

Sharing patient data: competing demands of privacy, trust and research in primary care

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ABSTRACT

Background

Patient privacy may conflict with the advancement of knowledge through data sharing. The data contained in primary care records are uniquely comprehensive.

Aim

To explore the knowledge and attitudes of patients and members of the primary healthcare team regarding the sharing of data held in primary care records, with particular reference to data sharing for research and the impact that this may have on trust between patients and health professionals.

Design of study

Qualitative study using quota sampled, semi-structured interviews.

Setting

Five general practices in Leicestershire, UK.

Method

Grounded theory and framework methodology were used. Interviews were transcribed and analysed thematically.

Results

Twenty patients and 15 healthcare professionals and managers were interviewed. Patients had limited knowledge of the type of information held in their general practice records and the ways in which these data are shared, but appeared ready to form preliminary views on issues such as data sharing for audit and disease registration. In this climate of limited awareness, there was no suggestion that concern about data sharing for research adversely affects patient trust or leads patients to withhold relevant information from health professionals in primary care. Interviews carried out with staff suggested a lack of clear practice policies regarding data sharing.

Conclusions

General practices may need to develop policies on data sharing, bring these to the attention of their patient population and improve patient awareness about the nature of the data contained in their records. Researchers should ensure that patients are adequately informed about the nature of data contained in patient records when seeking consent for data extraction.

Keywords

confidentiality; ethics; general practice; medical records; research.

INTRODUCTION

Balancing patients' right to data protection/confidentiality against the need to promote public health through research has been a topic for debate over recent years.¹ This potential conflict of interest has been highlighted by the passing of the Health and Social Care Act 2001; Section 60 gives the Secretary of State the power to authorise the processing of patient data in the interests of patient care and public health, while Section 61 gives advisory powers to patient representatives through the Patient Information Advisory Group. From a public health and research perspective, advocacy of rigorous respect for patient autonomy has been criticised in the UK for potentially limiting the scope for maintaining useful disease registers and conducting valid epidemiological research.²⁻⁴ In other countries, similar problems relating to the tension between privacy and research validity have been experienced, for example in the US where legislation such as the Health Insurance Portability and Accountability Act has highlighted similar issues.⁵

Health professionals' respect for privacy through good practice in terms of confidentiality is central to a trusting relationship between patients and healthcare providers, and the link between trust and the use of patient data has been acknowledged by previous authors.⁶ The issue of access to

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How this fits in

It is known that patients are inadequately informed about data sharing throughout the NHS, but this has not previously been considered in depth specifically in relation to data held in general practice records. We were able to confirm that patients may have a limited understanding of the scope of information held in their GP records and the ways in which these data are shared, for example for research and audit. However, we also identified a readiness to consider and formulate views on data sharing, justifying our view that general practices may need to be pro-active in informing patients about data sharing. We have also identified and considered limited awareness of data sharing issues among health professionals and managers working in primary care.

confidential data is particularly relevant in general practice, where a unique lifetime record covering all aspects of patient health is held. The Medical Research Council has commented on the lack of 'research evidence on how people view the use of confidential information'.⁷ Research in this field remains limited, but supports the view that we cannot assume that patients are happy for information contained in their health records to be shared for research. A project conducted by the NHS Information Authority in conjunction with the Consumers' Association⁸ found that people generally wanted data to be anonymised when used other than for treatment, unless consent was sought. A study from the Netherlands found that not all patients were happy for their medical record to be shared fully with an on-call GP or practice assistant⁹ and in the UK approximately 10% of patients who were prepared to complete a questionnaire as part of a research project withheld permission for researchers to review their general practice records.¹⁰

The impetus for our study was the premise that concern about sharing data held in general practice records, in particular for research, may influence patients' willingness to divulge clinically relevant information to primary healthcare professionals. This in turn may compromise professionals' ability to provide optimum care. The overall aim of the study was to explore the knowledge and attitudes of patients and general practice staff regarding the sharing of data held in medical records. In particular, we sought to focus on sharing information for research and the relationship between data sharing and trust.

