Informatics Approaches to Understand Data Sensitivity Perspectives of Patients with Behavioral Health Conditions

by

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ABSTRACT

Sensitive data sharing presents many challenges in case of unauthorized disclosures, including stigma and discrimination for patients with behavioral health conditions (BHCs). Sensitive information (e.g. mental health) warrants consent-based sharing to achieve integrated care. As many patients with BHCs receive cross-organizational behavioral and physical health care, data sharing can improve care quality, patient-provider experiences, outcomes, and reduce costs. Granularity in data sharing further allows for privacy satisfaction. Though the subjectivity in information patients consider sensitive and related sharing preferences are rarely investigated. Research, federal policies, and recommendations demand a better understanding of patient perspectives of data sensitivity and sharing.

The goal of this research is to enhance the understanding of data sensitivity and related sharing preferences of patients with BHCs. The hypotheses are that 1) there is a diversity in medical record sensitivity and sharing preferences of patients with BHCs concerning the type of information, information recipients, and purpose of sharing; and 2) there is a mismatch between the existing sensitive data categories and the desires of patients with BHCs.

A systematic literature review on methods assessing sensitivity perspectives showed a lack of methodologies for characterizing patient perceptions of sensitivity and assessing the variations in perceptions from clinical interpretations. Novel informatics approaches were proposed and applied using patients’ medical records to assess data sensitivity, sharing perspectives and comparing those with healthcare providers’ views. Findings showed variations in perceived sensitivity and sharing preferences. Patients’ sensitivity perspectives often varied from standard clinical interpretations. Comparison of patients’ and providers’ views on data sensitivity found differences in sensitivity perceptions of patients. Patients’ experiences (family history as genetic data), stigma towards category definitions or labels (drug “abuse”), and self-perceptions of information applicability (alcohol dependency) were influential factors in patients’ sensitivity determination.

This clinical informatics research innovation introduces new methods using medical records to study data sensitivity and sharing. The outcomes of this research can guide the development of effective data sharing consent processes, education materials to inform patients and providers, granular technologies segmenting electronic health data, and policies and recommendations on sensitive data sharing.

DEDICATION

This dissertation is dedicated to,

My Husband,

Thank you for your patience, sacrifices and unconditional love and faith in me throughout all these years. Without your constant encouragement and support, I would never be where I am today. Thank you for encouraging me to chase my dreams. Bhaumik, I love you!

My Parents,

It is impossible to thank you for all that you have done for me. I could not have asked for better parents. You both have sacrificed a lot for our happiness and for that I will be forever indebted to you. Thank you for everything. Mumma and Daddy, I love you!

My Grand Parents,

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ABBREVIATIONS

42 CFR Part 2	Title 42 of the Code of Federal Regulations Part 2: Confidentiality of Substance Use Disorder Patient Records
AIDS	Acquired Immunodeficiency Syndrome
EHR	Electronic Health Record
GMH	General Mental Health
HIE	Health Information Exchange
HIV	Human Immunodeficiency Virus
IRB	Institutional Review Board
MEDINFO	World Congress of Medical and Health Informatics
NCVHS	National Committee on Vital and Health Statistics
NIMH	National Institute of Mental Health
ONC	Office of the National Coordinator of Health Information Technology
PCRH	Personally Controlled Health Records
SAMHSA	Substance Abuse and Mental Health Services Administration
SMI	Serious Mental Illness
UBACC	University of California, San Diego Brief Assessment of Capacity to Consent

CHAPTER 1

INTRODUCTION

1.1 Background

Behavioral health refers to mental/emotional well-being and/or actions that affect wellness.(*Key substance use and mental health indicators in the United States: Results from the 2015 National Survey on Drug Use and Health*, 2016) Behavioral health problems include substance use disorders, serious psychological distress, suicide, and mental disorders.(*National Behavioral Health Quality Framework*, 2017) Behavioral health conditions affect around 46 million adults in the US, a quarter of whom suffer from a serious mental illness (SMI).(*SAMHSA-HRSA Center for Integrated Health Solutions. The Current State of Sharing Behavioral Health Information in Health Information Exchanges*, 2014) Among patients with behavioral health conditions (BHCs), approximately 70% also have at least one medical condition, such as type 2 diabetes or hypertension as well as SMI patients, on average, have higher rates of emergency room, primary care and specialty care visits.(*SAMHSA-HRSA Center for Integrated Health Solutions. The Current State of Sharing Behavioral Health Information in Health Information Exchanges*, 2014)

Integration and coordination of primary and behavioral health care could help address the health problems of patients with BHCs and needs of their providers for providing better care via a team-based approach.(*NIMH » Integrated Care*, n.d.) Caring for a total person is essential to achieve positive health outcomes and reduce healthcare costs.(*NIMH » Integrated Care*, n.d.) Cross-organizational health data sharing between various providers upon patient consent can be vital in providing integrated and coordinated care.

