	51.8%	108	54.8%	81	42.0%
no	78	39.6%	64	32.2%	74	37.9%	95	48.2%	89	45.2%	112	58.0%
A social worker looks at your notes*, as part of her or his job, in arranging for a part time carer to help you at home while you are unable to manage to cook and shop for yourself												
	Caldicott		Sheffield		Itemised		DoH		Trust		BUPA	
yes	158	80.2%	176	87.1%	164	83.2%	166	83.0%	162	81.8%	111	57.8%
no	39	19.8%	26	12.9%	33	16.8%	34	17.0%	36	18.2%	81	42.2%
A NHS manager looks at your notes* which contain all your past medical history and your name and address, to see what proportion of the population have HIV												
	Caldicott		Sheffield		Itemised		DoH		Trust		BUPA	
yes	132	67.0%	160	79.6%	145	74.4%	152	75.6%	146	74.5%	121	62.4%
no	65	33.0%	41	20.4%	50	25.6%	49	24.4%	50	25.5%	73	37.6%
A medical student studying with your consultant has been told to look at your notes* to read up about your case before a ward round												
	Caldicott		Sheffield		Itemised		DoH		Trust		BUPA	
yes	189	95.5%	196	97.5%	183	92.9%	178	89.0%	177	89.8%	142	73.2%
no	9	4.5%	5	2.5%	14	7.1%	22	11.0%	20	10.2%	52	26.8%
Had you thought about your health information being used in this way when giving consent?												
	Caldicott		Sheffield		Itemised		DoH		Trust		BUPA	
Yes	143	73.3%	147	73.9%	139	70.9%	128	64.6%	121	61.4%	110	57.0%
No	52	26.7%	52	26.1%	57	29.1%	70	35.4%	76	38.6%	83	43.0%
With these uses in mind, would you still give consent?												
	Caldicott		Sheffield		Itemised		DoH		Trust		BUPA	
Yes	162	84.8%	176	88.9%	158	84.5%	160	82.9%	155	80.7%	142	74.7%
No	29	15.2%	22	11.1%	29	15.5%	33	17.1%	37	19.3%	48	25.3%
* The questionnaire did not define in detail what was meant by "looks at your notes". The implication is that the individual looks only at the part of the notes relevant to their function. However, paper-based notes would mean that the individual could also look at other aspects of the health record. This would be more difficult with electronic health records.												

The BUPA sheet was rated significantly worse than the Sheffield ($p<0.001$), Caldicott ($p<0.001$), Itemised ($p<0.001$), and DoH sheets ($p=0.007$) (table 10.4). The difference between the BUPA and Trust sheets was not significant ($p=0.109$). The Trust sheet was rated significantly worse than the Sheffield ($p=0.004$), Caldicott ($p=0.006$), Itemised ($p=0.009$). The difference between the Trust and DoH sheet was not significant ($p=0.277$). There were no statistically significant differences between the Sheffield and Caldicott ($p=0.911$); Sheffield and Itemised ($p=0.854$); Caldicott and Itemised ($p=0.886$). The differences between the DoH sheet and the three more popular sheets also failed to reach statistical significance: Sheffield ($p=0.058$); Caldicott ($p=0.075$); Itemised ($p=0.106$)

Table 10.4: Rating of information sheets according to whether they meet subjects' information needs

	n	Mean	95% C.I. lower limit	95% C.I. upper limit	Median	Standard deviation
Sheffield	210	7.29	6.95	7.63	8	2.51
Caldicott	203	7.28	6.93	7.63	8	2.53
Itemised	203	7.21	6.86	7.57	8	2.58
DoH	212	6.80	6.43	7.17	7	2.74
Trust	211	6.41	6.00	6.82	7	3.01
BUPA	205	5.88	5.44	6.32	7	3.18

While the sample size was not big enough to distinguish been the mean scores for some of the information sheets, subjects were explicitly asked to give a preference between the two sheets that they were asked to assess. Those subjects who had a preference seemed to prefer the Caldicott information sheet (table 10.5)

Table 10.5: Preference between the two information sheets assessed by each subject

Information sheet	Strongly prefer	Slightly prefer	Information sheet	Strongly prefer	Slightly prefer	No preference
Caldicott	13.2%	23.7%	Sheffield	7.9%	21.1%	34.2%
Caldicott	26.3%	18.4%	Itemised	7.9%	5.3%	42.1%
Caldicott	17.1%	24.4%	DoH	0.0%	14.6%	43.9%
Caldicott	20.9%	16.3%	Trust	14.0%	11.6%	37.2%
Caldicott	38.6%	18.2%	BUPA	2.3%	6.8%	34.1%
Sheffield	47.5%	15.0%	BUPA	5.0%	7.5%	25.0%
Sheffield	4.9%	19.5%	Itemised	4.9%	24.4%	46.3%
Sheffield	24.5%	16.3%	DoH	4.1%	16.3%	38.8%
Sheffield	25.6%	18.6%	Trust	14.0%	11.6%	30.2%
Itemised	5.4%	37.8%	DoH	10.8%	10.8%	35.1%
Itemised	22.0%	14.6%	Trust	7.3%	12.2%	43.9%
Itemised	33.3%	8.9%	BUPA	2.2%	8.9%	46.7%
DoH	20.0%	20.0%	Trust	8.9%	13.3%	37.8%
DoH	30.8%	25.6%	BUPA	7.7%	7.7%	28.2%
Trust	36.8%	15.8%	BUPA	7.9%	2.6%	36.8%

There were no statistically significant differences between information sheets when analysed according to gender, age or information seeking style (table 10.6).

