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Research and Applications

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iCONCUR: informed consent for clinical data and bio-sample use for research

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ABSTRACT

Background: Implementation of patient preferences for use of electronic health records for research has been traditionally limited to identifiable data. Tiered e-consent for use of de-identified data has traditionally been deemed unnecessary or impractical for implementation in clinical settings.
Methods: We developed a web-based tiered informed consent tool called informed consent for clinical data and bio-sample use for research (iCONCUR) that honors granular patient preferences for use of electronic health record data in research. We piloted this tool in 4 outpatient clinics of an academic medical center.
Results: Of patients offered access to iCONCUR, 394 agreed to participate in this study, among whom 126 patients accessed the website to modify their records according to data category and data recipient. The majority consented to share most of their data and specimens with researchers. Willingness to share was greater among participants from an Human Immunodeficiency Virus (HIV) clinic than those from internal medicine clinics. The number of items declined was higher for for-profit institution recipients. Overall, participants were most willing to share demographics and body measurements and least willing to share family history and financial data. Participants indicated that having granular choices for data sharing was appropriate, and that they liked being informed about who was using their data for what purposes, as well as about outcomes of the research.
Conclusion: This study suggests that a tiered electronic informed consent system is a workable solution that respects patient preferences, increases satisfaction, and does not significantly affect participation in research.

Key words: informed consent, tiered informed consent, EHR data use for research

BACKGROUND AND SIGNIFICANCE

Use of information technologies to improve the informed consent process is gaining more attention. Many studies have attempted various approaches to informed consent, especially with information technologies, to improve patients' understanding of the materials presented with informed consent forms and to streamline the process.[1,2] One study reported successfully implementing an electronic research permission management system, which captures patient preferences on having their medical data available for research in a nontiered way, and integrating the research permission information with the institution's clinical data warehouse.[3] Dynamic consent was also proposed as a new approach that better serves both patients (ie, data donors) and researchers (ie, data receivers) in terms of promoting trust around data use and facilitating recruitment and continuous management of study participants.[4] The Food and Drug

Table 1. iCONCUR data elements for which patients could indicate intention to share or not, according to type of recipient

Demographics	Current or previous disease or condition	Laboratory and test results
• Age	• Substance abuse related disease or condition	• Genetic test
• Ethnicity	• Mental health disease or condition	• Sexually transmitted disease test
• Gender	• Sexual or reproductive disease or condition	• Drug screening test
• Race	• Other	• Other
Socioeconomic information	Family's current or previous disease or condition	Social history
• Education level	• Substance abuse related disease or condition	• Alcohol consumption status
• Insurance status	• Mental health disease or condition	• Recreational drug use
• Marital status	• Sexual or reproductive disease or condition	• Smoking status
• Occupation	• Other	Health care encounter
• Income	Tissue and blood sample use	• Location of the hospital or clinic
Sexuality	• Tissue sample	• Physician's name
Past pregnancy	• Blood sample	• Specialty of the hospital or clinic
Anthropometrics	Therapy or treatment procedures	• Visit dates
Vital Signs	Medications	• Charges and billing related to encounters

Administration has highlighted the increased importance of having a robust e-informed consent system in place and has made recommendations on use of such a system in clinical studies.[5]

However, current mechanisms for patient consent for the use of electronic health data for research are limited. Unchangeable, all-or-nothing consent for long-term general use of data may not suit the needs of all patients. HIPAA-compliant de-identified data can be used for research without the need for explicit patient consent or inspection of what has been shared. However, the depth of understanding that patients have related to consent for the study of personal data is unclear. The feasibility and impact of a personalized model of consent have not been well studied in a real-world setting, given the lack of tools to enable dynamic patient preference selections and verification of data access (eg, which items are shared with whom, for what type of research). Additionally, there is some concern among researchers that patients would more readily decline participation in research if they were given the opportunity.

OBJECTIVE

We developed, implemented, and evaluated the feasibility of a secure, tiered e-consent web service designed to elicit and honor data sharing preferences in an academic medical center data delivery system for research.

