ELSEVIER

Social Science & Medicine 64 (2007) 223–235

SOCIAL SCIENCE & MEDICINE

www.elsevier.com/locate/socscimed

Patients, privacy and trust: Patients' willingness to allow researchers to access their medical records

Laura J. Damschroder[a,b,*], Joy L. Pritts[c], Michael A. Neblo[d], Rosemarie J. Kalarickal[b], John W. Creswell[e], Rodney A. Hayward[a]

[a]*Healthcare System, VA Health Services Research & Development Center for Practice Management and Outcomes Research, VA Ann Arbor, USA*

[b]*University of Michigan/Center for Behavioral and Decision Sciences in Medicine, Ann Arbor, MI, USA*

[c]*Georgetown University, USA*

[d]*The Ohio State University, USA*

[e]*University of Nebraska, USA*

Available online 11 October 2006

Abstract

The federal Privacy Rule, implemented in the United States in 2003, as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), created new restrictions on the release of medical information for research. Many believe that its restrictions have fallen disproportionately on researchers prompting some to call for changes to the Rule. Here we ask what patients think about researchers' access to medical records, and what influences these opinions. A sample of 217 patients from 4 Veteran Affairs (VA) facilities deliberated in small groups at each location with the opportunity to question experts and inform themselves about privacy issues related to medical records research. After extensive deliberation, these patients were united in their inclination to share their medical records for research. Yet they were also united in their recommendations to institute procedures that would give them more control over whether and how their medical records are used for research. We integrated qualitative and quantitative results to derive a better understanding of this apparent paradox. Our findings can best be presented as answers to questions related to five dimensions of trust:

(1) Are medical records kept confidential?
(2) Does the research being conducted demonstrate high priority on patient welfare?
(3) Are researchers held accountable and responsible for protecting privacy?
(4) Are systems to protect medical records sufficiently secure?
(5) Do researchers fully disclose the research being conducted and how medical records are used to conduct that research?

Patients' trust in VA researchers was the most powerful determinant of the kind of control they want over their medical records. More specifically, those who had lower trust in VA researchers were more likely to recommend a more stringent

*Corresponding author. Tel.: +1 734 615 8377.

E-mail addresses: vancouvl@med.umich.edu (L.J. Damschroder), jlp@georgetown.edu (J.L. Pritts), neblo.1@osu.edu (M.A. Neblo), rkalaric@med.umich.edu (R.J. Kalarickal), creswell@unlserve.unl.edu (J.W. Creswell), rhayward@med.umich.edu (R.A. Hayward).

0277-9536/$ - see front matter
doi:10.1016/j.socscimed.2006.08.045

process for obtaining individual consent. Insights on the critical role of trust suggest actions that researchers and others can take to more fully engage patients in research.

Keywords: USA; Deliberative democracy; Trust; Privacy; Medical records; Health insurance portability and accountability act (hipaa); Health policy

Introduction

The federal Privacy Rule was implemented in the United States in 2003, as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), with hopes that it would allay growing concerns about the way personal medical information was being used for non-patient care purposes. However, the Rule has had some unintended consequences. Its restrictions may have fallen more heavily on medical researchers than commercial interests that provoked much of the public's anxiety about medical privacy. The Rule generally permits health care providers to disclose health information to researchers only if either they have the patients' permission to disclose to the researcher or the researcher demonstrates that an oversight board (an Institutional Review Board (IRB) or a privacy board) has granted them a waiver of the authorization requirement. Go to http://www.sciencedirect.com/science/journal/02779536 for a summary of the HIPAA Rule.

The Privacy Rule does not permit general blanket authorizations to conduct future research, (US HHS, 2003). Because medical records research requires reviewing thousands of medical records, researchers often find obtaining individual authorization for each study difficult if not impossible (US HHS, 2005). Moreover, requiring patient permission for each study can induce selection biases that vitiate the scientific validity of studies, as well as adding significant monetary costs (Ingelfinger & Drazen, 2004).

There are a number of possible alternatives to obtaining individual authorization. Researchers can attempt to obtain a waiver of the authorization requirement. But ambiguity in the waiver criteria has driven many IRBs to interpret the criteria conservatively, resulting in less health services research in many settings (O'Herrin, Fost, & Kudsk, 2004). Prior to HIPAA, some organizations used blanket consents for using medical records for research, with varying degrees of success (Lo, 2005; Melton, 1997). Some organizations have low rates of obtaining consent, due to a variety of factors (Lo, 2005). Some have been successful, however. In advance of a new state law, the Mayo Clinic requested its patients provide blanket consent to use their medical records for research; 96% of patients agreed (Melton, 1997). Ironically, both high and low consent rates have raised issues about the need to obtain individual consent for research. Some say that low consent rates mean that researchers should not have to ask for consent because low consent rates will result in invalid data (Lo, 2005). High rates of consent raise the question whether it is worth the cost of asking for consent if most patients agree anyway (Melton, 1997). Others suggest it is always appropriate to seek consent because even if patients say yes, they want to be asked in the first place (Kass et al., 2003). What factors lead to a high rate of consent? Perhaps one factor is a high level of trust that the organization will protect privacy (Mechanic, 1998).

