
Brief Communication

Public attitudes toward an authorization for contact program for clinical research

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ABSTRACT

We conducted an online experimental survey to evaluate attitudes toward an authorization for contact (AFC) program allowing researchers to contact patients about studies based on electronic record review. A total of 1070 participants were randomly assigned to 1 of 3 flyers varying in design and framing. Participants were asked to select concerns about and reasons for signing up for AFC. Logistic regression and latent class analysis were conducted. The most commonly selected concerns included needing more information (43%), privacy (40%), and needing more time to think (28%). A minority were not interested in participating in research (16%) and did not want to be bothered (15%). Latent class analysis identified clusters with specific concerns about privacy, lack of interest in research, and not wanting to be bothered. A novel flyer with simple and positive framing was associated with lower odds of both not wanting to be bothered ($P = .01$) and not being interested in research ($P = .01$). Many concerns about AFC programs appear nonspecific. Addressing privacy, lack of interest in research, and not wanting to be bothered warrant further study as ways to enhance recruitment.

Key words: electronic health record, recruitment, clinical research

INTRODUCTION

Background and Significance

Electronic health record (EHR) systems offer opportunities to enhance recruitment for clinical research. After identifying eligible participants through EHRs, investigators can contact them directly, using platforms such as patient portals. However, the power of EHR-based recruitment is generally contingent on whether patients have authorized investigators to contact them directly. Various approaches exist to facilitate authorization for contact (AFC). Some institutions have adopted opt-in approaches, whereas others utilize opt-out approaches.¹⁻³ Some use separate forms for AFC, while others integrate this into consent for treatment. All of these approaches aim to support patients' ability to make a values-consistent choice to be notified directly by researchers conducting studies applicable to them.

Previous research has described willingness to authorize contact for participation in future research studies based on specific demographic characteristics.⁴⁻⁶ However, little is known about individuals' reasons for participating or concerns about signing up. Related, little is known about the effect of strategies for describing programs on these reasons and concerns. This study was designed to understand patterns of concerns and reasons for interest in AFC among the general public to inform strategies to optimize recruitment while respecting patient preferences.

Objectives

We conducted an online experimental survey to assess willingness to participate in and perceptions of an AFC program that allows researchers to directly contact eligible patients about research participation based on EHR review.

MATERIALS AND METHODS

The survey was fielded during July 2018 using the Growth from Knowledge (GfK) Knowledge Panel, an online probability-based panel representative of the U.S. population.⁷ Participants receive compensation from GfK.

Respondents were randomly assigned to receive 1 of 3 flyers describing AFC. The primary analysis focused on the impact of flyer type on willingness to participate.⁸ This secondary analysis focuses on reasons to participate and concerns about participating.

Participants were shown 1 of 3 flyers and told to imagine being presented with the flyer during a doctor's visit (Supplementary Figure 1). Flyer 1 was a detailed, neutrally valenced flyer, modeled after a flyer used at one academic center, containing information about AFC and other methods for research involvement. Flyer 2 was simpler and positively valenced, containing information in bullet form with more positive framing encouraging participation. Flyer 3 was similar in content to flyer 2 but utilized a flow chart describing steps for authorizing research contact.

Survey questions assessed comprehension of AFC, likelihood of authorizing contact, and attitudes about research participation. Participants were also asked "What, if any, would be your concerns about signing up for what's described in this flyer?" and "What, if any, reasons would you have for considering signing up for what's described in the flyer?" They were instructed to select up to 3 responses for each question; choices represent common concerns and motivations related to research participation. Participants who selected "other" or "personal benefit" were given the option to pro-

vide free-response answers. Participants who selected more than 1 concern or reason were asked to rank them in importance.

Analyses were conducted using SAS 9.4 (SAS Institute, Cary, NC) and R version 3.6.0 (R Foundation for Statistical Computing, Vienna, Austria). *P* values $\leq .05$ were considered statistically significant. All analyses were conducted using poststratification weights supplied by GfK based on Census data in order to represent the target population. Descriptive statistics (eg, counts and percentages) were used to summarize respondent characteristics across flyer types. Health literacy was categorized as "high" if the response to "How confident are you filling out medical forms by yourself?" was "somewhat," "quite a bit," or "extremely."⁹ General attitudes toward research were assessed by the item "I have a positive view about medical research in general."¹⁰ Previous experience with medical research was assessed by asking "Have you ever been part of a medical research study?"