MATERIALS AND METHODS

Tiered consent and sharing options

We based the iCONCUR tiered consent tool on the following: (1) 17 items, including the data types that are considered particularly sensitive by the National Committee on Vital and Health Statistics, such as information about genetics, mental health, sexually transmitted diseases, and substance abuse history[6]; (2) preliminary data from a small survey of healthy volunteers[7]; and (3) requests for clinical data at the Clinical and Translational Science Awards–funded medical center translational research unit.[8] This resulted in 37 data items (Table 1) and 3 nonmutually exclusive groups of data users: (1) researchers from any nonprofit organization, (2) researchers from any for-profit organization, and (3) researchers from the academic medical center and its affiliated Veterans Affairs medical center. Help texts with definitions and examples were available for each data item and each data user group. A screenshot of the iCONCUR user interface where participants made data sharing choices is presented as Supplementary Appendix 1.

Implementation in clinical settings

Recruitment and surveying of data sharing preferences occurred from August 2014 to August 2015. After approval from the Institutional Review Board, we recruited patients from 2 academic primary care locations serving complementary patient populations: 3 primary care internal medicine (IM) clinics and a primary care Human Immunodeficiency Virus (HIV) specialty clinic. The IM clinics serve a diverse patient population with chronic disease and high health literacy. The Ryan White Program–funded HIV clinic provides comprehensive multidisciplinary care, including optional participation in research of banked specimens and personal health information. The HIV clinic provides health education including e-health literacy training and a detailed consent process for patients of diverse socioeconomic and literacy backgrounds.

Research staff approached patients in waiting areas and explained the study by demonstrating the iCONCUR tool on a tablet device. A printed flyer with a summary of the study was also distributed (Supplementary Appendix 2). During recruitment, the research staff explained that the goal of the study was to test the online informed consent system called iCONCUR and to understand people's preferences on sharing their health data for research. The staff explained details on how participants indicate data sharing preferences in iCONCUR and emphasized that participants were to make decisions on sharing their data for future research, and their preferences would be honored during the study period. The recruitment script is presented as Supplementary Appendix 3. Each patient who agreed to participate in the study signed an informed consent form specifically designed for the study (Supplementary Appendix 4) and provided an email address where the research staff could send additional information about participation. Of 1152 patients who were approached about iCONCUR, 394 consented to participate.

Weekly emails to participants who had not already logged in included information on how to use the iCONCUR tool: creating an account, indicating data sharing preferences, and reviewing data usage. Participants were allowed to modify their preferences as frequently as they wanted. A research staff member was available via email and phone to answer any questions on using iCONCUR during the study period. Delivery of data for researchers was monitored

to ensure that preferences were honored. A database analyst double-checked all patient preferences to make sure each choice was honored.

We conducted a web-based user experience survey (http://goo.gl/forms/lOib0vQ4mo) in the last month of the study period to obtain feedback on how participants felt about using the iCONCUR tool and allow them to submit suggestions for data elements in the taxonomy or user interface changes.

Of the 394 patients recruited, 126 actively logged in to the website, 84 from the HIV clinic and 42 from the IM clinics. Our main hypothesis was that there would be no difference in the proportion of data sharing between the 2 types of clinics. The estimated statistical power to detect a difference in the mean willingness-to-share rate between the 2 clinics was 84% at 0.05 significance level, 0.7 control rate, and 0.2 expected difference using a 2-sample proportion test.[9]

RESULTS

Feasibility of iCONCUR

The system was easily integrated into our data delivery process for research. Participants did not indicate problems with understanding or making selections in the user experience survey. From 1150 patients approached, 394 patients (259 from the HIV care clinic and 135 from the IM clinics) agreed to join by signing the study's informed consent form. However, not all those patients accessed iCONCUR to change the way their data should be used (84 patients from the HIV clinic and 42 patients from the IM clinics indicated their data sharing preferences in iCONCUR). Table 2 shows the sociodemographic characteristics of the participants who logged in to the iCONCUR system and made a data sharing choice. The demographic distribution of the study participants somewhat differed from the overall populations of the 2 types of clinics. From the HIV clinic, the study participants had higher proportions of males, Hispanics, and whites compared to the overall HIV clinic patient population. On the other hand, in the IM clinics, females, non-Hispanics, and whites were overrepresented compared to the IM clinic population.

