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Research use of electronic health records: patients' views on alternative approaches to permission

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Introduction

The widespread adoption and use of electronic health records (EHRs), driven by the Health Information Technology for Economic and Clinical Health Act (HITECH Act 2009) and integral to learning healthcare systems (Califf, Sanderson, and Miranda 2012; Institute of Medicine and National Academy of Engineering 2011), has made an unprecedented amount of information available not only for clinical care, but also for health-related research (Kukafka and Ancker 2007; Menachemi and Collum 2011; National Research Council 2011; Häyrinen, Saranto, and Nykänen 2008). EHRs are being increasingly used for research and clinical trial recruitment due to the depth and breadth of the information they contain as well as new technological tools to mine, assimilate, analyze, link, reproduce, and transmit information (Caine and Hanania 2013; Tan et al. 2016; Wu et al. 2016). For example, a process called "EHR phenotyping" allows researchers to identify cohorts of patients with

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Data availability statement

The datasets generated and analyzed in this study are not publicly available due to privacy and confidentiality considerations, but are available upon reasonable request from qualified researchers conducting IRB-approved studies that fall within the scope of the study purpose and data use described to interviewees at the time of participation.

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precise attributes by applying high-throughput algorithms to EHR data to classify patients based on exact constellations of information (e.g., demographics, symptoms, diagnoses, procedures, laboratory values, vital signs, medications, lifestyle and environmental factors) (Hripcsak and Albers 2013; Boland, Hripcsak, et al. 2013; Pathak, Kho, and Denny 2013; Richesson et al. 2013). Research use of EHR data, including EHR phenotyping, is expected to result in clinical, observational, outcomes, and comparative effectiveness research with greater power and lower costs (Boland et al. 2013; Pathak, Kho, and Denny 2013; Beresniak et al. 2016; Dupont et al. 2016).

Although EHRs offer opportunities for research, the massive amount of personal information available and the ways in which it may be linked and used raise pressing questions concerning privacy, confidentiality, and patient awareness (Kukafka and Ancker 2007; Menachemi and Collum 2011; National Research Council 2011; Barrows and Clayton 1996). The success of the research enterprise depends on building and maintaining public trust, and patient input is critical to developing sound approaches to research use of EHRs (Hripcsak et al. 2014; Rynning 2007). Indeed, the ethical use of such comprehensive resources requires patients' acceptance of, and confidence in, the stewardship of their EHR data (Grande et al. 2013; Lucero et al. 2015; Kelly et al. 2015). Yet, little is known about patients' perspectives on research use of their EHR or the need for, and acceptability of different approaches to, asking their permission (Caine and Hanania 2013; Grande et al. 2013; Grando et al. 2017; Bell, Ohno-Machado, and Grando 2014; Garrison et al. 2016; Botkin et al. 2014; Willison et al. 2008; Cho et al. 2015). The studies investigating these topics in the United States have tended to focus on individuals' personal preferences, rather than the *acceptability* of different approaches given their perceptions of the advantages, disadvantages, and trade-offs involved for a range of interests they may value (Beskow 2016). Additionally, the few qualitative studies have often been limited by small sample sizes and focus on a single healthcare system and/or geographic location.

To help fill these gaps, we conducted empirical research to contribute to the development of ethical approaches to research use of EHRs that enhance public trust while facilitating scientific progress. Here we report key findings from qualitative interviews conducted with 120 patients in highly diverse regions of the southeastern United States: Appalachia, the Mississippi Delta, and the Piedmont area of North Carolina. Specifically, we focus on their considered opinions on the necessity and acceptability of different approaches to notifying patients of, or obtaining permission for, research use of their EHR data.

Methods

Participants

We conducted in-depth interviews with patients in four counties: Cabarrus, North Carolina (C); Durham, North Carolina (D); Mingo, West Virginia (M); and Quitman, Mississippi (Q) (Appendix A). These counties were selected due to wide variation in demographic and socioeconomic characteristics, enabling us to gather data representing a rich array of perspectives.

We worked with commercial vendors to mail recruitment letters to a random selection of adults (n=3,000) in each county. In Mingo and Quitman counties, less-populated rural areas, we also used word-of-mouth, inviting enrolled participants to share study information with potentially-interested individuals (Ellard-Gray et al. 2015). In all cases, interested individuals who contacted us by phone to learn more about the study were screened for eligibility and purposively selected to maximize demographic diversity across interviews. English-speaking adults who had seen a healthcare provider in the past two years were eligible. Those who had participated in more than two medical research studies in the past year or whose jobs involved regular access to patient medical records or clinical research were excluded.

Among the 263 individuals who contacted us to learn more, 93 were not eligible or were unable to enroll due to scheduling conflicts. Of the 178 eligible individuals who scheduled an interview, 50 did not arrive. No individual dropped out of an interview in progress.

Instruments

Interview instrumentation included four elements:

- A *questionnaire* eliciting basic demographic information; health status information; general level of concern about health information privacy; and responses to validated measures of trust in healthcare providers (Hall et al. 2002), healthcare institutions (Rose et al. 2004; Shea et al. 2008; LaVeist, Isaac, and Williams 2009), and medical researchers (Hall et al. 2006).
- An *educational video* describing and explaining EHRs, research use of EHRs, and oversight mechanisms and privacy protections employed in such research (in order to gather informed opinions, rather than measure understanding).
- A *semi-structured interview guide* including open-ended questions and standard probes addressing, among other topics, participants' perspectives on the advantages and disadvantages of different approaches to notifying patients of, or obtaining permission for, research use of their EHR data. We obtained limited quantitative data by asking key closed-ended questions about the acceptability and relative appropriateness of these approaches.
- *Visual aids* depicting each approach to support participants' understanding of and ability to distinguish between approaches.

