

Patients' Consent Preferences Regarding the Use of Their Health Information for Research Purposes: A Qualitative Study

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Objective

To explore the consent preferences of patients whose health data are currently being used for research purposes.

Methods

Semi-structured interviews were conducted with 17 patients whose primary physicians were taking part in a study that utilized de-identified individual-level health information from their electronic medical record. All physicians practiced in southwestern Ontario. All interviews were taped, transcribed verbatim and analyzed using a constant comparative method. All transcripts and debriefing notes were read and reread to elicit general themes.

Results

Three main themes emerged from the data: patients recognized the need to balance their consent preferences with time pressures in the clinical encounter when deciding the nature of consent for a study; patients generally regarded the seeking of consent as being an issue of respect for them as individuals; and patients were also weighing their perceived benefits and concerns related to the research. For these patients, seeking their consent was an important step in research participation. For some patients, the sponsor and the research topic were factors that would influence their decision to provide consent.

Conclusion

Patients want their consent to be sought when their data are used for research purposes. This will involve explicitly informing patients that a study is taking place, providing written consent and offering regular updates about the study.

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Introduction

Increasingly, personal health data collected for clinical care are also being used for other purposes, including health research. The last decade has seen an increase in the use of computerized electronic health records (EHRs) in medical practice. Many developed countries have health information strategies that promote even further use of EHRs as a vehicle to increase the quality and portability of care.^{1,2} Research examining the use of EHRs has found that, despite some concerns regarding impact on the doctor – patient relationship and the confidentiality of their health information, most patients have supported the presence of computers in the physician – patient encounter.^{3–10} Use of EHRs in physicians' practices has also drawn attention to the potential value of organized data in studying the true effectiveness and cost-effectiveness of care, as well as forming a powerful medium for interventions to improve care. These and other secondary uses of EHRs have raised the issue of the role of patient consent as policy-makers struggle to find a balance between the competing societal benefits to be had from using health data to improve the efficiency of publicly funded health care systems and patients' rights to personal privacy. Recent commentary has noted the potential

negative impact on research – particularly the introduction of selection biases – that mandatory consent by patients could induce.^{11–13}

To date, there has been relatively little research examining the views and preferences of patients regarding consent. Aside from a body of literature examining consent in clinical trials, it is only recently that patients have been questioned about their consent preferences. A recent report from the UK found that patients were generally uninformed about how their health information was being used by the National Health Service.¹⁴ These respondents felt that they should be allowed to restrict access to ‘sensitive’ information and that consent would not be required for anonymized information. In 1998, at the start of an EHR study aimed at improving prescribing by family physicians, we conducted focus groups to determine physician and patient opinions about privacy and confidentiality issues related to computers and EHRs.

We found that focus group participants who were not part of EHR practices wanted to be consulted regarding who had access to their health data (even if these data were anonymized) and also expressed concern that database research could threaten their privacy if hackers gained access to their information or companies such as insurance companies used this information to determine eligibility for coverage.¹⁵ Another study found that approximately 10% of patients ($n = 3429$) who had completed a questionnaire about their health condition refused the collection of further data from their medical records.¹⁶ This study was asking patients for use of personal health data that was not anonymized and the authors made a recommendation that consent should always be sought from patients.

Although these studies provide some insight into the perspective of the public, there is little information on the views of patients whose physicians are currently using an EHR system. Therefore, the present study sought to explore the consent preferences of patients whose de-identified health data were *currently* being used for research purposes. De-identified data differ from anonymized data. De-identified data have direct identifiers such as name, address and telephone number removed. However, the possibility remains for indirectly identifying individuals through the unique combination of other data present in the record. This phenomenon is also known as ‘residual disclosure’. Unless specific measures are taken to statistically reduce the disclosure potential of indirect identifiers such as date of birth, most EHRs retain some risk of residual disclosure. Full anonymization of data, such that residual disclosure is impossible, is extremely dif. cult to achieve without aggregation, particularly with detailed health records.