We reported a study that used a deliberative democracy approach through which a sample of informed patients from primary care clinics at four diverse Veteran Affairs (VA) facilities deliberated about issues and recommendations for the kinds of consent processes that should be implemented (Pritts, Damschroder, Neblo, & Hayward, Working Paper). Seventy-eight percent of the deliberation groups recommended a process that would give patients more control over how their medical records are used in research compared to current guidelines. The groups were divided on just how much control patients should be able to exercise. Surprisingly, when asked individually in a follow up survey, 96% of participants said they would be inclined to share their medical records for research. It thus appears that patients' inclination to allow their medical records to be used for research does not equate to willingness to cede control to an institution about whether and how their medical records can be used in research. Why were patients overwhelmingly inclined to share medical records for research and yet united on wanting more control over how their medical records are used in research?

Why were patients divided about the degree and type of consent required?

We conducted a mixed methods study with the goal of better understanding why there was wide variation in consent process recommendations in light of a high inclination to share medical records for research. The question that guided our study was: Why did some veterans make the extreme recommendation that researchers obtain permission for every study while others were happy with status quo? In addition to intrinsic scientific interest, the answer to this question can clarify how different groups, whose voices would otherwise be drowned in the aggregate, might respond to various policy proposals. Moreover, understanding the foundations for support could help us understand how to implement an optimal policy.

Methods

We conducted a mixed methods analysis based on a study design where qualitative data collection was embedded within a quantitative framework (Caracelli & Greene, 1997). We collected quantitative descriptive data in a baseline phone administered survey. Consenting veterans then participated in a deliberation session followed by another phone survey administered 4–6 weeks after the deliberation session. The deliberation sessions were held between November 2003 and June 2004. We conducted separate analyses of the quantitative and qualitative data and then integrated these results together in the interpretation phase of the analysis. The combined qualitative and quantitative data in a mixed methods analysis increases construct validity of our conclusions (Creswell, 2003). We provide a brief overview of our study design here. Please refer to http://www.sciencedirect.com/science/journal/02779536 for a more detailed description.

Study participants

We selected a random sample of patients from four geographically diverse VA facilities, stratified by tertiles of clinic visits, age, and race/ethnicity to ensure a balanced representation. We used the number of clinic visits and age as proxies to indicate relative levels of morbidity or chronic health issues. Ensuring balanced numbers of older and heavier users of the healthcare system allows insight into whether these patients are more sensitive about researchers using their medical records or whether they have special incentives to want more research compared to those who may have a lower burden of illness. In past studies, African-American patients have expressed a reluctance to participate in clinical research and have exhibited lower levels of trust in researchers than white patients. (Shavers, Lynch, & Burmeister, 2002, #638; Corbie-Smith, Thomas, & St. George, 2002, #293). We invited those who completed the baseline survey to an all-day deliberative session, randomly assigning each subject to one of 9–10 small groups of 4–6 participants at each of the four sites. We obtained IRB ethics approvals for this study from each of the sites.

Deliberation sessions

We used deliberative methods in this study to overcome limitations of standard surveying methods often used to assess views on privacy (Bartels, 2003). Specifically, we gave subjects background information on the need for medical records research, the need to protect the privacy and confidentiality of medical information, and the Privacy Rule's restrictions on sharing medical information for research. We then allowed them an opportunity to question experts and to deliberate with a group of their peers (Fishkin, 1995) before making recommendations.

Although there are advantages to facilitated deliberation (e.g. Fishkin, 1995; McCombs & Reynolds, 1999), we chose to utilize non-facilitated deliberation in order to minimize any potential researcher bias (Habermas, 1989; Neblo, 2005) We began the deliberative sessions by reviewing background information about medical records, minimal risk research, and the HIPAA Privacy Rule. Small groups were given a detailed, written protocol, that we developed based on results of a pilot study, to guide them through the deliberation process. The protocol and background information explained that researchers cannot use personally identifiable medical records in a research study unless the IRB agrees whether three waiver criteria are met. We presented the 3 criteria using lay language as follows:

1. the researchers could not do the study without using medical records;
2. the researchers have an adequate plan to make the risk of violating privacy very small; and
3. the researchers could not "practicably" do the study if they had to get permission from each patient.

We asked participants to imagine they were acting as an advisory committee for an IRB (defined as a "research review board…[that] judges whether a research study will pose minimal risk and whether the study will adequately protect private information."). The day was comprised of deliberation in small groups, guided by the written protocol, interspersed with plenary sessions led with presentations by an expert in medical records research and one in privacy advocacy. Participants had the opportunity to pose questions to the experts and hear the answers as a plenary group. Precedence for day-long sessions are well-established among political scientists who are deliberation experts (Fishkin & Luskin, 1999) and in health policy through the use of citizen's juries which can span several days (Lenaghan, 1999). We found most participants to be engaged in the process, showing near-instant camaraderie and high levels of respect for one another.