Consent decisions related to sharing health data, especially sensitive data, can be influenced by social stigma, fears related to discrimination and insurance or legal concerns.(California Healthcare Foundation, 2008; M. A. Grando et al., 2017; Hiestand et al., 2017; Soni et al., 2017) Examples of sensitive health data often include information related to mental health, reproductive health, drug and alcohol abuse, communicable diseases (such as HIV/AIDS), etc. There is no universal agreement on types of data generally considered sensitive. Data sensitivity, therefore, is subjective and preferences for defining and sharing sensitive data vary among individuals.(*National Committee on Vital and Health Statistics. Recommendations Regarding Sensitive Health Information*, 2010) This diversity could potentially influence preferences or willingness to share sensitive data which could impact one's care and treatment. The National Committee on Vital and Health Statistics (NCVHS) identifies the necessity for more comprehensive sensitive categories requiring special handling to satisfy patient privacy needs.(*National Committee on Vital and Health Statistics. Recommendations Regarding Sensitive Health Information*, 2010; Simon P. Cohn, 2008)

In support, the Office of the National Coordinator of Health Information Technology (ONC) also recommends to provide patients with individual choices with respect to making informed decision about use and disclosure of their data as well as limiting health data disclosure to specified purpose.(*Health IT policy committee, privacy and security tiger team, letter to David Blumenthal, Chairman of the Office of National Coordinator for Health IT*, 2010) The ONC suggests that consent tools should allow patients more granular control over their consent decisions including authority to exchange specific health information with capability withhold other records per individual patient choices.

Moreover, researchers have acknowledged the need for more comprehensive sensitive data categories, assessing individual’s perceptions towards those categories as well as desires control over sharing their health data to satisfy their privacy needs.(E. Bell et al., 2014; E. A. Bell et al., 2014; Caine & Hanania, 2013; M. A. Grando et al., 2017; *SAMHSA-HRSA Center for Integrated Health Solutions. The Current State of Sharing Behavioral Health Information in Health Information Exchanges*, 2014; Whiddett et al., 2006) While patients seem to want choices on what data to share for care and research, traditional data sharing consent models often support broad consent choices such as share all or none of the data. There is a need for effective consent tools that support patient-driven granular data sharing control.

Overall, there is a lack of understanding of what the preferences of patients with BHCs are regarding sensitivity and sharing of medical records information. **My hypotheses are: 1) there is a diversity in medical record sensitivity and sharing preferences of patients with BHCs with respect to type of information, recipients and purpose of sharing; and 2) there is a mismatch between the existing sensitive data categories and the desires of patients with BHCs.**

I introduce novel informatics approaches to characterize and compare data sensitivity perspectives and apply them to inform the development of patient-centered sensitive data sharing technologies. The insights gained from our research will help to provide recommendations to effectively support consent mechanisms affording patient-driven granular control over data sharing.

Although this research focuses on a specific population of patients with BHCs the proposed approaches can be readily applied to other clinical environments with minimal modifications. Along with behavioral and physical health patients, healthy individuals and legal guardians of children and adult patients are often involved in consent decisions. The approaches could be adapted and applied in understanding their perspectives on medical records sensitivity and sharing and compare perspectives on various types of data categories and sensitive types, not just the one considered here.

1.2 Research Aims

Aim 1: Systematic review of literature on perceptions on data sensitivity and sharing

Conduct a systematic literature review of methodological approaches to assess perceptions on data sensitivity, data privacy and data sharing preferences.

Aim 2: Survey patients with behavioral health conditions on their perspectives on sensitive medical record sharing

Design a survey to address knowledge gaps identified in Aim 1. Survey English and Spanish speaking patients with BHCs to capture their perceptions on data privacy and data sensitivity.

Aim 3: Interview patients with behavioral health conditions to understand their perspectives on sensitive medical record sharing

Leveraging on the outcomes of the completed survey (Aim 2), propose and apply a **mixed method approach** that uses information extracted from the patient’s own medical records to personalize card sorting tasks and interviews. The aim of the method is to assess patients with BHCs’ opinions regarding sensitivity of medical records and related sharing preferences to assess the research hypothesis that there is a diversity in medical record sensitivity and sharing preferences of patients with BHCs with respect to type of information, recipients and purpose of sharing.

Aim 4: Contrast patient and provider perspectives on sensitive medical record sharing

Apply a **mixed method approach** to contrast perceptions on sensitivity of medical records of patients from Aim 3 and healthcare providers to discover rationale behind agreements, partial agreements, and disagreements. This aim tests the hypothesis that there is a mismatch between the existing sensitive data categories and the desires of patients with BHCs.

1.3 Outline of Thesis

This introduction chapter presents an overview of the scope of the research, aims and research hypotheses. Chapter 2 provides a summary of a literature review on methods assessing patients’ data privacy and data sensitivity perceptions. Chapters 3 summarizes the outcomes of the completed patient survey to understand the data sharing preferences and perceptions towards data sensitivity. A new methodology to assess individual’s perceptions of medical records sensitivity and medical records sharing preferences using their own medical records is proposed and applied in Chapter 4. Chapter 5 compares medical records sensitivity perspectives of patients with BHCs and healthcare providers. Conclusions, limitations and impact are provided in Chapter 6.

