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EHR phenotyping for research recruitment: Researcher, IRB, and physician perspectives on approaches to contacting patients

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ABSTRACT

Introduction: Failure to achieve accrual goals is a common problem in health-related research. Electronic health records represent a promising resource, offering the ability to identify a precisely defined cohort of patients who meet inclusion/exclusion criteria. However, challenges associated with the recruitment process remain and institutional policies vary. *Methods:* We interviewed researchers, institutional review board chairs, and primary care physicians in North Carolina and Tennessee. Questions focused on strategies for initiating contact with potentially eligible patients, as well as recruitment letters asking recipients to opt in versus opt out of further communication. *Results:* When we asked about initiating contact with prospective participants, qualitative themes included trust, credibility, and established relationships; research efficiency and validity; privacy and autonomy; the intersection between research and clinical care; and disruption to physician–researcher and physician–patient relationships. All interviewees said it was acceptable for researchers to contact patients through their physicians; most said it was acceptable for researchers to contact patients directly. Over half chose contact through physicians as more appropriate. Regarding recruitment letters, qualitative themes included the quality of the participant pool; privacy and control; research efficiency and representativeness; and patients' opportunity to make their own decisions. All interviewees said asking recipients to opt in to further communication was acceptable; nearly all said opt out was acceptable. Similar proportions chose each approach as more appropriate. *Conclusions:* Comparing these results to our previous research with patients reveals potential differences in stakeholder perspectives. We offer suggestions for developing balanced approaches that respect patients and facilitate the advancement of science.

Introduction

Failure to achieve accrual goals is a common and costly problem in much health-related research, the success of which depends on achieving robust participation rates among eligible individuals [1–3]. The widespread adoption and use of electronic health records (EHRs) represent a promising resource, offering the ability to rapidly identify a precisely defined cohort of patients who meet inclusion/exclusion criteria [1,4–8]. There are concerns, however, about researcher access to patients' personal information prior to consent, and institutional policies governing contact with potentially eligible patients about their interest in research participation vary [2,9–12]. For example, researchers could initiate contact with prospective participants either directly or through their physicians, asking for either an opt-in or opt-out response regarding further recruitment communication. Each of these strategies entails both ethical and practical challenges [13,14], and stakeholder perspectives are essential to developing balanced approaches that respect patients as well as facilitate the advancement of scientific knowledge.

We previously asked patients about these issues in mixed methods research conducted in diverse regions of the southeastern US [15]. Nearly all said it would be acceptable for researchers to contact patients directly and three-fourths said it would be acceptable for researchers to contact patients through their physicians. When asked which would be more appropriate, a substantial majority chose direct contact. Cross-cutting qualitative themes included trust and transparency, decision-making power, and the effects on research and patient care. Regarding response expectations, the vast majority said opt-in and opt-out would both be acceptable, typically finding neither especially problematic.

Here, we report the perspectives of other key stakeholders – researchers, institutional review board (IRB) chairs, and primary care physicians – gathered through in-depth interviews conducted in North Carolina and Tennessee.

Table 1. *Hypothetical study*[a]

Researchers want to determine the effect of daily, standardized telephone calls by a health educator on metabolic control and treatment compliance among adult patients with type 2 diabetes. They design an IRB-approved, 6-month randomized controlled trial of 100 adults with type 2 diabetes. Subjects will be randomly assigned to 6 months of standard diabetes management or standard management plus a daily telephone call that provides information about diabetes care. HbA1c, compliance with glucose monitoring, and quality of life measures will be assessed at baseline, at 3 and 6 months, and 6 months after the conclusion of the intervention. To identify patients with type 2 diabetes who may be eligible to participate, researchers plan to extract information on diagnostic codes, lab results, and medications from electronic health records (EHRs) at their healthcare institution.