Table 10.6: Preferred information sheet according to gender, age and MBSS information gathering style

	Sheffield	Caldicott	Itemised	DoH	Trust	BUPA
	Mean (n)	Mean (n)	Mean (n)	Mean (n)	Mean (n)	Mean (n)
Gender						
Male	7.57 (83)	7.03 (77)	7.28 (75)	7.05 (86)	6.38 (68)	6.22 (95)
Female	7.36 (122)	7.49 (125)	7.33 (124)	6.83 (121)	6.71 (137)	5.63 (109)
Age group						
17-43	7.16 (64)	7.38 (55)	6.97 (68)	6.53 (74)	6.40 (68)	4.88 (67)
44-58	7.74 (68)	7.21 (73)	7.17 (76)	6.48 (65)	6.24 (67)	5.88 (69)
59-93	7.42 (63)	7.36 (74)	7.93 (55)	7.82 (67)	7.15 (68)	6.94 (67)
Information seeking style						
High monitor	7.29 (72)	7.16 (50)	8.00 (38)	7.65 (65)	6.77 (73)	6.27 (44)
Low monitor	7.66 (62)	7.88 (60)	7.11 (53)	6.90 (58)	6.96 (55)	5.76 (46)

10.5 Discussion

The information sheets varied in length, content and ease of readability. The longer sheets contained more information and the extra space facilitated the use of language, layout and explanations that was more easily understood by a lay audience. While these longer sheets may be more informative, they will only be effective if people take the time to read them. Shorter information sheets may therefore be more effective, providing language and layout are accessible and attractive.

Quantitative (see chapter 5) and qualitative (see chapter 11) research has shown that it is the people who will use the information, not what it will be used for that determines whether the public are happy to allow access to their personal health information. The emphasis within many of the information sheets that were evaluated was on use of data rather than users. This may in part explain the popularity of the 'Caldicott', 'Sheffield' and 'Itemised' sheet, because these provided most information about who will have access and, perhaps more importantly, why they need it.

The general public study (chapter 5) found that males and older people were happier to allow access than females and younger people. While males and older people rated all information sheets higher than the other groupings, these differences were not statistically significant. Nor was there a clear pattern of preference among high or low monitors (i.e. informing seekers versus information avoiders).

The 'BUPA' sheet has been approved by the Information Commissioner and is currently being used by BUPA. The BUPA sheet may have been given a lower score as it contains phrases such as "aggregated data" and "clinical governance" which may have little meaning to many people. It also refers to organisations such as "the National Institute for Clinical Excellence (NICE), the Cancer Registry, or the Public Health Laboratory Service", which have limited public profiles.

Concerns have been raised about the feasibility of informing patients about the way their personal health information is used. [123,124] In Schedule 1 Part II, The Data Protection Act 1998 only requires that the data controller ensures that the data subject has the relevant information "so far as practicable", and provides exemption of the need to do so if the provision of that information would involve "disproportionate effort".

There have also been concerns about the consequences of asking for explicit consent. Researchers and health professionals are worried that if the public are asked for explicit consent or are given the chance of 'opting-out' then, through apathy or conscious decision, the representativeness of their data would be adversely affected. While maximising completeness is desirable, especially if the processing is in the public interest, the degree to which non-response affects the ability to make valid interpretations will vary from one context to another. However, the right to privacy and control over access to personal information is guaranteed by the European Convention on Human Rights and the Human Rights Act 1998 and has been recognised by the UK courts.

This study shows that the proportion of the public/patients willing to give consent is likely to be high. It was made clear to subjects that the content of the information sheets was factually accurate but that they were only being asked for hypothetical consent. When faced with a real choice, consent may be lower, or apathy may mean that filling out a form is not high on their priorities and so it is not completed.

Many people seemed to think that the uses of data presented to them was not covered by the hypothetical consent that they had given which indicates that their consent was not fully informed. However, when given the opportunity to reconsider their consent, few withdrew permission.

Further research will be required to assess the effectiveness of information sheets. Other issues will need to be addressed, such as the best means of informing patients (e.g. written or oral) and how often the informing process should be repeated (e.g. during every health care contact, or every few years). It is important to determine whether information sheets are actually read if people are specifically asked to look at them and, perhaps more importantly, whether the information is understood and remembered. An assessment of cost-effectiveness will be required. Health care providers will need to undertake public education as a minimum and potentially introduce consent procedures in order to comply with human rights and data protection legislation. However, the resources needed to do this may be considerable, and will have opportunity costs for health care provision. A dialogue with the public will therefore be required to address this tension between autonomy (providing information) and beneficence (providing health care).

[123] Statement by the U.K. Association of Cancer Registries (UKACR) on the General Medical Council (GMC) Guidance on Confidentiality. BMJ 2000; 321: 854.
[124] Doll R, Peto R. Rights involve responsibility for patients. BMJ 2001; 322: 730.

Chapter 11

When do the public think that they should give consent for use of their personal health information?

A qualitative research study

11.1 Summary

Objectives: To gain a better understanding of when patients think NHS staff should ask for or, equally importantly do not need to obtain, informed consent from patients for the use of their information.

Design: Five focus groups were conducted for this qualitative study. Each group was tape recorded and the transcripts provided the basis for a framework analysis.

Setting: Groups were convened in Sheffield and Chesterfield.

Participants: 13 men and 22 women from across the adult age range were recruited comprising employed, part time and retired people.

Results: Participants were surprised at the range of uses of their medical records and expressed initial concern about the variety of medical and associated staff with access to their personal data. Ideally patients would like to be asked for consent to the different uses of their health information on a regular basis, especially where named data is involved. However, after discussion and considering the real choice of spending money on advising patients about the use of the health information, or providing health care, participants decided that staff time and costs made the former impracticable.

Conclusions: Patients would like to be asked for consent to use their health information; if this is not feasible or practicable they would like to be informed; if this is not practicable they would trust the NHS to do whatever is in the best interests of patients rather than take money away from health care.