We used multivariable logistic regression to examine associations between age, sex, race, health literacy, and flyer type and individual concerns about AFC. To further understand potentially underlying clusters (or patterns) of concerns, we performed an exploratory weighted latent class analysis (LCA) to identify subgroups who had at least 1 concern based on their maximum likelihood class membership.^{11,12} Flyer exposure was not considered as a variable in the LCA. The best model and optimal number of clusters was chosen according to the Bayesian information criterion.¹² Those expressing no concerns were treated as a separate cluster. Demographic characteristics and flyer exposure among identified LCA clusters were summarized and compared.

RESULTS

The survey was completed by 1070 of 2038 panelists (53% response). Forty-nine percent of respondents were women, and 37% were 60 years of age or older (Table 1). Participants were 71% White, and 66% had educational attainment above high school. Eighty-one percent demonstrated high health literacy, 61% had a positive view of medical research, and 15% had previously participated in medical research. Supplementary Table 1 displays characteristics by flyer group.

The most frequently selected reasons to consider authorizing research contact (Table 2) were helping others with similar conditions (48%), supporting medical research (46%), and potential for payment (38%). Almost a third (29%) of participants selected wanting to know about research being done. Fewer than 10% selected personal benefit or trust in researchers.

The most frequently selected concerns (Table 2) were need for more information (43%), concern about privacy (40%), and need for more time (28%). Seventeen percent had no concerns. Participants who selected "other" listed concerns including time and burden of participation, how their health would be affected by experimental drug side effects, concerns about who has access to health records, and a need for adequate personal benefits, including payment. The least common concern was lacking trust in researchers (9%). Supplementary Table 2 displays the frequencies of ranking each reason and concern as most important.

Flyer type was associated with different patterns of concerns (Figure 1). More participants exposed to flyer 1 (original flyer) reported not wanting to be bothered and not being interested in research participation. More participants exposed to flyer 2 (simple-positive) reported a need for more information. More participants

Table 1. Demographic characteristics of participants (N = 1070)

Age ^a	
18-29 y	177 (17)
30-44 y	237 (22)
45-59 y	262 (25)
60+ y	394 (37)
Sex ^a	
Female	527 (49)
Male	543 (51)
Race ^a	
White, non-Hispanic	758 (71)
Black, non-Hispanic	104 (10)
Hispanic	114 (11)
Other or 2 or more races, non-Hispanic	94 (9)
Income ^a	
<\$25 000	146 (14)
\$25 000 to <\$50 000	206 (19)
\$50 000 to <\$75 000	174 (16)
\$75 000 to <125 000	335 (31)
\$125 000 or more	209 (20)
Education ^a	
High school or less	361 (34)
Some college	327 (31)
Bachelor's degree or higher	382 (36)
Health literacy	
High	866 (81)
Low	200 (19)
Attitude toward research	
Negative	85 (8)
Neutral	326 (31)
Positive	649 (61)
Have you ever been a part of a medical research study?	
Yes	158 (15)
No	903 (85)

Values are n (%).

^aVariables used to create survey weights.

exposed to flyer 3 (graphics-based) reported a concern about privacy.

The optimal number of LCA clusters, among participants with concerns, was 4 (Figure 2). Class 1 was characterized by need for more information, along with a need for more time and some concern about privacy; class 2 was primarily characterized by concern about privacy with a small proportion of other concerns; class 3 was primarily characterized by lack of interest in research; and class 4 was characterized by not wanting to be bothered. A fifth class was created to capture respondents with no concerns.

Education level and health literacy were highest in class 2; these participants were mostly concerned about privacy (Supplementary Table 3). The group with no interest in research (class 3) contained participants with the highest average age. This group also contained the greatest proportion of people who viewed flyer 1 (original flyer). Average age was lowest in the group that did not want to be bothered (class 4). The highest proportion of Black participants was in the group with no concerns (class 5).

In a regression model adjusting for age, sex, race, flyer type, and health literacy, we examined associations between demographic predictors and specific concerns (Figure 3). Higher health literacy was significantly associated with privacy concern (odds ratio [OR], 1.4; 95% confidence interval [CI], 1.01-1.93), as was Hispanic ethnicity (OR, 1.78; 95% CI, 1.02-3.1). Hispanic ethnicity (OR, 0.35; 95% CI, 0.18, 0.67) and Black race (OR, 0.61; 95% CI, 0.43-0.88) were

Table 2. Reasons and concerns associated with signing up for a front door authorization program

	Frequency
What, if any, reasons would you have for considering signing up for what's described in the flyer?	
Help other patients/people living with similar medical conditions ^a	518 (48)
Support medical research	489 (46)
Potential for payment	408 (38)
Want to learn more about the research being conducted	313 (29)
Not a big deal to be asked about being in a study	134 (13)
Personal benefit	93 (9)
Trust in researchers	70 (7)
Other	12 (1)
No specific reason	159 (15)
What, if any, would be your concerns about signing up for what's described in this flyer?	
Need more information	455 (43)
Concerned about privacy ^b	431 (40)
Need more time to think about it	294 (28)
I'm not interested in participating in research	175 (16)
Don't want to be bothered	163 (15)
Do not trust researchers	91 (9)
Other	54 (5)
No specific concerns	178 (17)

Weighted data. Values are n (%).