Table 2. Demographics of patients who indicated sharing preferences

Demographics (*P*-value*)	HIV Clinic ($N = 84$)	IM Clinics ($N = 42$)
Race (.07)		
Asian	2	3
Black	9	1
White	52	32
Other	17	4
Not answered	4	2
Gender (<.001)		
Male	77	13
Female	5	28
Not answered	2	1
Ethnicity (<.001)		
Hispanic	24	1
Not Hispanic	56	39
Not answered	4	2
Perceived health status (.06)		
Excellent	5	10
Very good	14	8
Good	26	8
Fair	14	6
Poor	4	1
Not answered	21	9
Income level (<.001)		
>$125 K	1	11
$75–125 K	4	10
$25–75 K	15	9
<$25 K	43	3
Not answered	21	9
Education level (<.001)		
Graduate level	10	15
4-year college	12	11
High school ~ some college	29	6
<High school	12	1
Not answered	21	9

*P-value for homogeneity between 2 clinics using Fisher's exact test
HIV: human immunodeficiency virus, IM: internal medicine.

Data sharing preferences

iCONCUR allows users to indicate their data sharing preferences for 3 types of researchers. This yielded 8 data sharing combinations:

A. No one;
B. For-profit researchers only;
C. Nonprofit researchers only;
D. Researchers from the affiliated institutions (the academic medical center and Veterans Affairs) only;
E. Researchers from for-profit and nonprofit institutions but NOT from the affiliated institutions;
F. Researchers from for-profit and affiliated institutions but NOT nonprofit institutions;
G. Researchers from nonprofit and affiliated institutions but NOT for-profit institutions; and
H. Everyone.

Data sharing preferences for individual data item are presented in Figure 1. Combinations B, C, E, F were somewhat atypical and were used by 5 male participants only. Excluding these 4 options, to simplify the analyses, we recoded the response options with 4 scale ordinal scores that reflect the researcher types with whom participants were willing to share data:

0: Sharing with no one.
1: Sharing with researchers from the affiliated institutions only.
2: Sharing with researchers from the affiliated and nonprofit institutions only.
3: Sharing with everyone.

Figure 2 shows the distribution of the mean willingness-to-share scores. The difference in the means between the 2 types of clinics was significant ($P = .002$) when tested with the Wilcoxon rank sum test. Participants from both types of clinics were most willing to share their demographic data. Participants from the HIV clinic were least willing to share their income data, followed by drug screening test results. Those from the IM clinic were least willing to share family history of mental health, followed by billing information and their own mental health history.

Overall, participants from the HIV clinic were more willing to share their data than those from the IM clinics. A total of 43 participants (34%; 35 from the HIV clinic, 8 from the IM clinics) were willing to share every data item with every type of researcher, while 5 (4%; 3 from the HIV clinic and 2 from the IM clinics) were unwilling to share their data with any type of researcher.

