RESEARCH ETHICS

Public attitudes towards the use of primary care patient record data in medical research without consent: a qualitative study

M R Robling, K Hood, H Houston, R Pill, J Fay, H M Evans

Objectives: Recent legislative changes within the United Kingdom have stimulated professional debate about access to patient data within research. However, there is currently little awareness of public views about such research. The authors sought to explore attitudes of the public, and their lay representatives, towards the use of primary care medical record data for research when patient consent was not being sought.

Methods: 49 members of the public and four non-medical members of local community health councils in South Wales, UK gave their views on the value and acceptability of three current research scenarios, each describing access to data without patient consent.

Results: Among focus group participants, awareness of research in primary care was low, and the appropriateness of general practitioners as researchers was questioned. There was general support for research but also concerns expressed about data collection without consent. These included lack of respect and patient control over the process. Unauthorised access to data by external agencies was a common fear. Current data collection practices, including population based disease registers elicited much anxiety. The key informants were equally critical of the scenarios and generally less accepting.

Conclusions: This exploratory study has highlighted a number of areas of public concern when medical records are accessed for research without patient consent. Public acceptability regarding the use of medical records in research cannot simply be assumed. Further work is required to determine how widespread such views are and to inform those advising on confidentiality issues.

Although access to patient records for medical research has come under increasing scrutiny in the UK, the debate has largely been confined to professional circles, and very little is known about the views of the general public on this matter. Researchers face a confusing situation. On the one hand the 1998 Data Protection Act strengthened the law protecting an individual’s privacy and implemented stricter controls on the use of personal data. However, the 2001 Health and Social Care Act makes provision for the disclosure of patient identifiable information in certain circumstances—including medical research—and constituted an advisory group to consider the processing of such data on behalf of patients and the general public.

Standards for transparency and confidentiality have been set for researchers by the Department of Health, but guidance from the UK Medical Research Council describes research scenarios where a breach of confidentiality may be permissible under the Data Protection Act and the Common Law of Confidentiality. Further complications arise since such professional guidance has been criticised by patient groups concerned about the use of patient data without consent.

Recent court rulings have also raised doubts about the legality of even anonymised data being used in research.

The acceptability to patients of access to medical records without their consent has frequently been assumed. However, the lack of any evidence about the acceptability of such activities from the potential research subjects—members of the UK public—is striking. Studies that have been done in primary care relate to the issue of confidentiality of records in routine clinical practice rather than the use of records for research. The aim of this study was to explore issues of importance to the public regarding the use of primary care records when consent was not being sought.

The choice of primary, rather than secondary, care as the context of investigation was determined by two considerations. Firstly, general practitioners (GPs) are increasingly participating in research in accordance with the principles of evidence based medicine. Secondly, given the nature of the ongoing relationship between patients and their general practitioner, there was no reason to believe that patients’ attitudes to confidentiality and consent would be the same in both settings.

The acceptability of research designs excluding patient consent (to patients, professionals, and the public in general) will reflect the moral position of those key players. O’Brien and Chantler, for example, identify GPs more with a rights based approach to citizenship whereas public health and epidemiological professionals may be more aligned with a utilitarian perspective. This paper will consider the moral issues raised by this empirical study and, in particular, potential sources of tension between differing perspectives.

METHODS

Study design

An exploratory qualitative approach was chosen to identify issues of concern to the public. Focus groups were chosen as they are especially good for exploring attitudes and experiences. The method actively uses group interaction (both supportive and contrary) to allow the observation of a range of views, and identify the nature of arguments and counter arguments deployed within a group. Eight meetings were held with members of the general public drawn systematically from the register of four electoral divisions in South Wales, UK. The groups were stratified by gender, geographical setting, and level of deprivation. Gender was chosen as a stratifying variable to aid rapport amongst participants.
Groups were selected to be either urban or rural to reflect different communities in South Wales and either relatively affluent or deprived to reflect differing socioeconomic circumstances.\textsuperscript{17} Stratification emphasised major factors affecting health status and access to services. Two pilot meetings used participants drawn from a different electoral division.

