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Research and Applications

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Research use of electronic health records: patients' perspectives on contact by researchers

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ABSTRACT

Objective: The use of electronic health records (EHRs) for research has the potential to improve the diagnosis and treatment of disease, yet contact with patients based on results of EHR phenotyping has received little attention. Researchers will almost certainly discover discrepancies in EHRs that call for resolution and, in some cases, raise the ethical dilemma of whether to contact patients about a potentially undiagnosed or untreated health concern. The objective of this study was to explore patients' attitudes and opinions about potential contact by researchers who have had access to their EHRs.

Materials and methods: We conducted 15 focus groups in four diverse counties in the southeastern United States. We designed vignettes to describe different situations in which researchers conducting a hypothetical study might have reason to consider contact with patients.

Results: Many patients believed it was important for researchers to take action if they discovered information suggesting a current serious health concern. Relaying the information through patients' physicians was considered the most appropriate course of action. Across vignettes, there were significant differences between urban and rural sites.

Discussion and conclusions: Researchers may increasingly encounter situations involving contact with patients following EHR phenotyping. They should carefully consider the possibility of such contact when planning their studies, including the time and expertise needed to adjudicate potentially serious discrepancies. Our focus group results are one source of input for the development of ethical approaches to the research use of EHRs.

Key words: electronic health records, patient perspectives, research ethics, physician-patient relationship, trust

BACKGROUND AND SIGNIFICANCE

The widespread adoption and use of electronic health records (EHRs) will make an unprecedented amount of information available for health-related research. With over one billion physician office and outpatient visits annually in the United States,[1] EHR data may contribute to improved understanding of the diagnosis and treatment of disease, and the study of more diverse populations and rare conditions.[2]

EHR data do not, however, directly reflect patients and their physiology, but rather the complex set of recording processes involved in healthcare.[2] Data quality issues, including inaccuracies, missingness, and bias, create nontrivial hurdles.[3] Richesson and colleagues,[4] for example, applied prominent diabetes phenotype definitions to a dataset of Duke University Health System patients (n = 173 503) to compare the characteristics of the diabetes cohorts identified. Using the components of the phenotypic definitions

Table 1. Research scenario

Let's pretend that researchers want to find ways to help people who are having trouble managing their diabetes to be more successful. They want to see whether people who receive a daily telephone call reminding them to check their blood sugar levels will do a better job of keeping their blood sugar at healthy levels. They want to conduct a study with patients who have diabetes and agree to be in the study to determine if the telephone reminders actually work. Half of the patients in the study would receive a daily phone call reminder to check their blood sugar. The other half of the patients would not receive the call. The researchers would keep track of all of the patients' blood sugar levels over a 3-month period to see whether patients who got phone calls were managing their blood sugar better than patients who were not getting calls.
In order to conduct the study, the researchers first need to identify people with diabetes who they can invite to be in the study. To find people with diabetes, the researchers use a computer program to search through thousands of EHRs. They create a search that tells the computer to pull EHRs based on diagnostic codes, lab results, and medications that may indicate that someone has diabetes. The computer runs the search, which provides the researchers with the EHRs of patients who likely have diabetes, and thus, might be eligible to be in the study.

Adapted from Lawson ML, et al. A randomized trial of regular standardized telephone contact by a diabetes nurse educator in adolescents with poor diabetes control. *Pediatr Diabetes*. 2005; 6: 32-40.

(ICD-9 diagnosis codes, abnormal lab values, and diabetes-related medications), 24 520 patients who met any of the criteria were identified. Of these, 39% met all three criteria and 36% met only one. Notably, 20% had diabetes-specific diagnosis codes and abnormal lab values but no documented diabetes medications, and 17% had abnormal lab values but no diabetes diagnosis codes or medications. Spratt et al.[5] assessed an expanded set of EHR-based phenotypes and, using gold standard chart review by clinical experts to determine the true presence of type 2 diabetes, found that the sensitivity of the phenotypes ranged from 62% to 94%. These findings illustrate not only the difficulty of devising phenotypic definitions, but also the problem that researchers using EHRs will almost certainly encounter — the discovery of discrepancies that call for resolution and, in some cases, raise the ethical dilemma of whether to contact patients about a potentially undiagnosed or untreated health concern.