^aOverall, "Help other patients/people living with similar medical conditions" was most frequently ranked as the most important reason.

^bOverall, privacy was most frequently ranked as the most important concern.

associated with lower odds of needing more information. Being 30-44 years of age compared with being 60 years of age (OR, 0.38; 95% CI, 0.23-0.65) and viewing the simple positive flyer (OR, 0.58; 95% CI, 0.39-0.87) were associated with lower odds of not being interested in research; being female (OR, 0.69; 95% CI, 0.49-0.98), being other or multiracial (OR, 0.51; 95% CI, 0.28-0.92), and exposure to the simple, positively valenced flyer (OR, 0.58; 95% CI, 0.38-0.89) were associated with lower odds of not wanting to be bothered.

DISCUSSION

Effective AFC programs are essential for EHR-based research recruitment. Prior work suggests that more positively valenced, simpler communication strategies may improve willingness to participate in AFC and do not appear to compromise participants' understanding.⁸ This analysis identifies reasons, concerns, and patterns of concerns among the general public. Designing communications programs to address those concerns may improve participation.

The most common reason to consider enrolling in AFC—helping others with similar conditions and supporting medical research—highlights altruism as a motivator. Helping others was also most often ranked as the most important reason to participate. This finding is consistent with other data examining participants' motivations for involvement in clinical research.¹³ The potential for payment was also an important consideration, though this group of respondents is

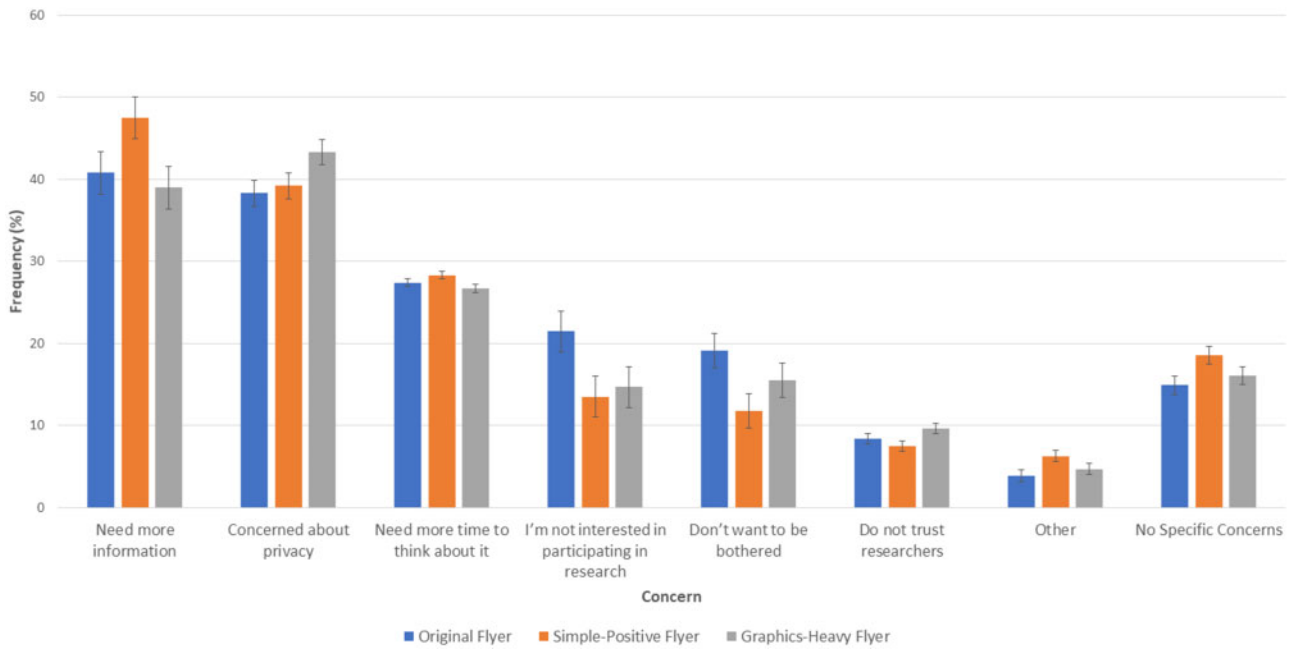


Figure 1. Concerns about signing up for an authorization for contact program distributed by each of the 3 flyer designs. Error bars represent standard error.