Survey data

We administered a baseline survey, several surveys during the deliberative sessions, and a follow-up survey 4–6 weeks later. The baseline survey elicited each patient's trust in various healthcare entities, attitudes about privacy, prior knowledge about research and privacy, and general demographic information. The surveys administered on the day of deliberation included measures specific to the topics being deliberated, as did the follow-up survey. The baseline and follow-up surveys were administered by phone and the surveys during the deliberation were written.

Data analysis

Quantitative

We used Chi-square tests for categorical data and one-way ANOVA tests for continuous data to test for differences between: (1) the four locations; and (2) veterans who agreed to participate in the baseline and follow up surveys but did not consent to participating in a deliberation session. Where appropriate, we used the non-parametric Wilcoxon test for differences in matched data or McNemar's test to test for changes in measures before, during, or after deliberation. Our main dependent measure was the consent process participants recommended. We used simple bivariate Chi-square tests and logistic regression models that adjusted for racial minority status, age, education, number of clinic visits, location, and a measure of the importance placed on conducting research to test for relationships. All statistical analyses were conducted using Stata 8.2. (2004)

Qualitative

Our qualitative analysis approach is best described as descriptive (Sandelowski, 2000), using a conventional content analysis approach where themes were derived from the transcripts of the deliberations (Hsieh & Shannon, 2005). Our intent was to capture issues participants raised as they deliberated and the reasoning articulated for their recommendations. We identified themes in the transcripts and open-ended written recommendations. A codebook was developed by which to code themes. All deliberations were audio-recorded. A sample of deliberations were transcribed verbatim and qualitatively analyzed. We compiled the qualitative sample by randomly selecting four groups from each location, sampling purposively to include groups in the sample who fully engaged in the deliberation. We analyzed all written recommendations from all groups.

Our verification procedure involved establishing consensus among three independent judges who developed a codebook of themes. Over a period of 5 months, the three judges independently coded the selected transcripts from the four locations. NVivo software facilitated the coding (Creswell, 2002). Text segments were coded and emerging themes were compared. One of the judges organized themes into a codebook and revised the codebook as themes were refined. We sought to improve consensus between the judges with each new round of coding, targeting an 80% inter-coder agreement rate which indicates a substantial degree of coding scheme trustworthiness (Miles & Huberman, 1994). No new themes were identified after three transcripts and no new sub-themes arose after six transcripts. We achieved 86% average agreement at the theme level and 83% average agreement at the sub-theme level with three judges after the fourth transcript. We achieved theme saturation before reaching the end of the sample of 16 coded transcripts, which also contributes to coding trustworthiness (Miles & Huberman, 1994).

Results

Participants

We recruited 217 veterans who participated in one of 39 deliberation groups across the four sites. Fig. 1 provides a flow chart of the level of participation for each step of the recruiting process. Table 1 shows demographic attributes, prior knowledge, and opinions about research and privacy at baseline. Comparisons are shown between the sampling frame and those who participated in the baseline survey and between participants who attended a deliberation session (deliberators) and those who did not (non-deliberators).

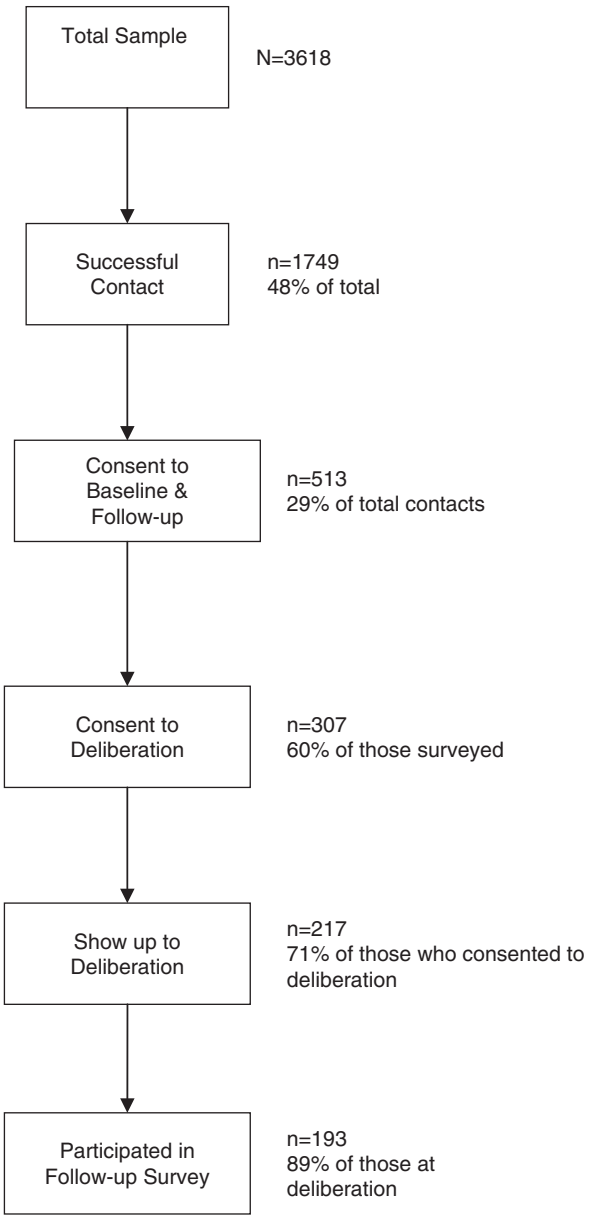

Fig. 1. Recruiting sequence and level of participation.