These instruments (available upon request) were developed and finalized by the research team, with input from a multidisciplinary Expert Advisory Group as well as extensive pilot testing with patients in Durham, NC, to ensure that participants understood the questions and content as intended and could complete the activities as planned.

Data Collection

Three trained members of the research team conducted the in-depth interviews; one highly-experienced team member routinely reviewed transcripts to ensure continued fidelity to the interview guide. Interviews were conducted in person at a central location within each county between June 2015 and February 2016. At the start of each interview, we provided a

study information sheet and obtained each interviewee's verbal agreement to participate and to audio recording of the interview. Participants then completed the questionnaire and viewed the general educational video on EHRs.

We then began a structured series of questions about each of the following approaches to permission (Table 1): General Notification, Broad Permission (with Opt-Out and Opt-In alternatives), and Categorical Permission. Beginning with General Notification, we presented a verbal explanation and a visual aid depicting the approach, then asked participants to explain it in their own words, answering any questions and resolving any misunderstandings. We then asked participants to describe all of the advantages and disadvantages of that approach that they could think of from multiple stakeholder perspectives (e.g., patients, researchers, healthcare organizations), followed by whether they believed it would be *acceptable* if their healthcare organization adopted that approach to use with all of their patients, regardless of what the interviewee's personal response to that notification/permission would be. We repeated this process with each of the remaining approaches. After considering all the approaches, we asked participants to identify which would be *most appropriate* for use in their healthcare organization. Interviews lasted an average of approximately one hour and participants were offered $50 compensation for their time. Institutional Review Boards at Duke University and Vanderbilt University deemed this research exempt under 45 CFR 46.101(b)(2) (2009).

Data Analysis

We used an overarching grounded theory approach (Strauss and Corbin 1990) and a standard iterative process (MacQueen et al. 1998) to code and analyze the professionally-transcribed audio recordings using NVivo qualitative coding software (QSR International, Doncaster, Victoria, Australia). Specifically, two team members each independently reviewed six transcripts to identify frequently expressed themes for inclusion in an initial codebook. Next, they independently applied these codes to a seventh transcript and compared the results to revise the codebook as needed. They followed this process with additional transcripts until they achieved at least 80% inter-coder agreement. The remaining transcripts were then divided between the two coders; each independently coded every sixth interview to maintain inter-coder agreement. Throughout each coding iteration, revisions to the codebook were made and transcripts were recoded, as needed, to capture additions and refinements.

Once all data were coded, a third team member systematically generated narrative summaries of relevant codes to explore the range of thematic responses and identify additional sub-themes. Narrative summaries were reviewed by another team member who read the corresponding code reports to confirm agreement with the summary and sub-themes. To avoid redundancy, we have integrated data regarding advantages and disadvantages into our reporting of rationales for acceptability and appropriateness. We conducted Pearson chi-square tests using Stata v.15 (StataCorp LLC, College Station, TX) to assess differences by study location in participant characteristics and views on approaches to permission for research use of EHRs.

Results

Participant Characteristics

We interviewed 120 patients representing an array of demographic diversity (Table 2). Although many characteristics varied by study site, statistically significant differences were found only in self-reported race and overall health. Despite our secondary goal to achieve a study population with demographics broadly reflective of the counties from which we sampled, our passive recruitment approach resulted in over-representation of women.

Views on General Notification

Three-fourths of participants found General Notification to be acceptable (Table 3). Most commonly, participants recognized that such an approach would facilitate research by reducing the burden on researchers ("it would cut down on a lot of their work [and] would be easier on them" [Q07]) and making a greater volume of data available:

> It's definitely good for people doing research because they'll have access to all sorts of information that they might not otherwise have access to if they had to ask people's permission to look at it. [C11]

Additionally, some believed the potential benefits of EHR research—which they often identified as improvements to the health of participants, their family, community, or society—outweigh what they perceived as a generally low privacy risk:

> The reason I would be okay with it is because... it would help research and also it may be a little bit of risk involved, but I don't feel as much risk that could probably affect me very badly or anything. [Q05]

Many tied their acceptance of General Notification to the trustworthiness of their healthcare organization, with some specifically noting that their trust in their healthcare organization or provider extended to associated researchers.