CHAPTER 2

LITERATURE REVIEW ON METHODS TO ASSESS MEDICAL RECORDS SENSITIVITY AND SHARING PREFERENCES

2.1 Introduction

Sensitive health information possesses risks, such as stigma and discrimination, when disclosed. This chapter outlines the outcomes from a completed systematic review on methodological approaches to evaluate individual's willingness to share health data and sensitivity perceptions, corresponding to Aim 1.

Electronic and manual keyword searches were performed using five databases including PubMed, Scopus, Elsevier, BioMed Central and IEEE Xplore. Titles and abstracts were reviewed to identify suitable publications based on a set inclusion and exclusion criteria. Full texts of articles meeting inclusion criteria were reviewed. Author citations of the selected articles were reviewed to find additional relevant articles.

A total of 1,065 articles were found. Upon removal of duplicates, 961 unique articles were identified. Titles and abstracts of these unique articles were reviewed. Five publications focusing on assessment of patients' perspectives on data sharing and sensitivity were found based on full text review. Additional three relevant articles were added after full text review of author citations.

Qualitative approaches (such as interviews, survey, focus groups, etc.) came across as prominent methods used in understanding such perspectives. Only two studies used patients' own medical records to explore what types of information are considered sensitive and how their perceptions affect data sharing preferences. No study was found to quantify and explain differences in data sensitivity perceptions between patients and standard definitions (e.g. clinical providers or health policies).

The main findings of this review indicated that the participating individuals were less willing to share sensitive information about sexually transmitted diseases, abortions and infertility, family medical history/genetic disorders, mental illness, drug/alcohol related incidents, previous operations/procedures/dates and their current medications. Participants' willingness to share data also varied based on purpose of sharing, for example, treatment or research. Participants' lack of EHR comprehension encouraged the desire to know more about their health data for making informed data sharing decisions.

In summary, we identified that there is a need for methodologies to study medical record sensitivity and willingness to share various types of sensitive and non-sensitive data personalized to the individual's own medical records. The studies identified in this review and approaches employed by the studies to understand sensitivity perspectives inform the development of novel mixed methods approach to assess data sensitivity and sharing preferences of individuals with behavioral health conditions (Aim 3).

This systematic review has been published in the Journal of Biomedical Informatics-X along with outcomes of Aim 3 (Details in Chapter 4).(Soni et al., 2020)

"**Soni, H.**, Grando, A., Murcko, A., Diaz, S., Mukundan, M., Idouraine, N., Karway, G., Todd, M., Chern, D., Dye, C., & Whitfield, M. J. (2020). State of the art and a mixed-method personalized approach to assess patient perceptions on medical record sharing and sensitivity. *Journal of Biomedical Informatics, 101,* 103338. https://doi.org/10.1016/j.jbi.2019.103338"

2.2 Literature Search Methods

2.2.1 Search Strategy

Preliminary narrative searches were conducted to identify keywords and candidate search terms. Based on this, the following standard search string containing generalized keywords was used for the search to avoid any potential bias in searching for studies representing the state of the art:

(Share OR Sharing) AND (Sensitive OR Private) AND (Health Record OR EHR OR Medical Record OR EMR)

Synonyms of the candidate terms were included using Boolean operator 'OR' to maximize the efficiency. As a first step, *electronic* searches were performed using five electronic databases: PubMed, Scopus, Elsevier, BioMed Central and IEEE Xplore. In addition, database specific criteria were defined to refine the search as explained in Table 2.1. Next, the title and abstract of each article was *independently* and *manually* audited by two researchers (Hiral Soni and George Karway). The articles meeting inclusion criteria (section 2.2.2) were included for the full text review. Full text for each paper was reviewed to select potentially relevant articles. The snowballing approach was used to audit the reference lists of included articles in the full text review to find additional relevant articles.(Wohlin, 2014) Full text of each selected article was reviewed for inclusion in the final review (Figure 2.1). Disagreements between the two reviewers were resolved by consensus. Final outcomes were revised by a third reviewer.

Table 2. 1 Literature Search Strategy and Database Specific Criteria

Database	Included Journals/Conferences	Other Criteria
Biomed Central	BMC Medical Informatics and Decision Making	-
Elsevier	International Journal of Medical Informatics Journal of Biomedical Informatics Patient Education and Counselling	-
IEEE Xplore	All	-
PubMed	All	Species: Human
Scopus	All	-

2.2.2 Inclusion and Exclusion Criteria

This study focuses on reviewing the literature with a concentration on design, assessment, or evaluation of willingness to share data and/or data sensitivity perceptions of patients, legal guardians or surrogates of the patients, healthy individuals and health providers. Only English language studies were included. Research, journal and conference articles from 2009 and 2019 were used. Incomplete studies, editorials, opinion papers, reviews and commentaries were excluded from consideration.

2.3 Review of the Literature on Individual Perceptions of Data Sensitivity and Sharing Preferences

Electronic searches resulted in a total of 1,065 articles of which 104 articles appeared in the multiple databases. Upon de-duplication, we manually screened titles and abstracts of 961 unique articles. Applying the inclusion and exclusion criteria, 956 articles were excluded after screening; *five* were included in the full text review. Table 2.2 outlines the primary objectives of the excluded articles. We also identified *three* additional articles through forward snowballing. The snowballing process was iterated until no more relevant articles were found in the author citations. *Three* of the *eight* articles were found to be related to assessing, both individuals' preferences of sharing healthcare data and data sensitivity perceptions. Given the scarcity of research, we also included five articles with a focus on willingness to share healthcare data. Figure 2.1 depicts the literature search strategy and process.

