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The Use of Medical Records in Research: What Do Patients Want?

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In the past ten years, there has been growing interest in and concern about protecting the privacy of personal medical information. Insofar as medical records increasingly are stored electronically, and electronic information can be shared easily and widely, there have been legislative efforts as well as scholarly analyses calling for greater privacy protections to ensure that patients can feel safe disclosing personal information to their health-care providers. At the same time, the volume of biomedical research conducted in this country continues to grow. The budget of the National Institutes of Health, for example, was $20,298 million in 2001,[1] having more than doubled from a budget of $9,218 million 10 years before.[2] This growing body of research includes increased efforts to use stored medical records as a source of data for health services, epidemiologic, and clinical studies. Given that it can be cumbersome, if not impossible, to find and seek consent from patients whose current or past records might be used, an important policy question is the degree to which medical records ought to be available to researchers and under what circumstances. Interpretations of recent U.S. federal health privacy regulations suggest that medical records research is allowable under some circumstances without consent, assuming the research has undergone review by an institutional review board (IRB), is deemed to be of no more than minimal risk, and the research could not practicably be conducted without the waiver.[3] Despite the considerable policy debate, there are few studies that have examined what patients, particularly those with preexisting medical conditions, think about researchers using their records, either with or without their prior knowledge and consent.

Various options exist for how medical records might be used in research. Current practice in many settings is for IRBs to allow researchers access to identifiable patient records without patients' consent if the research is of minimal risk, methods for protecting confidentiality are well outlined, and identifiers are destroyed as soon as possible. Another option, one that now is required in the state of Minnesota,[4] is to allow identifiable patient records to be used in research only with patients' explicit and written consent. Finally, records could be stripped of any identifying information before researchers are allowed access to them.

In Great Britain, several commentators have argued that new regulations calling for anonymization of records before they can be used for research and limits on sharing among professionals are too broad. Some believe the usual communication that occurs between colleagues will be hampered, which will compromise the ability to synthesize knowledge for important discoveries. They further believe that obtaining consent for all studies — studies with no clinical relevance to patients — might end up worrying patients unnecessarily.[5] Others argue that some observational studies and audits will suffer from such rules, since

identifiers may be necessary to avoid duplication and, in some studies, for follow up.[6] Moreover, they worry about selection bias when some patients, particularly those who are extremely sick, are unable to provide consent.

In 1996, an Equifax-Harris Consumer Privacy Survey sought the attitudes of 1,005 American adults regarding the privacy of their consumer information.[7] Respondents generally were more protective of their personal medical information than other consumer information, including motor vehicle and criminal records. Moreover, while 34 percent felt the use of medical records to detect insurance fraud was “very acceptable,” only 18 percent felt the use of medical records for research purposes reached *this* level of acceptability, even if the identity of records were kept strictly confidential and if it were not feasible to obtain advance permission for records use. Another 39 percent felt such use of medical records was “somewhat acceptable,” while 31 percent found it “not at all acceptable.” In contrast, of 214,000 patients from the Mayo Clinic who returned forms sent with appointment notices asking for consent for future research, 96 percent agreed to have their medical records accessible to Mayo Clinic researchers.[8] Similarly, all patients seen at the Olmstead Medical Center in Minnesota for two months in 1997 were asked to give general authorization to release their medical records for research.[9] Of 15,997 patients, 91 percent granted authorization. Those seen for mental health care, eye care, trauma, or gynecology care were most likely to refuse permission.

We conducted a survey with 602 persons with a serious genetic or other chronic medical condition (or family history of such a condition) concerning their experiences with and attitudes toward the privacy of their medical information. Questions were asked related to respondents' views about the acceptability of their medical records being used for research purposes. Our goal in these analyses was to document these views and to determine whether views differed among disease and demographic groups.

Methods

Participants were enrolled from March 1996 until February 2000. The 602 participants were approximately equally divided among the following six categories: adults or parents of children with cystic fibrosis (CF); adults or parents of children with sickle cell disease (SCD); adults or parents of children with diabetes mellitus (DM); adults with HIV infection; adults with breast cancer (BC); and adults with colon cancer (CC). The breast and colon cancer samples were each comprised of fifty individuals with a personal history of the condition and fifty with a family history (at least two first degree relatives). These study populations were chosen to represent a mixture of single-gene disorders and disorders of other etiology, to represent more and less stigmatizing conditions, and to create an overall sample that was heterogeneous in terms of race and class, all factors which might be related to respondents' views about the privacy of their medical records. Sample size for each group was determined based on power calculations to allow comparisons between and among disease groups for key research questions.