Recruitment scenario

Let's say the researchers have reviewed all of the EHR data and have limited their list to people who have type 2 diabetes and are eligible to participate in the telephone study. They plan to send a recruitment letter to these patients; there will be an informed consent process for the study, so that people who are invited to participate can learn about the study and then decide whether they want to participate or not.

a. Initial contact: There are two general ways that researchers could reach out to patients to invite them to participate in the study.
   - *Through physicians*: One way would be to contact patients' physicians and ask them to let their patients know about the study (e.g., send the invitation letter, signed by the physician, on the physician's letterhead). Under this approach, it would be up to the physician to decide whether to let patients know about the study and, if so, which patients.
   - *Direct contact*: The other way is to contact patients directly (e.g., send a letter from themselves directly to patients)
b. Response requested: Now, let's set aside the question of whether the recruitment letter comes from the researchers or the physician and focus on the letter itself. After describing a little bit about the study, there are two different things the letter could say:
   - *Opt-in*: One thing the letter could say is "If you would like to learn more about this study, please call the research team at 1-800-555-1212." In other words, the patient would need to take the step of calling if he or she wanted to find out more about the study – otherwise, researchers would not contact that person further.
   - *Opt-out*: The other thing the letter could say is "Someone from the research team will give you a call next week to see if you would like to learn more about this study. If you would rather not hear more, please call 1-800-555-1212 to let the research team know you'd like to be taken off the list." In other words, the patient would need to take the step of calling only if he or she wanted no further contact – otherwise, researchers would call to see if that person wanted to find out more about the study.

[a]**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**(1): 32–40.

Materials and Methods

Participants

We conducted qualitative interviews in North Carolina and Tennessee with members of three stakeholder groups likely to have diverse perspectives and experiences with respect to research recruitment, including:

- *Primary care providers (PCPs)* affiliated with academic medical centers, private healthcare networks, and stand-alone clinics;
- *IRB chairs* at academic medical centers;
- *Researchers* at academic medical centers whose work focuses on diabetes-related studies involving human subjects.

For each group, we compiled lists via online searches and then used purposive sampling to maximize demographic and institutional diversity. Our goal was to interview at least six individuals per group, the minimum expected to reach saturation [16].

Instrument Development

We adapted our semi-structured interview guide (available upon request) from the focus group guide we used to explore patient reactions to several scenarios that may arise during the conduct of a hypothetical diabetes study in which researchers use EHRs to identify prospective participants [15,17]. Here, we report findings from interview questions we asked about research recruitment (Table 1).

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

Data Collection

Interviews were conducted by telephone between November 2017 and April 2018. At the beginning of each interview, we reviewed a study information sheet and obtained the individual's verbal agreement to participate and for audio recording. Interviews lasted an average of 45 minutes and participants were offered $100 compensation for their time.

Data Analysis

Interviews were professionally transcribed and coded in Excel and NVivo 12 using standard iterative processes [18,19]. Specifically, we developed an initial codebook based on the interview guide and a review of five transcripts. Two experienced research team members independently applied the codes to eight transcripts. The coders then compared code applications, resolved conflicts, and made additional revisions to code definitions before each coded approximately half of the remaining transcripts.

Narrative segments presented here (along with participant IDs) are exemplary of frequently mentioned ideas; see Supplemental Material for additional examples.

Results

Participant Characteristics

We interviewed 41 participants representing a range of perspectives and demographic diversity (Table 2).

Initial Contact with Prospective Participants

We began by asking interviewees to discuss the advantages and disadvantages of two ways researchers could reach out to patients – identified as potentially eligible through review of EHR data – to invite them to participate in the hypothetical diabetes study (Table 1): (1) contact patients' physicians and ask them to let their patients know about the study or (2) contact patients directly.

Through Physicians

Interviewees saw advantages for both researchers and patients in initial recruitment contact occurring through prospective participants' physicians. For researchers, interviewees suggested

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Table 2. *Participant characteristics* (n = *41*)

	n	%
Primary role*		
IRB chair	7	17
Primary care provider	17	41
Researcher	17	41
Gender		
Men	21	51
Women	20	49
Race~		
Black or African American	3	7
White	33	80
Asian	7	17
Others	2	5
State		
Tennessee	19	46
North Carolina	22	54

*Because many held more than one role (e.g., researchers and IRB chairs who were also clinicians), we asked participants to self-report their primary role and maintain that perspective throughout the interview.
~Participants could choose >1.

physicians could help increase the size and quality of the participant pool. For example, physicians might serve as an authoritative advocate for the study: "You get the credibility of the physician" (02, PCP) and "many patients trust their physicians a lot, so sometimes, if things are endorsed by their physicians, they may be more likely to consider it" (40, Researcher). Physicians could even champion the study, either directly . . .