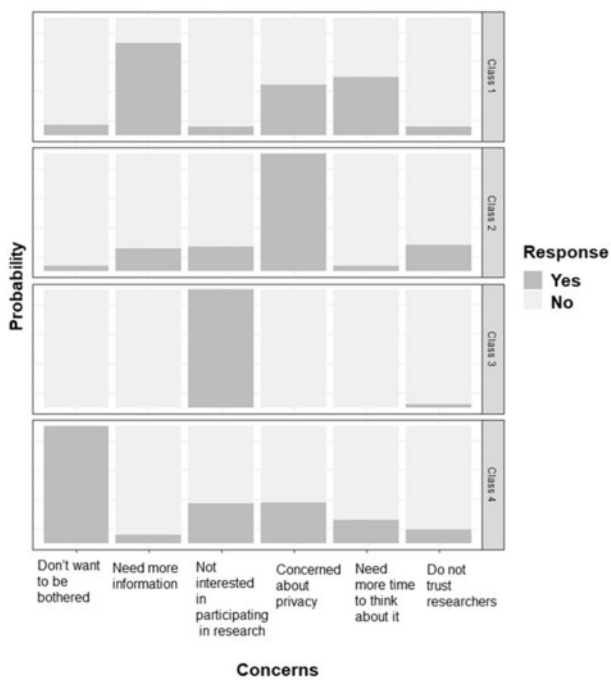


Figure 2. Weighted latent class analysis yielded 4 classes representing patterns of concerns about participating in an authorization for contact program.

accustomed to being paid to complete surveys. Recognizing reasons associated with willingness to enroll in AFC may help in refining informational materials to target barriers.

Our principal focus was identifying concerns about participating in AFC. Two of the most common concerns were “need more information” and “need more time to think about it.” These 2 concerns are nonspecific, and it is notable that needing more information was not meaningfully lower among those who viewed the

original, more comprehensive flyer. These 2 concerns may simply reflect lack of engagement in the survey. Privacy, which was the second most commonly selected concern, was most often ranked as most important and was somewhat more common among individuals with higher health literacy. It is interesting that we observed a difference in the frequency with which this concern was identified in flyer 2 vs flyer 3; the content of these 2 flyers was largely identical. Whether this is a concern that can be addressed by communication strategies is unclear, but these findings highlight that more directly addressing privacy protections and limitations in communications materials warrants further study.

These data are also interesting in what they did not show. For example, lack of trust in researchers was not a prominent concern. This is encouraging because overcoming trust barriers in medical researchers would be a tall order for messaging strategies. Additionally, demographic characteristics often thought to be associated with trust and lack of interest in research, such as race and health literacy, were not observed to be significant.

The exploratory LCA demonstrated that some concerns were more likely to be “lone considerations” than others. Classes 2, 3, and 4 were primarily defined by the presence of privacy concerns, lack of interest in research, and not wanting to be bothered, respectively. In this respect, these issues may represent important content areas on which future communication materials might focus and are discrete considerations that could be addressed in short flyers. The plausibility of this suggestion is bolstered by the fact that reductions in not wanting to be bothered and lacking interest in research were observed with the novel, simplified, positively valenced flyer designs, as compared with the original, neutrally valenced design. The increase in frequency of being shown flyer 3 among those in the class characterized by privacy concerns is difficult to explain. It may be a result of chance but reinforces the importance of evaluating patients’ perceptions of materials to discover unanticipated effects.

Results of this study should be interpreted with several limitations in mind. First, the hypothetical design does not account for participants’ relationships to clinicians and health systems and the