Quantitative results

Fewer deliberators were inclined to share their medical records with university researchers (75%) for a study about a serious medical condition compared to VA researchers (89%) at the time of the baseline survey ($p<.001$). Compared to university researchers, participants were even less inclined to give permission for a local hospital to use their medical records for a preventive health program (61%; $p<.001$) and even fewer (51%; $p = .002$) were inclined to give permission to a drug company for marketing purposes. These levels of willingness did not change at the time of the follow-up survey for any situation (p-values $>.19$) except for VA researchers (increased to 96%; $p = .04$).

Table 2 shows the level of trust participants had in researchers who affiliated with various entities to keep their medical records private and confidential. Post-hoc pairwise comparisons suggested that VA affiliated researchers garnered the highest level of trust (p's $<.001$).

Fig. 2 summarizes consent recommendations from participants, based on the follow-up survey administered 4–6 weeks after the deliberation. The individual recommendations reported here are comparable to the recommendations made on the day of deliberation (Wilcoxon test; $p = .75$).

Table 3 shows the percent distribution of the level of trust in VA researchers by the recommendation made along with odds ratios for choosing a recommendation giving more control to patients. Veterans who said they always trusted VA researchers to keep their medical records private and confidential were about half as likely to recommend ceding more control to patients than veterans who trusted VA researchers "most of the time". Conversely, veterans who said they never trusted VA researchers were five times more likely to do so.

Qualitative results

A list of the themes that arose from analysis of our sample of transcripts and all written recommendations can be found in Appendix 6 in the Online Supplement. Trust issues loomed large though few exchanges explicitly mentioned trust.

Table 1
Demographic attributes and baseline attitudes of participants

		Baseline survey participants				
	Sampling Frame	Non-deliberators	P^a	Deliberators	P^b	Overall
n	3618	296		217		513
Age–Mean(SD)	63 (.13)	63 (.12)	0.39	65 (12)	0.08	63 (.12)
Mean (SD)						
Male	95%	95%	0.60	95%	0.68	95%
#Clinic Visits			0.10		0.60	
Least frequent tertile	33%	35%		37%		
Most frequent tertile	34%	30%		28%		
Race/ethnicity						
Minority	31%	33%	0.60	37%	0.40	35%
Education						
BS/BA or higher		20%		24%	0.05	22%
Employment						
Employed (F/T or P/T)		27%		24%	0.60	26%
Disabled		38%		37%	0.82	37%
All in all, you have complete trust in your doctor:					0.75	
Agree		82%		83%		83%
Disagree		18%		17%		17%
Have you ever heard of HIPAA?[c]						
Yes		54%		61%	0.10	57%
Were you aware that sometimes your medical record can be used without permission?[c]						
Yes		29%		25%	0.44	27%
Inclined to give permission for VA researchers to use your medical record?[c]						
Yes		86%		89%	0.21	87%
Importance of conducting medical records research[c]					0.29	
Critically-Very important		83%		89%		86%
Importance of getting permission for each study[c]					0.89	
Critically-Very important		73%		74%		73%
Trust medical researchers at a VA hospital to keep my records private and confidential[c]					0.86	
Always		42%		37%		40%
Most of the time		44%		47%		45%
Compared to usual medical practice, the security system for protecting patient confidentiality in research should be[c]:					0.60	
Somewhat or much more secure		66%		72%		69%
As secure as		29%		25%		27%

[a]For difference between those who participated in the baseline survey ($n = 513$) versus those who did not ($n = 3105$).
[b]For difference between deliberators and non-deliberators.
[c]Please refer to the online supplement at doi:10.1016/j.socscimed.2006.08.045.

Table 2
Deliberators' level of trust by entity at the time of the follow-up survey

How often do you trust _____ to keep this information private and confidential?				
	Always (%)	Most of the time (%)	Less than 1/2 the time or never (%)	
Medical researchers at a VA hospital ($n = 174$)	32	54	13	[a]
Medicare program researchers ($n = 145$)	10	48	41	[b]
Medical researchers at a university ($n = 167$)	15	50	34	[b]
Pharmaceutical (or Drug) company researchers ($n = 168$)	9	32	58	[c]
Health insurance company researchers ($n = 160$)	8	19	73	[d]

1. Pair-wise Wilcoxon test. Alpha significance set to 0.005 for multiple comparisons. a, b, c, and d indicate significantly different entities.