> The physician could be a great advocate, and could say, "Hey, this is a great study, this would be great." (17, PCP)

. . . or indirectly, simply by their involvement in the recruitment process:

> If the patient is receiving this notification from the PCP, I think they're more likely to say, "Oh yeah. My doctor wants me to do this. This is something worthwhile and important." There's a higher percentage of patients who will agree to participate in the study under that model. (06, Researcher)

More generally, interviewees said patients might be more receptive and attentive to information from a known source:

> If the patient receives something from someone they know, they're more likely to look at it and consider it . . . It certainly would be better for your recruitment [and] probably more comfortable for the patient. (21, Researcher)

Physicians could also help "identify the right kinds of patients for the trial" (39, Researcher), based on their knowledge of patients' lives and health conditions. This could include knowledge beyond eligibility criteria – although these insights may not always lead to accurate assumptions about patients' interest in research participation:

> The physician knows the patient. I just know what's going on in people's lives. I know, "This is a patient that could do this study and maybe get compensated a few extra bucks." That might be really helpful to them. Or alternatively, "This is a patient whose daughter is in the hospital with cancer right now. She doesn't really need to hear about a research study." I think you just sort of know what's going on in people's lives and probably how receptive they'd be to research. I guess that has its own complications, too, in that you make assumptions that people would be receptive [or not] based on what's going on in their lives . . . and certainly there's a possibility that those assumptions would be wrong. (34, PCP)

For patients, interviewees described established relationships and trust as a primary advantage of initial contact through physicians: "It does feel most respectful that way – nobody wants a cold call sale regarding their health" (27, PCP). In particular, hearing about a research opportunity through a trusted source might reduce patients' concerns about privacy and who has access to their information:

> When a patient gets a letter like that it feels more personal, they would probably be less concerned about their privacy being violated, their medical records being reviewed by people that they don't know. (04, Researcher)

As some interviewees commented, however, researchers might be able to gain similar benefits by clearly explaining how they came to have patient information or making a direct connection to a source known to the patient:

> A letter would at least need to say, "We are working with your physician and he or she has agreed for us to contact you." . . . I think that would make the patient more responsive, maybe not toss a letter thinking it's junk mail or whatever but actually make them feel more comfortable receiving that information. (24, IRB)

A few interviewees saw advantages for patients' healthcare, noting that involving physicians in the recruitment process – or ensuring that physicians are at least aware of research participation – would enable them to "take that into consideration when doing the patient's care" (36, PCP).

Interviewees also identified disadvantages associated with initial contact occurring through prospective participants' physicians. For researchers, interviewees commonly anticipated that involving physicians would produce a bottleneck. Research recruitment may be a burdensome task with which busy physicians have little time to assist:

> My gosh, I don't have time to do my regular job, I certainly don't have time to recruit for a research study. I'm working 60 or 70 hours every week trying to just stay afloat with all the stuff I have to do as a primary care doc in general, so adding recruiting for somebody else's study to that list is probably not a very viable option for me. (34, PCP)

In particular, physicians may not have time to be involved in a meaningful way:

> Oftentimes, if the information comes from the primary care provider, that provider probably has a very limited understanding of what the research even involves, in my experience. They've probably heard about it, they've either agreed to send out a letter or someone is sending it out on their behalf, and so it's like they're involved in name only and not necessarily involved with the trial itself or deciding whether or not their patient is a candidate in a really meaningful way. (04, Researcher)

Further, physicians may have little incentive to assist unless they are directly involved in the research . . .