We conducted 15 focus groups in diverse regions of the southeastern United States —Appalachia, the Mississippi Delta, and the Piedmont area of North Carolina — to assess patients' attitudes and opinions about potential contact by researchers who have had access to their EHRs. We used a series of vignettes to explore several situations in which researchers might consider contacting patients, including discovery of an undiagnosed health problem, contraindicated medications, and high risk of a future health problem.

MATERIALS AND METHODS

Participants

We conducted focus groups with patients in four counties: Cabarrus, North Carolina; Durham, North Carolina; Mingo, West Virginia; and Quitman, Mississippi. 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 conducted additional focus groups in Cabarrus County with research participants enrolled in the MURDOCK Study, a population-based biobank,[6] to explore whether individuals currently enrolled in research have perspectives differing from other patients.

We worked with commercial vendors to mail recruitment letters to a random selection of adults in each county; MURDOCK study staff mailed letters to a random selection of participants and also reached out through social media. In all cases, interested individuals contacted us to learn more about the study. We used purposive selection and scheduling to maximize demographic diversity within groups. In Mingo and Quitman counties, where there seemed to be more distrust of depersonalized letters, we also used snowball sampling to fill remaining seats.

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.

Instrument development

Focus group instrumentation included four elements:

- *A questionnaire* eliciting basic demographic information, general level of concern about health information privacy, and responses to validated measures of trust in healthcare providers,[7] healthcare institutions,[8–10] and medical research.[11]
- *Educational videos* to convey basic information needed to support opinion formation. The first described EHRs, research use of clinical records and data, and oversight mechanisms and privacy protections employed in such research. The second introduced a hypothetical study (Table 1) to explain how and why researchers using EHRs could discover potentially concerning discrepancies.
- *A moderator's guide* to explore participants' opinions regarding four vignettes (Table 2) in which researchers conducting the hypothetical study might have reason to consider contact with patients. These included instances in which researchers, based on information in a patient's EHR, suspected that the patient may (1) have an undiagnosed health problem; (2) be taking contraindicated medications; or (3) be at high risk of a future health problem.
- *A worksheet* for participants to record their individual responses to key closed-ended questions, prior to full group discussion, with the goal of enhancing engagement with the issues and generating some limited quantitative data for comparison within and across study sites.[12]

All of these instruments (available upon request) were developed, reviewed, and revised by the research team, with input from a multidisciplinary expert advisory group as well as extensive pilot testing.

Data collection

We conducted 15 focus groups between August 2015 and February 2016. One research team member (KMB) moderated all of the groups. Institutional Review Boards at Duke University and

Table 2. Summary of vignettes

Vignette 1 (Undiagnosed Health Condition): In reviewing the EHRs of potentially eligible patients, the researchers notice that one patient has an abnormal laboratory test result that suggests he or she might have diabetes. However, there are no diagnostic codes or medications for diabetes in the chart, so the researchers are concerned that the patient might actually *have* diabetes and not know it.
Vignette 2 (Contraindicated Medications): Now imagine the researchers are reviewing a different patient's EHR. This person was identified as potentially eligible because of high blood sugar levels, but has no diagnostic codes or medications for diabetes. Upon further inspection, the researchers see that the patient is taking a drug for epilepsy that can raise blood sugar levels. However, the researchers also notice the patient is taking another drug that is not supposed to be taken together with the epilepsy drug. When the two are taken together, it can cause serious side effects.
Vignette 3 (Future Health Risk): The researchers are still reviewing EHRs to find potential participants for the diabetes telephone study. During the review, they come across a patient who has lab results showing blood sugar levels that are higher than normal. Unlike the patient in our last example, this patient is not taking any medications that would explain the high blood sugar levels. Although the patient's levels are not high enough to be classified as diabetes, the researchers are concerned because the patient has other risk factors for becoming diabetic: the patient is older, overweight, and has high blood pressure. Each of these increases the chance that a person might become diabetic. Based on the medical record, the patient has not had a recent test for diabetes and is not taking any medications to reduce the risk of developing diabetes. So nothing is *specifically* wrong with the patient right now, but it looks like the patient is at high risk for developing diabetes in the future — and there are things that could be done to help the patient reduce that risk.