Key informant interviews were also conducted with non-medical members of local community health councils. It was thought that the interviewees might represent lay people with a greater familiarity and interest in confidentiality issues. Bro Taf Local Research Ethics Committee advised that approval was not required.

**Recruitment of sample**

As previous focus group work shows variable rates of interest to postal invitations, letters of approach were mailed to at least 100 people per focus group.\textsuperscript{18} Up to eight people per group were selected. One non-medical member from each of the four community health councils in the area covered by Bro Taf Health Authority was approached and interviewed.

**Discussion guide and procedure**

Each focus group was moderated by two researchers (MR/KH). Discussion guide and procedure

Each focus group was moderated by two researchers (MR/KH). Upon arrival, participants completed a brief questionnaire, including details of age, occupation, and awareness of their own GP’s involvement in research. Participants were asked to consider in turn three scenarios describing the use of patient information for research without informed consent (see box). The extent of breach in confidentiality was designed (in the eyes of the authors at least) to increase from scenario one to three. Participants were asked to consider the acceptability and value of each scenario. Prompts were used to explore specific variations for each scenario, including measures proposed to address confidentiality issues (for example, using a research nurse).

Discussion was recorded and transcribed for analysis. In addition, the assistant moderator made notes during the focus groups and both moderators discussed their initial observations following the meeting.

**Key informant interviews**

Each semi-structured interview was conducted by MR using the same research scenarios as the focus groups. Interviews were recorded and transcribed.

**Analysis**

Transcripts were reviewed independently by MR and KH and narrative summaries for each scenario and group were prepared. The researchers met to agree a summary of the key themes for each scenario. Of particular interest was the level of consensus across groups expressed towards each scenario, the range of views described, and the arguments put for and against a particular opinion. The aim of the analysis of key informant interview data was to determine whether any additional issues arose not described already in the focus groups. A third researcher (RP) provided additional guidance and review of the process.

**Role of the funding source**

The study was financially supported by the Wales Office of Research and Development who provided constructive feedback on the funding application and on the final study report but played no role in study design (collection, analysis, and interpretation of data) or the decision to submit the paper for publication.

**RESULTS**

**Sample recruitment**

Of 1145 people approached, 226 (19.7\%) returned the response form, and of these 112 were willing to be contacted further. Between three and eight people attended each focus group, 49 in total. Thirty two (71\%) of the 45 people reporting their age were older than 50, and 36 were in a non-manual social class (table 1). Focus groups lasted approximately 90 minutes and were characterised by initial clarification of the process and subject matter. Subsequently, participants felt able to debate each scenario within their group, exhibiting a range of positive and negative views. Analysis exploited the discussion guide to summarise these views by scenario and by specific prompt.

**RESEARCH IN PRIMARY CARE**

One of the most striking features revealed by the group discussions were the general assumptions about research, researchers, and more particularly of GPs as researchers. People had high expectations of confidentiality from their GP and felt a greater level of control within primary care compared with other settings. Looking at each scenario in detail there is evidence that concern increased as control was perceived to move away from participants’ own GP and local surgery.

Anxiety increased with more sensitive conditions, such as mental health problems. Serious concerns were expressed
There was a common wish to be informed about the data collection, firstly out of courtesy and, secondly, to enable patients to opt out (table 3). The desire for courtesy is shown in the extended interaction at the beginning of table 3. The interaction also illustrates the value of focus groups in facilitating questioning and debate among participants and exploring opposing views. The adverse consequences of informing patients were suggested in one group. Informing patients was seen as a way of making patients feel that they were helping, although the difficulties and cost of processing consent were recognised. Concerns about unauthorised access to patient data were aired, including individuals being penalised on the basis of their own medical record and also their membership of a population subgroup.