Participants were recruited from outpatient clinics of the Johns Hopkins Hospital, from Johns Hopkins ongoing research studies, from disease registries within the state of

Maryland, and through newspaper advertisements. A single structured interview was developed by a team that included experts in survey methodology and was pilot-tested with relevant populations and then revised. The interview was administered by a trained interviewer to each participant, either in person (50 percent) or by phone (50 percent). The interview contained quantitative and qualitative questions, and lasted approximately forty-five minutes. Participants were paid twenty dollars for their time. Written informed consent was obtained from those interviewed in person; oral consent was obtained for telephone interviews. This protocol was approved by Institutional Review Boards (IRBs) from the Johns Hopkins Medical Institutions and the State of Maryland.

The interview included quantitative and qualitative items regarding knowledge, attitudes, and experiences with privacy and disclosure, confidentiality and discrimination, employment, health and life insurance, and demographics. Data are reported here from items that focused specifically on respondents' attitudes about the use of medical records in research. These items either had binary response options (“good idea”/“bad idea”) or ordered response options (“strongly agree”/“agree”/“neutral”/“disagree”/“strongly disagree”). For purposes of analysis, “strongly agree” and “agree” were collapsed into one category, and “strongly disagree” and “disagree” were collapsed. Contingency tables for these responses versus various demographics were created, and Pearson's chi-square test for independence was performed. Logistic regression models (binary responses) and ordinal logistic regression, or proportional odds, models (ordered responses) were used to obtain odds ratios for different demographics of interest, including the disease groups. All models were also run with a parent indicator variable (parent versus affected adult responding), to check for possible confounding: however, the odds ratios were nearly identical to those obtained from models without this variable. Finally, because each survey item was examined in a separate model, adjustment of p-values for multiple comparisons was not necessary.

Results and Conclusions

Five hundred ninety-seven surveys were available for quantitative analysis. Thirty-one percent of respondents agreed that medical researchers should be able to get their medical records without respondents' permission “if it will help them to do research that will advance medical knowledge” (Table 1); those with incomes less than $20,000 were twice as likely to agree that researchers should be able to use records for research without permission ($p < .05$, data not shown).

Another series of questions addressed these issues from different perspectives, and defined terms. Participants were told that some people think computerized databases are a “good idea … [because] this would make it easier to keep track of medical records and would help medical researchers — both of which would help patients. Those who think the database is a bad idea argue that this would make it too easy to get medical information about people.” Participants were not told, specifically, whether or not the computerized database would be obtained with their permission. Thirty-five percent of respondents thought this sort of database was a good idea; those with HIV or breast cancer were least likely to think such a database was a good idea (Table 2). Among the eight respondents who told us, qualitatively, why they thought it was a good idea, three said it would be helpful in an emergency

("because if somebody gets hurt or anything, they need to know your medical history"), three said it would increase the efficiency of delivering patient care ("You can lock out people that don't have the security code and get into it. There is different advantage of having it on a computer than carrying the file all around the hospital, taking up a lot of space"), one said for public health benefit and one for medical research. Among the thirteen who told us, qualitatively, why they thought the computerized record was a bad idea, all were concerns about privacy violations ("If you put everything in a computer, then anybody can go to the computer and…look up your file and find out what they want to know and use it against you"), and one specifically said it could lead to discrimination.

When the question was further qualified, however, and participants were told that only those whom *they* authorized could gain access to the database and that security measures actually worked, twice as many individuals, 71 percent, thought it was a good idea, generally saying things like "If the measures actually worked, then I would say yes." Those who thought it was a bad idea generally were skeptical that measures really would work, saying, for example, "I feel that in a perfect world that could happen, but we don't live in a perfect world" or "I still think that people are going to be able to get into the database."

Finally, when asked if they approved of a computer database set up anonymously for research purposes, still more individuals, 86 percent, thought it was a good idea (Table 2). Those at risk for breast cancer, white participants, those of middle age, and unemployed participants were most likely to think this was a good idea (*data not shown*). Sixty-five respondents answered, qualitatively, why they thought an anonymous database for research purposes was a good idea, generally reiterating that it would advance research without violating privacy: "That helps everybody … as long as there's no name. That way, you can't scar another person"; or "Well, in order to help researchers, but it would still protect people that have conditions that they did not want known." Sixteen explained why they thought it was a bad idea, with most (nine) saying they did not trust it would be secure enough, three saying they were worried discrimination would still occur, and three saying they would still prefer a paper to a computer database.