Vanderbilt University deemed this research exempt under 45 CFR 46.101(b)(2).

Participants reviewed a study information sheet, provided verbal agreement to participate, and completed the questionnaire. Each group started by watching the general educational video on EHRs and brainstorming potential benefits and risks of research use of EHRs. Next, we introduced the hypothetical study, after which participants watched the educational video on EHR discrepancies.

The moderator then introduced the first vignette and asked the group to think of all the ways the researcher could respond to the discrepancy. Groups readily identified the three possible actions: do nothing, contact the patient directly, or contact the patient's healthcare provider. To encourage participants to consider a wide range of views before forming their own opinions, the group was asked to generate a comprehensive list of the advantages and disadvantages of each action from patient, researcher, and provider perspectives.

Participants then answered questions on their individual worksheets regarding the *acceptability* of each possible action, followed by a question about which action would be most *appropriate*. The moderator then led a group conversation in which participants shared their opinions. We followed the same process for each of the remaining vignettes.

Data analysis

We used NVivo 11 (QSR International, Doncaster, Victoria, Australia) and a standard iterative process[13] to code and analyze transcribed audio recordings of the focus groups. Specifically, two team members developed a structural and thematic codebook by each reviewing three different transcripts to identify frequently expressed ideas. They independently applied generated codes to the six transcripts and confirmed >80% inter-coder agreement. One coder then applied codes to the remaining nine transcripts, consulting with the second coder in cases in which new codes seemed warranted or there was uncertainty regarding code application. Finally, the second coder read the nine transcripts, reviewed all code applications, and worked with the first coder to address any areas of disagreement.

Basic descriptive and comparative analyses of questionnaire and worksheet data were conducted using Stata 14.2 (StataCorp, College Station, TX, USA). We used Fisher's exact test to examine differences by study site and logistic regression to assess differences by rural vs. urban location (Quitman and Mingo vs. Durham and Cabarrus counties), controlling for demographic characteristics, including age, gender, self-reported race, educational attainment, and self-reported health. Because this was primarily a qualitative study, we provide here a high-level summary of selected regression findings rather than detailed numeric results.

RESULTS

Participant characteristics

Overall, our participants (n = 110) represented substantial diversity (Table 3). Compared to US census data, participant race and education characteristics broadly mirrored those of the target counties, with our sample being slightly more educated; our sample also included a larger proportion of women and older individuals. Although many characteristics varied by study site, statistically significant differences were found only in self-reported race and having a regular healthcare provider.

Vignette 1: Researcher discovery of potentially undiagnosed health condition

In response to Vignette 1, nearly two-thirds (65%) of participants said it was important for researchers to take some sort of action if they discovered potentially undiagnosed Type 2 diabetes (Table 4).

Physician Notification

When asked what action researchers should take, nearly all participants (95%) said it would be *acceptable* for researchers to notify patients' physicians of a concern about undiagnosed Type 2 diabetes (Table 4). In particular, those in rural locations were more likely to react positively to physician notification.

Participants cited trust, communication, and clinician role as reasons they would find physician notification acceptable, suggesting that physicians are best positioned to investigate discrepancies, determine whether follow-up is required, communicate medical information to patients, and answer questions. As one participant explained, "You just have more confidence in your doctor. He's got your whole health record. He's seen you throughout your life for different medical reasons. As opposed to a researcher that just sees what's on the screen." [MU_FG2_P8]

A few participants (5%), however, felt physician notification would be *unacceptable*, primarily because it would be time