> The physician isn't doing the research, isn't involved with the research, and many times these days, doesn't want anything to do with this. They're busy. They have other patients to see. They are not a member of the research team. They're not getting any credit for it. They're not getting any money for it, and really don't want to have their time taken up with being a recruitment tool for the researchers. (01, IRB)

. . . or see direct relevance to patient care:

> I [recruit patients] in cases where I feel like the research is very pertinent and would result in significant benefits, and the question that is being asked is of interest to me. But in some cases, I do turn it down if I feel like the hour spent trying to recruit patients wouldn't lead to significant gain and knowledge that primary care practices can use. (18, PCP)

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Table 3. *Responses to recruitment vignette*

	Total (n = 41)		IRB (n = 7)		Provider (n = 17)		Researcher (n = 17)	
	n	%	*n*	%	*n*	%	*n*	%
Initial contact								
Through physician: acceptable = yes	41	100	7	100	17	100	17	100
Direct contact: acceptable = yes	27	66	3	43	12	71	12	71
More appropriate approach:								
Through physician	24	59	4	57	10	59	10	59
Direct contact	15	37	3	43	5	29	7	41
Depends	2	5	0	0	2	12	0	0
Response requested								
Opt in: acceptable = yes	41	100	7	100	17	100	17	100
Opt out: acceptable = yes	37	90	5	71	16	94	16	94
More appropriate approach:								
Opt in	14	34	4	57	8	47	2	12
Opt out	16	39	1	14	7	41	8	47
Depends	8	20	2	29	2	12	4	24
Both appropriate	3	7	0	0	0	0	3	18

As a result, interviewees predicted that physician involvement could lead to nontrivial recruitment challenges. These included the prospect of slower and/or biased accrual:

> If you have to go through the provider . . . it's one more step that another person has to get involved, another person has to look through and say yes or no, that person may be busy or tied up and so they don't get back to you for a couple of weeks, and then you're delayed in being able to reach out to patients, which means maybe you don't get the full quota of patients that you were hoping to by a certain date. (17, PCP)

> If physicians are doing the referrals that may skew the population. That's no longer representative of the general populous. They may only refer patients they think will do well with the study or something like that. So it leads to more of a selective population. (06, Researcher)

For patients, interviewees emphasized decreased autonomy if patients never hear about the research opportunity because they are either excluded by their physician . . .

> You go through the physician and . . . it's almost setting up [a] paternalistic dynamic whereby the physician could potentially screen and filter and make decisions on behalf of the individual. (10, IRB)

. . . or unduly influenced by their physician:

> It may suggest some sort of coercion—that people would feel obligated to participate. "Well, if I don't do that, then maybe I'll get not as good care as otherwise." It has to be very clearly stated that this is not affecting your care in the normal clinical setting, this is something extra. (31, Researcher)

Direct Contact

When asked about researchers contacting prospective participants directly, interviewees highlighted efficiency as an advantage for researchers, that is, that recruitment would be "more likely to be successful" (06, Researcher), "more expedient" (21, Researcher), and "more timely" (36, PCP). In particular, interviewees expected that by not actively involving physicians, "skipping them as a middleman" (14, PCP), researchers would have more control over the process:

> You would have more control over the patient list. You wouldn't have to rely on if one set of physicians did or did not inform them of the study. (11, Researcher)

Further, researchers undertaking recruitment activities themselves align directly with their time and incentives:

> There's a strong incentive for the research team to meet recruitment [goals], so that motivation is there—that they would be more actively screening and recruiting patients and sending a letter directly to the patient . . . It is a direct and efficient way of meeting those recruitment goals. (03, IRB)

For patients, interviewees pointed to increased autonomy as an advantage of direct contact. Patients could choose whether to learn more about the study "directly from the people who can describe the research, explain what it's about, the people who are actually conducting the study" (01, IRB) and make their own participation decisions . . .

> It's the ultimate respect for persons in terms of putting the decision-making directly in the hands of that individual. (10, IRB)

. . . without being unduly influenced by their physician:

> It allows the patient to truly make the decision if they want to be engaged in the study. I take care of mostly older adults, and . . . even when I try really hard not to guide them, if I were to bring up the study they would be more inclined to do it because they think it will make me happy, than potentially if they were just left to make the decision on their own. (20, PCP)

Interviewees described contact by an unknown source as the primary disadvantage of direct contact. For researchers, they expected this would lead to recruitment challenges because patients "don't know you from Adam" (40, Researcher):

> You'll lose some by people not recognizing who you are and not interested in dealing with a third party. (11, Researcher)

Specifically, the lack of an established relationship or connection to a trusted entity could be a barrier:

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> Unless you have the physician's or the practice's name on there, it might have gotten tossed in the trash with the Bed, Bath and Beyond coupons, because they don't know who you are or trust you. (02, PCP)