METHOD

Five general practices known to have been previously involved in research were recruited from the former Leicestershire Health Authority area. To aid diversity, we purposively selected these general practices to represent a mix in terms of location

(city and rural practices reflecting differences in deprivation) and size. We set a quota of a total of 20 patient and 15 staff interviews, reflecting our estimation of a target that would be achievable within the constraints of the funding available, but would enable us to reach theoretical saturation. A sampling frame was used to ensure a varied sample of patients (sampled by age, sex, frequency of consultation, and history of being asked to participate in research), and staff (GPs, nurses, practice managers). Staff were recruited by the practices and patient volunteers were sought through publicity materials displayed and distributed at participating surgeries. Patients provided written consent for contact by the research team and later signed a second consent form giving permission for an audiotaped interview.

Topic guides for one-to-one semi-structured interviews were developed and a draft version of the patient schedule was piloted with a patient involvement group from a local general practice not otherwise involved in the study. The guides contained suggestions for open-ended questioning. Potential topics for discussion included the extent and nature of trust between patients and general practice staff; knowledge about confidentiality and data sharing within and outside the practice; and attitudes to information sharing for purposes such as health care, audit, public health and research. The interview schedule was reviewed and revised during the course of the study. In later interviews, for example, emphasis was placed on discussing areas that had not yet been fully explored as well as those new issues that had emerged from earlier interviews. Staff were interviewed at general practices and patients in their own homes. All interviews were conducted by the same experienced interviewer, audiotaped, and transcribed verbatim.

All interview transcripts were coded using QSR NUD*IST free nodes to identify themes directly from the interviews, in line with grounded theory.¹¹ To ensure that no themes had been missed and to facilitate discussion of findings, each interview was also reviewed and coded by another member of the research team by hand or using NUD*IST software. Broad themes were identified from the coded data, which were then summarised using framework charts¹² to aid more detailed thematic analysis.

RESULTS

Interviews were conducted with 20 patients, five GPs, five practice nurses, two health visitors and three practice managers from two city and three county general practices. Recruitment of a varied sample of interviewees was in accordance with our

pre-set sampling frame and after completing this quota it was considered that topics suggested in the topic guide and emerging from the interviews had been fully explored and that saturation had been reached in terms of the emergence of new themes.

Awareness and understanding

These were challenging and thought-provoking interviews, raising awareness of issues that had not been previously considered in depth by interviewees. Patients generally saw the relationship with their surgery and the implicit contract made by registering at the practice purely in terms of health care and had not previously considered confidentiality issues relating to data sharing:

Patient: *'I don't think many people even think about it [data sharing] personally. I mean I didn't think about it until you've just brought it up.'*

Interviewer: *'When you registered at the surgery, you know, what sort of things were you kind of signing up to, what were you agreeing to?'*

Patient: *'Don't know really, just for somebody to see me if I'm ill, you know.'*

This view was endorsed by health professionals:

GP: *'I suspect most patients don't think about confidentiality at all really ... they sign up at a practice because they can, you know, get their health issues dealt with. I think the only time that ... most patients would think about any form of confidentiality is if there's something specific ...'*

When questioned about the information held in general practice records, it was clear that this was not something that patients had previously considered or about which they had felt concern. They often demonstrated a limited understanding of the type of information held in their records and did not necessarily know the length of time that data are retained or whether they are transferred when patients move between practices. They also tended to be unaware of, or unclear about, the ways in which data are shared both within and outside the practice. Patients were mostly unsure about the level of access to patient information given to administrative staff and they were generally unaware of data sharing with national disease

registries or with primary care trusts or health authorities for audit.