Several participants felt General Notification would be sufficient for letting people know about EHR research because it provides basic information and is clear, simple, and "upfront" [Q25]: "In our population, sometimes simplicity is best. It's just, 'Here's what we're doing.' It's in there. They were notified." [M25]

Some suggested General Notification would be acceptable only if steps were taken to ensure it was visible; they reasoned that because this approach involves only brief notification and lacks checkboxes or other visual cues, it would be easy to miss:

> As long as it's not hidden in pages and pages of text that people are never going to read, as long as it's upfront, and clear to the patient and the person going there, then I have no problem with it.... I don't have a problem with them telling, as long as they're *actually* telling and not superficially telling. [M10]

Among the one-fourth of participants who found General Notification to be *un*acceptable (Table 3), nearly half were concerned by the lack of choice and control. Some felt aggrieved at being *told* that their EHRs would be used for research, rather than being asked: "It just

seems more draconian. ‘You have to do this or you can’t be seen here.’ It doesn’t seem to have a great deal of respect for the patient.” [M20]

Many participants took issue with the idea that patients who object to a healthcare organization’s policy could not opt out of EHR research. While some considered the ability to decline care to be a sufficient level of choice, others felt it was unfair and potentially coercive to link the provision of healthcare with accepting a policy allowing researchers to use EHRs. These participants argued that switching providers would be burdensome or even impossible given that other healthcare organizations may also use General Notification. Those in rural areas also noted that there are often no alternative healthcare organizations in communities like theirs. Participants also suggested that seeking alternative care may interfere with the provider-patient relationship and could cause delays in addressing urgent medical needs:

> Well they can refuse care with that organization … But if they are … between a rock and a hard place, there’s really not much you can do if there’s only one or two medical providers in the area. [M10]

> I think it would really stink if you didn’t have an option and you like really loved your doctor, because I adore my doctor. I’m a huge fan of my doctor. … And if I had a problem with it, that would really stink because he’s an excellent provider. [C06]

Some participants suggested that regardless of issues of control and choice, health care organizations and providers themselves may be negatively affected insofar as they “might lose a lot of their clients” [M24] because this approach “can definitely turn off people” [C21]:

> Then word of mouth get to say: ‘that’s a good clinic, but they give your information out to somewhere else.’ And so if people not comfortable with you giving [their] information, you gonna lose clientele. [Q32]

Some participants found General Notification to be unclear, both in terms of its substantive content and its potentially surreptitious presentation. In addition to not seeing the notification, some were concerned that those who *do* see it may not fully comprehend it due to time constraints, insufficient information, or other factors:

> Someone like you or I might completely understand what they’re talking about, but maybe if you have … no college education, maybe you’re even a high school kid who’s there without their mom, you might be an elderly person who’s just not familiar with a lot of the terminology. I imagine there’s a lot of situations where people just don’t get it, and they might not even be aware of what’s happening [with their data] because of that. [C08]

Views on Broad Permission

Nearly all participants found Broad Permission to be acceptable (Table 3). Compared to General Notification, most perceived and valued a sense of increased control and autonomy, which they considered appropriate and “respectful” [M24]:

> It's now giving you the option, and it's not just saying, 'This is how we do it, you don't have any choice in the matter other than to go somewhere else.' I think it's good to give people agency about what they want with their records and what they want with their healthcare. [D29]

Some specifically appreciated that Broad Permission, unlike General Notification, would not require patients to leave their healthcare organization to decline inclusion in EHR research:

> Those who feel strongly that they don't want to be part of a research system, then they have this advantage that they can still have their healthcare provider that they might love, but they won't have to worry about being part of a research study. [D08]

A few participants described Broad Permission as a clear, simple, "straightforward, easy to understand" [C30] mechanism for notifying patients of, and asking their permission for, research use of their EHR data:

> If you're at the doctor's office, and you've got an infant here, and you've got an elementary school person here, and they're asking questions, and the baby's crying, and the people behind you are [talking], you're not always reading everything. This way, you know that you have read the box and you have made a decision, yes or no, so you're informed, and you're able to make a decision. [C26]

Some cited a general trust in their healthcare organization or the research enterprise as a reason why Broad Permission would be acceptable, and a few believed that the transparency of this approach could *increase* patients' trust and confidence in their healthcare organization and in research: "They gave me a choice. They didn't tell me I had to do this… [I'm] more comfortable with them." [M15]

Participants identified a few disadvantages of Broad Permission, including the inability to make granular decisions about particular types of information. They were concerned this could lead to more blanket refusals, thus limiting the data available and potentially hindering research:

> Some people will not understand the use of their information for research studies and they may inadvertently just say no and not really understand what they are saying no to… [and] that would maybe lead to less information that can be gathered for the study. [D05]

Nonetheless, only a few deemed Broad Permission to be *un*acceptable (Table 3). These participants objected to a lack of detail on the potential research uses of their data and believed it would not afford adequate control over specific parts of their EHRs: "It doesn't give me the choice to reserve some of my information as private, which I think is important." [D13]

Alternative Response Options for Broad Permission: Opt-Out and Opt-In

Beyond "yes" and "no" checkboxes, we also asked about two other ways of eliciting a basic yes/no choice: Opt-Out (in which permission for EHR use is assumed unless the patient checks a box to revoke it) and Opt-In (in which permission is assumed to be withheld unless

the patient checks a box to grant it) (Table 3). A large majority of participants considered Opt-Out to be acceptable, while nearly all found Opt-In to be acceptable.

Those who expressed reservations about Opt-Out and/or Opt-In were concerned that the lack of clear yes/no checkboxes (with no default assumptions) may cause patients to overlook or misunderstand the action required. Indeed, many participants stressed that the acceptability of both Opt-Out and Opt-in would depend on the prominence and clarity of the instructions, citing important differences in the defaults and their effects.