11.2 Background

The Data Protection Act 1998 introduced the measures necessary for the UK to comply with the European Directive (95/46/EC).[125] The first data protection principle requires that data subjects are provided with information about who controls the information and what it will be used for. It also requires that at least one of the conditions in Schedule 2 is met and in the case of sensitive personal data (which would include health information) at least one of the conditions in Schedule 3 is also met. Both Schedules 2 and 3 would be satisfied if "the data subject has given his explicit consent to the processing of the personal data". The UK Government has indicated that the NHS should endeavour to obtain explicit informed consent. However, there are conditions other than informed consent laid out in the Act

[125] The Official Journal of the European Communities of 23 November 1995 No L. 281 p. 31.

which would satisfy Schedules 2 and 3. The research in this chapter asks the public about which NHS functions they consider are "of a public nature exercised in the public interest" (an alternative condition to informed consent within Schedule 2). Use of data for medical purposes is an alternative condition to informed consent within Schedule 3. The Act defines medical purposes as "preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of health care services". The consultation also addresses public understanding of these terms.

Even disclosure of the identity of the data controller and the purpose of processing is not mandatory in all circumstances. Schedule 1 Part II paragraph 2(1) requires that the data controller ensures that the data subject has the relevant information "so far as practicable" and provides exemption of the need to do so if the provision of that information would involve "disproportionate effort". PERIC was commissioned, in part, to obtain the views of the UK public on the degree of effort that would be appropriate to inform patients about or seek consent for the processing of their personal health information.

The fifth data protection principle within the Act requires that "personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes". Patients provide information for the purpose of receiving health care. The research reported in this chapter also aimed to ask the public about the scope of the definition of this purpose, and whether it would be reasonable to expect clinical audit, public health functions and certain forms of research to form part of a purpose defined in terms of the provision of quality, cost effective health care.

In a BMJ editorial Al-Shahi and Warlow[126] suggested that public consultation was "needed to determine the ideal balance between, on the one hand, individual confidentiality and data protection and, on the other, the legitimate use of patient-identifiable data without consent". The subjects within this research were also asked to address this issue.

11.3 Methods

Five focus groups were held in the Sheffield and Chesterfield areas. Participants were recruited from those individuals who indicated at the end of the questionnaire used for the information sheet evaluation (chapter 10) that they would be willing to participate in a focus group. While these individuals will be self-selected, purposive sampling from this group meant that focus group participants would have previously been asked to consider issues related to protection of health data. They would also have read the information sheets and so be more familiar with some of the ways in which health information is used and hence be better placed to contribute to the focus group.

The groups were told about the results from previous elements of the study, and these findings formed the basis for part of the discussion. The concepts of informed and uninformed consent were discussed so that participants were clear about the issue of asking patients for their specific consent. Implications associated with the time and cost of asking for specific consent in different ways were also discussed.

[126] Al-Shabi R, Warlow C. Using patient-identifiable data for observational research and audit. BMJ 2000;321:1031-2

Each group lasted for 1.5 hours in total, and was tape recorded and transcribed verbatim. A framework analysis was carried out from the transcripts.

Participants were given a £10 gift voucher for participating in the focus groups.

Ethics approval was obtained from South Sheffield Local Research Ethics Committee (reference number: SS/00/298).

11.4 Results

Thirteen men and 22 women from across the adult age range were recruited. They comprised employed, part time and retired people. There was a range of employment experience including some who worked in the NHS.

Despite their previous involvement in evaluating information sheets describing the use of patient data, participants were surprised at the many different categories of staff who have access to their health information. The results provide a picture of developmental thinking as, within the hour and a half allocated for each group, participants demonstrated a growing awareness of previously unconsidered issues. Several group members commented on their own lack of awareness:

"I have never really actually thought about it before..."
"It never even crossed my mind."

Even within the brief period of the focus group, people's ideas about the range of issues associated with consent procedures developed as they became aware of implications which were new to them. Views may well have continued to develop further once participants departed from the groups and had the opportunity for a longer period of consideration.

11.4.1 Informed and uninformed consent

Discussion to distinguish between informed and uninformed consent demonstrated the small amount of attention paid to consent forms for medical interventions. Some group members who described signing a consent to undergo surgery showed little recall of what, if any, information was provided on the consent form. In particular, participants began to ask within the group if the form had incorporated a clause so that the patient's signature confirmed they had received an adequate explanation of the procedures to be carried out and the associated implications. The group then began to comprehend the importance of giving informed consent, rather than simply signing a piece of paper without having a proper understanding of some of the possible consequences. There was a clear message from several group members that proper information would be required for consent to be informed:

"I think it is quite important that an explanation is given that people understand."
"Without any explanation or information you can't make a choice because you don't have enough knowledge."

Conversely, a requirement for signed consent was perceived by a small number of participants to show a lack of trust between the patient and the doctor, demonstrating the tension between paternalism and transparency:

"It's to do with trust ... implicit acceptance is fine for me. Lack of trust ... worries me."

The main body of thought then, at this stage of the discussion, was that patients should be given sufficient information to feel in a position to make an informed decision about what happens with their health information as well as more control over how the information is used.

A solicitor in one group explained that:

"My clients sign a consent [form] *when they come and see me that says I can discuss their case with whoever I need to. If they don't sign I can't act for them."*

She suggested a similar procedure for doctor and patient information sharing. The amount of staff time which would be needed to take patient signatures to consent to continual varied usages of their health information was discussed in some detail. This issue aroused some concern:

"There is going to be a tremendous increase in bureaucracy and filing and clerical work."

It was suggested that verbal consent be used to expedite the process, but this idea was dismissed as inadequate validation for a consent procedure.

11.4.2 Confidentiality and passing information to other professionals

Participants in the groups overall tended to be unhappy about the sharing of named data, whereas few concerns were expressed about sharing anonymous information with practically any organisation.

All focus group members were more concerned about *who* has access to their health information than the use to which it is put. Apart from those who worked in the NHS, the idea of a prescription as an item of health information which they might wish to keep confidential was novel to these participants. They began to realise that this kind of information could be sensitive, for example when AZT was prescribed, which would alert a pharmacist or pharmacist's assistant that the patient was suffering from HIV, or an anti-depressant which would indicate mental ill health. They recognised that the counter staff in a pharmacy might have a personal curiosity in patients, and especially if they knew the person presenting the prescription.