Two important themes emerge from these data. First, when asked in the abstract whether they were willing to have their records used for research, without their knowledge or permission, the majority of our participants say no. Asking such a question in the abstract clearly seems negative to respondents, who perhaps see only the personal invasion without seeing any potential benefit. When the request was further qualified, however, by stating that the database would be set up anonymously for research or that access to the data would be under their control, the overwhelming majority thought it was a good idea. This, in turn, indicates an interest by patients in supporting the research enterprise, provided safeguards are established to protect the privacy of their medical information.

It is striking to compare our findings to the small number of other studies in the literature on this subject. The Equifax-Harris poll of members of the general public, like our study, asked respondents in the abstract whether they were willing to have their records used for research purposes, confidentially, but without their knowledge. In that poll, only 18 percent said yes, compared with 31 percent of participants in our study of persons having or at risk for

diverse, serious medical conditions who were willing to have their medical records used for research purposes without their consent. Given that some of our study populations were recruited from research studies or were receiving clinical care at research institutions, it is possible that our respondents were biased toward more favorable attitudes about research. Of note, however, when patients with cancer were asked for blanket permission to use their records for research by the Mayo Clinic, where they were receiving ongoing care, essentially all agreed. This suggests that persons may not need to know about the specific study, or its timing, in order to feel comfortable with their records being used, but they still may want to be asked permission, even if in the most general way. Second, who is doing the asking may make a difference to patients. In both the Mayo Clinic and the Olmstead Medical Center studies, patients were asked their permission by a provider or organization from whom they were receiving ongoing care. If patients trust the entity doing the asking, they may better trust that the records will remain confidential and will be used for worthwhile purposes. Finally, patients *with* a disease, asked for permission to use records for research by someone working on that disease, may be particularly likely to say yes, given that the potential benefits of research may seem more directly relevant.

Based on our findings and those in the literature, a series of recommendations for public policy can be provided that attempt to balance respectfully the rights and wishes of patients to safeguard personal medical information with a broader, shared interest in furthering medical and public health knowledge and practice. First, researchers and policy makers need to do a better job describing to the public and to patients *why* research is important, why it may be relevant to them and/or their family members, and why medical records often are essential to conducting such research. Examples of the benefits of such research ought to be provided, for instance, that we now understand the role of oral contraceptives in increasing the risk of thromboembolism,[10] that women are now known to be at increased risk of uterine rupture if they have a vaginal delivery after a prior Cesarean delivery,[11] and that we can now examine the degree to which Medicare beneficiaries receive appropriate care for a wide variety of medical conditions,[12] based on the use of medical record review in research. Citizens also must be told the circumstances under which medical information might be mishandled in research if confidentiality safeguards were not followed, and consequences that might result, including social stigma or discrimination A General Accounting Office report documents breaches of confidentiality of research, and notes that complaints about lack of privacy and confidentiality were among the most common complaints made by research subjects to IRB chairs.[13] Furthermore, citizens should be meaningfully engaged in the process of addressing how medical records are used for research, and through this process not only share what the potential benefits and harms of record review in research can be but also which options, and which types of studies, seem most and least acceptable to them. Indeed, such dialogues might lead to the development of better protection techniques, which is in everyone's best interests.

Second, asking for blanket consent for the use of medical records for research purposes, for example, when patients are admitted to hospitals or join medical practices, as recommended by Appelbaum et al.,[14] may be significantly more acceptable to patients than using records without having ever discussed such a possibility. The use of “future consent” has been debated widely, and argued by some to be of questionable validity, insofar as patients are

unable to know to what, precisely, they are consenting. Blanket consent should never become a substitute for individual informed consent to medical record use when the latter is feasible, and researchers should never feel that they may invoke this option simply out of convenience; institutional review boards can serve as a safeguard to assure appropriate use of blanket consent in human studies. On the other hand, in light of the knowledge that future consent seems to be far more preferable to patients than never being asked for their input at all, this option may serve as a compromise, allowing researchers to use patients' records when individual consent is impossible. Nonetheless, even in the context of future consent, patients always should be told what mechanisms are in place to protect their confidentiality when future records are used for research purposes without their specific knowledge, and what constraints on such use exist. Further, future consent requests with some level of specificity (for example, asking permission to use the records for future cancer research rather than for any research, or for use by providers within that health-care organization, rather than by any researchers) may be more acceptable to patients, and will be more respectful of their right to as much information as possible to guide their consent decision.