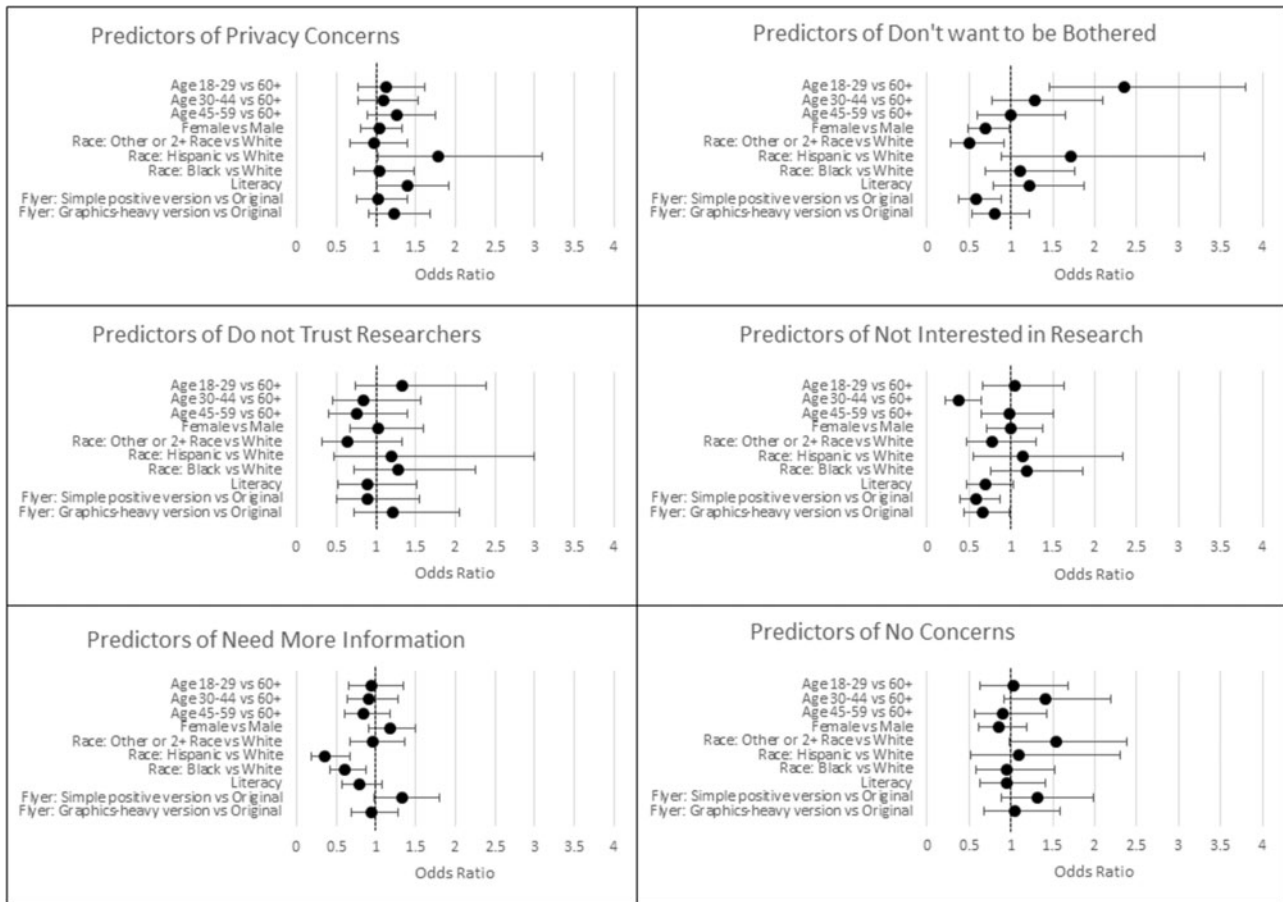


Figure 3. Odds ratios from logistic regression models that describe associations of demographic characteristics and flyer designs with selected concerns. AFC: authorization for contact.

context in which they are asked. Second, GfK respondents were selected from a representative sample of the general public but are familiar with paid survey research. However, only 15% had participated in a medical research study. These findings are primarily hypothesis-generating and point to the need for future research that includes testing various communication materials and evaluating concerns and reasons to participate in a real-world context.

CONCLUSION

AFC programs expand the number of potential future participants within health systems while allowing individuals to decide whether they are contacted. Successful implementation involves understanding patients' motivations and concerns so that barriers can be addressed and patients' informational needs are met. Findings from this study suggest that emphasizing privacy protections, clarifying the value of research participation, and succinctly describing the AFC process in flyers and other materials may encourage patients to authorize contact for research.

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AUTHOR CONTRIBUTIONS

NKN, CDS, CG, Y-AK, SAK, ARM, BGP, KMP, SKS, JS, BSW, and NWD contributed to the conception and design of the work, interpretation of data, drafting the article, critical revision of the article, and final approval of the version to be published. Data collection and analysis were done by Y-AK, NKN, CDS, and NWD. All authors agree to be accountable for ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

SUPPLEMENTARY MATERIAL

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

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CONFLICT OF INTEREST STATEMENT

JS is a member of Merck KGaA's Bioethics Advisory Panel and Stem Cell Research Oversight Committee, IQVIA's Ethics Advisory Panel, and Aspen Neurosciences' Scientific Advisory Board; and has consulted with Portola Pharmaceuticals, Inc. No other authors report any significant financial conflicts of interest.

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