Table 3. Participant characteristics

	Total (15 groups)		Cabarrus (4 groups)		Durham (3 groups)		Mingo (3 groups)		Quitman (3 groups)		MURDOCK (2 groups)		*P*-value
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	
Total participants	110		31		28		15		16		20		
Gender													
Men	44	(40)	15	(48)	14	(50)	4	(27)	4	(25)	7	(35)	0.32
Women	66	(60)	16	(52)	14	(50)	11	(73)	12	(75)	13	(65)	
Age group													
18-35	16	(15)	5	(16)	2	(7)	1	(7)	2	(13)	6	(30)	0.52
36-64	65	(59)	18	(58)	20	(71)	10	(67)	9	(56)	8	(40)	
65+	29	(26)	8	(26)	6	(21)	4	(27)	5	(31)	6	(30)	
Education													
Less than high school	4	(4)	1	(3)	2	(7)	0	(0)	1	(6)	0	(0)	0.23
High school	29	(26)	7	(23)	5	(18)	6	(40)	7	(44)	4	(20)	
Some college	26	(24)	6	(19)	6	(21)	6	(40)	4	(25)	4	(20)	
Bachelor's degree or higher	51	(46)	17	(55)	15	(54)	3	(20)	4	(25)	12	(60)	
Race													
Black	40	(36)	7	(23)	14	(50)	4	(27)	12	(75)	3	(15)	0.00
White	67	(61)	22	(71)	13	(46)	11	(73)	4	(25)	17	(85)	
Other	3	(3)	2	(6)	1	(4)	0	(0)	0	(0)	0	(0)	
Self-reported health[a]													
Poor	3	(3)	0	(0)	1	(4)	1	(7)	1	(6)	0	(0)	0.41
Fair	9	(8)	2	(6)	2	(7)	2	(13)	1	(6)	2	(10)	
Good	41	(37)	14	(45)	10	(36)	6	(40)	6	(38)	5	(25)	
Very good	38	(35)	12	(39)	11	(39)	5	(33)	4	(25)	6	(30)	
Excellent	18	(16)	3	(10)	4	(14)	0	(0)	4	(25)	7	(35)	
Healthcare visits in past year[b]													
≤2	59	(54)	16	(52)	14	(50)	6	(40)	10	(63)	13	(65)	0.43
3-4	28	(25)	9	(29)	5	(18)	5	(33)	4	(25)	5	(25)	
5-9	15	(14)	2	(6)	8	(29)	2	(13)	1	(6)	2	(10)	
≥10	8	(7)	4	(13)	1	(4)	2	(13)	1	(6)	0	(0)	
Healthcare prohibited by cost?[c]													
No	86	(78)	24	(77)	20	(71)	13	(87)	13	(81)	16	(80)	0.87
Yes	24	(22)	7	(23)	8	(29)	2	(13)	3	(19)	4	(20)	
Have regular healthcare provider?[d]													
No	11	(10)	1	(3)	4	(14)	2	(13)	4	(25)	0	(0)	0.03
Yes	98	(89)	30	(97)	24	(86)	12	(80)	12	(75)	20	(100)	

[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?

consuming, costly, would seldom uncover legitimate issues or problems, and could actually result in medical errors:

> U.S. healthcare's the most expensive in the world. And now you're a physician and you've got an obligation to reach out to this patient — or *somebody* in the system, 'cause it won't be the physician. Now the physician's gotta contact an assistant and say, "Call [this patient] and tell him this." You're gonna increase costs. And I really think 99 percent of the time, the physician's got it covered anyway. [DC_FG2_P3]

> [Contacting physicians] might even increase mistakes made. Now you're involving more steps in a whole process of figuring out what might've already been figured out the first time. This is a crazy process. [DC_FG2_P8]

Patient Notification

In contrast, the majority (62%) of participants felt it would be *unacceptable* for researchers to notify patients directly (Table 4).