Specifically, several took issue with Opt-Out's default of implied permission, objecting to the idea that patients who overlook or misunderstand the action required would be unknowingly agreeing to research use of their data: "I would feel they were using my information without my consent just because I didn't see that box" [M15]. Some considered this default of implied permission to be difficult to understand or even "deceptive" [D15]:

> [Patients] may not be aware that they're giving consent, and it could be deceiving… it would almost make it seem like the organization, or whoever was doing this, might be relying on the fact that people aren't looking… I would see how people would feel as though they were taken advantage of. [C26]

> I would think that some patients might see this as maybe less upfront or less transparent, feel like they would have less control in the sense that if they simply miss the statement then their records may be used. They might almost feel like they're being tricked a little bit. [D18]

> It's like you're asking your significant other, like if they're asleep and you say 'if you don't mind if I go get drunk with my friends, don't say anything.' [Q36].

Nonetheless, a few participants favored Opt-Out because it would increase the amount of data available, thereby furthering research:

> For researchers, this is probably preferable because 9 times out of 10, people are going to miss that because people have children and they're not paying attention to their forms and they're just gonna go through unless they're reading every single line item, which is generally not what they do… you get access to the information but you still put that on there. You gave them the choice but they missed it. [C28]

With respect to Opt-In, many participants approved of the mechanism of actively granting (rather than revoking) permission:

> I like the Opt-In, because you're saying 'Yes, I want to participate' … But if for some reason you overlook that box, and you walk out the door, and you didn't check it … they still don't have access to my records, and I'm okay with that. [C07]

Still, some were concerned that patients may not recognize that action would be required to opt in, thereby mistakenly withholding permission and ultimately limiting the amount of data available for research:

> This Opt-In, … a lot of people, they're not even gonna read it and that's gonna limit research. It's gonna put it almost to a halt because if a lot of people like me, I chuck it. [C31]

Conversely, others believed that Opt-In could prompt an erroneous *affirmative* response

> Most people would probably get mixed up and check that box, because normally everything that you do is checking boxes, nine times out of ten – instead of leaving it blank. [M22]

Duration of Broad Permission

After participants discussed the acceptability of Broad Permission (including Opt-Out and Opt-In responses), we asked their opinions on whether health care organizations should ever confirm patients' decisions and, if so, how often.

Slightly more than 40% of participants did *not* believe that healthcare organizations need to ask patients again. They considered one-time permission to be sufficient and regarded re-confirmation as unnecessarily burdensome. Some said the imperative to withdraw or change such decisions rested on patients, rather than on researchers or healthcare organizations:

> It's a relationship, so you set the guidelines at the beginning of the relationship, and if for some reason something changes, then it's up to [the patient] to notify if you wanna change anything. [D30]

Nearly 60% of participants believed that healthcare organizations *should* periodically ask patients to confirm their decisions about EHR use, arguing that evolving technological and security concerns, as well as changes in an individual's health status (e.g., new diagnoses), may cause patients to reconsider:

> Because your life circumstances change, and your opinions change, and especially if there's something going on that has changed with your health, you may feel the need to keep that more private. [C26]

> Yeah, and security might change, too. I would assume in the future, that securities will continue to get better and better, encryption methods and whatnot. So, yeah, maybe someone's not okay with it now. Maybe a year or two from now, they've read about something that made them feel more comfortable with it. [C08]

A few believed the need to confirm prior decisions depends on several factors, including whether patients were told about the duration of permission or the ability to update their decisions, or whether the original decision was made under a default of granting permission (i.e., Opt-Out).

We asked participants who believed that permission for EHR use should be periodically confirmed about *when* this should occur. Most commonly, they suggested it occur at a particular interval, most often annually or at each visit. A few participants thought confirmation should coincide with changes to a patient's health status.

Views on Categorical Permission

The vast majority of participants considered Categorical Permission to be an *acceptable* approach to seeking patients' permission for research use of their EHR data (Table 3). Participants identified several advantages, including the ability to make granular choices,

such as the types of researchers who could access their data and the types of data that could be used:

I'd have more control over this one with a specific types breakdown of each one. … I can like say yes to type A and no to B, C, and D and it'd be my choice. [Q06]Several found Categorical Permission to be acceptable because, unlike General Notification and Broad Permission, more information would be provided by virtue of the choices offered, thereby increasing transparency. Others valued the potential for increasing the amount of data available to researchers, thinking that granular options would allow patients to grant permission for access to at least some data rather than giving a blanket "no":

> Instead of them saying no to all of it in general – like if a guy has HIV but he's got other things going on, he might say no to that but leave all that other stuff open for research. So, the other ways, he'd just say no to everything. And this right here, he would say no to one thing and leave all the other stuff open. The more stuff you can get into an equation or a study, the more answers you can potentially come up with… [Q19]

A few participants indicated that Categorical Permission is acceptable, but expressed some reservations. In particular, they were concerned about burden created by multiple complex choices for patients, healthcare organizations, and researchers:

> Walking into the doctor's office always seems very daunting and there is all kinds of information that comes at you, so this wouldn't be the only thing I'd be receiving. I'd have to fill out my information, you always get some sort of HIPAA notification, and you're worried about getting it all completed before the nurse comes in and calls you back. So, it would be another thing that, especially if I was slow to complete things, that I would be nervous about getting done and maybe rush through. [C21]

> I'm thinking about the whole administration of it. I think it would be timely and cumbersome and probably not as accurate in the long run. [C13]

A small minority of participants found Categorical Permission to be *un*acceptable (Table 3). Several felt the amount of detail and sophistication in this approach would be inappropriate; they reasoned that most patients are not well positioned to assess the different types of data and researchers, and the number of options may be overwhelming, confusing, or unnecessarily burdensome:

> No, it would not be acceptable. … It's like choosing the sauce and choosing the spice, you want me to also choose the sauces and the spices that are going to go on my meat. Really? There's too much detail. I leave that up to the chef to decide, thank you. It's what they do best. [D21]

Some of these participants were concerned that patients may be less likely to make careful choices, and thus share less or more than they intended: "I'd be overwhelmed. I'd probably just be as prone to either sign off onto it 'yes' or 'no,' and I think you'd probably get more 'no's than 'yes'es." [Q37]

Several opposed the default of implied permission for all categories (meaning, if no choices are made, the presumed answer is 'yes'). As one explained, "I find it acceptable because I have a choice. I don't find it acceptable because of the default" [D22]. These participants noted that the complexity and length of Categorical Permission could cause patients to put off making their choices until after their appointment, leading some to not submit their forms and thus trigger default inclusion:

> It's also negative that if they take it home and forget about it that it would end up all 'yes'es because maybe they didn't really intend for it to be that way. [C21]

> The problem would be … if you don't fill it out, it's a default yes. If you don't fill it out and send it in, I think it should be a default no. That seems more logical to me. Because what are you going to do, if this is mailed to you after your visit, what are you going to do? You're going to open this up and say, oh, this isn't a bill, this is just junk mail. So, I'm going to throw this away and I'm never going to think about it. Then, researcher is going to say, 'oh, we never got a disapproved consent from this person, so that means we have the consent to do everything.' In which the intent of the person really isn't reflected in that. [M10]

However, others acknowledged that, in situations where patients have made no choices, the default of implied permission for all categories could increase the amount of data available:

> It does have an advantage that you could... if you really wanted to take the time to, opt out of sharing certain information, and that the default is that everything is shared. So, you kind of have to go out of your way rather than just like checking a checkbox, it's a little bit more work to fill something out. … I see it as an advantage, actually, because the patient has to be a little bit more thoughtful and go out of their way a little bit more to kind of have their information not shared … Information sharing is a good thing. [C23]

Mode of Categorical Permission

We asked participants their opinions about their healthcare organizations' having a secure website by which patients could make and change their choices in Categorical Permission at any time. Most generally approved of an online portal. Many cited the convenience of having this information in a single, easily-accessible location, as well as removing the need for patients to travel to their healthcare organization to make or update their choices. Others noted that the portal would afford patients time to think over their decisions:

> If it's in the same place where I am obtaining other information—like you mentioned my appointments, lab result records—it's right there and it's easy to access, and again, it gives me the opportunity to decide if I want to partake trusting that the particular link is going to give me all of this information that I would have received had it been on a paper document. So, I think it's very acceptable. [C30]

Many participants speculated that patients may be more likely to fill out Categorical Permission in a portal (compared to paper) and could act quickly if they changed their minds:

> That would be wonderful to have something like that at your disposal. I mean, anything that you could have to go and look at your stuff and say, 'Okay, well, something's changed. I don't want this.' To be able to make changes – I think that would be nice to have. [Q27]

Other advantages of a web portal included increased efficiency for researchers and healthcare organizations, as well as increased privacy and security for patients

> I think the website would be more secure and more private, and you wouldn't have to worry about if you want to protect your information. I think your information would be more protected on a website than on a sheet of paper. [D08]

Some participants generally did not approve of implementing Categorical Permission through an online portal. Most of these indicated that data security would likely be insufficient to protect against the high likelihood of hacking:

> I have a hard time believing that there's not somebody out there who would lose sight of the moral strictures of medical research and just say, 'If we get a few more data points, we could probably push this drug through trials and approval and get the FDA stamp on it, but I just need 150 more folks. So, I'm going to go hack this website, change my people's answers because they're never going to check it again,' and then all of a sudden, your information is out there. I think a paper form where you have physical evidence that would have to be altered or destroyed to change your answer is much more secure than a website. [D13]

Some participants found the online portal to be problematic because it would exclude patients who lack computer literacy and access:

> I'm not 100 percent sure about the portal thing because I come from a place where the population is only 143 people and there's a lot of older people that don't believe in computers, don't believe in cell phones and they don't have access to it. Especially here in West Virginia, there's a lot of people that don't have computers, they don't have the internet … or they don't want to get into [the internet] and they would rather do it old-fashioned paper and pen. [M16]

One was concerned that on-going changes to decisions through a web portal would be problematic for researchers

> If you had said yes, and you changed your answer to no, the researchers could already be using that information. And if that person changed it to no, then they found out that the researchers was using it, it would cause confusion. [D10]

A few suggested that the portal should be an optional, rather than mandatory, alternative to a paper form.

Most Appropriate Approach to Permission for Research Use of EHRs

After considering the advantages, disadvantages, and acceptability of each approach, participants were asked which would be the most appropriate way to let patients in their healthcare organization know that their EHR data might be used for research, or obtain permission for such use. Well over half believed Broad Permission was most appropriate

(Table 4). In particular, among those who chose Broad Permission, nearly two-thirds (63%) favored implementation with yes/no checkboxes. Approximately one-fourth (23%) favored Opt-In implementation and the remainder (14%) favored Opt-Out.