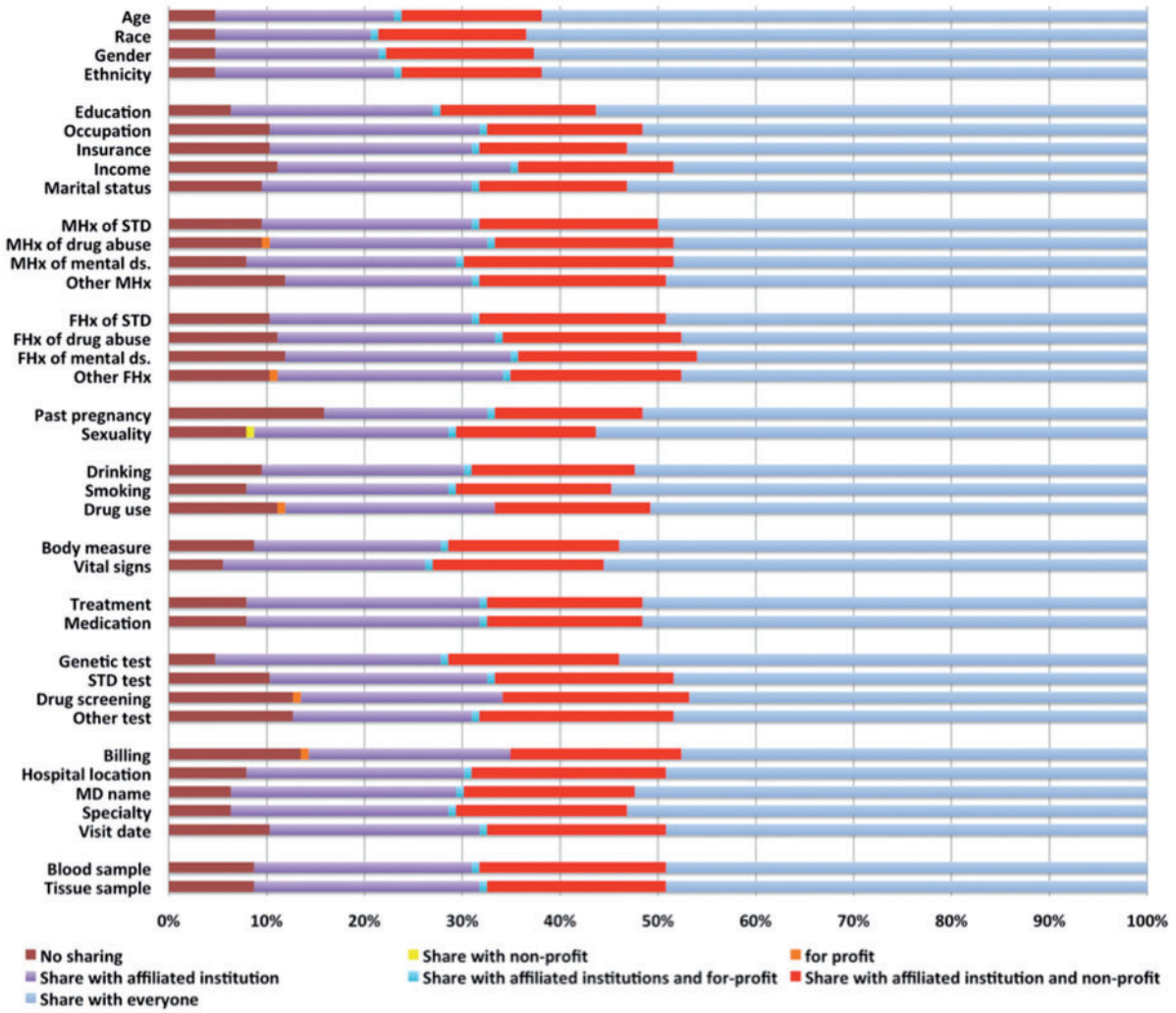

Figure 1. Sharing preference by individual data item (Hx: History, FHx: Family History, Dx: Diagnosis, STD: Sexually Transmitted Disease, MD: Medical Doctor)

Time spent on data sharing decisions

On average, participants spent about 3.6 minutes indicating their data sharing preferences. Those from the IM clinics spent significantly more time (mean = 4.2 min, sd = 5.5 min) than those from the HIV clinic (mean = 2.4 min, sd = 2.6 min) using the system ($P = .02$). Help texts were used by <40% of participants (47). Twenty-six participants from the HIV clinic (30%) read help texts, while 21 from the IM clinics (50%) did so. No statistically significant difference between the 2 groups was observed on the overall average time spent on help texts. On average, the participants spent the longest time reading the help texts on for-profit organizations and anthropometrics. A screenshot of the help texts provided with these 2 items is presented in Supplementary Appendix 5.

We observed statistically significant differences in the time spent on completing the sharing choices between participants with different preferences for data sharing ($F = 4.07$, $P = .009$). Overall, those who spent more time making sharing decisions were less likely to share their data for research. However, the time spent reading help texts did not have a significant influence on data sharing preferences for the 47 participants who read help texts.

Sharing choices by perceived health status and sociodemographics

No statistically significant difference was observed in the mean overall sharing scores related to gender ($P = .13$) and race (whites vs non-whites, $P = .99$). The mean overall sharing scores tended to be higher among those who reported their health status as excellent or poor, although the differences were not statistically significant among the groups with different perceived health status (analysis of variance, $F = 1.40$, $P = .25$). Negative trends were observed between mean overall sharing scores and income level (Pearson corr = −0.24, $P = .02$), as well as education level (Pearson corr = −0.31, $P = .003$).