Issues of trust and professional role figured prominently in discussions of why patient notification would be unacceptable. Many participants said they would be suspicious if they received personal health information from an unknown researcher and questioned whether the practice violated privacy protections. They felt that direct contact could cast doubt on the legitimacy, trustworthiness, and integrity of both the researcher and the research process:

> A researcher's role is to research. You're not my doctor so I can't trust you. And then there's also privacy for me: that's none of your business. OK, you saw it. And you are under an oath to not share that. I don't need you to call me and tell me anything about my information. Let my doctor handle that. [DC_FG3_P5]

Some also worried that direct contact would erode patient trust in healthcare providers, particularly if patients assumed that EHR discrepancies were the result of provider error. Moreover, several participants worried the approach could jeopardize trust between

Table 4. Responses to vignettes

	Total (15 groups)		Cabarrus (4 groups)		Durham (3 groups)		Mingo (3 groups)		Quitman (3 groups)		MURDOCK (2 groups)		*P*-value
	n	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	*n*	(%)	
VIGNETTE 1: MAY HAVE TYPE 2 DIABETES													
Importance of doing something													
Not too important	38	(35)	8	(26)	16	(57)	4	(27)	4	(25)	6	(30)	0.09
Important	71	(65)	23	(74)	12	(43)	11	(73)	12	(75)	13	(65)	
Physician notification													
Unacceptable	6	(5)	1	(3)	5	(18)	0	(0)	0	(0)	0	(0)	0.04
Acceptable	104	(95)	30	(97)	23	(82)	15	(100)	16	(100)	20	(100)	
Patient notification													
Unacceptable	68	(62)	21	(68)	21	(75)	6	(40)	6	(38)	14	(70)	0.04
Acceptable	42	(38)	10	(32)	7	(25)	9	(60)	10	(63)	6	(30)	
Most appropriate action													
Do nothing	11	(10)	2	(7)	8	(29)	0	(0)	0	(0)	1	(5)	0.00
Notify patient directly	15	(14)	1	(3)	2	(7)	5	(33)	5	(31)	2	(10)	
Notify physician	84	(76)	28	(90)	18	(64)	10	(67)	11	(69)	17	(85)	
VIGNETTE 2: CONTRAINDICATED MEDICATIONS													
Importance of doing something													
Not too important	31	(28)	6	(19)	8	(29)	2	(13)	4	(25)	11	(55)	0.06
Important	79	(72)	25	(81)	20	(71)	13	(87)	12	(75)	9	(45)	
Notify physician													
Unacceptable	5	(5)	0	(0)	4	(14)	1	(7)	0	(0)	0	(0)	0.04
Acceptable	105	(95)	31	(100)	24	(86)	14	(93)	16	(100)	20	(100)	
Notify patient directly													
Unacceptable	66	(60)	21	(68)	21	(75)	4	(27)	6	(38)	14	(70)	0.01
Acceptable	44	(40)	10	(32)	7	(25)	11	(73)	10	(63)	6	(30)	
Most appropriate action													
Do nothing	7	(6)	2	(6)	3	(11)	0	(0)	0	(0)	2	(10)	0.09
Notify patient directly	22	(20)	5	(16)	4	(14)	7	(47)	5	(31)	1	(5)	
Notify physician	81	(74)	24	(77)	21	(75)	8	(53)	11	(69)	17	(85)	
VIGNETTE 3: AT RISK FOR TYPE 2 DIABETES													
Importance of doing something													
Not too important	76	(69)	21	(68)	23	(82)	9	(60)	5	(31)	18	(90)	0.00
Important	33	(30)	10	(32)	4	(14)	6	(40)	11	(69)	2	(10)	
Notify physician													
Unacceptable	27	(25)	7	(23)	10	(36)	3	(20)	1	(6)	6	(30)	0.25
Acceptable	83	(75)	24	(77)	18	(64)	12	(80)	15	(94)	14	(70)	
Notify patient directly													
Unacceptable	81	(74)	29	(94)	22	(79)	8	(53)	5	(31)	17	(85)	0.00
Acceptable	29	(26)	2	(6)	6	(21)	7	(47)	11	(69)	3	(15)	
Most appropriate action													
Do nothing	38	(35)	13	(42)	12	(43)	5	(33)	0	(0)	8	(40)	0.02
Notify patient directly	13	(12)	2	(6)	2	(7)	3	(20)	5	(31)	1	(5)	
Notify physician	59	(54)	16	(52)	14	(50)	7	(47)	11	(69)	11	(55)	

[a]Asked on a 5-point scale: Not at all important, not very important, somewhat important (collapsed here to "Not too important"), important, very important (collapsed here to "Important").

researchers and physicians, predicting that healthcare providers would object to the approach if they perceived it to challenge their expertise or interfere with the doctor-patient relationship.