Similarly, few participants had considered the logistics of a GP contacting a consultant for an appointment. They had given no thought to the various secretaries and/or administrators through whose hands their health information might pass, but accepted that it was reasonable to assume that, as patients who had presented themselves requiring treatment for a medical condition, they had given implied consent.

Some group members were particularly unhappy about receptionists having access to their information. Several participants gave examples from their personal experience of receptionists behaving irresponsibly with patient health data:

"I've been asked personal questions by the receptionist in full hearing of other people in the waiting area."
"Receptionists are usually young and inexperienced and don't understand about things like confidentiality."
"Mine [receptionist] has been there for years and years but she is always discussing patients over the phone."

Participants described problems for patients living in small villages where most of the residents were familiar to the receptionist. Members within each of the focus groups believed that some non-medical staff might examine medical information out of 'nosiness.' After initial concern and further discussion participants perceived that, if they wished to have treatment, there was no realistic alternative to their medical information being passed to non-medical personnel such as a GP receptionist or a pharmacy assistant. It was, however, suggested that there should be a separation of duties between medical secretaries and receptionists within a general practice. Secretaries should be office-based as they have access to information about health data when they write to consultants or file test results, in contrast to receptionists whose sole duties should be contact with patients at the front counter.

A group member who worked for social services explained that:

"You could have a mental health team working side by side and it would be crazy to suggest that a psychiatric nurse couldn't talk to the social worker with whom he shares a case load."

Access to personal health information by social workers was accepted as necessary by the rest of that group once they had been given this example from an actual situation. However, they continued to perceive issues associated with mental ill health to be particularly sensitive, and were concerned that confidentiality should be paramount within any team.

Passing on anonymous information to drug companies for commercial use was generally perceived to be perfectly acceptable by group members. However, some participants saw this as a moral issue rather than associated with confidentiality. Other group members believed it was important that all organisations carrying out research should have access to all the available information, and that it should be freely available perhaps as a national database. Personal gain by doctors or the private sector from this anonymous information was seen as wrong, especially if this was to the detriment to the NHS, e.g. if pharmaceutical companies used information on the prescribing habits of specific GPs to target the marketing of less cost-effective drugs.

Concern was also expressed about insurance companies gaining access to health information by deception, perhaps paying GP secretaries to pass on information, and cancelling life cover of clients with a shortened life expectancy.

Some groups realised over the course of the discussion that patients too have a responsibility, and that care cannot be provided if they will not agree to the sharing of at least some of their health information.

11.4.3 Communicable diseases and disease registers

Participants expressed some confusion about the need for information to be sent to disease registers to include their name and address. There was a view that they would want to be told about this use of personal information although, at the same time, it was felt that the shock of a diagnosis of cancer would distract a patient's thought processes so that they would be unlikely to grasp the essence of the information. They began to consider that asking for patient consent could prove to be counterproductive, and came to the conclusion that the system used currently was the most appropriate.

The suggestion was made that the public should be better informed about the kind of information that is collected and stored, and its purpose. Group members were clear that they would like to be advised if information containing their name and address was being sent to a register:

"It would be nice to know how it helps and where it is used and what happens."

At the same time there was a recognition of the impracticality of allowing individual patients a right of veto over their information being passed on to disease registers.

After some explanation and discussion members of all the groups were happy for their information to be placed on the appropriate register. They agreed that if something was for the common good then it is important that information is passed on and while specific consent to disclosure or consent may be desirable it is not essential. It was, however, felt to be important that provision is made to improve general awareness of the ways in which the NHS uses information.

Concern was expressed about the large number of people who have access to information, which appears to render it less secure. The suggestion was made that external checks could be made on the appropriateness and necessity for collecting different kinds of information.

11.4.4 Contact tracing for communicable disease

Participants tended to see a difference between passing on information about diseases which were 'neutral' in terms of social acceptance and those which carried a stigma, for example sexually transmitted diseases. Despite the previous discussion, it was felt that a patient's permission should always be sought before passing on details of a stigmatising disease. Some group members expressed concern that someone who knew them might inadvertently acquire this kind of sensitive information as a result of their employment situation:

"I would want to know who was being told."

After further discussion, while group members remained unhappy about sensitive information being given to other people as a function of contact tracing, four of the groups recognised that a patient's right to confidentiality should be superseded by a public duty to prevent disease from spreading among the population. The fifth group, however, remained generally unwilling for information about a person having a sexually transmitted disease to be passed on. Members of all the groups maintained that they would want to be told who would receive sensitive information.

11.4.5 The dissemination of how health information is used

The question of how much detail should be provided for patients when describing the ways in which health data is used, emerged as problematic. Group members recognised that different patients will want different amounts of information and participants felt it was important that comprehensive information should be available for those who want it. Different levels of education among the population were seen to affect the amount and type of information that patients would require.

Several participants in this part of the study appeared to be information seekers which, doubtless, is why they decided to join the group in the first place. Patients who, on the other hand, only want a minimum of information and prefer to trust their doctors to make a decision in the best interest of patients, should not be overwhelmed with information. It was seen as important to make provision for both types of need.

Some participants suggested leaflets as a cost effective means of disseminating information about how health records are used. However, after some discussion there was general agreement in all groups that leaflets in doctors' surgeries already represent information overload. Group members themselves rarely looked for information from leaflets:

"I can't remember the last time I picked one up."

Or appeared to perceive leaflets as light reading while awaiting their appointment:

"People pick them up and read them while they are waiting and then put them back."

A suggestion that an explanatory leaflet be sent to each household was, on reflection, thought to incorporate several drawbacks. Primarily, group members could see no way of ensuring that everyone would read the information, nor of ascertaining if it had been satisfactorily understood. Not everyone can read, and not everyone can read English. Not everyone is a householder, and those who are not may think the leaflet does not apply to them.