Methods

A qualitative approach was used in this study. Individual interviews were held with patients between March 1999 and May 2000 in the Hamilton area (Ontario, Canada). All interviews took place at a location that the patient deemed convenient: their home, their physician’s office, or the interviewer’s office. This study received ethics approval from the St Joseph’s Healthcare Research Ethics Board, Hamilton, Ontario.

Convenience sampling was used to recruit patients for the study. Patients who were over 18 years of age and who were patients of COMPETE physicians were eligible to participate. They were recruited either by direct response to notices posted in the office waiting rooms or by physician nomination of those they felt might be interested in talking about the broad issue of using EHRs for research purposes. Potential participants were mailed information about the study from their physician’s offices. These patients were invited to call the interviewer if they were interested in participating. Interviews were conducted until theoretical saturation was reached.¹⁷

All interviews used a semi-structured interview guide that comprised open-ended questions relating to:

- (1) how patients wished to be informed that their physician was participating in research;
- (2) their preferred option for consent;
- (3) their thoughts about future uses of their health information;
- (4) whether they had concerns over different potential sponsors of research; and
- (5) their views about the potential commercialization of health information.

The interview guide was pilot-tested with two people to establish the order and wording of the questions. Each interview lasted between 30 and 60 minutes. Consistent with qualitative methods, modifications to the interview guide were made as the interviews progressed. This helped to ensure that the issues that were most salient to patients were being explored. All interviews were audiotaped. An experienced interviewer (KN) facilitated each of the interviews. For five interviews, at least one other research team member (DW or KK) was present. All tapes were transcribed verbatim and cleaned prior to data analysis.

At the beginning of the interview, patients were reminded that their physician had agreed to be part of the COMPETE study and, as a result, the health information of patients with certain diseases, minus identifiers, would be used to explore questions related to medication use. Patients were told that names, addresses and all other direct identifying data were removed prior to automated transfer to a separate research database and that research findings would be reported in aggregate form. Patients were asked to use the COMPETE project as an example of research that utilized health information so that they would have a framework for answering the interview questions. Patients were told that the present study was taking place to help researchers and health care professionals better understand patients' consent preferences. Patients were not given any further information regarding 'research' or what constituted a research study.

The verbatim transcripts and debriefing notes were read independently by two research team members and coded to identify themes using an operational codebook. This type of investigator triangulation helped to minimize bias in the analysis process. Modifications were made to the codebook as the analysis was conducted to reflect the emerging themes. Summaries were created for each theme. A constant comparative method of analysis was used, with the summaries and transcripts being read and reread to ensure that the themes generated truly reflected the data that were collected.¹⁷ All transcripts were reviewed to extract both confirming and disconfirming evidence of the themes being developed. A qualitative data retrieval computer program, QSR NUD*IST (version 4.0)¹⁸ was used to assist with data organization.

Results

Eighteen patients (7 male and 11 female) agreed to be interviewed. One male patient withdrew from the study and data from this interview were excluded from the analysis. The mean age of patients was 52 years (standard deviation, SD = 13). Patients had been with their physician for an average of 10 years (SD = 8). The median number of physician visits by these patients was four per year. No other demographic information was collected from patients. Interviews were conducted at the patient's home ($n = 7$), the interviewer's office ($n = 7$), a coffee shop ($n = 1$) or at the office of the patient's physician ($n = 2$).

Most patients were unaware that their health data were being used for research purposes despite signs being posted in their physician's office (negative consent option). While some patients commented on the presence of the computer in the consultation room, they were often not aware that use of the computer was related to a research study that used their health data.

Three major themes emerged from the data: balancing consent preferences with time pressures in the clinical encounter; being treated with respect; and balancing the benefits and concerns related to research. Each is described in more detail below.

Balancing consent preferences with time pressures in the clinical encounter

Patients seemed to be attempting to weigh their needs against their physician's needs as they discussed research using their data. This was particularly true when talking about the various possible consent options: advise only that research is taking place (no consent sought); negative consent (advise and give option of saying no); positive consent (written or verbal consent sought). Some patients acknowledged that the time - consuming nature of getting written consent could result in administrative difficulties for their physician and the possibility of less time being given to them. Patients did not want their already busy, overworked physician to be burdened with extra, externally driven research responsibilities. As one patient noted:

I could see the doctor going absolutely barmy if he or she had to get the consent signed and everyone had to read it . . . they seem so pressured, that I can't see that being very practical, can you?
(Patient 13)

The majority of patients supported a positive consent option. They were clear and forthright in their belief that it was their right not to only be informed about research taking place but to be given the option of whether or not to participate. These patients wanted to have control over the use of their data.