User experience survey

Ninety-six participants (63 from the HIV and 33 from the IM clinics) completed the user experience survey, with an overall participation rate of 76%. No significant difference was observed in the mean sharing choice scores between those who completed the survey and those who did not ($P = .10$).

Overall, having more granular choices available via the iCONCUR tool for indicating data sharing preferences did not negatively affect data sharing decisions for the majority of respondents (59%).

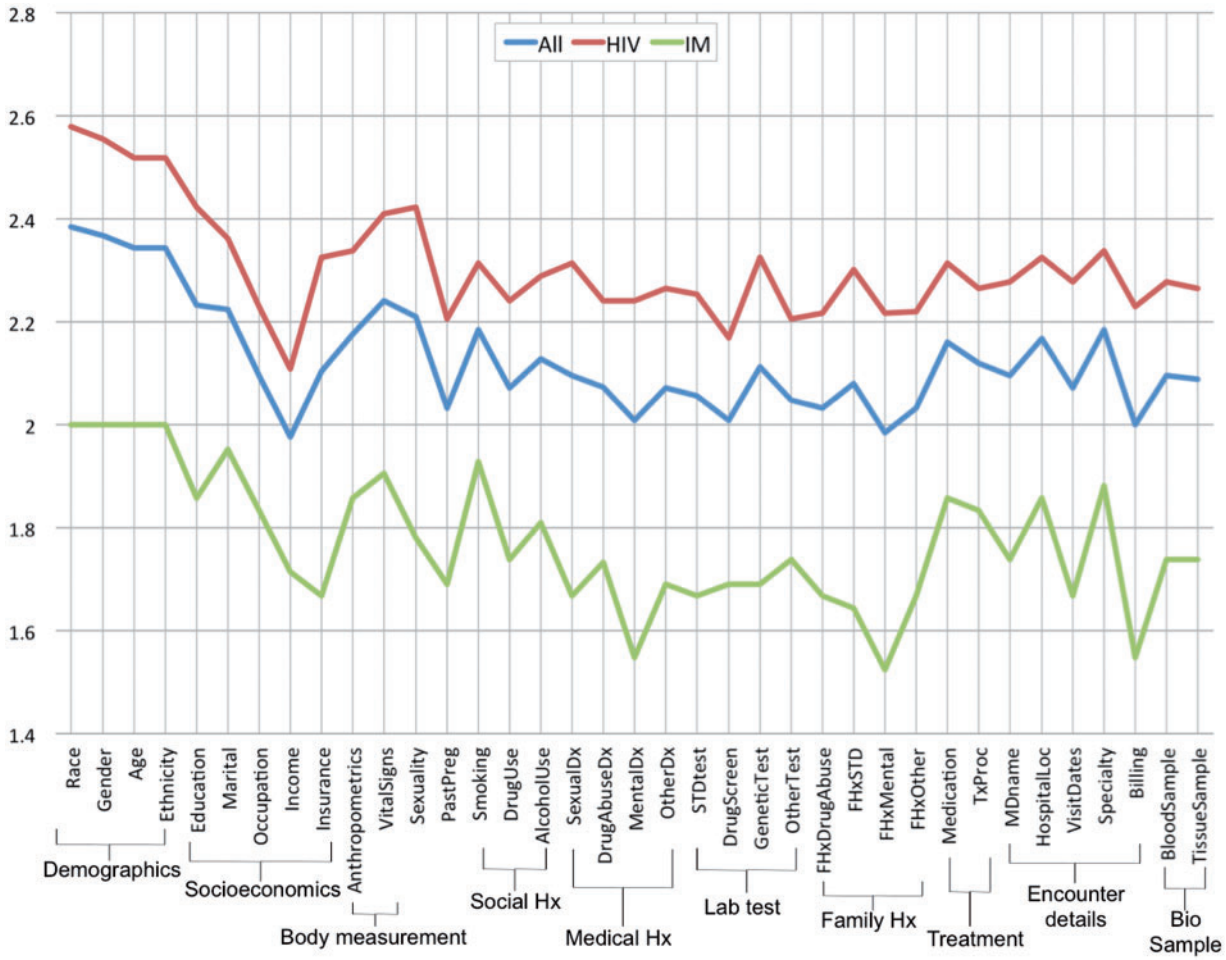

Figure 2. Mean willingness-to-share score by individual data item (HIV: HIV clinic, IM: IM clinic, Hx: History, FHx: Family History, Dx: Diagnosis, STD: Sexually Transmitted Disease, MD: Medical Doctor)