A personal approach to patients with an explanation of how their health information is used, and of the implications of giving consent for their information to be used, was seen as the ideal. However, this method was perceived to be too costly in terms of staff time.

A further suggestion, that information should be disseminated by television to maximise coverage either as an advertisement or as a storyline in a soap opera, was made. Participants agreed that this would be the most effective method of reaching the largest proportion of the population, but expressed concern about the excessive cost of television time.

Discussion of information sheets that are currently used by the NHS[127,128] or BUPA[129]

[127] The Caldicott Committee. Report on the review of patient-identifiable information Leeds: NHS Executive, December 1997. Appendix 10. (see http://www.doh.gov.uk/confiden/app10.htm – accessed March 2002)
[128] Department of Health. The Protection and Use of Patient Information: Guidance from the Department of Health. London: Department of Health, 1996. (http://www.doh.gov.uk/ipu/confiden/protect/pguid6.htm – accessed March 2002)

highlighted a dislike of repetition in the provision of information. The most popular information sheet described in everyday language exactly why the information was required and who would use it. An initial preference for one sheet because of its brevity gave way to preference for sheets which were seen to provide useful information in an accessible manner. Overall the consensus was for two sides of A4.

11.4.6 Frequency

The impracticality in terms of time, and therefore cost, of taking written consent from a patient for each minor medical procedure, for example taking a sample of blood, was recognised quickly by group members. Following this discussion of consent for medical procedure, the group discussed frequency of consent for use health information. There was a divergence of views. Some people considered that a once only consent is adequate, if this was for NHS use only, and no named data was provided for commercial use.

Several participants suggested that re-consent should be prompted by the onset of a major illness, or a change of use of health information as a result of major qualitative developments in the way that information is used. Otherwise, those who wanted some control over the use of their data suggested 10 years as a reasonable interval, which might take account of the changes described.

Overall there was a consensus from all focus group participants that doctors' valuable time should not be wasted in specifically asking a patient for consent every time information is shared.

11.4.7 The Data Protection Act

While almost all group members knew of the existence of the Data Protection Act, only two individuals from the five groups were able to describe its purpose. These people had received training on the terms and function of the Act as a part of their occupational duties.

A solicitor spontaneously recalled the Act when the discussion was focused on sending information to the cancer registry. She described this use as other than the original purpose for which the data had been collected, and therefore saw it as not strictly within the terms of the Act.

11.4.8 Issues raised about an electronically held record

There was, in one of the groups, initial amusement at the thought that a GP would write a letter which went directly to a consultant with no intermediaries having access to this information. However, hilarity gave way to serious consideration of the electronic health record as a more secure means of storage when a nurse explained that it might indeed constitute a means of by-passing non-medical staff, so that a GP might type into the computer and send the letter directly to the consultant's computer. This would obviate the need for any intermediary (although it was pointed out that in practice there may still be a need for intermediaries, for example if doctors are not computer literate).

[129] Hinde S, Warren V. BUPA wants to ensure systematic transfer of data. BMJ 2001;322:730

There appeared to be a certain gender bias in relation to views on the security of a paper system compared with computer. The female perception was that very few people have the knowledge to hack into computers, which are therefore more secure than a building. The view of some of the men in the groups was precisely the opposite, and they saw a computer database as an easy target.

Some people expressed a concern that, if the computer crashed and a patient was admitted as an emergency, their notes would be unavailable and urgently required treatment would be subject to delay.

There was overall agreement that neither system could ever be completely secure, and a recognition that electronic systems greatly reduce the number of personnel who would need to handle health records. An electronic system was therefore perceived as preferable.

11.5 Discussion

The UK General Medical Council (GMC) [130] have required that patients are made aware that personal information about them will be shared within the health care team and, if appropriate, with another organisation providing health or social care, and of the reasons for this disclosure. The GMC also recognised that information about patients is required for purposes such as epidemiology, public health safety, administration of health services, education or training, clinical audit, or research. Even so, in all such cases the GMC require that patients have access to written material informing them of such processing, as required within the Data Protection Act 1998, and are given the opportunity to object.

Similar rights to disclosure about the use of health information exist outside Europe. For example, in the USA, patients have rights to understand and control how their health information is used.[131] Providers and health plans are required to give patients a clear written explanation of how they can use, keep, and disclose their health information. However, the U.S. government has recently proposed changes to the health privacy regulations[132] because of concerns about unintended consequences that threatened patients' access to health care.

The implications of the Data Protection Act 1998, Human Rights Act 1998, European directives[125] and conventions,[133] GMC standards and recent court judgements[134,135] for the activities of epidemiological research, cancer registries and other public health surveillance have caused considerable concern.[136] Reference is frequently made to American studies

[130] General Medical Council. Confidentiality: Protecting and Providing Information. 2000
[131] National Standards to Protect the Privacy of Personal Health Information. Washington D.C.: Health and Human Services, 2001
[132] HHS proposes changes that protect privacy, access to care: Revisions would ensure Federal Privacy Protections while removing obstacles to care. http://www.hhs.gov/news/press/2002pres/20020321a.html
[133] Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo, 4.IV.1997
[134] Regina v Department of Health, Ex parte Source Informatics Ltd, 1999.
[135] Health Authority v X, 2001.
[136] Walton, Doll R, Asscher W et al. Consequences for research if use of anoymised patient data breaches confidentiality. BMJ 1999; 319: 1366.

where apathy and explicit withholding of consent resulted in significant volunteer bias.[137,138]

A statement by the U.K. Association of Cancer Registries (UKACR)[139] interpreted the GMC statement to require explicit consent from every person with newly diagnosed cancer (over 280,000 people per year in the U.K.) before information could be passed to cancer registries. The UKACR pointed to experience in Germany and elsewhere which showed that this would be logistically unmanageable and unworkable in practice. They suggested that "the hypothetical additional safeguards introduced by explicit consent are likely to be negligible in comparison with the potential loss to the whole community and to future cancer patients if this population basis becomes compromised". The UKACR believed that "the process of seeking consent at a particularly stressful time may jeopardise the relationship between the cancer patient and those providing care". The members of the focus groups shared this concern and recognised that the cancer registry function could benefit patients and hence was justified in the public interest.