Some participants also worried that contacting patients directly would be too burdensome for researchers:

> It's a slippery slope. Where do you draw the line? Are researchers gonna contact patients about everything that they start to see? I think once the genie's out of the bottle, that it gets very hard to put it back in. [DC_FG2_P3]

Even if the researchers are also physicians, many participants believed they would be unqualified to interpret clinical information for patients who were not their own. Compared to individuals' own physicians, researchers would be less able to assess the clinical correctness of discrepancies or to answer patients' immediate questions, which could leave patients feeling helpless, confused, and unnecessarily anxious.

However, more than a third (38%) of participants, particularly those in rural areas, found direct patient notification *acceptable*. Most of these felt that researchers have a moral duty to report discrepancies directly to patients to ensure patients have the ability to act:

> They are giving you a head's up. It may not be anything. It may be something very important. But now you have the information.

> Now you can follow up on it and see if there's anything. [CC_FG4_P8]

> I think it's their moral or ethical obligation to do something … this person is going to be hurting. This person slipped through the cracks. You need to call them. You need to notify them. You need to send them a note. [MU_FG2_P4]

Of primary concern to many of these participants was that the patient receive the information, regardless of who delivered it: "As long as the patient somehow gets the information they need for help, then that's acceptable." [DC_FG2_P2]

Most Appropriate Approach

Three-fourths (76%) of all participants felt *physician notification* was the most appropriate course of action in response to Vignette 1 (Table 4). Among the remainder, roughly similar proportions identified patient notification (14%) and doing nothing (10%) as most appropriate. Overall, these proportions differed significantly by study site, with participants in rural counties more likely than others to choose patient notification as most appropriate and none choosing inaction.

Participants who favored physician notification most often pointed to trust, enhanced communication, and an established patient-physician relationship as key factors, believing patients would be more receptive to information communicated by their own physicians who are better equipped than researchers to convey it in a clear and meaningful way. Others added that the approach maintained clear researcher and physician roles, thereby reducing distrust and tension. As one person put it, "I just think that when [a researcher] contacts the patient, that's kinda like overstepping the physician … No doctor wants anyone calling his patients telling them something and then they go into his office telling him something somebody else done told them over the phone." [QC_FG3_P1]

Participants who favored notifying patients directly cited the value of the information, the patient's right to know, physician burden and time constraints, and the timeliness of action as key factors. Those who felt doing nothing was most appropriate cited the burden of action on researchers and the research enterprise, the unreliability of notification systems, and the belief that acting on information would erode trust among stakeholders.

Vignette 2: Researcher discovery of contraindicated medications

In response to Vignette 2, nearly three-fourths (72%) of participants said it was important for researchers to take some sort of action if they discovered that a patient might be taking medications that could adversely interact (Table 4). Compared to Vignette 1, there was little change in overall proportions of participants who found physician notification and patient notification *acceptable* (Supplementary Appendices S1 and S2, respectively). A large majority of participants (74%) again chose physician notification as the *most appropriate* approach (Table 4). As with Vignette 1, participants in rural counties were more likely than others to choose patient notification as most appropriate and none chose inaction.

Overall, compared to Vignette 1, opinions shifted slightly toward patient notification. The largest proportion of discordant responses was among participants who indicated physician notification was the most appropriate course of action in Vignette 1, but patient notification was most appropriate in Vignette 2 (Supplementary Appendix S3). These individuals often felt that the second scenario was far more time sensitive; in a life-threatening situation, it was best for the researcher to directly contact the patient, who could immediately follow-up with a physician. Otherwise, they worried, physicians may not respond to the issue quickly enough:

> You can notify the doctor, but the doctor might not take it as serious because it coming from a researcher. But they'll take they time about doing something about it. But then sometime they might not never get to it. And then it could be it got worse. [QC_FG3_P5]

Some participants felt more comfortable receiving the information directly from researchers because they believed that only physician error could account for someone taking contraindicated medications.