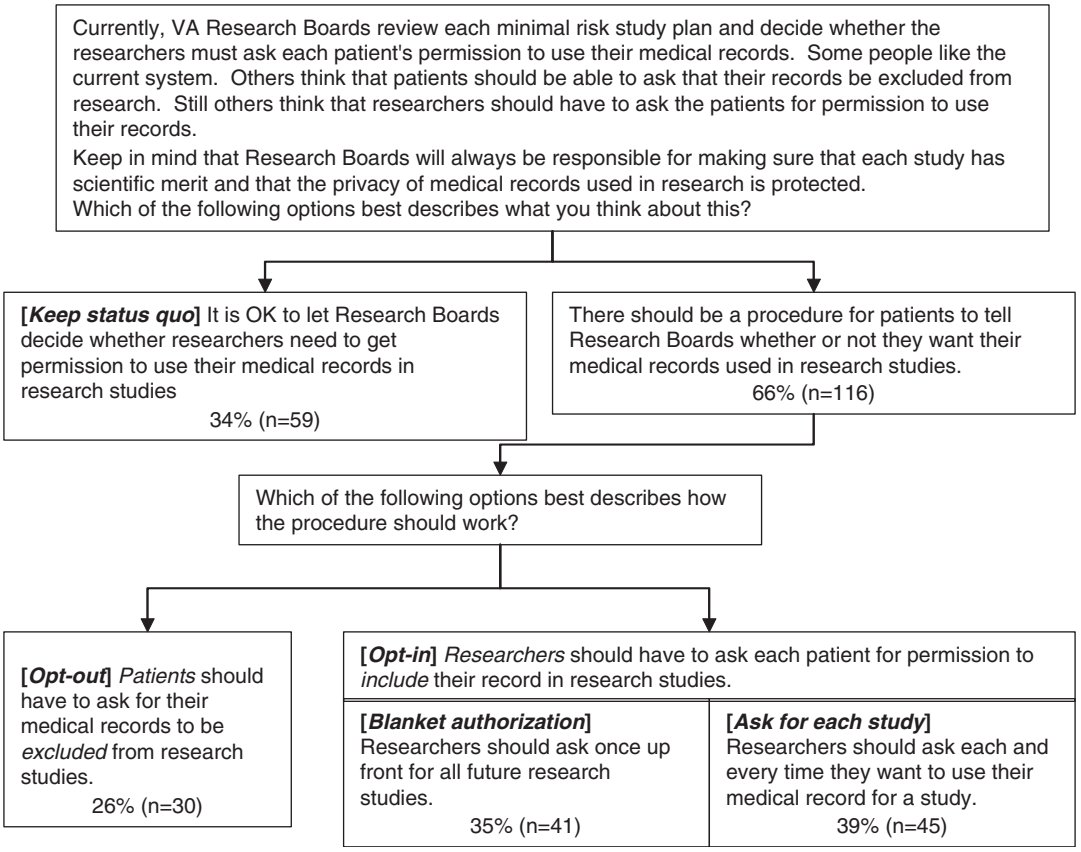

Fig. 2. Flow chart showing percentage distribution of consent recommendations from deliberators at the time of the follow-up survey.

Table 3
Percent distribution of recommendations made by deliberators and their the level of trust in VA researchers with odds ratios[a]

	How often do you trust VA researchers to keep this information private and confidential?[a]				
n	52	94	13	11	170
Recommendation[b]	Always	Most of the Time	Less than 1/2 the time	Never	Overall
Keep status quo	53%	26%	46%	9%	34%
Opt-out	15%	20%	8%	9%	17%
Blanket authorization	13%	29%	15%	27%	23%
Ask for each study	19%	25%	31%	55%	26%
Total	100%	100%	100%	100%	
Odds ratio for choosing an increasingly stringent recommendation with "most of the time" as the baseline of comparison (95% confidence intervals)[c]	.48* (.24–.97)	baseline	.73 (.23–2.31)	5.15* (1.33–19.9)	

*$p < .05$.

[a]Respondents who gave a recommendation and indicated level of trust in follow-up survey.

[b]See Fig. 2 definitions

[c]Odds ratios are from ordinal logistic model controlling for importance of research in the VA, age, location, racial minority status, education, and number of clinic visits.

An example best illustrates how dimensions of trust came through indirectly: "usefulness of research and results" was a theme that included discussion about understanding how research is funded and who decides what gets funded. Many participants expressed the importance of making sure that all funded research truly helps patients. This led to the question of whether decision-makers were acting out of self-interest or not. While the word trust may not have been mentioned explicitly, it is reasonable to interpret these concerns through a lens of trust. Qualitative healthcare research can draw on pre-existing bodies of theory for explanations (Barbour, 2000). Using prior work found in the trust literature, we developed a framework to help integrate findings in a more informative way.

Mixing qualitative and quantitative results: the lens of trust

Mechanic and Slesinger's work on trust (Mechanic, 1996 #880) inspired a framework to describe trust between patients and a medical research enterprise: (1) Are medical records kept confidential? (2) Does the research being conducted demonstrate high priority on patient welfare? (3) Are researchers held accountable and responsible for protecting privacy? (4) Are systems to protect medical records sufficiently secure? (5) Do researchers fully disclose the research being conducted and how medical records are used to conduct that research? Our proposed framework helps to highlight fundamental interrelationships among qualitative themes and their relationship with trust. Affirmative answers to these questions indicate a higher level of trust in the VA research process and people. The following sub-sections describe findings in response to each question in turn.