The House of Lords Select Committee on Science and Technology[140] was concerned that the Data Protection Act 1998 could seriously inhibit legitimate medical research. They proposed a procedure for seeking consent for participation in research which suggested that there was a duty for people to participate in research, since "... the medical treatment that all receive is based on studies carried out on very many earlier patients and that the request is for them to provide similar help for future generations". Peto[141] believed that "every UK citizen has the right to medical care, but those rights also involve responsibilities". Doll and Peto[142] also suggested that the "right to medical care should … continue to include the responsibility to allow the information gained in its course to be used for the benefit of others". They also claimed that confidential sharing of personal health information "between doctors and bona` fide medical research workers (with the exceptions only in particular cases) has done no harm and has achieved much good". The members of the focus groups seemed to agree that there was a 'duty to be altruistic'.

While there was agreement that personal information could be shared within the 'NHS family', there was not a consensus as to whether researchers, even if still within the public sector e.g. universities, would be included within a definition of 'NHS family'. The Public inquiries at Alder Hey[143] and Bristol[144,145] demonstrated public concern about research without proper consent procedures.

[137] McCarthy D, Shatin D, Drinkard C, Kleinman J, Gardner J. Medical records and privacy: empirical effects of legislation. HSR Health Services research 1999; 34(1): 417-425.
[138] Jacobsen S. Xia Z, Campion M, Darby C, Plevak M, Seltman K, Melton L. Potential effect of authorization bias on medical record research. Mayo Clin Proc 199; 74: 330-338.
[139] Statement by the U.K. Association of Cancer Registries (UKACR) on the General Medical Council (GMC) Guidance on Confideniality. BMJ 2000; 321: 854.
[140] House of Lords Select Committee on Science and Technology. Human Genetic Databases: Challenges and Opportunities. Fourth Report 2000/2001 Session.
[141] Kmietowicz Z. Registries will have to apply for right to collect patients' data without consent". BMJ 2001; 322: 1199.
[142] Doll R, Peto R. Rights involve responsibility for patients. BMJ 2001; 322: 730.
[143] The Royal Liverpool Children's Inquiry Report. (Chairman: Mr Michael Redfern QC). London: Department of Health, 2001
[144] The Inquiry into the management of care of children receiving complex heart surgery at the Bristol Royal Infirmary. Interim Report: Removal and retention of human material (chair: Professor Ian Kennedy). May 2000

Helliwell[146] claimed to be supportive of the rights of patients, but thought that the trend in policy and legislation would hinder the gathering of data that could benefit the whole population. He called for a substantial public information campaign to present to the public the benefits of epidemiology and public health data sets and the dangers if these data are lost. The members of the focus groups seemed to think that such a campaign and its associated financial cost would be appropriate.

The focus groups were aware of two major tensions: firstly, between the wish for a personal explanation and the excessive amount of staff time this would take; and, secondly, between the wish to keep information between doctor and patient only, and accepting that the NHS as an organisation requires the use of administrative procedures which employ non-medical staff.

The electronic health record could have particular attractions from a patient perspective. The focus groups confirmed the findings of the quantitative studies. The participants were concerned about who has access to their health records, rather than what it was to be used for. They were particularly concerned about people in administrative roles who they perceived as having lower professional and contractual standards. This was in part borne out of experience of observing the behaviour of receptionists. While they recognised that referral letters need to be organised, test results filed etc., the public may be reassured by technology that limits administrator access to the more sensitive clinical information.

The patient electronic record could allow the tracing of every patient with a specific disease seen in the NHS. Patients could be identified using their NHS number in a similar way to the current Swedish electronic record system. This would allow the patient's electronic record to pass between the general practitioner and each hospital the patient visits. This system will have benefits to every aspect of the NHS including clinical management, clinical governance, health economics and research and development. The Swedish electronic patient record and unique identifiable number has allowed the rapid study of thousands of patient records to answer important questions, for example in relation to the efficacy, adverse effects and costs of different therapies. Lindelöf et al.[147] demonstrated that the risk of skin cancer following one form of phototherapy for psoriasis was higher than following another. This type of study could not be carried out in the UK at present. While it is likely that patients are likely to be supportive of the use of electronic health record in anyway that will be of benefit to the public interest, it would in theory allow patients to opt out of specific uses of health information. In practice it may be too complex to provide detailed information of all foreseeable uses and patients may have to consent to all or none of their electronic health record being used for purposes other than direct clinical care, or will have to give consent for broad categories of use, although it is unclear whether broad consent would comply with the first data protection principle. Very few people who evaluated the itemised information sheet (chapter 10) took the opportunity to selectively provide or withhold consent for the various uses of health information

[145] Learning from Bristol: The report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984 -1995 (Chairman: Professor Ian Kennedy) Command Paper: CM 5207. London: The Stationery Office, 2001
[146] Helliwell T. Need for patient consent for cancer registration creates logistical nightmare. BMJ 2001; 322: 730
[147] Lindelöf B, Sigurgeirsson B, Tegner E et al.. PUVA and cancer: a large-scale epidemiological study. Lancet 1991; 338: 91-3.

described. It is therefore possible that most people will agree to all the uses of the electronic health record proposed by the NHS, provided they are in the public interest.

The public seem to recognise that fully informed consent in all circumstances would require 'disproportionate effort', especially when set against the opportunity costs in terms of scarce health care resources.