Others felt Vignette 2 was the only scenario presented in which there was a definite issue that required immediate resolution. As one explained:

> [In Vignette 1] they *may* have diabetes. And so that's not necessarily a serious condition, 'cause … there's things that you can do to keep your blood sugar in check. But when you have two medications that're being taken that can cause serious problems, I just thought it was a higher risk. [CC_FG4_P6]

A smaller proportion of discordant responses was among participants who indicated patient notification was the most appropriate course of action in Vignette 1, but physician notification was the most appropriate in Vignette 2 (Supplementary Appendix S3). Most of these viewed Vignette 2 as less urgent than Vignette 1, reasoning that if there really were a serious problem with medication, the patient would have already reported the resulting symptoms to the doctor. A few participants also noted that there are cases in which people simply do not fill prescriptions, which might explain the apparent contraindication:

> Just because someone's prescribed something doesn't necessarily mean they're taking it … I know doctors prescribe all kinds of crap to all kinds of people, and they don't take half of it. So, I mean, this may be something that you flag and it seems important, when in reality, the person may or may not take this medication. [MC_FGD3_04]

Finally, a small proportion of discordant responses was among participants who felt it was most appropriate to do nothing in Vignette 1, but to notify the provider in Vignette 2 (Supplementary Appendix S3). These participants typically pointed to the potential severity of the drug interaction threat and need to take immediate action.

Vignette 3: Researcher discovery of future health risk

In response to Vignette 3, only about one-third (30%) of participants said it was important for researchers to take action if they discovered a patient was at high risk for developing Type 2 diabetes and interventions were available to reduce that risk (Table 4). This finding varied by study site, with those in rural counties more likely than others to say taking action was important.

Compared to Vignettes 1 and 2, smaller proportions of participants found physician notification and patient notification *acceptable* (Supplementary Appendices S1 and S2, respectively). Regarding the *most appropriate* approach, opinions shifted notably toward doing nothing (Supplementary Appendix S3). In general, participants were concerned that if researchers contacted physicians or patients every time they identified a patient at risk for developing a future disease, it would significantly interfere with researchers' ability to conduct research and physicians' ability to treat patients, since they

might spend considerable time notifying "half the population" of health risks. After describing the risk factors in Vignette 3 (eg, overweight, older age, high blood pressure), exchanges such as the following often commenced:

> MU_FG1_P4: That's true of half the population.
>
> MU_FG1_P9: I was gonna say — that's everyone I work with.
>
> MU_FG1_P1: Go walk in Walmart; that's everybody in there.
>
> MU_FG1_P5: Only thing right now you got is older and overweight and high blood pressure.
>
> MU_FG1_P5: Well, that's me all around right there.

Most participants did not think it was a researcher's responsibility to notify patients at risk of developing conditions in the future, especially for diseases such as diabetes and heart disease for which risk factors were perceived to be well known. One person commented, "To me, [these risk factors are] stuff we read in the paper every single day" [DC_FG2_P4]. Others believed doctors already notify patients of risk factors: "I think it's a waste of researchers' time. If you've got a good doctor, that doctor is gonna follow up and keep a close watch on you." [MC_FG2_P3]

DISCUSSION

Contacting patients to offer information resulting from research has been the subject of substantial scholarship in other contexts, including genomic research in particular. Because genetic testing is not yet commonplace, many participants are likely unaware of their genetic risk for future disease. Thus, extensive ongoing debate centers on researchers' obligations to offer genetic results, participants' right to information about themselves vs. their right not to know unwanted information, and the medical actionability of the results.[14] Current best practice guidelines point to the critical role of informed consent and IRB oversight, careful decisions about which results will be offered, and the allocation of research resources to support an ethical process of return.[15–18]

In contrast, contact with patients based on the results of EHR phenotyping is a novel area that has received little attention. In this context, researchers use existing data generated in the course of clinical care. Thus, primary concerns are patients' lack of consent or even awareness that their clinical records are used for research, and their reactions to learning of a potentially substantive inconsistency in those records. The assessments of EHR-based diabetes phenotypes by Richesson[4] and Spratt[5] preview the nature and magnitude of the challenge researchers could increasingly confront when using EHRs for cohort identification.