Instead, 35% of respondents indicated that the tiered informed consent mechanism made them more willing to share data for research (Figure 3a).

Also, a majority of respondents (79%) indicated that they would be equally willing to share their data for research and for health care (Figure 3b). A majority of respondents (73%) indicated that knowing who is using their data for research would make them feel more comfortable sharing their data (Figure 3c). A majority of respondents wanted to know who is using their data for what research purpose, and to be informed of the outcomes of the research (Figure 3d). They would like to be notified each time someone used their medical data for research (Figure 3e). The participants were satisfied with the iCONCUR experience, but 2 respondents suggested improving the usability of the tool by adding or removing sharing choice items and making the tool easier to navigate (Figure 3f).

DISCUSSION

Some patients have reported withholding information from their doctors due to concerns about data security and personal privacy.[10] Concerns about allowing patients to have control of access and use of their medical data do exist.[11] Some researchers we consulted feared that it would be more difficult to access clinical data for research if patient preferences for data sharing were taken into account. Anecdotally, when we disclosed our plans to conduct this feasibility study, we were advised by colleagues to refrain from doing it, or to keep the number of participants small to avoid "en masse withdrawal" of participants. They were also concerned that exclusion of patients who elected not to share data might bias the research study samples. Our study showed that the majority of our participants were willing to share a large portion or all of their data for research.

The possibility of sample bias was not directly studied, although it is reasonable to believe that data could be skewed if too many patients withdrew particular data items from disclosure and/or data were withdrawn in a non-random fashion, for example, by some particular segments of the patient population due to cultural, ethnic, socioeconomic, health condition, disease severity or acuity, or other factors. We intend to study these issues in phase II of the iCONCUR study, which will include a larger sample.

A recent study by another team surveyed patients on their data sharing preferences and showed that they were less willing to share "sensitive information," as defined by the National Committee on Vital and Health Statistics,[6] and preferred to have granular control of data sharing for research purposes.[7] This survey was conducted in the form of an interview between research staff and participants, where the research staff provided additional help with understand-