Some staff also appeared to be stimulated to formulate initial views on specific aspects of data sharing, for example situations where patients should (or need not) be asked for consent. Practice staff acknowledged patients' lack of awareness and, in some cases, appeared to be stimulated by the interview to consider that this might be a problem that needed addressing:

GP: *'... I think we don't perhaps explain it or discuss it with patients as much as perhaps we could.'*

Practice nurse: *'Perhaps we ought to ask them ... be a bit more explicit about what we're doing with all these, all the stuff that's in the computer.'*

Practice manager: *'When patients register, perhaps we ought to inform them about the issues, you know, because I don't physically say to them "we are involved in research and audit and your medical records may be looked at." But perhaps that's something that we ought to be doing.'*

Trust and patients' willingness to divulge information to health professionals

Trust within the healthcare relationship was generally viewed by patients and staff as being built up through interaction between patients and providers, for example through continuity and empathy, rather than being based on health professionals' respect for patients' rights. As one patient commented, 'once you get somebody listening then the trust starts to build'. Other participants highlighted the same thoughts with regard to trust:

Interviewer: *'Where does trust come from, do you feel?'*

Patient: *'Well I think it's a matter of when you go in and he makes you feel easy. He will sit, he will make the time to sit and talk to you.'*

Interviewer: *'And how does that [trust] happen, do you feel?'*

Patient: *'I think by building up confidence and seeing the same person. You know, I am, I am uneasy if I have to make an appointment with somebody else, because I don't think they've got the true picture.'*

All groups felt that providing the full picture was important for patient care, but that there were certain types of information, such as details about sexual or mental health, that patients might sometimes be unwilling to entrust to health professionals. Reasons given for withholding information included embarrassment and difficulty with acknowledging problems like abuse, and were not, therefore, generally related to data sharing.

Confidentiality and data sharing within and outside the practice

Patients were happy for data from their records to be shared in relation to medical care both within and beyond the practice, such as one GP asking another for a second opinion, or in referrals to secondary care. Although staff had some concerns relating to data sharing, these were not linked to research. Problems with family members asking for information about a patient, such as mothers asking whether their daughters had consulted about contraception, were the most frequently cited concerns.

Data sharing with employers and insurance companies were also seen as potential problem areas, particularly by staff but also by some patients. During staff interviews, third-party information held in patient records was mentioned as a specific issue in relation to insurance reports. Health professionals mentioned that they sometimes made patients aware that they could protect their interests in terms of employment and insurance by using alternative services, such as counsellors and genitourinary medicine clinics, to prevent sensitive data from being recorded in their general practice notes. More practical concerns were also raised, such as the visibility of information on computer screens and the difficulty of maintaining confidentiality in busy waiting rooms:

GP: *'I think the problem comes in with we are getting insurance requests and often they want all the information and often more and more [of] what we are doing is just printing off everything on the computer and I think that raises issues which I'm not sure we always think about when we're putting stuff on ...'*

Practice manager: *'... and somebody comes in and says to you, "Um, can you tell me if my 16-year-old daughter is in with the doctor?" ... Or you get people ring up and say, "I'm ringing up for the results of my, um, for my husband," and you'd say, "I'm not allowed to give you that information." "Well, why not? He's sitting here next to me".'*

Practice nurse: *'My screen's directly opposite the hatch and so people can quite easily look straight in and see who is on Viagra down the road ...'*

The impact of national electronic record development was not specifically introduced into the discussion by the interviewer and it was noted that this issue was not raised spontaneously during either staff or patient interviews. Some more general awareness of the impact of computerisation was, however, sometimes evident. One patient expressed uncertainty about the extent to which computerised data could be transferred between healthcare providers and some interviewees suggested that computerisation might facilitate inappropriate access to data:

Patient: *'When it's on a computer ... what I don't know is whether the computer system will be linked in ... if you go into any other surgery around, that [data] will be transferred, one assumes. But I don't really know.'*

Patient: *'Databases can be stolen and you'd have access then to everybody's [records]. And although people try and restrict access, there are still people about who can generally access most things.'*

Data sharing for audit, public health registers, and research

After being given explanations of concepts such as audit and national disease registries, patients were ready to enter into discussion about data sharing and consent issues and their increased awareness helped them to formulate preliminary views.

After audit was explained, patients generally saw this positively and were happy for anonymous, aggregated data to be shared with primary care trusts in order to monitor and promote good standards of care. They could also appreciate the usefulness of disease registers. Some said they would be happy for names to be shared with registries without explicit consent and felt that even where cases were identifiable the interest of disease registries would be in aggregated data rather than individuals. Most, however, said that they would prefer anonymisation. Completeness of data sets and traceability of cases for tracking the course and outcome of disease were not necessarily seen by patients as more important than obtaining patient consent before sharing identifiable data.