Table 2. 2 Objectives of Excluded Articles based on Title and Abstract Review

Objectives of Excluded Articles	**# of Articles**
Big data and blockchain in healthcare	9
Clinical workflow and communications	11
Conference summary and recommendations	2
Data reuse in care and research	7
Development/discussion of technology for data sharing	56
Development/discussion of other healthcare technology, databases, models, frameworks, etc.	454
Discussion of health status	19
Ethical and legal considerations of health data and sharing	11
Ethical and legal considerations of health information technology	5
Health information management and practices	5
Impact of cultural barriers	1
Integrated and patient-centered care	7
Patient and family engagement in health care and related decisions	29
Patient experiences related to health	1
Patient and provider interaction	29
Patient or provider education	11
Preferences or attitudes towards electronic health records (EHRs)	42
Preferences or attitudes towards health information exchange	18
Preferences or attitudes towards health information technology	42
Preferences or barriers in using and/or sharing data	11
Review of existing technology/solutions	16
Security and privacy concerns of sharing data	16
Security and privacy of health data	93
Security and privacy of health information technology	23
Shared decision making in healthcare	8
Storage and/or management of health data	22
Use and management of health information technology	8
Total	**956**

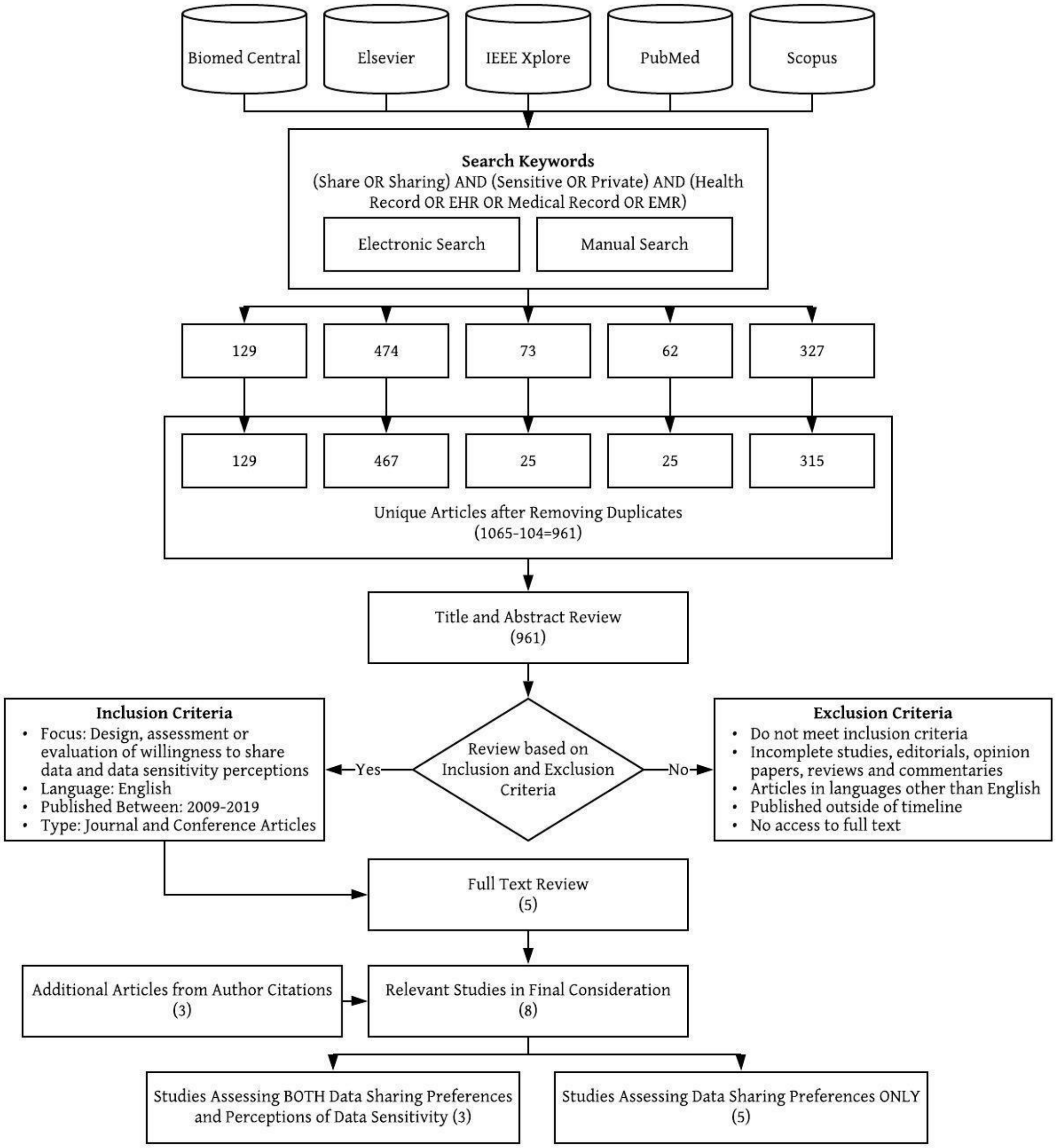


Figure 2. 1 Literature Search Strategy and Process

2.3.1 Main Findings

Various qualitative and quantitative methods were employed in understanding individuals' perspectives of sensitive data sharing. In this section, describe the included studies and method used. Three studies (Grande et al., 2015; King et al., 2012; Weitzman et al., 2012) provided insight into perceptions of health data sensitivity as well as preferences for sharing the data for care and/or research. Five studies (Caine et al., 2015; Caine & Hanania, 2013; Schwartz et al., 2015; Teixeira et al., 2011; Tierney et al., 2015) focused on evaluating preferences towards sharing health data. Table 2.3 summarizes the eight selected papers, population of interest and objectives, methods used and key findings.

2.3.1.1 Assessment of both Sensitivity Perceptions and Sharing Preferences

In a **semi-structured web-based** survey, Weitzman et al. captured attitudes and practices related to sharing health information of patients and parents/guardians using the personally controlled health records (PCHR) system.(Weitzman et al., 2012) As a part of a larger survey, authors asked participants about their willingness to share data from PCHR, conditions and context of sharing and sensitivity towards a set of categories. The categories included contagious illness, violence, sexually transmitted diseases, tobacco, alcohol, other substances, genetic disorders, mental illness, family information and financial information.

King and colleagues. focused on discovering Australian adults' (18 years or older) attitudes towards privacy in health care via focus groups and a social survey.(King et al., 2012) The **focus groups** asked participants about their views on privacy of health information used for research and a **social survey** of 700 adults asked about privacy concerns towards certain types of health record items including sexually transmitted disease, abortion and infertility, family medical history/genetic disorders, mental illness, drug/alcohol incidents, list of previous operations/procedures/dates and current medications. The survey also asked participants' concerns about sharing their information for research. The study did not focus on participant’s willingness to share information for care and treatment purposes.