The cost for the NHS of a member of staff explaining all of these potential data flows, or ensuring that written information has been understood, would be prohibitive. In 1999/2000 there were 11,116,161 admissions within the NHS[148]. In addition there will be considerably more patient contacts within primary care. The calculations of the cost of complying with the requirements of the Data Protection Act 1998 for all of the data flows relating to these NHS contacts will depend on the procedures introduced: for example, whether explicit consent is sought from every patient admitted, or just text included within patient information booklets. Similarly, if a member of staff is required to explain the information, should this happen on every contact with the NHS or just once every few years. There is also likely to be a variation in the time patients will need to absorb all the information that they need to understand the NHS information policy. However, even if every health professional took only a few minutes to explain the purpose for which data will be used, or additional staff are employed specifically to discuss data protection with patients, then the opportunity costs for the NHS would be considerable.

The people within the focus groups also recognised the importance of using personal health information for performing public functions such as epidemiological and public health activities that are in the public interest. Indeed they expect the NHS to use their information in these ways, and hence accept that implied consent for such activities is given when they seek health care. However, they would not want their altruism to be taken for granted. In a climate of increased awareness of consumer rights, dialogue with the public on such matters will be essential.

[148] http:/www.doh.gov.uk/hes/beginners/0001_key_facts_and_figures/index.html (last accessed 07/06/02)

Chapter 12

Conclusions and recommendations

The general public are generally happy to allow access to their health records. Men, older people and higher socio-economic groups tended to be most content. Hospital patients were also happy for the NHS to use their personal health information, and were also willing to give consent to do so. There are particular issues relating to consent for use of information within the health records of young people and people with learning difficulties.

The public were most concerned about *who* has access to their information. Release of the minimum amount of information necessary and in anonymised form was also important. The reason for requesting access was relatively unimportant. These were consistent findings from the various quantitative and qualitative studies.

The design of the electronic patient record could help reduce access to the majority of the electronic record for individuals who did not need to have access to it. An important example, that caused particular concern, is a GP receptionist. Using the current paper records a receptionist has access to the entire record. The patient electronic record would allow access to only the patient's demographic information in order to make appointments. Laboratory results would be directly entered into the electronic record from the laboratories. A secretary would have a slightly increased level of access to the electronic record. Only the general practitioner and selected specialists would have access to the entire record. This above system is used in the patient electronic record in Sweden and illustrates that an electronic record can provide solutions rather than just represent new problems.

Many of the information sheets that are currently being used to explain to patients how their health information is being used, concentrate on the reasons for access rather than who needs to see it. The information sheets that were evaluated within PERIC were effective in obtaining consent, but failed to ensure that this consent was informed, since many patients were still oblivious to many of the ways that the NHS uses information or why various health professionals need access.

Based on the evaluation of the information sheets and feedback from the focus groups, a modified information sheet is contained in the appendix. The NHS Information Authority is currently working with the Consumer Association to develop a generic consent form for the NHS. The findings of PERIC support the need for this work and should be helpful in guiding the development of these new NHS procedures.

The qualitative research indicated that the public have a very limited understanding of the roles of people involved in their care, particularly those involved with administrative and support functions. People seemed reassured when the importance of these roles was explained.

The NHS should consider how to make patients more aware of the important role that various categories of staff have in the overall provision of care

There was also some concern that some NHS staff are not sufficiently aware of their obligations to maintain confidentiality.

The NHS should make the contractual obligation that staff already have more explicit.
NHS staff should be made aware of the implications of even trivial breaches of confidentiality on patient trust.

Guidance should be produced for NHS staff with examples of good practice on how to discuss protection and use of personal health information with patients. Training and continuing professional development of staff should place more emphasis on data protection issues.

It would probably be legally unacceptable to depend on provision of information and/or obtaining consent at only one point in time. Similarly it would be too costly and not feasible to inform or obtain consent, every time information is obtained or used. It may be more practical to use the patient electronic record to trigger the health professional accessing the record to re-consent or re-inform the patient at intervals through a patient's life. This may be after a set period of time since it was last discussed, for example, ten years. Alternatively, the patient may develop a particular disease or use a certain service where it is felt particularly important to re-consent or re-inform because of the sensitive nature of the disease or the use to which information is to be put. If the health professional is not able to discuss protection and use of personal health information on that occasion because of lack of time or patient distress, the electronic record could continue to flag the need for this discussion on future patient contacts within the NHS.

The size of the opportunity costs may mean that it will be impractical to develop the most desirable mechanisms to inform the public and seek consent. However, every effort should be made to use the opportunities that do arise to inform patients and seek explicit consent, in order that the NHS can fulfil the requirements of the Data Protection Act 1998. The patient electronic record could help ensure that information is provided on a sufficiently regular basis to ensure that the NHS complies with data protection legislation.

It is possible that subjects' 'happiness' to allow access to their health record may increase or decrease if they had more information about what a particular person did or what they were going to do with data. Evidence from PERIC would suggest that in general people who are or perceive themselves to be more informed about the workings of the NHS, tend to be happier to allow access. In practice, it is likely that any consent procedure developed by the NHS in accordance with data protection provisions is unlikely to allow detailed descriptions.

The fact that privacy receives qualified guarantees within the Human Rights Act 1998 may mean that consent must be sought in all circumstances, even though only a very small proportion of the population are unhappy about allowing access to their personal health information. The *Health Authority v X* judgement confirmed that release of data without consent may be a breach of human rights.

Public policy that potentially involves infringements of human rights such as individual privacy may involve a different standard than what is acceptable to the majority, even if

this amounts to an overwhelming majority of the population. Civil liberties arguments would require that the concerns and objectives of even a small proportion of the population will need to be addressed and accommodated.

The practical, ethical, legal and public health significance of 2% of subjects refusing access to their health data in any circumstance will require further discussion.