Patients usually viewed health research as valuable and generally had altruistic views about participation in research that might benefit the future health of the

population. However, as with registry data, most felt that it was essential to obtain patient consent before sharing identifiable data for other research purposes. A common stance when probed was that they that they would be quite happy to give consent in most instances, but would like to be asked as a mark of courtesy. A few took more extreme views ranging from a 'what I don't know can't hurt me' standpoint to a strong wish for autonomy:

Interviewer: *'Would you like to be asked for your permission [to look at general practice records] first or not, or wouldn't it matter?'*

Patient: *'It wouldn't matter, it wouldn't matter. It's like I said before, if I'm not told, I don't know it's happened.'*

Interviewer (in relation to general practices sharing data to assist research): *'... and who should decide about the importance of a piece of research?'*

Patient: *'I think the patient, the individual. I mean, all research is important but not necessarily important to every individual. The importance of one [piece of] research might be different to me than to somebody else.'*

Patient (on being questioned about the need to obtain consent for sharing data with disease registries): *'I mean that's got to be up to the patient to decide.'*

Interviewer: *'And then what happens if the information is incomplete because patients refused to have their, you know, information passed on?'*

Patient: *'Well it's still patient privacy, if that person really doesn't want it to happen, and I think they've got the right to say that.'*

University research was seen by most patients and staff in a more positive light than that undertaken by pharmaceutical companies, whose commercial motives were sometimes questioned. Staff felt that screening of research proposals by ethics committees provided an important level of confidentiality protection, which reduced their own responsibility as guardians of their patients' right to privacy in the context of research.

DISCUSSION

Summary of main findings

The interviews conducted for this study highlighted

the fact that patients' knowledge of the type of data held in general practice records and the ways in which they are shared can often be limited. Patients were, however, generally ready to begin to formulate views on various aspects of data sharing. Staff interviews also suggested a limited awareness of the issues involved and a lack of clear relevant policies in general practices. Moreover, in this climate of limited awareness, there was no suggestion that concern about data sharing for research leads patients to withhold information from health professionals in primary care.

As views were developed during the interviews, patients expressed varying degrees of concern about delegating the right to share or withhold data held in their general practice records. Staff concerns mostly related to everyday practice rather than research, for example in connection with writing insurance reports and sharing information with relatives.

Comparison with existing literature

There has been considerable debate and discussion in the literature about data sharing, consent and confidentiality,^{1-6,13,14} in particular in terms of the effect that restrictions on data sharing may have on public health research. The sharing of genetic information has also raised particular issues for debate in relation to consent and confidentiality.¹⁵ In addition, the issue of access to patient records has recently again become topical as regulatory authorities such as primary care trusts express the desire to verify data submitted by GPs in support of payments under the Quality and Outcomes Framework. However, very little actual research — particularly qualitative research exploring, in detail, the nature and interactions of key issues — has been reported regarding data sharing.

Qualitative elements were included in the work carried out by the NHS Information Authority with the Consumers Association⁸ and as part of the Patient Electronic Record: Information and Consent (PERIC) group of studies¹⁶ conducted by the School of Health and Related Research (ScHARR) in Sheffield. Some of the issues explored in our own study, such as awareness of and attitudes to data sharing, were also considered in the latter two projects.^{8,16}

Our study differs, however, in focusing specifically on the identification and detailed consideration of relevant issues in relation to primary care data, including awareness and views of general practice staff as well as patients. These issues included consideration of the potential for the breakdown of trust between patients and healthcare providers.

Primary care data could be considered to be unique in nature in covering 'cradle to grave' patient information. In addition, other particular features of primary care, such as the long-term relationship between GPs and their patients, may also raise different issues in the context of general practice.¹⁴

Strengths and limitations of the study

We aimed to take a broad view of our research question by seeking the views of both users and providers of primary health care. Our quota sampling frame for patients was designed to ensure recruitment of a range of people attending general practices, rather than necessarily capturing what might be extreme views of those whose general practice records hold particularly sensitive information. However, although it was not within the scope of this study to specifically target patients in this category, it is considered unlikely that their views would materially alter our findings in terms of the areas of concern raised in our interviews.