Lastly, a comparative study by Grande et al. administered an **online survey** with embedded **conjoint experiments** to understand the differences in willingness to share health information and sensitivity of health information of individuals with and without history of cancer.(Grande et al., 2015) Conjoint analysis is marketing research tool to understand the preferences towards individual attributes of consumer products.(Grande et al., 2013) Using scenario-based conjoint experiments, the authors compared three attributes related to information use including who will access the information, for what purpose as well as sensitivity of the information. The participants were randomly assigned six scenarios created by the researchers and were asked to rate their willingness to share personal health information on a 1–10 scale (1=low, 10=high).

2.3.1.2 Assessment of Data Sharing Preferences

Caine and Hanania conducted a study to assess desires of adult patients receiving healthcare in central Indiana regarding granular privacy control of their health information and diversity in preferences based on the sensitivity of electronic medical record information.(Caine & Hanania, 2013) As a part of a larger study, two **card sorting** tasks were designed to understand patient preferences for sharing medical records with potential participants (for example, providers, researchers, family members, etc.). **Card sorting** is a commonly used approach to understand user perspectives on information architecture or organization.(*Card Sorting*, 2013) The authors introduced the five NCVHS sensitive categories during the study and assessed preferences of sharing high and low sensitive items, though sensitivity perceptions were not captured In (Caine et al., 2015), Caine et al. reported on the outcomes of the **semi-structured interviews** designed to identify user needs to inform the design of an interface recording individual choices regarding EHR access. The interviews assessed selected aspects of an individual's knowledge about their EHR contents and desire for granular control over this data.

Schwartz et al. studied primary care patients' willingness to share EHR data by allowing patients to restrict EHR access to various providers via a computer-based program.(Schwartz et al., 2015) In a **demonstration project**, patients could exert granular control and restrict access to all data or specific NCVHS sensitive categories and for a specified time period. Additionally, a follow-up **Likert-style survey** partially assessed control over access to information. In a concurrent study, Tierney et al. asked providers their opinions about patients controlling the access to their EHR data.(Tierney et al., 2015) If patients in (Schwartz et al., 2015) restricted access to EHR for any providers, relevant data was redacted for the providers whose access was restricted. However, if providers felt that important information might be being redacted, they could "break the glass" to view the redacted data during that EHR use session.

Providers in (Tierney et al., 2015) participated in the **demonstration project**, as well as completed a post-study **semi-structured survey** containing Likert-style and open-ended questions partly focusing on their opinions and comfort level regarding patient control over EHR data access, the effect of such restrictions and related concerns.

Teixeira et al. conducted a **survey** study to understand attitudes of persons with HIV towards their personal health information storage and sharing.(Teixeira et al., 2011) Authors assessed individual's willingness to share their personal health information with various recipients.