Interviewees also mentioned that direct contact could disrupt physician–researcher relationships. They noted physicians "... who are really uncomfortable with the research community reaching out to their patients without their knowledge and consent" (23, PCP) or even basic awareness:

> It's really nice to at least know somebody's going to be engaged in a study. My patients are often eager to tell me that they'll be participating, or that they'll be meeting somebody after our visit to talk to them about the study, so it's nice to have a better understanding ... so that they're not like, "you don't know about this?" Sometimes that's really distressing if I'm not aware. I don't need to know every detail, but I do like to know that they're going to be involved in something. (20, PCP)

They suggested "cutting out a physician entirely can lead to some bad feelings" (14, PCP), including that their patients are being poached:

> There is sometimes bad blood between the research groups and the primary care providers, because in some cases, the providers are concerned that you're taking their patients, or poaching their patients... Providers see it as losing control of their patients, and because of that, it could put stress ... on your relationship with colleagues. (08, Researcher)

For patients, interviewees commonly cited privacy concerns as a disadvantage of direct contact. They expected patients might question how researchers got their information ...

> Sometimes if the patient doesn't know who you are, that can throw them off... Even if it's all IRB-approved, but they don't understand those things. "How did you get my name? Why are you calling me? How do you know my labs?" All that kind of thing. (08, Researcher)

... and feel that their privacy has been violated:

> Subjects are hearing from somebody who they don't know, who they're wondering why they have access to their medical information, so they may end up feeling like their privacy has been invaded. (01, IRB)

Interviewees also pointed out the potential for direct contact to erode physician–patient relationships:

> If you were the person being contacted, you might be offended that somebody you were never in their office before or it was an institution three states away was recruiting you into something, and then you might be mad at your physician for allowing that information to be shared. (11, Researcher)

Acceptable and More Appropriate Approaches to Initial Contact

After discussing the advantages and disadvantages, we asked about the acceptability of the two basic ways researchers could reach out to potentially eligible patients to invite their participation in the hypothetical study. All interviewees said it would be acceptable for researchers to contact patients through their physicians (Table 3). Two-thirds said it would be acceptable for researchers to contact patients directly – although a smaller proportion of IRB chairs said this was acceptable compared to PCPs and researchers.

When asked which of the two approaches was more appropriate, over half of interviewees chose contact through physicians (Table 3). Direct contact was chosen as more appropriate by similar proportions of IRB chairs and researchers but a smaller proportion of PCPs.

Response Requested from Prospective Participants

We next asked interviewees to discuss the advantages and disadvantages of two responses that could be requested in a recruitment letter (Table 1): Recipients could be asked to take action (e.g., call the study line, return a postcard) to (1) opt in to learning more about the study or (2) opt out of learning more about the study.

Opt In

For researchers, interviewees highlighted a motivated participant pool as the primary advantage of using an opt-in approach:

> If a patient is willing to take that step and ... make a phone call because they're interested, those are going to be the ones who are going to follow through with the research study. They're going to be the more engaged. They're going to be more involved. They're going to show up on time. They're going to do all the things you ask them to do if they opt in. (41, PCP)

For patients, interviewees cited respect for privacy as the main advantage of opt-in:

> If you assume somebody out there doesn't want anybody contacting them, then you are respecting them, because if they get this and they want to throw it away and never talk about it, that's fine. That is probably the highest bar of respecting the patient's privacy. (22, IRB)

In these discussions, patients having control over any future contact was a prominent aspect:

> The patient is totally in control of whether or not there's any future contact... If the patient doesn't want to be bothered again, they just throw the letter away and that's it, they're never bothered again. (29, Researcher)

Interviewees identified research inefficiencies as the major disadvantage of using an opt-in approach. They anticipated researchers would have to spend significant time ("It's so very difficult to get people to opt in, particularly within a given timeframe" (04, Researcher)) and money ("So few people are going to actually call you that it's expensive for what you get back" (08, Researcher)). Even then:

> It might be acceptable from an ethical standpoint, but from a scientific standpoint, it falls short because you're not going to get half the people that you need to do the study. (01, IRB)

Opt Out

For researchers, research efficiency was seen as the primary advantage of opt-out: "You're likely to be able to recruit larger number of patients in a shorter amount of time" (06, Researcher). Interviewees particularly underscored the opportunity to achieve a more representative and diverse sample: "I suspect that you'd get a wider swath of the folks that you're reaching out to be involved" (19, PCP).