They also noted the necessity of being given sufficient information about the nature of the research project and the security measures in place before giving consent. Patients requested study processes and measures that would result in the least amount of confusion. **Box 1** depicts patients' comments relating to the different consent options they were presented with during the interview. The number of patients who endorsed each particular option is also noted. No patients endorsed a fourth option that had been provided, whereby a panel of patients from the physician's office would make decisions regarding use of health information for research purposes. Three of the 13 patients who preferred the positive consent option indicated that the provision of consent verbally was acceptable.

Box 1 Patients' comments relating to different consent options

Advise only ($n = 3$)

. . . one assumes if a doctor is taking part in research he's trying to do the best for his patients. And as far as I am concerned, you should trust him enough to rely on him to do that. (Patient 15)

Negative consent (advise and have option to say no) ($n = 1$)

... send me something in the mail saying, 'We're going into your file, unless you say no'. (Patient 8)

Positive consent ($n = 13$)

If the verbal one carried as much weight as the other one [written consent], then I would go with the verbal. (Patient 11)

I think asking for consent and signing a consent form explaining the research will probably be the best option for me. Um, it would give me a good idea as to what's involved and I would have the option of getting involved or not. (Patient 16)

I think you need to give conscious consent to having any data, any personal data used, whether you are identified or not. That's certainly a right. That's your information, it's your medical history. Whether it's identified or not, you should control it. (Patient 14)

Patients were asked whether they wanted to know about every study that their physician was taking part in and how much detail they wanted to know about potential research studies. Patients were only interested in knowing about studies that would involve their own data. Patients talked about wanting to be given a basic overview of the research topic, knowing why their physician wanted to use *their* data and the security measures that would be in place. **Box 2** provides examples of typical responses.

Being treated with respect

A second theme that emerged from the interviews was patients' association of consent with respect. Patients wanted to be treated 'like human beings' as opposed to objects of research, and wanted to be consulted about research that was taking place involving their data. The majority of patients were unaware that this type of research (database or chart audit) was relatively commonplace. Many patients noted that it was only courteous that their physician let them know when they were engaging in research that used their data. When patients were asked how they should be informed about research that their physician was doing, most patients indicated that they preferred being verbally informed by their physician that research would be taking place and being given written information that they could refer to later. Most patients wanted to be informed about research directly from their physician and felt that having a verbal dialogue was a key component of the doctor-patient relationship. As one patient noted:

...ask me as opposed to telling me ...[when] you're approached personally, verbally... your doctor can see in your facial reaction whether you're understanding, whether you're following and there's a chance of questions, answers. (Patient 8)

A consideration is the trust patients placed in their physicians. A number of patients expressed the view that, because they trusted their physician, this would influence their views relating to their health data being used:

I like Dr XX . . . if that is going to help her, hey why not? (Patient 5)

I know my physician well enough to have a good feel for the types of things he would be involved with. (Patient 12)

If you trust the doctor, I don't think it would worry me how much [data] you needed, and I do trust the doctor. (Patient 15)

When discussing the possibility of future new uses of their health information, most patients were comfortable with further research taking place, providing their consent had originally been sought. However, they still felt it was important for them to be informed and engaged in this process. Patients were not only keenly interested in the research that used their data but wanted to ensure that the appropriate accountability measures were in place.

I'd probably just want to be told that the study had expanded a little bit . . . that it was something different. Yeah, to keep everything above board. I would still say go ahead and use it, but . . . provided that the patient is aware. (Patient 1)

From my own point of view, I'd like to know what is happening because accountability, it's really very important. (Patient 13)

Box 2 Patients' information needs prior to giving consent

Overview of research topic

The purpose, the how they're going about it and precautions they're taking and so on (Patient 14)

I would like to have the background to the study and understand what the purposes are... (Patient 4)

Why my data?