Table 2. 3 Summary of Findings

#	*Article*	*Year*	*Population*	*Objective*	*Methods*	*Findings*
Assessment of both Sensitivity Perceptions and Sharing Preferences						
1	Weitzman et al. (Weitzman et al., 2012)	2012	Patients, parents, or guardians of patients	Assess willingness to share health information	Cross-sectional Web-based survey	63.3% of 261 reported they would be more willing to share all information with the state/local public health authority than with an out-of-hospital provider (54.1%) (OR 1.5, 95% CI 1.1, 1.9; p = .005); few would not share any information with these parties (respectively, 7.9% and 5.2%). For public health sharing (ORs 4.9 to 1.4, all p-values < .05) and provider sharing (ORs 6.3 to 1.5, all p-values < .05), reticence was higher for most topics compared to contagious illness.
2	King et al. (King et al., 2012)	2012	Adults 18 years or older	Discover privacy concerns towards sharing data for research	Focus groups, Social survey	Great support for medical research (98%), and concern about privacy of health information (66%) was found. Participants preferred to be asked for their permission before their health information was used for any purpose other than medical treatment (92%). There was a concern (42-60%) about any possibility of linking patient's name with sensitive data (such as sexually transmitted diseases) in a situation not related to medical treatment.
3	Grande et al. (Grande et al., 2015)	2015	Individuals with and without history of cancer	Compare willingness to share data between individuals with and without history of cancer	Online survey, Conjoint experiments	Participants with and without a diagnosis of cancer had similar willingness to share health information (0.27; P = .42). Both cancer and noncancer participants rated the purpose of information use as the most important factor (importance weights, 67.1% and 45.6%, respectively). Cancer participants were more willing to share their health information when the information included more sensitive genetic information (0.48; P = .015).
Assessment of Data Sharing Preferences						
4	Teixeira et al. (Teixeira et al., 2011a)	2011	Adults 21 years or older living with HIV	Assess attitudes towards personal health information storage and sharing	Survey	The majority (84%) of individuals were willing to share their personal health information (PHI) with clinicians involved in their care. Fewer individuals (39%) were as willing to share with non-clinical staff. Willingness to share PHI was positively associated with trust and respect of clinicians.
5	Caine and Hanania (Caine & Hanania, 2013a)	2013	Adults receiving healthcare in central Indiana	Assessment of desire towards granular control and sharing preferences	Card sorting tasks	No patients reported that they would prefer to share all records with all potential recipients. Sharing preferences varied by type of information and recipient. Overall sharing preferences varied by participant. Patients with and without sensitive records preferred less sharing of sensitive versus less-sensitive information.
6	Caine et al. (Caine et al., 2015a)	2015	Adults receiving healthcare in central Indiana	Derive user needs for an interface recording granular sharing choices	Semi-structured interviews	Patients rarely knew what data were in their EHRs but would have liked to know. They also wanted to be able to control who could access what information in their EHR and wanted to be notified when their data were accessed.
7	Schwartz et al. (Schwartz et al., 2015a)	2015	Adults 18 years or older	Assess patient's willingness to share EHR data	Demonstration project, Likert-style survey	Sixty patients (57 %) did not restrict access to EHRs for any providers. Thirty-four (32.3 %) patients blocked access to all personal information by all doctors, nurses, and/or other staff, 26 (24.8 %) blocked access to all doctors and/or nurses, and five (4.8 %) denied access to all doctors, nurses, and staff.
8	Tierney et al. (Tierney et al., 2015)	2015	Physicians, nurses, and other clinic staff	Assess provider views on patient control over EHR access	Demonstration project, Likert-style survey	Providers "broke the glass" for 14 % of 43 patients with redacted data vs. zero among 49 study patients without redactions (p = 0.01); 54 % agreed that patients should have control over who see their EHRs, 58 % believed restricting EHR access could harm provider-patient relationships and 71 % felt quality of care would suffer.

2.3.2 Summary

With the exception or Tierney et al, the other seven papers focus on the populations of patients and/or parents/guardians of patients.(Tierney et al., 2015) The outcomes from our literature review suggest that the type and sensitivity of the health information, (Caine et al., 2015; Caine & Hanania, 2013; Grande et al., 2015; King et al., 2012) the type of data recipient (Caine et al., 2015; Caine & Hanania, 2013; Schwartz et al., 2015; Teixeira et al., 2011; Weitzman et al., 2012) and the purpose of data use (Grande et al., 2015; King et al., 2012; Weitzman et al., 2012) may influence subjects' attitudes towards sharing medical data. Subjects are less willing to share information that is highly personal, such as sensitive information about sexually transmitted diseases, abortions and infertility, family medical history/genetic disorders, mental illness, drug/alcohol related incidents, operations/procedures/dates and current medications. Subjects' willingness to share decreases when the research is done by commercial or for-profit entities and the purpose of data use is different from treatment. Caine et al. found that subjects' lack of knowledge of what data is in their EHRs and with to know more to make better informed data sharing decisions.(Caine et al., 2015)

Qualitative methods such as surveys and interviews emerged as prominent methods to assess individuals' views of sensitive data and pertinent sharing preferences.(Caine et al., 2015; Caine & Hanania, 2013; Grande et al., 2015; King et al., 2012; Schwartz et al., 2015; Teixeira et al., 2011; Tierney et al., 2015; Weitzman et al., 2012) In conjunction with qualitative methods, other approaches, such as conjoint experiment and hands-on project demonstrations were used.(Grande et al., 2015; Schwartz et al., 2015; Tierney et al., 2015)