About one-third identified Categorical Permission as the most appropriate approach (Table 4), primarily pointing to the increased choice and control over what data may be used for research and by whom. The remainder chose General Notification as the most appropriate way to let patients know that their EHR data might be used for research (Table 4). Of these, most valued its simple, straightforward presentation, noting that it would be efficient for patients, healthcare organizations, and researchers alike.

Overarching Considerations

Throughout their discussions of all approaches, participants referred to the potentially sensitive nature of EHR data as well as privacy and confidentiality issues related to research use. Despite our extensive efforts to provide baseline education to elicit informed opinions, there were lingering misconceptions among some participants; in particular, some were confused by the idea that their EHR data might be used by multiple researchers and/or for multiple purposes, the specific details of which may not be knowable at the time of notification or permission.

Regardless of whether patients are merely notified or given an opportunity to make choices, participants often expressed desire for more information about research use of EHRs in general, such as a basic description of the types of data that might be used, broad research purposes and goals, and how the data would be protected. Some expressed the need for additional specific information, including details that would be unknowable at the time of notification or permission, such as “the research name or what the research [is] looking for in the file” [Q15]:

> I’m going to have to have specifics. Know from point A to point Z, I need to know all of the in-betweens… not just the beginning and the end. I want to know the whole entire output of what you’re going to use my information for. [Q23]

These comments are suggestive of more elaborate models to obtain full informed consent for research use of the EHR data, such as broad consent or even specific consent for each study. However, it was beyond the scope of our already lengthy interviews to explore all possible models, particularly those unlikely to be considered feasible by researchers or healthcare organizations.

Finally, many participants noted that the acceptability and appropriateness of any approach would depend on visibility and comprehensibility. They stressed that the information, choices (if any), and instructions must be prominent and easily understood to ensure that patients are clearly aware of the institutional policies and/or options available to them regarding research use of their EHR data.

Discussion

The increased use of EHRs in healthcare has resulted in new opportunities for clinical trials and other research, but has also raised ethical issues regarding patient privacy, confidentiality, and patient awareness (Kukafka and Ancker 2007; Menachemi and Collum 2011; National Research Council 2011; Barrows and Clayton 1996). Because public trust is crucial to the success of the research enterprise, patient perspectives are essential to the development and implementation of ethical approaches to the research use of EHRs (Hripcsak et al. 2014; Rynning 2007; Grande et al. 2013).

Our study engaged 120 patients in four geographic locations throughout the southeastern United States to share their views via in-depth interviews. These diverse participants identified and weighed, from multiple perspectives, the advantages, disadvantages, and trade-offs of different approaches to informing patients of, or seeking their permission for, EHR research. They valued not only individual choice, control, and autonomy, but also efficiency for researchers and healthcare organizations. The vast majority of participants found General Notification, Broad Permission, and Categorical Permission each to be an acceptable way to inform, or obtain permission from, patients regarding EHR research. When asked which approach would be most appropriate, most chose Broad Permission.

For our participants, the acceptability and appropriateness of any of the approaches depended on its clarity, simplicity, and usability; the level of transparency, trustworthiness, choice, and respect for patients it conveys; and its effects on research. These findings are largely consistent with other US studies that have examined public perceptions of various permission models in the context of sharing EHR data for healthcare and research (Botkin 2013; Damschroder et al. 2007; Kim, Joseph, and Ohno-Machado 2015; Weinfurt et al. 2017; Weinfurt et al. 2016; Kass et al. 2016; Cho et al. 2015).

However, in contrast to Caine and Hanania's (2013) findings, our results suggest that transparency and trust may be more important to patients than granular choice and control (Botkin 2014). Compared to Broad Permission, fewer participants considered Categorical Permission to be acceptable and fewer selected Categorical Permission as the most appropriate approach. Participants expressed concern about the burden of understanding and making the detailed choices required under Categorical Permission, often specifically referencing their preference for the simplicity of Broad Permission.

The majority of studies examining patient perspectives on research use of EHRs have been conducted in countries other than the U.S. and, thus, are of limited applicability given sociocultural and healthcare differences (Riordan et al. 2015; Buckley, Murphy, and MacFarlane 2011; Haddow et al. 2011; Stevenson et al. 2012; Willison et al. 2003; Willison et al. 2007; Nair et al. 2004; Clerkin et al. 2012; Robling et al. 2004; Spencer et al. 2016; Whiddett et al. 2006). The few qualitative studies on this topic conducted within the U.S. have tended to be limited to one geographic location and/or healthcare system (Caine and Hanania 2013; Caine et al. 2015; Damschroder et al. 2007; Grando et al. 2017; Kim, Joseph, and Machado 2015). Participants in our study—patients in several different healthcare organizations in four diverse geographic areas—considered the particular sociocultural

context of their communities in assessing the advantages, disadvantages, acceptability, and appropriateness of each approach. For example, those in rural areas (Quitman County, MS, and Mingo County, WV) often referenced limited access to alternative healthcare organizations, low literacy, and life-long doctor-patient relationships in their decisions and explanations. This tendency is in keeping with literature showing that residents of rural areas often have access to, experience with, and perceptions of healthcare and research that differ from residents of urban and suburban areas (Brelsford, Spratt, and Beskow 2018; Warner et al. 2005; Buzza et al. 2011). Thus, it may be important for researchers and healthcare organizations to attend to the context of the communities they serve when developing policies for patient permission for EHR data research.