First, we must point out that not all our findings can be filtered through a lens of trust. Some participants expressed a "rights based" rationale for their position. One participant stated, "… just get the veterans' permission… that's not asking too much to protect one of our many basic rights as a US citizen." Another rationale for wanting control over their medical records was a desire to be able to change their preferences saying, "why would they not want to obtain permission from patients for each study? What if the patient's views on their information…have changed since the last study?" Nonetheless, a compelling story can be told that reflects the majority of findings using a lens of trust.

Are medical records kept confidential?

We saw in our quantitative results that participants trusted that VA researchers would keep their medical records private and confidential. This level of trust was associated with the level of control they recommended patients have over their records. This finding is supported by qualitative analysis. Though a few veterans mentioned distrust with the VA's ability to keep their medical information private and confidential, saying, "I think if you had any involvement with the VA, nothing is private," most participants exhibited an inherently high level of trust through statement like, "I trust them enough that they would do all they can to make sure that privacy is not violated."

Does the research being conducted demonstrate high priority on patient welfare?

Veterans were concerned about whether the VA placed high priority on their welfare at two levels: (1) whether the research being conducted really helps veterans; and (2) whether VA researchers are committed to protecting privacy. One participant reflected this dual concern by saying, "… since the VA does all the research with our medical records, I don't have any concerns…*if it is going to help somebody else*, they can use mine for anything they want. I trust them enough that *they would do all they can to make sure that privacy is not violated*". Veterans were clear about the importance of doing research that truly helps other people and that great lengths be taken to protect privacy. This latter point is quantitatively supported by the 69% of veterans who thought that systems to protect confidentiality should be more secure than those used in usual medical practice in the baseline survey.

Participants said that research studies must have high value with an "overall impact on society" and not be "an academic …exercise" and should consider whether "just a few hundred [people] or … several thousands" would benefit. Another exchange highlights the suspicion that not all research is done to improve the welfare of veterans:

> … I think the government spends enough money on stupid research. Like what time of the day a frog croaks.
>
> Yeah … is this study politically motivated or is it for scientific [purposes]?

One veteran was clear in his belief that his medical records had been used in research related to his medical condition while he languished without medical treatment. Consequently, he was adamantly against the VA using his medical records without his permission.

Participants were concerned about whether VA researchers were committed to protecting privacy. One veteran said, "I don't think they would deliberately let anything out but I will bet you there are a lot of things they could be doing for privacy that they are not" and another said, "if you [a researcher] have an adequate plan to make the risk of violating very small … you presume that researcher is going to try to make the risk very small; he's going to be taking ultra precautions, not leaving papers on a pool table."

Many participants were comfortable with allowing VA researchers to use their records if they were assured that information stays within the VA. They did not believe that other entities placed high value on the welfare of veterans because of conflicting interests. One veteran said "…I am worried about how they do share the information especially if they are sharing it with some of these universities. There is one down the street for sure. The way they use the information for research and the way they go about research, I have a problem with them … some of the researchers from the university [are] doing a research study at the same time they are treating you. You know, they are taking this information and how are they are actually using it?" One veteran said, "I think this sort of goes down the line of level trust as you just read those out and start with the VA at the top and the colleges and universities to the drug companies. I think there is probably more of a third party investment or some sort of monetary rewards for that kind of information as you go down that [list]."

Are researchers held accountable and responsible for protecting privacy?

Even if participants believed the VA placed high value protecting veterans' privacy, they wanted to be sure that mechanisms were in place to ensure that this priority was implemented in research. A number of veterans discussed the potential for researchers abusing the privilege of using patients' medical records during the course of their research: "there are some people, [that] regardless of the consequences will defy rules and regulations to justify their existence or to prove they can do it…" Participants wanted to be sure that researchers are held responsible and accountable to keep records confidential. One participant wrote, "The trust required to get participation from vets [sic] is dependant on the perception of accountability, enforcement, and consequences. This perception is dependent upon seeing examples of [this]." Participants wanted anyone who violated privacy to suffer stiff penalties, such as job termination, paying fines, and/or going to jail. They called for clearly communicated consequences, consistent throughout the VA.

Most veterans did not have direct interaction with VA researchers and used experiences they had during their clinic visits to assess the competence of researchers in handling their medical records. Some veterans believed protocols were adequate: "A clerk couldn't pull up your file. The doctor could. Okay. But there is a safeguard against that…" Others were skeptical: "I went in there and I was trying to get things signed by my doctor and he could go in there and tell me what my diagnosis was; tell me if I was competent or incompetent; tell me what medicines I was taking. He has nothing to do with medical health. He is a clerk at the VA. That's all he is… To further it, I never showed an ID. I said I am [*last-4 SSN*] and that's it… Let's just say, it's not very secure at all."

Are systems to protect medical records sufficiently secure?

The majority of participants wanted security systems for protecting patient confidentiality to be more secure than those used in usual medical practice. Our qualitative findings support this. One group who wanted researchers to obtain permission to use medical records for every study wrote, "I don't trust computers to put my information on my records because there will always be a way for people like hackers [to get in]".