SCENARIO 2: TRANSFER OF NAMES AND ADDRESSES TO RESEARCH TEAM

Initial acceptance of this scenario appeared to be based upon the choice patients had to return a questionnaire once contacted by researchers, and that only names and addresses were being released. However, a number of concerns were expressed about this scenario and some felt the approach should come directly from the doctor. The credibility of the “researcher” was questioned amid concerns about their duty of confidentiality (table 4). Objections arose from participants’ lack of faith in computer security—a high level of computerisation within primary care was assumed and protection against unauthorised access inadequate and difficult to achieve. To some participants, providing a

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Table 1 Demographic characteristics of focus group participants*

| Variable       | Category | n (%)
<table>
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<tr>
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<tr>
<td></td>
<td>30–39</td>
<td>6 (13)</td>
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<tr>
<td></td>
<td>40–49</td>
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<td>50–59</td>
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<td>15 (33)</td>
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<tr>
<td>Social class†</td>
<td>I</td>
<td>5 (11)</td>
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<tr>
<td></td>
<td>II</td>
<td>16 (36)</td>
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<tr>
<td></td>
<td>III-NM</td>
<td>15 (33)</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>V</td>
<td>0 (0)</td>
</tr>
<tr>
<td></td>
<td>Other‡</td>
<td>4 (9)</td>
</tr>
</tbody>
</table>

*45/49 respondents completed the questionnaire.
†Using Standard Occupational Classification.
‡Could not be classified.

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Table 2 Research in primary care

| UDM2           | Is that the job of a family doctor would be my concern. I'm not sure technically it should be your family doctor in isolation, working alone, would be the right way to do it. There are research bodies, hospitals and universities and things like that. I would have thought personally that would have been a better place to do the research... rather than the family doctor himself who would appear to be under great pressure to just do the family doctoring.
| RDM2           | The only concern I would have is if the practice was doing too much research because it was getting funded... at the cost of patient care.
| UDM1           | I'd like to be informed if they are going to dwell into our medical... records. Because sometimes doctors... not only work as a doctor they work in medical schools as well, they go to the hospitals to work. And if they are using our records for some reason or another it would be nice to be consulted.

U/R, urban/rural; A/D, affluent/deprived; M/F, male/female.

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Table 3 Comments from scenario 1: single GP reviewing own practice records

| UAF2           | Well, personally I would like to have had the opportunity. I would probably say ‘yes’. I would still like the common courtesy of being asked if I was willing for that to happen.
| Anon           | Exactly.
| UAF5           | I’m like you—I think that would have to be a must to be asked.
| MR             | Right.
| UAF4           | But they’ve got your records and they can look at them any time, so why would it be of any concern to you?
| UAF5           | In as much as research—and they could be using those records within their research and other people are looking at them.
| UAF4           | But it says here your own doctor is going to be looking. So anytime that he can look in your records and see what you’ve had.
| UAF5           | Yes, but that’s your own doctor, that’s not any one else involved.
| UAF4           | But it says, it says here your own family doctor has decided to look at your medical records.
| UAF2           | But you should expect still common courtesy from your family doctor.
| UAF4           | Well he doesn’t look at—ask you every time he wants to look up your records. He doesn’t ring you up and say “I’m going to get your file out today...” and ask you, does he? I mean.
| RDF5           | Maybe it would affect the results, perhaps how they communicated things to doctors... they would withhold some or say there were more, so I think in some instances it could affect results.
| UAM5           | I worry when it’s published because once something is in the public domain... I mean you often see in the papers there will be some pilot study or something that’s been grabbed out and sort of put in the papers and you sort of open the paper one day and hidden—people might think. “Oh! You know, it seems a certain mistrust and they think “oh hang on, I didn’t think this was going on”.

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minimal amount of data in the form of names and addresses appeared to increase this risk.

Prompts
Using a “research nurse” to contact patients was favourably greeted. A nurse was viewed as abiding by professional regulations and had a duty of confidentiality towards patients. A nurse provided accountability and a point of contact. Furthermore, the approach now came from the practice. However, some saw the doctor alone as the person to provide the approach.