Data collection for our study involved providing baseline education about EHRs and research so that we could elicit *considered* opinions about a complex and typically unfamiliar topic. Even so, our findings contribute valuable input concerning patients' perceptions and expectations regarding research use of their EHR data. Because it is reasonable to expect that patients who do not have the benefit of focused education and explanations will have similar (and additional) misunderstandings, there is a need for patient and public education on EHRs and their use in research, especially in conjunction with efforts to increase transparency and perhaps increase patients' choice and control. Misconceptions regarding research use of EHR data may cause perceived or actual violations of trust by healthcare organizations and/or researchers.

Our study has several strengths. Our participants were recruited via letters sent to a random sample of residents across each of four demographically diverse counties with varying access and choice regarding healthcare. We used educational materials and interview probes to encourage informed, careful consideration of each approach from multiple perspectives (Beskow 2016). We asked participants to think through the advantages and disadvantages of each approach from multiple viewpoints (e.g., patients, researchers, healthcare organizations) before commenting on its *acceptability*—rather than *preference*—and asked them which would be the *most appropriate* approach for use in their healthcare organization only after they had an opportunity to consider all approaches. By situating acceptability and appropriateness within each interviewee's particular healthcare organization, we encouraged participants to reflect not only on their personal values, but also on the context of their communities and healthcare systems.

Our study is subject to some limitations. Although we collected data in four disparate regions, our findings are geographically limited to the southeastern United States. Additionally, the goal of qualitative research is to elucidate the range of perspectives as articulated by participants; thus, our findings do not provide definitive answers but, rather, highlight important considerations for the development of ethical policy and practice. Further, non-probabilistic sampling for qualitative research is guided not by statistical power but by the concept of "saturation," the point at which no new information or themes are observed in the data. We provide some quantitative data, purposely captured via closed-ended interview questions. These proportions should be viewed as an indicator of how commonly various themes and responses were expressed among our diverse group of participants. They do not necessarily provide an accurate forecast of the results if our

findings were used to, for example, generate closed-ended items for a survey fielded in a sample drawn to be representative of an entire population. Future research should examine the extent to which opinions regarding approaches to research use of EHRs may differ within and between other regions and populations. Finally, our findings comprise patient perspectives; research is needed to explore how other stakeholder groups, such as researchers and healthcare organizations, view these issues.

While patient perspectives are key to developing and implementing ethical approaches to EHR research, they are one of *several* important factors warranting careful consideration by institutions in shaping their own approaches to permission for such use. For example, sufficient attention should be afforded to balancing allocation of finite resources in implementing these approaches, as well as feasibility challenges and effects on public trust in both the healthcare and research enterprises. Further, while permission for research use of EHR data is an important mechanism for protecting patients, it is one of myriad protections in research, such as technical security measures (e.g., encryption, audit trails), monitoring and oversight procedures (e.g., IRBs), and various other legal, regulatory, and policy protections at the federal, state, local, and even institutional levels. Thus, due consideration should be given to the effectiveness of other existing protections beyond patient permission. Indeed, as the use of EHRs expands, along with the depth and breadth of information they contain, the ethical use of EHR data for research requires building and maintaining patient trust and acceptance in the stewardship of their data. Future studies should focus on the perspectives of other key stakeholder groups, such as researchers and healthcare organizations, and assess additional burdens and/or efficiencies associated with the implementation of each approach.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Summary of Approaches to Permission for Research Use of EHR Data

General Notification	*When you first visit a healthcare organization, you receive a notice that tells you about all the ways the organization uses your health information. Somewhere in the notice, there are a few sentences telling you that the organization sometimes shares information in EHRs with qualified researchers who are conducting approved research. So, with general notification, the organization is not asking you for permission, but rather just informing you about their policy.*
Broad Permission	*Just like general notification, you receive a notice that tells you how the organization uses and shares health information, including a few sentences telling you that the organization sometimes shares information in EHRs with qualified researchers who are conducting approved studies. However, unlike general notification, with broad permission you get a yes/no choice—a chance to say whether or not researchers can include information from your EHR in approved studies.*
Opt-Out	*Another way this yes/no choice could be presented would be for the notice to state that information in your EHR might be used for research unless you check a box saying you don't want that to happen. In other words, if you do nothing, qualified researchers could access your information for approved studies. But if you check the box to "opt out", researchers would not be able to access it.*
Opt-In	*Another way the yes/no choice could be presented would be for the notice to state that information in your EHR will not be used for research unless you check a box saying that it is okay. In other words, if you do nothing, researchers would not be able to access your information. But if you check the box to "opt in", qualified researchers could access your information for approved studies.*
Categorical Permission	*The last approach would be to give you a "menu" of choices. Just like the other approaches, you would get information about how the organization uses and shares health information —including notice that the organization sometimes shares information in EHRs with qualified researchers who are conducting approved studies.* *What's different here is that you would be asked to make detailed choices about whether and with whom your information could be shared for research. For example, you might be asked to choose which types of researchers could use your information. You might be asked to choose which kinds of information from your EHR researchers could access.* *Let's say you could make these choices during the clinic visit or take it home to complete. The default would be that it is okay to share all information with all researchers. In other words, unless patients make other choices, the organization would assume it is okay to share information with qualified researchers for approved studies.*

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Table 2.