In general, most of the studies attempted to understand individual’s perspectives of health record sensitivity or sharing preferences as part of a larger study.(Caine et al., 2015; Grande et al., 2015; King et al., 2012; Teixeira et al., 2011; Tierney et al., 2015; Weitzman et al., 2012) Except for Schwartz and Tierney et al., none of the studies identified used own patient’s EHRs.(Schwartz et al., 2015; Tierney et al., 2015)

Previously, individuals have been asked about their preferences towards NCVHS recommended sensitive date categories for care and research.(Caine & Hanania, 2013; Schwartz et al., 2015) Individuals ’ preferences towards a broader list of potentially sensitive categories have been explored.(King et al., 2012; Weitzman et al., 2012) Researchers and policy makers have advocated for better understanding of patient perception and the need for identifying sensitive data categories.(Caine & Hanania, 2013; *National Committee on Vital and Health Statistics. Recommendations Regarding Sensitive Health Information*, 2010)

Overall, there is a need for methodologies to study medical record sensitivity and willingness to share various types of sensitive and non-sensitive data personalized to the individual’s own EHRs. In the next section, we propose a novel mixed-method approach that uses individuals’ own EHRs to assess perceptions of the sensitivity of medical records and willingness to share these records for care and research.

2.4 Conclusion

Driven by a need to identify and employ standard approaches to understand data sharing and preferences, this chapter reviews the current state of the art on such methodologies. It was found that there is a need for methodologies to study: 1) data sensitivity and willingness to share data, especially methods personalized to the individual’s own medical records, and 2) differences in patient and provider views on data sensitivity to inform the development of effective processes, technology and policies on sensitive data sharing.

In support of the goals of this research, this literature review informed the development of a preliminary semi-structured survey (Aim 2; Chapter 3) and personalized card sorting interviews (Aim 3; Chapter 4). Next chapters aim to address the knowledge gaps identified through the completed systematic literature review.

CHAPTER 3

PERCEPTIONS AND PREFERENCES ABOUT GRANULAR DATA SHARING AND PRIVACY OF PATIENTS WITH BEHAVIORAL HEALTH CONDITIONS

3.1 Introduction

The outcomes of the literature review conducted in the previous chapter suggested the lack of studies assessing perceptions on data sensitivity and willingness to share data. Especially, there is a lack of research focusing on data sharing preferences of patients with BHCs for care and research.(Caine et al., 2015; Caine & Hanania, 2013; Grande et al., 2015; King et al., 2012; Schwartz et al., 2015; Teixeira et al., 2011; Tierney et al., 2015; Weitzman et al., 2012) We developed a preliminary survey to elicit data sharing views of Spanish and English-speaking patients with BHCs, including those with SMI.

We designed a semi-structured 19-question survey on demographics, self-stigma, quality of life, granular data sharing and sensitiveness of information to understand the perceptions of sensitive data and data sharing preferences of patients with BHCs (Aim 3). Descriptive and inferential statistical methods were used for analyses.

Eighty-six patients with BHCs (n=37 Latinos; n=32 with SMI) completed questionnaires, in either English or Spanish, with items assessing their views on privacy and sensitivity of health record information. Patients self-reported having sensitive information in their medical records and many participants (64.15%) wanted to restrict those records from some or all health care providers. Participants indicated they would be extremely to somewhat willing to share their data for research purposes with their care facilities and universities (96.5%). Most patients (82.5%) considered mental health information as sensitive. In general, there was a direct correspondence between perceived sensitivity of information and willingness to share with all or some providers. Survey participants asked frequent clarifications on the meaning of some types of sensitive data, such as genetic data. The 'It does not apply to me' response was frequently used when asked about sensitive data sharing (34.4% for all types of data, and 29.7% for behavioral health data). Most participants (96.5%) indicated they would be extremely to somewhat willing to share their data for research with their care facilities and universities.

The results indicated variations in patient preferences of sensitive data sharing. The frequent selection of 'It does not apply to me' responses and clarifications asked by patients related to data categories (e.g. genetic data) point towards potential lack of understanding of sensitive medical information, or stigma related to sharing certain information.

The results of this research are published as a conference paper in the 17th World Congress of Medical and Health Informatics (MEDINFO) 2019 conference.(Soni et al., 2019)

"**Soni, H.**, Grando, A., Aliste, M. P., Murcko, A., Todd, M., Mukundan, M., Saks, M., Horrow, C., Sharp, R., Dye, C., Chern, D., Whitfield, M. J., & Callesen, M. (2019). Perceptions and Preferences About Granular Data Sharing and Privacy of Behavioral Health Patients. *Studies in Health Technology and Informatics*, *264*, 1361–1365. https://doi.org/10.3233/SHTI190449"

3.2 Methods

3.2.1 Study Sites

Study site 1 is a community clinic in Arizona providing general mental health (GMH) treatment and social services to adults of all ages. Site 2 offers case management services to adult patients in Arizona with SMI. This study was approved by the Arizona State University (ASU) Institutional Review Board (IRB) (Studies# 4371 (3/2/2017) and 5835 (3/8/2017)).