Whereas some participants saw value in additional information being provided, generally participants saw this as the thin end of the wedge towards full disclosure of confidential data. Particular groups (for example, the elderly) were seen as especially vulnerable. Providing a general consent in advance for names and addresses was acceptable if sufficient information was provided. Such consent had to be updated to account for changes in personal and practice circumstances.

SCENARIO 3: TRANSFER OF PATIENT DATA TO EXTERNAL DISEASE REGISTER
Collecting anonymised and unlinked data appeared to be the most acceptable of the three scenarios, although some preferred consent to be sought. Some considered this an obligatory service, which should be part of the GP contract (table 5). Potential harms identified included failure to anonymise data adequately and unauthorised access by insurers and employers. Some drew a distinction between data used for service planning and research, with the latter only acceptable when obtaining consent.

Prompts
Collecting linked data appeared to enhance its value, although for some participants the ability to prospectively monitor patients necessitated consent. Transferring personally identifiable data stimulated much concern. For some it ignored common courtesy, removed personal choice, and reflected a lack of respect for human rights. Indirect harms expressed included the sensitivity of the medical condition and database security. Consent was generally viewed as obligatory for linked anonymous and personally identifiable data. One interviewee was more accepting of the latter but preferred consent to be sought. Some considered this an acceptable when obtaining consent.

KEY INFORMANT INTERVIEWS
Three interviewees found the first scenario unacceptable, with concerns about harm to the doctor-patient relationship and wanting the opportunity for “opting out” of the process. Providing patients with results and a patient committee to review research proposals were suggested. All interviewees found the second scenario unacceptable, as decisions about the release of patient names and addresses were being made on behalf of the patients. An approach from the researchers was seen as potentially anxiety provoking. Waiting room posters to recruit (rather than inform) patients was advocated and seen as preferable to an approach from the nurse.

All four interviewees were unhappy about the collection of unlinked anonymous data in scenario three, although it was considered more acceptable for service planning. Concerns expressed included the sensitivity of the medical condition and database security. Consent was generally viewed as obligatory for linked anonymous and personally identifiable data. One interviewee was more accepting of the latter but still worried if patients discovered subsequently that their records had been accessed.

DISCUSSION
The acceptability of research requiring access to general practitioner records without patient consent was explored using focus groups with members of the public and interviews with lay representatives from community health councils. Participants quickly became comfortable with the group format and a number of patterns started to emerge. Despite support for the aims of the activities discussed and some approval for such data collection, this exploratory study has raised a number of important areas of concern that require further investigation.

Recent UK legislation and its interpretation has caused consternation for clinicians, researchers, and patient representative groups alike. Its actual and potential impact has been discussed widely amidst concern for damage to the work of cancer registers, public health surveillance, and broader epidemiological work. Justifications proposed for not formally obtaining patient consent and respective counter arguments have often made assumptions about what patients and the public in general would find acceptable. Perhaps as may be expected, the picture evolving from the current work is a little more complex.

Members of the public and their lay representatives expressed concerns about breaches of confidentiality that may occur in current and legitimate research practice. Furthermore, the public may be unaware of current safeguards for research and data security and may also be dissatisfied with some solutions proposed for minimising breach of confidentiality. It is possible that some of these

| Table 4 | Comments from scenario 2: transfer of patient names and addresses to external research team |
| RAM3: | So presumably the researchers then have got no way of knowing anything else other than a name. So they have got to presumably waste time and money writing to everybody on the list although people below a certain age and above a certain age, perhaps are not really going to be part of the study anyway |
| UAF5: | I would hate the thought of say half a dozen people, researchers looking and going through the notes and saying ‘Have you seen this one, wow!’… People especially going back to mental health problems because people are very sympathetic towards any physical problems but often times, when it comes to mental health problems they see it as a huge joke. |
| UDM3: | Everything is done on computer nowadays and computers can be hacked. I mean if it’s on a piece of paper in somebody’s office that’s generally where it stays. But it’s not that way anymore. |
| UAF4: | Because once you come out of the realms of confidentiality of the doctor, you accept or you hope you have got the confidentiality with your doctor, but once it’s out in a wider thing, it’s not so it. Nobody owes the same allegiance to you as the doctor-patient. |