Numerous concerns have been raised within the research and public health communities about the implications of the Data Protection Act 1998, the Human Rights Act 1998, court judgements and various professional guidelines based on this legislation and the Common Law for cancer registries, other registers and surveillance programmes that are dependent on comprehensive population data collection. It is alleged that protection of individual privacy may mean that these activities and lives that may be subsequently saved would be put in jeopardy. However if the vast majority of the public would be willing to give informed consent, then the people responsible for these programmes may be attempting to avoid inconvenience in seeking informed consent rather than avoiding harm to the public interest. While it is true that those who volunteer to participate in research should be assumed to be systematically different from those who do not, the degree to which this bias effects the ability to make valid extrapolation needs further consideration. It may be that if the non-response rate is low, or if these individuals are not significantly different to those who do provide consent, then useful conclusions can still be drawn.

The Health Services (Control of Patient Information) Regulations 2002 will allow data collection to continue for cancer registries and communicable disease control for 12 months before the regulations are reviewed. Prior to this review, evidence should be obtained on whether it is practicable to obtain consent or to provide information for these purposes. The impact of people not being asked by clinicians too busy or too concerned for the patient's immediate psychological welfare, withholding consent, choosing to 'opt-out' or not responding to request for consent on the validity of surveillance and epidemiological databases should be assessed.

The findings of PERIC would suggest that the public are generally supportive of research, public health surveillance and epidemiology activities that they perceive to be in the public interest. Just because people are happy for the NHS to use their information if it is in the public interest, this may not mean that they do not want to be asked for consent, or even informed about the way the NHS protects and uses health data. The public inquiries into the Bristol Royal Infirmary and The Royal Liverpool Children's Hospital indicate public concern when patient dignity is not respected. The public do however recognise that where informing or obtaining consent from patients is not feasible, the public interest would require that information should be used, albeit with the minimum quantity of data released preferably in anonymised form.

The NHS should examine further what the public see as acceptable boundaries for informed consent i.e. in what circumstances is explicit consent required, when is providing information adequate, and when should the NHS just use information for the public interest because it is not practicable to seek consent or provide sufficiently detailed information.

Appendix: Proposed NHS Information Sheet

PRIVACY AND CONFIDENTIALITY OF YOUR HEALTH INFORMATION

The doctor-patient relationship is based on mutual trust and confidence and the story of that relationship is your medical record. It is a life-long history of your consultations, illnesses, and treatments.

YOUR RIGHT TO PRIVACY

Once you are over the age of 16 years (and in certain cases under sixteen) you have a right to keep your health information confidential between you and your doctor. The law imposes a few exceptions to this rule, described below. Apart from those you have a right to know who has access to your medical record.

WHO ELSE SEES MY RECORDS?

There is a balance between privacy and using the information that the NHS collects to improve the quality of care and the public health. Information is normally shared with people involved in your health care. Doctors, nurses, therapists and others need to find out what has happened in the past to help them provide the most effective treatment for patients. People who work in laboratories and x-ray departments need information to help them interpret test results.

All NHS staff have a legal, ethical and contractual duty to protect your privacy and confidentiality. This obligation applies to clinical staff e.g. doctors, nurses, therapists and pharmacists; people who work in laboratories and x-ray departments, or are involved in other investigations; and other support staff such as porters, receptionists and administrators.

Teaching new doctors, nurses and other staff often involves looking at medical notes, x-rays and test results to teach them about different kinds of illness.

The NHS monitors the quality of care that patients receive by letting staff check back that the treatments provided are of a high standard. Wherever possible information will be made anonymous by removing your name and address or just using a NHS number.

Statistics are prepared to find out how many operations have been performed, to see how well treatments worked, and to ensure that services can meet patient needs in the future. The NHS uses information to work out how many doctors, nurses, dentists and other staff it needs to employ, and ensure that hospitals have enough money to buy medicines and equipment. The NHS audits accounts to make certain that money is not being wasted and to check for fraud.. The NHS also uses medical records to investigate complaints or legal claims.

Receptionists and secretaries file test results and letters in notes and arrange appointments. Other staff from social services may work with the NHS to plan discharge from hospital or additional care in the patient's home.

Records are sometimes used to identify people with a particular illness so that they can be contacted and asked if they would take part in a study, such as trying out a new treatment.

WHERE ELSE DO WE SEND PATIENT INFORMATION

We are required by law to notify the public health department of certain infectious diseases (e.g. meningitis, measles but *not* AIDS) to monitor infectious illnesses such as flu and look for outbreak of diseases such as food poisoning. We also measure whether cancer is becoming more common and if patients with cancer are living longer, and monitor infectious illnesses such as flu and food poisoning.

Limited information is shared so that the NHS can organise national public health programmes such as childhood immunisations, cervical smear tests and breast screening.

The law courts can insist that the NHS disclose medical records to them.

Solicitors, life assurance companies and employers may ask for medical reports. These are *always* accompanied by your signed consent for us to disclose information. Doctors must disclose *all relevant medical conditions* unless you ask us not to do so. In that case, we would have to inform the insurance company or employer that you have instructed us *not to make a full disclosure*. You have the right, should you request it, to see these reports before they are sent.

Social Services, the Benefits Agency and others may require medical reports on you at some time. Failure to cooperate with these agencies can lead to loss of benefit or other support. However, if we have not received your signed consent we will not normally disclose information about you.

HOW CAN I FIND OUT WHAT'S IN MY MEDICAL RECORDS?

We are required by law to allow you access to your medical records and may charge a small fee to cover our administration and costs. All requests to view medical records should be made in writing to the person in charge of your care.

We have a duty to keep your medical records accurately. Please feel free to correct any errors of fact which may have crept into your medical records.

WHAT WE WILL NOT DO

Our staff are instructed to protect your privacy. This means we will not normally disclose any medical information, including test results, over the telephone unless we are sure we are talking to you. We will not disclose information to family or friends unless we know that we have your consent.

We will not normally release details about other people described in your records (e.g. wife, children, parents) unless we also have their consent.

If you have any queries or complaints about privacy and your medical records please talk to the person in charge of your care or there will be a person you can contact in every hospital or GP practice who is responsible for protecting your health information.

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