Participant Characteristics

	TOTAL		Cabarrus		Durham		Mingo		Quitman		p-value*
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	
Total participants	120	(100)	30	(25)	31	(26)	28	(23)	31	(26)	
Gender											
Men	44	(37)	10	(33)	14	(45)	9	(32)	11	(36)	0.72
Women	76	(63)	20	(67)	17	(55)	19	(68)	20	(65)	
Age group											
18–24	5	(4)	-	-	2	(6)	1	(4)	2	(6)	0.43
25–34	26	(22)	5	(17)	6	(19)	8	(29)	7	(23)	
35–44	20	(17)	7	(23)	7	(23)	4	(14)	2	(7)	
45–54	22	(18)	10	(33)	3	(10)	4	(14)	5	(16)	
55–64	26	(22)	4	(13)	7	(23)	5	(18)	10	(32)	
≥65	21	(16)	4	(13)	6	(19)	6	(21)	5	(16)	
Education											
Below high school (HS)	11	(9)	3	(10)	2	(7)	3	(11)	3	(10)	0.09
HS/GED/Vocational	31	(26)	4	(13)	7	(23)	11	(39)	9	(29)	
AA/Some college	32	(27)	7	(23)	5	(16)	9	(32)	11	(35)	
BA and above	46	(38)	16	(53)	17	(55)	5	(18)	8	(26)	
Race											
Black or African American	39	(33)	4	(14)	14	(45)	1	(4)	20	(65)	0.00
White	77	(64)	24	(80)	15	(48)	27	(96)	11	(36)	
Hispanic	2	(2)	1	(3)	1	(3)	-	-	-	-	
Asian	1	(1)	1	(3)	-	-	-	-	-	-	
More than one race	1	(1)	-	-	1	(3)	-	-	-	-	
Overall health[a]											
Poor/fair	26	(22)	2	(7)	4	(13)	10	(36)	10	(32)	0.01
Good	42	(35)	13	(43)	7	(23)	9	(32)	13	(42)	
Very good/excellent	52	(43)	15	(50)	20	(65)	9	(32)	8	(26)	
Healthcare visits in past year[b]											

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	TOTAL		Cabarrus		Durham		Mingo		Quitman		p-value*
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	
0	10	(8)	2	(7)	-	-	4	(14)	4	(13)	0.22
1–2	41	(34)	11	(37)	17	(55)	5	(18)	8	(26)	
3–4	36	(30)	10	(33)	8	(26)	8	(29)	10	(32)	
5–9	19	(16)	5	(17)	3	(10)	7	(25)	4	(13)	
≥10	14	(12)	2	(7)	3	(10)	4	(14)	5	(16)	
Healthcare prohibited by cost[c]											
No	89	(74)	23	(77)	26	(84)	21	(75)	19	(61)	0.23
Yes	31	(26)	7	(23)	5	(16)	7	(25)	12	(39)	
Have regular healthcare provider[d]											
No	24	(20)	2	(7)	7	(23)	6	(21)	9	(29)	0.17
Yes	96	(80)	28	(93)	24	(77)	22	(79)	22	(71)	

*p-values obtained using Pearson chi-square tests.

[a]Asked: *In general, how would you rate your health?*

[b]Asked: *During the past 12 months, not counting times you went to an emergency room, how many times did you go to a healthcare provider to get care for yourself?*

[c]Asked: *Was there a time in the past 12 months when you needed to see a healthcare provider but could not because of cost?*

[d]Asked: *Do you have one healthcare provider (such as a doctor, nurse practitioner, physician assistant, or other health professional) that you see for most of your care?*

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Table 3.

Participant Views on Acceptability of Approaches to Permission for Research Use of EHR data

	TOTAL		Cabarrus		Durham		Mingo		Quitman		p-value*
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	
Is the approach acceptable?											
General Notification											
No	30	(25)	3	(10)	5	(16)	11	(39)	11	(36)	0.02
Yes	90	(75)	27	(90)	26	(84)	17	(61)	20	(64)	
Broad Permission											
No	5	(4)	0	(0)	1	(3)	2	(7)	2	(7)	0.50
Yes	115	(96)	30	(100)	30	(97)	26	(93)	29	(93)	
Categorical Permission											
No	13	(11)	5	(17)	3	(10)	2	(7)	3	(10)	0.68
Yes	107	(89)	25	(83)	28	(90)	26	(93)	28	(90)	
Acceptability of alternative response options for Broad Permission											
Opt-Out											
No	23	(19)	6	(20)	4	(13)	7	(25)	6	(19)	0.71
Yes	97	(81)	24	(80)	27	(87)	21	(75)	25	(81)	
Opt-In											
No	11	(9)	1	(3)	4	(13)	3	(11)	3	(10)	0.61
Yes	109	(91)	29	(97)	27	(87)	25	(89)	28	(90)	

*p-values obtained using Pearson chi-square tests.

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Table 4.

Participant Opinions on the Most Appropriate Approach to Permission for Research Use of EHR data

	TOTAL		Cabarrus		Durham		Mingo		Quitman		p-value*
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	
Which approach is most appropriate?											
General Notification	11	(9)	4	(13)	2	(7)	0	(0)	5	(16)	0.05
Broad Permission	71	(59)	21	(70)	14	(45)	20	(71)	16	(52)	
Categorical Permission	38	(32)	5	(17)	15	(48)	8	(29)	10	(32)	

*p-value obtained using Pearson chi-square tests.