Many groups spent considerable time discussing their beliefs about whether computers could keep information confidential and many assumed that computers could be used to ensure that data were

encrypted, de-linked, and devoid of identifying information by the time it reached researchers. During deliberation, most participants said they would be willing to allow de-identified records to be used for research: "give them information on diabetes. It doesn't say, Ed's diabetes…. no name, social security number, or VA number;"

Do researchers fully disclose the research being conducted and how medical records are used to conduct that research?

Participants wanted to be informed about what research is being done and which studies their medical records were being used for. They wanted to know how they may have contributed to helping other veterans by allowing their medical records to be used for research: "…at least once a year. If nothing else, you know what is going on."

Participants also wanted to know who was using their medical records for what purpose. At baseline, 75% of participants were not aware that "under some circumstances, your medical record could be used in some research studies without your permission;" despite the fact that a *Notice of Privacy Practices* was mailed to all patients less than 12 months prior to our study. The *Notice* was not mentioned by participants in any of the deliberations. After participants realized that, indeed, their medical records are used without explicit permission (but only with IRB approval), some voiced concern: "I think what goes on now is that a whole lot of research is done and we don't know it was going on."

Several participants said they were fearful that some people in the VA "probably try to sell names to drug companies" and others were "…worried about how they do share the information especially if they are sharing it with some of these universities." They were also concerned about insurance companies or other entities that determine benefits: "Let's say the VA discloses to the medical information board or somebody who determines your insurance premiums. You want a life insurance policy. *We* don't want that information getting out to somebody like that." One veteran summed up his concerns on this topic by saying, "I guess it isn't so much that this researcher or that researcher sees my name on a file … the question is, is that information being taking out and sold out to somebody else?"

Some participants were particularly concerned about stigmatized conditions being disclosed to researchers such as HIV/AIDS or mental health illnesses: "…I don't want you to know that I broke down in combat or that I had this disease." In response, a number of groups developed a recommendation, where patients would be allowed to determine *which parts* of their medical records could be used for research. One participant suggested, "…there ought to be a form that you sign … So if you don't want to have something researched on you…that is in your medical records and you stipulate that on the form...." These concerns are not fully addressed by the HIPAA Privacy Rule, which treats all health information uniformly with the exception of additional protection for psychotherapy notes (narrowly defined as notes recorded by a mental health professional about the contents of conversation during a counseling session that are separated from the rest of a patient's medical record) (US HHS, 2002).

Discussion

Patients' *trust in the VA* is the most powerful determinant of the *kind* of control they want over how their medical records are used for research. Indeed, patients who trust the VA to keep their medical records private and confidential are more likely to recommend a less stringent consent process. However, even amongst those with high trust in the VA, most patients want to be fully informed about how their medical records are being used for research, assurance that the research benefits fellow veterans, and they want to know how their records may have contributed to new findings. They called for clearly communicated and consistent mechanisms to punish researchers who violate privacy and want high standards to ensure sensitive medical information is secure. The interactions patients have in their clinic encounters influence the level of trust they place in researchers, with whom they rarely interact.

The VA enjoys an extraordinarily high level of trust with the veterans they serve. The large majority of our participants trusted that the VA would keep their medical records private and confidential. This finding is not surprising. In two previous surveys of US general population samples, government researchers (CHCF, 1999) or more specifically, VA researchers (Princeton Survey Research Associates, 1999), garnered among the highest levels of trust when citizens were asked a similar question. Our findings point to several

recommendations. First, patients want to know that the VA is truly acting on behalf of veterans. As in other studies, participants wanted to know that findings would truly help veterans (Kass et al., 2003). This finding supports Jeffers' call for a *research report card* (Jeffers, 2005) and the reasoning behind a recent policy published by the US National Institutes of Health (NIH) calling for manuscripts from NIH-funded research to be entered into a publicly available database (US HHS, 2005) as ways to foster public accountability and as a mechanism to earn public trust in the research enterprise. It is also important for patients to know more about the role IRBs (and Privacy Boards) play in regulating researchers' access to their medical records.

Second, veterans want clear and consistent consequences for anyone who violates a patient's privacy through willful or negligent actions. Researchers must be held accountable and responsible for maintaining confidentiality. Typically, systems, policies, and procedures for protecting privacy are invisible to patients. Several of our participants appeared to base their lack of trust in VA's ability to protect their information on the manner in which their providers handled their health information during clinic visits. It is rational that participants who perceive the VA has inadequate mechanisms to ensure privacy want to retain more control over their medical records (Anderson & Dedrick, 1990). Organizations should ensure that those who have the most direct contact with patients consistently treat health information with respect. The trust elicited in the clinic may carry over to researchers. Organizations should communicate more to patients about their policies to protect privacy.

Third, the VA must have highly secure systems in place to protect privacy. Veterans were concerned about whether computerized databases were sufficiently secure to prevent unauthorized access. The VA has highly sophisticated technologies in place to ensure their systems are secure but these efforts and accomplishments are largely invisible to patients and can be compromised by one errant action of a single careless clerk. The attention given to computerized systems is in line with findings from one study that found only 35% of patients thought a "computerized database was a good idea…" However, when specifically told that the database would be "secure" the percentage rose to 71% and when told it would be "anonymous," 86% endorsed the idea (including 85% of patients with HIV) (Kass et al., 2003).