Why pick me to be in the study. Is there something that's of interest in my reaction to drugs... rather than just the fact that I was picked at random to be part of this. (Patient 2)

Security Measures

...the safeguard measures put in place to respect individual's privacy (Patient 4)

... I'd want to know whether or not my personal information, identifying information would be removed. Not so much from a physician's point of view, but from the other people looking into it. (Patient 16)

Balancing the benefits and concerns of research

These interviews also highlighted patients' beliefs about health research in general and the effect of funding source on attitudes towards research. Most patients felt that health research was vital and could be of assistance not only to them, but also to other people. All patients commented to the effect that 'research is good' and 'I want to help others'.

However, despite this generally positive tone noted by patients about health research, there were also a number of concerns raised by patients about the safeguards applied to protect their records. Patients wanted assurances that their data would be de-identified and that only the researchers and not the funders would have access to the data. This was particularly true for research that involved sensitive issues. For some patients, if research involved sensitive issues, adequate safeguards would make a difference between agreeing and refusing to participate. **Box 3** highlights some of the benefits and concerns raised by patients.

Patients were told that funding scenarios were changing in Canada and that partnerships with the private sector were becoming more commonplace and they were asked to comment on four possible types of funders for health research (pharmaceutical companies, software companies, insurance companies, the government). These funders were chosen as they re-presented private sector partnerships that the general public may not be aware of. When discussing these four possible funders, patients voiced the greatest apprehensions related to pharmaceutical and insurance companies. There were concerns that pharmaceutical companies would only be interested in endorsing their own products. In two interviews, patients mentioned a then recently publicized account in which a physician funded by a pharmaceutical company had been censured for attempts to go public about concerns over side-effects of a drug. A number of patients also commented on the potential detrimental impact if insurance companies were to have access to data. Despite these concerns, there was a general feeling that, if funding from

Box 3 Patients comments related to research

Benefits of research

... I'm all in favour of the advancement of science. (Patient 8)

Because when all is said and done, the more research the better really Try and provide a cure (Patient 15)

If I could help other people and they need help down the road then I'm more than happy to do what I can (Patient 16)

Concerns about research

I would certainly not want... certain things maybe that I feel sensitive about to be... blabbered all over and dissected or whatever. (Patient 7)

I'd really be ticked off if I had AIDS or something and someone traced that back. Then all of a sudden the insurance companies are going 'Sorry, nothing for you.' (Patient 9)

... my biggest concern is that there's no identifiers... when you're dealing with insurance companies... there's issues that you're not being covered... (Patient 14)

Box 4 Patients' comments about different funding sources for research

Software companies

I think that's all right because... it is not a direct tie-in with the patient. (Patient 15)

Pharmaceutical companies

... I don't believe for a minute that these people put money into projects from much of an altruistic vantage point. They're looking for a way to sell their product. Money is money, but you have to look at the strings that may be attached. (Patient 6)

... if it was a pharmaceutical firm who was then going to insist that you use their product, that's the type of funding I'd object to. (Patient 15)

Insurance companies

I wouldn't want to see a single insurance company maintaining control of any research project. (Patient 12)

Insurance companies have a nasty habit of immediately using it [health information] as a way of... somebody not getting insured. (Patient 15)

Government

...the government should definitely... we pay enough taxes here. (Patient 5)

... as long as the control that they had over the project was limited to the funds and ethical and moral issues, as opposed to big brother maintaining control. (Patient 12)

industry came with a proviso that they operate on an arm's length basis, funding from commercial sources would be acceptable. **Box 4** summarizes patients' comments relating to different funding sources.