| Table 5 | Comments from scenario 3: transfer of patient data to external disease register |
| RDM1: | …do you believe that there could be… that certain general practices would have the right to opt out? … Where the central body can say ‘No, that’s part of your agreement. You’re GP in that area and we need this information—to have it everywhere. No opting out mate, that’s part of what we are paying you for.’ … For the services to be planned… the database would have to be a full database. We couldn’t say have half a dozen people saying ‘No. I won’t fill in that. We don’t want to be part of that’, when there are people really being affected. |
| RDF5: | Strong words to use but it’s a bit like human rights isn’t it? It’s your right not to let that information go into other hands. There’s very few things we’ve got control over and that should be one area that you do have a choice. |
concerns are exacerbated by unfamiliarity with both the research process and routine record handling. This would indicate the need for raising public awareness of such issues, a considerable task assuming low baseline levels of current knowledge.

ETHICAL ISSUES RAISED

Individual rights and utilitarianism

Study participants recognised both the importance of and conflict between personal privacy and societal needs. This was probably best exemplified in their discussion of the third scenario—the disease register (table 5) but was apparent throughout the focus groups. O’Brien and Chantler reflect upon this tension within two ethical perspectives—a rights-based approach to citizenship and a broad utilitarian approach.24 Interestingly, they consider GPs in particular as sharing the former approach but place those concerned with public health, epidemiology, and other researchers within a utilitarian perspective. A perspective in which actions should be guided by what produces the greatest good for the greatest number presupposes a basic confidence in the benevolence of one’s government.25 It is not difficult to see how an increasingly sceptical public may have difficulties with this.

Whilst utilitarianism permits the interests of the majority to override minority rights, it has been argued that the pursuit of the goal of social utility is not necessarily morally wrong—if almost everyone’s interests are protected.26 However, a specification of what is critical and data from this study would suggest an expanded definition of “interests”—for example, to include certain moral harms.

Harms

Study participants recognised several potential harms when patient records are accessed without consent—even if it is solely the infringement of their human rights. This is generally in contrast with what is often considered the potential for harm in such non-interventional studies. However, Capron exemplifies such harms when describing the invasion of personal privacy and concomitant lack of respect for reserve and solitude.27 Such moral wrongs are committed even when the “wronged” is unaware of their occurrence. This is consistent with views expressed within our study. The data balance the views of, for example, O’Neill—that anonymised data cannot result in harm to an individual and therefore does not require consent.28

Autonomy

McLean asserts that not obtaining consent neglects the notion that good research must respect the subject.29 Offering patients the choice of research participation upholds autonomy, although Warnock prefers what she considers a more precise label—non-exploitation.28 For Warnock, the secondary use of anonymised data for a previously unthought of study involves no harm to subjects and is unlikely to represent exploitation. This may well be contrary to the feeling of those participating in the current study.

The moral balance

It is clear that members of the public recognise the necessity of a balancing act to resolve competing but legitimate interests (for example, individual versus community). Doyal discusses this moral balance in studies using medical records without consent, where the moral wrong being done can be set against the benefit to the patient and the public interest.30 Doyal asserts that the moral imperative of respecting human autonomy is not applicable in all circumstances and is defended in part by the proviso that there is no intention to contact patients subsequently.31 (for example, in epidemiological research). There is of course a danger that patients may unintentionally discover such (moral) abuse. Doyal acknowledges this but was perhaps more forcefully verbalised by our focus group participants (table 3). The position of concerned study participants is probably best reflected by Hurwitz who considers that there is insufficient moral warranty for wholesale use of personal data for purposes other than those for which it was originally supplied.29

The study provides empirical data both to exemplify the moral issues surrounding confidentiality and consent currently being debated, and also to cast doubt on some of the assumptions above that are being made on behalf of patients. The health of the debate can only be improved by results from current (and future) studies, and should help to facilitate a more transparent assessment of the balance of harms and benefits in individual studies.