In our focus groups, we found that many patients believed it was important for researchers to take action if they discovered information suggesting a serious current health concern, such as an undiagnosed condition or contraindicated medications. Relaying the information through patients' physicians was considered the most appropriate course of action by a substantial majority, primarily because of the trust and established relationship patients have with their providers, as well as recognition of provider vs. researcher roles and responsibilities. With regard to discovery of information suggesting a future health risk, however, there was a substantial shift toward the opinion that it was less important for researchers to take action. Prominent concerns were burdening researchers with a task outside their realm of obligation, and distracting busy providers — particularly given that health risk factors were likely already known.

Across all vignettes, we found significant differences by urban vs. rural location. Compared to their urban counterparts, a greater proportion of rural participants indicated that it was important for researchers to take action and that notifying patients directly was the most appropriate action. These differences may reflect the severely limited availability of healthcare providers and facilities in these locations, as well as broader socioeconomic and geographic constraints that limit access, such as long distances to clinics and lack of transportation. These factors may lead patients to view research — if it is being conducted at all — as a source of information that could be important for their immediate care. Informally, we often heard sentiments that people were glad we were conducting even focus group research in their community because they need "all the help we can get." It is possible, seen with this lens, that any effort to communicate health information may be perceived as worthwhile.

The scope and limits of researchers' moral obligations to provide ancillary care (care that is not necessary to complete the study) in resource-constrained areas has been the subject of scholarly analysis.[19–22] Researchers should consider the possibility of any such obligations when planning their studies, including the time and expertise needed to adjudicate potentially serious discrepancies and the process by which important information could be ethically communicated.

Strengths of our study included diverse study locations; our concerted efforts to enable participants to develop informed opinions about a complex topic; and asking participants not about personal preferences, but about the acceptability and most appropriate actions, after considering competing advantages and disadvantages of various approaches from multiple viewpoints. Moreover, we gathered data in often-overlooked rural areas, where individuals may have different access to, and perceptions of, healthcare and research.

Although our study involved four diverse locations, our findings are primarily qualitative in nature and geographically limited to the southeastern United States. Future research should examine whether, and to what extent, opinions differ in other regions or populations.

Despite our best efforts to enable participants to provide informed opinions, our findings reflect some knowledge-based limitations (eg, beliefs that the side effects of taking contraindicated medications would already be evident). Even though participants occasionally made erroneous assumptions, these are nevertheless valuable to understand because they inform patients' real-life expectations concerning acceptable and appropriate action.

Although patients are a crucial source of input, they are only one of many stakeholder groups whose feedback is essential to the development of sound policy. Future studies should examine how others, such as researchers, physicians, and ethics experts, view these same issues.

Our study used hypothetical scenarios to elicit input on a rapidly emerging issue; additional research will be needed to assess the outcomes of alternative policies in actual practice. Further, our hypothetical scenarios were premised on a minimal risk study of a behavioral intervention in Type 2 diabetes. Future studies should focus on elucidating key stakeholders' views on additional kinds of research facilitated by next-generation phenotyping of EHRs.[2,23,24] EHRs could also be used for non-research purposes similarly in need of empirical study of stakeholder perspectives. For example, healthcare organizations themselves could theoretically take an automated approach to identifying discrepancies and risk factors in EHRs, leading to the need for ethical approaches to determining if, when, and how to communicate this information to patients.

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CONTRIBUTORS

Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work: KMB, SES, LMB.

Drafting the work or revising it critically for important intellectual content: KMB, SES, LMB.

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SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* online.

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