Finally, some patients never will provide blanket consent for their records to be used, much as some patients and citizens never agree to join research studies, even when studies are explained clearly at the time of potential enrollment, and even when studies are low-risk. Such is the nature of informed consent and it is not to be faulted but, to the contrary, to be endorsed. The ramifications of a policy in which consent in any form was deemed consistently unnecessary for medical records review research, or one based on the belief that even blanket consent is impossible, unnecessary, or, as some have suggested, leads to compromised science or too great a bias, ultimately is untenable and dangerous. It is crucial for both the integrity of medical care and for the research enterprise for patients to trust their physicians and medical institutions, and not to become suspicious that activities of potential interest to them (including, for example, studies derived in part from their own data) are being conducted without their knowledge or by means they would find offensive. Institutions, in turn, have a responsibility to take that trust seriously, and never assume a simple right to conduct research with private, identifiable data. Institutions must scrutinize requests for private information carefully, determining on a case-by-case basis which proposals are worthy of going forward, and which ought to still require a new, individual consent from patients. Ultimately, patients must be partners in the research enterprise, and clearly they are unwilling to be partners when they believe research takes advantage of their personal data, without their knowledge, and for a benefit that may be elusive.

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Table 1

Percentage of respondents agreeing that medical researchers should be able to get their medical records without their permission "if it will help them to do research that will advance medical knowledge in the future."

A. Distribution of responses by disease group.									
Response (%)	**CF**	**SCD**	**Diabetes**	**HIV**	**BC Affected**	**BC At Risk**	**CC Affected**	**CC At Risk**	**Total**
Agree	32.7	35.7	24.8	33.0	36.0	26.7	31.9	26.0	31.1
Neutral	6.9	16.3	15.8	17.5	6.00	22.2	14.9	8.00	13.6
Disagree	60.4	48.0	59.4	49.5	58.0	51.1	53.2	66.0	55.4

Text of question presented here: "Medical researchers should be able to get my medical records without my permission if it will help them to do research that will advance medical knowledge." The odds quantities are the proportional odds of agreeing with the statement *and are adjusted for all other demographic variables listed*. Those who did not answer or answered "don't know" were not included.

• Odds ratio significant at $p \leq 0.05$.

CF = cystic fibrosis; SCD = Sickle Cell Disease; HIV = Human Immunodeficiency Virus; BC = breast cancer; CC= colon cancer

Table 2

Percentage of positive and negative responses regarding computerized health databases.

Question	CF	SCD	Diabetes	HIV	BC Affected	BC At Risk	CC Affected	CC At Risk	Total
Do you think a computerized health database is a good idea or a bad idea? (N = 587)									
Good idea	43.0	32.3	42.6	25.3	32.0	24.4	36.2	38.0	34.9
Bad idea	53.0	57.6	54.5	69.5	64.0	64.4	59.6	54.0	59.1
Refused	0.00	0.00	0.00	0.00	0.00	0.00	0.00	2.00	0.17
Don't know	4.00	10.1	2.97	5.26	4.00	11.1	4.26	6.00	5.79
Do you think a secure health database is a good idea or a bad idea? (N = 539)									
Good idea	79.4	70.3	64.4	71.3	63.8	72.7	83.3	67.4	71.4
Bad idea	20.7	26.4	31.1	24.1	31.9	20.5	16.7	27.0	25.1
Refused	0.00	0.00	1.11	0.00	0.00	0.00	0.00	0.00	0.19
Don't know	0.00	3.30	3.33	4.60	4.26	6.82	0.00	6.52	3.34
*Do you think an anonymous health database is a good idea or a bad idea? (N = 495)									
Good idea	85.2	73.4	91.8	86.4	87.2	95.6	90.9	85.4	85.9
Bad idea	13.6	19.2	8.24	13.6	10.6	2.22	9.09	10.4	11.7
Refused	0.00	0.00	0.00	0.00	2.13	0.00	0.00	0.00	0.20
Don't know	1.14	7.45	0.00	0.00	0.00	2.22	0.00	4.17	2.22

Note that small proportions of seemingly inconsistent answers to this series of questions were detected. Of those who said a computerized database is a good idea (205 respondents), nine (4.39%) said that a secure database is a bad idea and eleven (5.37%) said that an anonymous database is a bad idea. Of those who said that a secure database is a good idea (385 respondents), twenty (5.19%) said that an anonymous database is a bad idea. Finally, of those who said that computerized and secure databases are both good ideas (145 respondents), six (4.14%) said that an anonymous database is a bad idea.

*Significant at $p < 0.05$ (overall χ^2).