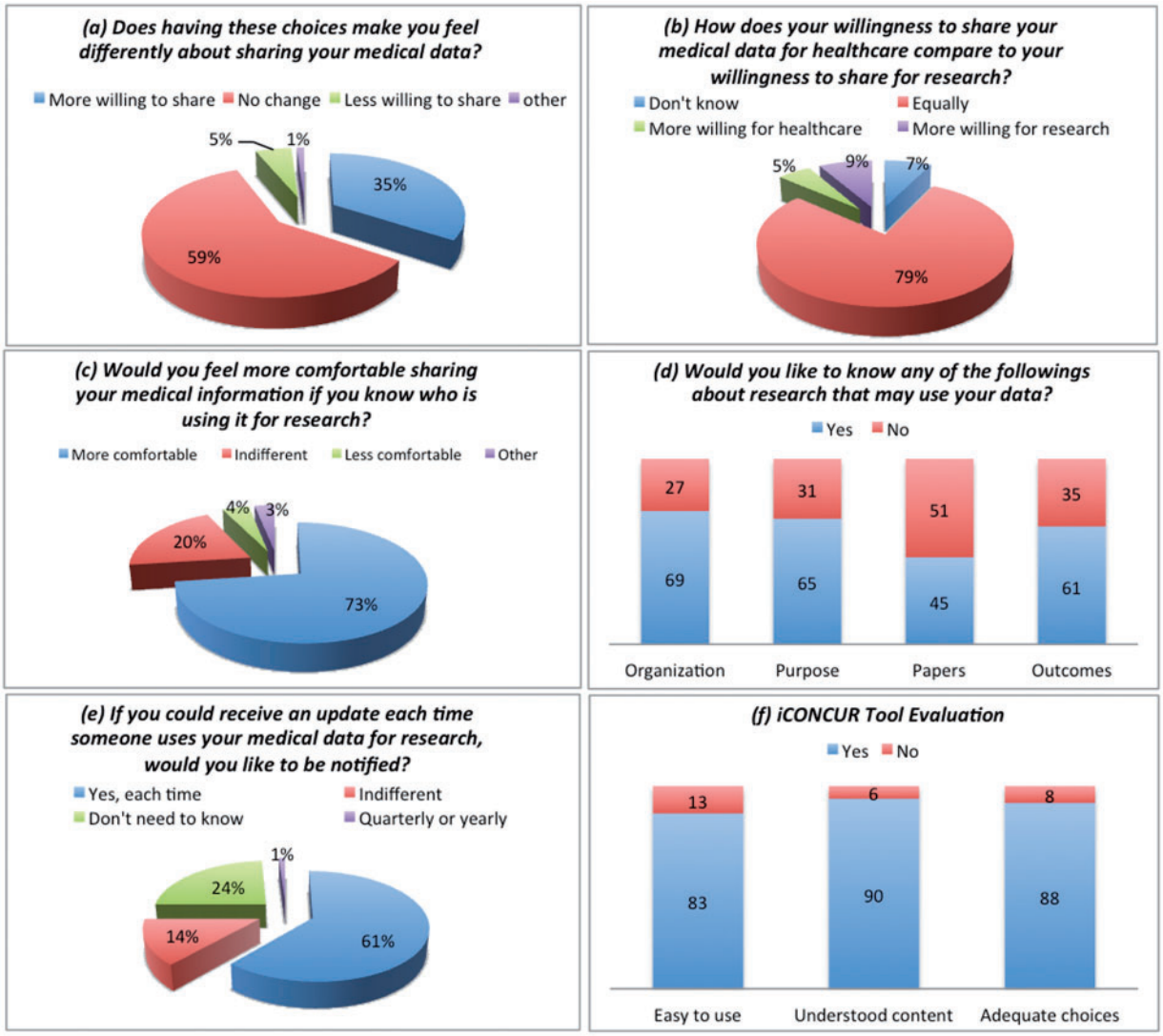

Figure 3. Results of survey on sharing options and overall user experience

ing what "sensitive information" categories meant. However, subjectivity problems associated with using predefined sensitive data categories for data-sharing consent have been also recognized.[13–20] Indeed, withdrawal of "sensitive" information was not more frequent than "nonsensitive" information in our study. Our finding is somewhat consistent with a recent British study on evaluating the consent process in the UK that reported participants did not view their DNA data differently from other medical information.[21] In our study, the participants in general were least willing to share their family history and financial data (eg, billing, income level, health insurance). Additionally, we implemented patient preferences in practice, as opposed to most studies that investigate patient intentions but not their actions.

We observed the statistically significant negative association between the willingness to share data and the total time spent on data sharing decisions. However, this trend was not found with the time spent reading the help texts in iCONCUR, suggesting that phrasing of the options did not influence preferences. One study reported that making an informed consent form more readable resulted in opting out of a study.[14] In our study, this association was not substantiated. The total time spent on data sharing decisions seems to reflect an intense contemplation process (ie, to share or not to share) rather than an attempt to comprehend the information presented in the informed consent system. Use of help text can be an indirect indication of the level of understanding of the presented data items. However, it is not a measure of comprehension. In this pilot study, we did not include a comprehension and/or health literacy test to make the survey easier for participants by minimizing the number of survey items. We plan to augment iCONCUR with comprehension and literacy measures in the next phase of the study.

The differences seen between the IM clinics and the HIV clinic warrant further discussion. A higher proportion of patients from the HIV clinic consented to release of their health information. We believe that local onsite access to health education, e-health literacy training, patient engagement through the web portal, and familiarity with research participation contributed to these differences. Expansion of more robust consent processes for research participation should help include patients by enhancing their personal understanding and access. An important limitation of this study was the absence of alternative means of participation that did not involve use of a computer. We plan to address this in our follow-up study.