Patients were unanimous in expressing that researchers should not personally profit financially from the commercialization of their databases. There was some sense that selling data to other researchers was allowable as a cost-recovery measure but that to sell database information to other companies (insurance, pharmaceutical) was not acceptable:

*...if a researcher were to sell it to gain monetarily, I don't know if that would be right
They may tend to focus monetarily instead of applying it to their original intentions....*

(Patient 16)

Discussion

Most patients were supportive of the use of their information for research purposes. Indeed, many noted the necessity of this type of research in assisting them or future generations. However, they also want to be consulted first on the use of that information – even if that information was de-identified. These patients felt that asking for consent was a means of ensuring accountability and this also displayed a respect for them as individuals and not as objects of research. This was intrinsically tied to their beliefs that the doctor – patient relationship should be built upon a foundation of open communication and respect.

For some patients, it was their experience of the lack of explicit communication to use 'their' data that seemed to create questions and queries about their physician's motives and goals for engaging in research. While they did not want the consent process for research to detract from time spent on their health concerns, they also did *not* want research to take place without their knowledge. Even for patients who expressed trust in their physician's motives, when consent preferences were explored, the majority voiced a preference for written consent. These findings are consistent with other Canadian studies showing that the public values both privacy and the use of their information for research.^{19,20} A recent British study of interviews with people from varying health states and cultural backgrounds found that women and those not from an ethnic minority group had more stringent consent requirements; that is, these groups wanted their consent to be sought *each* time their information was used, including when information was used for treatment purposes.¹⁴ This suggests that specific strategies may need to be developed to address the range of patient preferences.

It was apparent that many patients were formulating their thoughts as the interview progressed and that their opinions had not yet matured. During the interviews, many patients provided an answer to the posed question and then further revised their response as the interview progressed. It is clear that patients possessed a naive understanding of what research meant. These interviews were exploratory in nature and did not seek to educate patients. This shifting of responses over time has been noted by other researchers. Snowdon et al²¹ found that parents of critically ill children in a clinical trial had limited knowledge regarding the consent process for the trial and that this typically only became clear to them in their discussions with the researchers. As the seeking of consent is often tied to stressful health care experiences, it is not surprising that patients' opinions of consent may change, since they may take more time later to process information. However, even in a relatively low stress situation such as these interviews, the views of many of these patients were in flux. The present findings reinforce the need to educate patients further about how health information is used in research and their rights in this regard.²² We purposely attempted to sample patients with a relatively high level of interest in uses of their health information, so that we could explore issues in greater depth. However, even among this group, we found a general naivety about health research.

Respondents' general lack of distinction between identifiable and anonymized information is consistent with findings in Australia.²³ This is problematic for policy-makers, as it invokes a standard that goes well beyond the requirements of law.

Patients were generally supportive of commercial funding for health research, with the caveat that there be appropriate safeguards to limit funder access to data and control over analysis and publication decisions. This conditional willingness to allow the research use of the data to proceed even with industry funding points to the value that patients place on advancing the science.

There is a need for broader public engagement. Respondents exhibited conflicting desires both for privacy protection and for use of their information. Given the complexity of the issues bearing on this conundrum, we suggest the need for more deliberate public engagement, such as citizens' juries, allowing re-election, collective debate and the use of a broad range of evidence in coming to a recommended policy.^{24,25} Although such input is not required to develop laws governing the circumstances under which data may be accessed for research purposes, this type of public involvement could provide important guidance for those crafting laws, and imparts a legitimacy to those laws.

Regardless of what the law allows, in the absence of public buy-in, the subsequent loss of confidence in the research enterprise could result in a lose – lose scenario. Care for patients will suffer if they withhold or falsify information in order to conceal potentially stigmatizing information out of fear over the uses to which the information will be put. Worse, some may avoid seeking care for fear of stigmatization. Researchers would lose because it would not be possible to quantify the extent of missing or inaccurate data. Moreover, a serious breach of public trust could result in greater restrictions being placed on the use of health information than is currently being contemplated.

This study highlights the importance that some patients place on active consent for use of health information. More specifically, patients' preferences for written consent raises challenges for both policymakers and researchers. Setting policy that meets the needs of the many stakeholders involved will require thoughtful examination of the competing goals and safeguards that must be satisfied. Patients' willingness to participate in research is a complex interplay of beliefs and experiences and it is critical to create avenues for patients to become more informed about this area. This research is an important beginning to the long discussion that must follow in order to create policy that is both knowledgeable and respectful of patients' needs.

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