More generally, they highlighted the advantage of researchers being able to contact patients who might be interested but otherwise missed:

> If you have the opt-out option, that should eliminate that, "Oh, I was meaning to call. I just never got around to it."... You'll get the potential to recruit more folks. (12, PCP)

> The major advantage is that you know that you have contacted somebody. That's the big issue is that you don't have to worry did the letter get lost in the mail, did it get thrown out thinking it was junk mail, did coffee spill on it, did the dog chew it up, is the address accurate? ... As a researcher, you'd hate to think that maybe only 80% of the letters you send out actually get into the person's hands. You'd like to think that everybody you're attempting to reach at least has an opportunity to do it. (22, IRB)

Interviewees also saw not missing out as a potential advantage of opt-out for patients:

> There's [patients] that may be interested but maybe haven't looked at their mail. It would bring that to the surface for them. (24, IRB)

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They noted that patients who are not interested can simply turn down further contact:

> They can always decline when someone [calls]. If they wanted to proactively decline, they have that option. (12, PCP)

But for patients who might be interested, being contacted by the researcher provides an opportunity to learn more about the study and make an informed decision to participate or not:

> Having someone reach out to them might recruit people that could be great candidates—they just didn't understand enough from the two-sentence thing they saw or ... they weren't gonna take that extra step to find out that extra information. (17, PCP)

When asked about disadvantages, interviewees talked about the need for researchers to expend resources making many phone calls (to all who did not opt out), with perhaps a low rate of return because people tend not to answer calls from an unknown number: "[Patients] are going to assume they're some type of telemarketer and probably get your number blocked" (41, PCP). Some anticipated that opt-out would result in a less motivated participant pool: "You'll end up with a population that's probably less intrinsically motivated to really engage with the study" (06, Researcher).

For patients, interviewees commonly identified privacy as the main disadvantage of opt-out:

> There's probably some folks who are gonna view an automatic phone call as an intrusion, an interruption. Somebody is kind of stepping into their business and they'd rather just as soon not have them in their business. (19, PCP)

> There're going to be people out there who aren't going to like to be contacted... You could have somebody who's offended because they think, "Why are you looking at my record without my permission?" ... You might also have somebody who says, "I don't like these people calling me up out of the blue." (22, IRB)

Interviewees also noted the burden for uninterested patients of having to take action to opt out of further contact:

> If I had to call someone to say, "Don't call me," that would ... I hate to say it, tick me off. Because I'm like, "I already don't want to talk to them, and then I have to call them to tell them I don't wanna talk to them?" (17, PCP)

Finally, interviewees suggested some patients might feel pressured because "It's harder to turn down a phone call than it is a letter" (29, Researcher):

> Some patients may not want the additional solicitation but may or may not feel empowered to say that they really don't want to learn more about the study. (32, Researcher)

Acceptable and More Appropriate Approaches to Response Requested

After discussing the advantages and disadvantages, all interviewees said it was acceptable for recruitment letters to ask patients to opt in to learning more about the hypothetical study (Table 3). Nearly, all said an opt-out approach was acceptable – although a smaller proportion of IRB chairs found it acceptable compared to PCPs and researchers.

When asked which of the approaches was more appropriate (Table 3), similar proportions chose opt-in and opt-out. However, opt-in was chosen as more appropriate by a smaller proportion of researchers compared to the other two stakeholder groups, and opt-out was chosen as more appropriate by a smaller proportion of IRB chairs.

Discussion

EHR phenotyping – the application of algorithms to electronic data to classify patients based on an exact constellation of health-related criteria – provides an efficient means to identify a precisely defined group of prospective research participants [20–23]. Even so, stakeholders must still contend with the challenges associated with the recruitment process.