METHODOLOGICAL ISSUES

The aim of this study was exploratory in nature and not designed to facilitate broader generalisation. Hence, theoretical sampling was used to maximise sample variation rather than to facilitate group comparisons. Alternative approaches to identifying and approaching focus group participants were considered—for example, using family practice lists, but were considered inappropriate given the topic matter. That a large number of people had to be approached for the focus groups is not uncommon using this particular method. Nevertheless, participants were mostly middle aged or elderly and it is possible that different issues might be important to younger people or people from certain minority groups. Further targeted qualitative work would be required to determine this.

Focus groups offer advantages over interviews for people who feel they have nothing to contribute or may be intimidated by a one to one situation.13 This is particularly useful when addressing issues not previously considered by participants. Focus groups may also generate more critical comments than interviews and for scenarios where few harms are assumed; it is useful to explore such perceptions.30 The approach also allows participants to generate their own questions and discuss issues using their own vocabulary. Similarly, the interaction and debate within focus groups served to reveal participants’ views capitalising upon the natural tendencies to discuss, agree, and argue points. Whereas the focus groups allowed the exploration of participants’ viewpoints and their basis, the aim of analysis was mainly upon describing the range of views expressed.

The focus groups were conducted in an area where the academic general practice unit had conducted a large number of practice based studies. However, participants were generally unaware that research was conducted in primary care and there were doubts expressed about the suitability of GPs to conduct research. The special nature of the general practitioner-patient relationship, the continuity of care afforded in primary care, and also the public perception that research seldom occurs in this context, mark it out for special consideration in relation to records based research.

KEY INFORMANT INTERVIEWS

Lay patient representatives were interviewed to determine whether issues or concerns were expressed in addition to those raised by members of the general public. Issues arising in the interviews were generally congruent with those raised by members of the public, although the scenarios appeared somewhat less acceptable to the lay representatives. The study was not designed to representatively compare such groups. It does though hint at differences referred to by Turnberg, who feels that the public is generally happy for personal data to be used for research purposes—and that debate on the topic should encompass a wider public than...
those who have claimed to represent them in the past.31 We agree that the arena for debate should be broadened but value a balance of perspectives from both the public and also their formal representatives.

The consultation process regarding section 60 of the Health and Social Care Act produced comments that were broadly supportive.32 However, the power to allow access to patient information without consent did raise concern among groups representing patients. The Patient Information Advisory Group constituted to consider such applications for section 60 support has echoed these concerns, for example, in response to clinician claims that informing patients would be too burdensome. The advisory group points to the central role of GPs in informing patients about work requiring access to data without consent (for example, the Public Health Laboratory Service). There is clearly a lot for those working in primary care to do to satisfy the spirit of these recommendations.

Messages for researchers and GPs

Implied consent for access to and use of confident patient record data cannot necessarily be assumed and the public at least perceive some harms inherent in that process.33 Access to medical data has been facilitated by technological progress and data are now available that would not have been previously accessible. Demand for data across the health service and beyond continues to grow, as does the potential to exploit it. Consequently, the GP’s role as guardian of this service and beyond continues to grow, as does the potential for researchers and policy makers alike. However, how widely held such views are still needs to be determined by a representative quantitative approach. Such research could usefully inform the work of the Patient Information Advisory Group and others concerned with balancing wider societal benefit and demands for personal privacy.

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Authors’ affiliations

M Robling, K Hood, H Houston, R Pill, Department of General Practice, University of Wales College of Medicine, Llanedeyrn Health Centre, Maeifa, Llanedeyrn, Cardiff, CF23 9PN.

J Fay, St Bartholomews Medical Centre, Manzil Way, Cowley, Oxford, OX4 1XB.

H M Evans, Centre for Arts and Humanities in Health and Medicine, University of Durham, Old Shire Hall, Durham, DH1 3HP.

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