Fourth, veterans feared medical records might be shared with outside entities; a fear grounded in their perception that other organizations have conflicting interests. The HIPAA Rule requires that a notice of privacy practice be distributed to all patients. A notice was mailed or given personally to every veteran less than a year prior to our study, listing research as a use. And yet, only 25% of our participants knew that researchers could use medical records without explicit permission; 39% had never heard of the HIPAA privacy rule. Problems in delivery or receipt of the Notice cannot fully explain this level of ignorance. The Notices may have been written beyond the comprehension capacity of the average veteran (Breese & Burman, 2005). In addition, the stipulations for research may have been lost in the vast array of other topics that are mandated by the Privacy Rule. In the VA Notice, the paragraph about research is under the heading "When use or disclosure may or may not require your authorization" toward the bottom of the third of four pages using small font. This is striking in light of the fact that one of the VA's prime missions is to conduct research. Researchers in general and the VA in particular, would be well served by educating the public about the general value of research and why medical records are necessary to conduct the research (Kass et al., 2003).

Patients also want to know about findings and on-going research. In one study, 72% of HMO participants were more likely to participate in research if they were promised feedback on results (Purdy, Finkelstein, Fletcher, Christiansen, & Inui, 2000). Even negative feedback can be a positive: patients gave higher trust ratings to physicians who fully disclosed medical errors versus those who were less forthright (Mazor et al., 2004). Organizations may gain in the short term by not fully disclosing the extent to which medical records are used in research without consent, but as patients are exposed to more stories about unauthorized disclosure of sensitive medical information their suspicions will grow and not diminish over time.

In light of our empirical findings and bolstered by ethical arguments to do so (Appelbaum, Roth, & Detre, 1984), we can expect increasing pressure for opt-in or opt-out consent procedures. Despite some reports of dismal rates of participation by patients when they are asked for written blanket consent,

there are glimmers of hope that high rates are achievable. Building trust between patients and the research enterprise may be the essential element to engage patients in research and for medical records research to flourish.

This study is limited by the fact that participants in our study were veterans who received their medical care at the VA. They are older, on average, than the US general population and also were almost exclusively male. In addition, the VA healthcare system has more elements of a European-type centralized healthcare system than insurance plan-based systems prevalent in the US. Though we started with a random sample from which to recruit willing participants for our study, it is highly likely that those who participated fully in all phases of the study were different in ways we were not able to measure. One might presume that people participated to only if they had sufficient transportation, mobility, health, fortitude to engage in an all-day session, interest, workable schedule conflicts, and were sufficiently motivated by the incentive payments. The session was 7 hours; shorter attention spans and fatigue were apparent in some by the end of the day. However, the views of our participants mirrored results from other studies along various dimensions including their high level of trust in VA researchers compared to researchers affiliated with other institutions (CHCF, 1999, #557), their concern that the research done in the VA would truly help patients, and their concern about security of computerized systems that maintain personal information and medical records (Kass et al., 2003). Though our participants were generally more inclined to share medical records for any situation, the direction of differences between the various situations was comparable to national surveys (Princeton Survey Research Associates, 1999).

Group-think or group polarization (the tendency to for groups to make choices that are more extreme than pre-deliberation) can occur in deliberation. However, the method we used is less susceptible to this phenomenon than other designs (Fishkin & Luskin, 2005). Balanced materials, the structure of many small groups (39) spread over 4 locations across the US, make group-think unlikely. Group-think can pull a group in either direction from pre-deliberation views. If the premise of a balanced protocol and materials is accepted, then groups would vary in positions taken in both directions; which, in fact, occurred.

Conclusion

Patients' *trust in the VA* is the most powerful determinant of the *kind* of control they want over how their medical records are used for research. Indeed, patients who trust that the VA will keep their medical records private and confidential are likely to recommend a less-stringent process for obtaining consent. It is clear that patients highly value confidentiality but they also recognize the high value of medical records research. The ideal system, in the eyes of patients may well be one that garners high levels of trust by: (1) ensuring medical records are being kept private and confidential in a way that patients can see and understand; (2) demonstration that researchers are acting in the best interest of patients by conducting and publicizing studies that clearly help patients; (3) putting clear and consistent consequences in place to make researchers accountable for privacy violations; (4) maintaining and demonstrating that computerized systems are highly secure; and (5) fully disclosing what research is being conducted and how medical records are used being through the course of that research. Transparency in organizations conducting medical records research in each of these dimensions will go far toward engaging patients more fully in research.

Acknowledgements

We are very grateful for insightful comments from Jane Forman and Nataliya Ivankova and analysis support from Sanja Jankovic. Thanks also to the three reviewers who gave valuable comments and suggestions. We would also like to thank site investigators and their coordinators who were instrumental to carrying out the deliberations at the four locations: Alan Sooho, Elinor Pettee, James Tulsky, Annallys Goodwin-Landher, David Asch, Martha Trudeau, Les Lenert, and Tanya Stallworth. Many thanks also go to the members of our Steering Committee.

Appendix A. Supplementary Materials

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.socscimed.2006.08.045.

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