Consistent with a previous report,[22] we observed significant negative correlations between willingness to share data and education level as well as income level. However, a larger study of 4659 participants by the National Human Genome Research Institute reported that sociodemographic characteristics were not significant predictors of consent preferences, after adjusting for general privacy beliefs and attitudes about the value of research.[23]

Past studies have investigated peoples' views and attitudes on sharing their medical data for research and reported mixed findings: some concluded most people were willing to share their data for research[24–27] and others concluded the opposite.[28–30] However, common findings were that the majority of people wanted to be consulted about use of their data for research in advance of the research happening and to be informed of the results of the research.[31] Our participants highlighted the importance of providing information regarding use of their data. They wanted to know who was accessing their information and for what purposes, and to be informed about the outcomes of any research study that used their data. A third of our participants indicated that knowing information on research use would make them feel more comfortable with sharing their data for research.

As described in the Methods section, we excluded 5 cases with atypical responses (Figure 1), as drawing meaningful interpretations from these choices is challenging due to the small sample size. We will continue to investigate these types of responses in the next phase of the iCONCUR study. In addition, the high rate of nonparticipation in this study (66% of 1150 patients approached) warrants more investigation. The research staff did not have a chance to fully explain the study to many of them, as they were either rushing out of the clinic or called in to the exam room during the interview. Prior studies have suggested that patients were overall satisfied with the current way of executing data sharing decisions with "blanket" consent.[2,32] However, there were other confounding factors to consider, such as concerns that the categorical (ie, tiered) choices were confusing or hard to understand.[2] We plan to further investigate the factors that affect the decision to execute more granular consent on data sharing in the next phase of the study by interviewing nonparticipants.

Ten participants made multiple records of data sharing choices. However, the majority ($N = 8$) did so within a few hours of the first entry, which might indicate that they were completing the survey through multiple access. Two respondents completed 2 surveys more than a day apart. Both of them adjusted their sharing preferences more strictly (ie, excluded more items). We included only the latest record in the analysis. We anticipate more repeated visits and changes after implementation of MyDataUse, which shows how the data are used and for what purposes. In this pilot study, MyDataUse was able to show data usage information at the end of the study period, because few studies required patient samples that would include the patients who participated in the iCONCUR study. Therefore, we did not have enough time to study changes in participants' data sharing preferences after seeing how their data were used for research. We plan to study this aspect in the next phase.

Finally, this study focused on just 2 of several aspects of the process of obtaining consent, primarily in the documentation of consent and implementation of preferences for future studies. As mentioned before, other aspects will be subjects of a follow-up study.

CONCLUSIONS

Most research institutions are primarily focusing on obtaining patient consent for use of identified data through lengthy legal documents that are rarely read or fully understood, leaving a research assistant or clinician responsible for conveying a summary and answering questions. Studies have shown that this is not always optimal.[14–20] Obtaining consent for de-identified data is legally not necessary, but our results suggest that it is not only feasible but also confers a higher level of trust in research and has no negative impact on participation. We demonstrated that a tiered electronic informed consent system can be a workable solution to respecting patient preferences for electronic health record data sharing for research. Having more granular options for executing data sharing decisions did not negatively affect participants' willingness to share their data and made them feel more confident about their data sharing decisions. This level of trust will prove important to achieve national goals such as rapid recruitment and retention for the precision medicine initiative.[33]

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CONTRIBUTORSHIP STATEMENT

HK led the study, drafted the manuscript, and conducted data analysis. EB did patient recruitment, conducted literature review, and edited the manuscript. JK conducted study design, did data analysis, and edited the manuscript. AS edited the manuscript, helped with study design, and added critical discussion points. JR edited the manuscript, helped with study design, and added critical discussion points. CF developed the iCONCUR system and edited the manuscript. DF developed the iCONCUR system and helped with data processing. SFF conducted literature review and edited the manuscript. LO-M was principal investigator of the project; provided original idea, overall supervision of the project, and critical editing of the manuscript.

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COMPETING INTERESTS STATEMENT

The authors of this manuscript have no competing interests to declare.

SUPPLEMENTARY MATERIAL

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

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