We sought to achieve a balance between objectivity and subjectivity by using an interviewer who had not been involved in the concept of the study but who, as a patient and a research interviewer, had some empathy with, and knowledge of, the topic under discussion. It is acknowledged that her role within a university research team could have influenced some patient responses, for example regarding the relative merits of research undertaken by academic institutions and pharmaceutical companies. It is also acknowledged that patients' willingness to enter into a relevant discussion may have been partly influenced by a desire to please the interviewer and that hastily formed views may be liable to change on further reflection. Nevertheless, most patients appeared to take a genuine interest in the topics being explored and demonstrated a readiness to consider their views on these issues.

Using interim review of transcripts to inform the conduct of subsequent interviews may have led to a slight shift in emphasis with later interviewees, but also facilitated full exploration of emerging themes.

Implications for clinical practice and future research

As researchers, the possible effect that concerns about data sharing for research might have on patient trust, particularly in terms of willingness to divulge information to healthcare professionals, had been an area of potential concern to us. Our findings in this respect were reassuring. It could be speculated that the situation may change if patients were better informed and, therefore, more aware of data sharing; the impact on patient trust would

need to be reconsidered if effective measures to increase patient knowledge of data sharing were to be introduced.

Our interviews suggested, however, that other reasons, such as embarrassment or difficulty with acknowledging past problems, were far more likely to influence patients' willingness to divulge information. The potential tension between privacy and research is an ongoing issue for which evidence continues to emerge. A study from Canada published since our own work was carried out showed that obtaining written informed consent for inclusion in a stroke registry led to important selection bias.^{17,18} Our interviews suggested that, as guardians of confidential health information, general practices may need to improve their awareness of the issues involved in data sharing. They may also need to develop and document policies about sharing the data held in their patients' records, including the use of anonymous and identifiable data and the circumstances under which patient consent would or would not be sought.

Confidentiality guidelines^{7,19} have emphasised the importance of making patients aware of data sharing. The NHS Information Authority's study⁸ found that patients had a low awareness of how the NHS uses information, with 10% of those surveyed mentioning no other use than for treatment. The PERIC qualitative study¹⁶ also found that patients were surprised by the range of uses of the information contained in their medical records. Our study suggested that any measures taken to date to inform patients on this topic have had little impact on patients' awareness of the scope of the data held in general practice records and the ways in which this information is shared. Although we had expected patients' knowledge of primary care data sharing to be limited, we had not fully anticipated the readiness with which our interviewees were generally able to consider and discuss concepts such as data sharing for audit and disease registration.

The hypotheses generated by this qualitative study need further testing, but we believe that our findings may support the case for giving patients the opportunity to be better informed about the content and use of their primary care records, for example through the use of publicity materials such as newsletters, posters and practice leaflets. The importance of clarity in explanations used for obtaining consent for clinical trials has been recognised.²⁰ In preparing the topic guides for our interviews, we gave some thought to ways of describing concepts, such as audit, in terms that would be accessible to the lay person; we consider

that the findings of our study suggest that many patients would respond well to additional information about the content and use of general practice data. Policies adopted by general practices with respect to data sharing, for example regarding the passing of identifiable data to disease registries, could, in some instances, conflict with the views of some patients. However, patient preference is not the only factor to be considered and, where policies on issues such as consent are potentially controversial, the reasons for these policies may need to be clearly explained in patient information materials.

Consent for data sharing for research cannot be said to be truly informed if the person giving consent is not fully aware of the nature of the data to be shared as well as the way in which it will be used. Although we feel that our findings support the need for general practices to take steps to inform patients of the likely content of their notes, it may be that, as researchers, we should also take greater responsibility for ensuring that patients are adequately informed. Written or verbal information given to patients prior to obtaining consent for data extraction should perhaps, therefore, contain some explanation of the likely scope of the data that will be shared.

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Ethics committee

The study was approved by the ethics committee of Leicestershire, Northamptonshire and Rutland Health Authority (6663)

Competing interests

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