In this interview study, we asked researchers, IRB chairs, and physicians about two ways researchers could make initial recruitment contact with prospective participants: through patients' physicians or direct communication from researcher to patient. Broad themes emerged around trust, credibility, and established relationships with entities known to patients; research efficiency and validity; privacy and autonomy; the intersection between research and clinical care; and potential disruption to physician–researcher and physician–patient relationships. Further, the advantages and disadvantages of one approach were largely the inverse of the other, underscoring the trade-offs involved: initiating contact through patients' physicians reduces privacy concerns but also decreases patient autonomy and research efficiency, while researchers contacting patients directly raises privacy concerns but also increases autonomy and efficiency.

In our previously reported research [15], we explored patient perspectives on initial recruitment contact and similar qualitative themes emerged (see Introduction) – but patients seemed to weigh the trade-offs differently compared to the professional stakeholder groups in the present study. Most participants in both studies found both approaches to initial contact acceptable; however, 100% of professionals said contact through physicians was acceptable compared to 75% of patients, and 66% of professionals said direct contact was acceptable compared to 95% of patients. When asked which was more appropriate, a majority (59%) of professionals chose contact through physicians, while a large majority (70%) of patients chose direct contact.

When we queried researchers, IRB chairs, and physicians about recipients of recruitment letters being asked to opt in versus opt out of further communication, broad themes revolved around the quality of the participant pool; privacy and control; research efficiency and representativeness; and patients' opportunity to hear about research and make their own decisions. Again, the advantages and disadvantages of one approach were largely the inverse of the other: Asking patients to opt in to further communication may demonstrate respect for privacy and could result in a more motivated study sample but at the cost of research efficiency, while asking patients to opt out may be more burdensome and intrusive but ensures contact with patients who might otherwise be missed and promotes a larger and more diverse study sample.

When we explored patient perspectives on the response requested in recruitment letters [15], similar qualitative themes emerged, including research efficiency, convenience, control, intentionality, and intrusiveness. In this earlier study as well as the present one, nearly all participants found both opt-in and opt-out acceptable. Opt-in was acceptable to 100% and 94% of professionals and patients, respectively, and opt-out was acceptable to 90% and 83% of professionals and patients, respectively. Both afford patients the opportunity to make their own decisions and to avoid or ignore further contact (42).

To resolve potential differences in perspectives reported here among professional stakeholder groups (physicians less often favored initial direct contact between researchers and patients, researchers less often favored opt-in approaches, and IRBs less

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often favored opt-out approaches) and between professionals and patients, we concur with McHugh and colleagues [9] that, "In light of how healthcare delivery has evolved toward providing more collaborative, patient-centered, and data-driven care, individual IRBs and institutions must reconsider existing policies so that recruitment can similarly evolve" (p.384). Steps toward a patient-centered approach – one that addresses stakeholder concerns about privacy and research quality while also promoting fair access to research and decisional autonomy – could include [15]:

- Increasing trust and transparency through concentrated efforts to raise patient and public awareness about research use of EHRs, including applicable human research protections;
- Developing flexible policies that tailor physician involvement (ranging from no role to passive notification to active approval) based on the nature of the risks associated with the research; and
- Conducting empirical research to optimize recruitment materials with the goal of effectively informing patients' first crucial decision to opt in or out of further communication.

A strength of our interview design was asking participants about acceptable as well as most appropriate actions, after considering advantages and disadvantages of competing strategies from multiple viewpoints. However, interpretation of our findings is subject to some limitations. As a qualitative study, our goal was to elucidate a range of perspectives. Rather than statistical power, nonprobabilistic sampling was guided by the concept of "saturation," the point at which no new information or themes are observed in the data [16]. We provide some quantitative data, captured by closed-ended interview questions; however, these proportions should be viewed only as an indicator of how commonly themes and responses were expressed among our participants. Further research, designed to identify any statistically significant differences in larger and more diverse samples, may shed additional light. Finally, our study used a hypothetical scenario premised on a minimal risk study of a behavioral intervention for type 2 diabetes. Future research is needed to examine stakeholder views on recruitment for other types of research – such as studies that involve higher risk (e.g., a medication intervention) or information potentially considered even more sensitive (e.g., genomic information) [21,24] – and to assess the outcomes of alternative policies in actual practice.

Supplementary Material. To view supplementary material for this article, please visit https://doi.org/10.1017/cts.2020.524.

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