3.2.2 Survey

Our survey was based on a formative survey developed by Grando and colleagues to understand the data sharing preferences of patients with BHCs. (M. A. Grando et al., 2017) (Appendix D). Demographic information was categorized based on US Census Bureau classifications, except diagnoses, which were adapted per National Institute of Mental Health (NIMH) categorization.(Bureau, n.d.; *NIMH » Individual Mental and Behavioral Disorders for U.S.*, n.d.) The sensitive categories used in our instrument to ask questions related to sensitive data were based on those used by the National Committee on Vital and Health Statistics.(*National Committee on Vital and Health Statistics. Recommendations Regarding Sensitive Health Information*, 2010) The resulting survey was translated to Spanish and back-translated to English by native Spanish speakers.

3.2.3 Survey Reliability Testing

Reliabilities of questionnaire items were examined using a test-retest approach with 31 Spanish and English-speaking adult patients with BHCs from study sites 1 and 2. Participants completed the questionnaire, in either English or Spanish, on two occasions, 14-21 days apart. Questionnaire items were revised based on the outcomes of the reliability analyses. The revised questionnaire was used in the current study.

3.2.4 Study Participants

Potential participants were identified by study site staff members during routine clinical visits and referred to the recruiters. After the recruiter met with the prospective participant at the facility and explained the study to him/her (in either English or Spanish), the recruiter assessed the participant's decision-making capability (using the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) test).(Jeste et al., 2007) We excluded participants with low consent comprehension (i.e., with UBACC scores < 15). Adult patients (21 years old or older) diagnosed with GMH or SMI who agreed to complete the questionnaire in English or Spanish and were deemed capable of giving informed consent were considered eligible to participate.

3.2.5 Study Design

After initial screening and consenting eligible participant, the recruiter offered the participants the option of completing the questionnaire either in English or Spanish, and either electronically or on paper. The recruiter was present to help the participant with any questions or technical difficulties. Participants were compensated for their time.

3.2.6 Data Analysis

We used univariate statistics (e.g., frequencies, means, standard deviations, percentages) and plots to summarize the data. Parametric inferential statistical methods were used to analyze perceptions of data sensitivity and willingness to share data among English and Spanish-speaking, Latino and non-Latino participants from GMH and SMI populations.

3.3 Results

3.3.1 Demographics

Of the 88 participants recruited, 2 were excluded because of inability to understand and follow the study protocol, as measured by the UBACC test. Table 3.1 shows the demographics of participants included in the sample. The majority (n = 54; 62.8%) of patients had a GMH condition, while the rest were patients with SMI diagnoses. Most participants (n = 71; 82.5%) opted to have the questionnaire administered in English; the remainder opted for Spanish.

Table 3. 1 Demographics of Participants

Participant characteristic	*Patients (n=86)* *Freq. (%)*
Age (Years)	
21-30	19 (22.1)
31-40	24 (27.9)
41-50	16 (18.6)
51-60	15 (17.4)
61-70	9 (10.5)
>70	2 (2.3)
Unknown	1 (1.2)
Gender	
Male	26 (28.9)
Female	59 (70.0)
Other	1 (1.1)
Race/Ethnicity	
White Alone, Not Hispanic or Latino	34 (38.9)
Black or African American	11 (12.1)
Hispanic or Latino	37 (44.4)
Native American or Alaskan Native	3 (3.3)
Other, Unknown	1 (1.1)
Income	
≤$10000	50 (58.1)
$10001-$20000	23 (26.7)
$20001-$30000	10 (11.6)
>$30001	3 (3.5)
Education	
No Schooling	1 (1.2)
Middle school (grades 6-8)	9 (10.5)
Some high school (no diploma)	14 (16.3)
High school graduate (or equivalent)	19 (22.1)
Some college (1-4 years, no degree)	24 (27.9)
Associate degree (including occupation/academic degrees)	14 (16.2)
Bachelor's degree (BA, BS, AB, etc.)	5 (5.8)
Patient Diagnoses	
Anxiety or panic disorder	65 (74.4)
Bipolar Disorder	34 (37.8)
Depression	65 (74.4)
Impulse Control Problems	10 (12.2)
Identity or memory problems	22 (25.6)
Eating disorder	5 (5.6)
Obsessive compulsive disorder	9 (10.0)
Personality disorder	13 (14.4)
Schizophrenia or other psychosis	14 (16.7)
Drug or alcohol addiction	18 (20.0)
Post-traumatic stress disorder or adjustment disorder	36 (41.1)
Chronic pain or somatic disorder	24 (26.7)
Other	1 (3.3)

3.3.2 Data Sharing for Care

We asked questions to understand participant's desire for granular data sharing control based on type of information, information recipient (provider or researcher) and purpose of data usage. We asked participants how likely they were to share their behavioral health data with different behavioral and non-behavioral providers (Figure 3.1). Participants were most willing to always or sometimes share their health information with the behavioral providers at the study sites, followed by emergency providers, other non-behavioral providers at the study sites (e.g., primary and specialty care providers, pharmacists), behavioral providers outside the sites, and lastly with other non-behavioral providers outside the study sites.

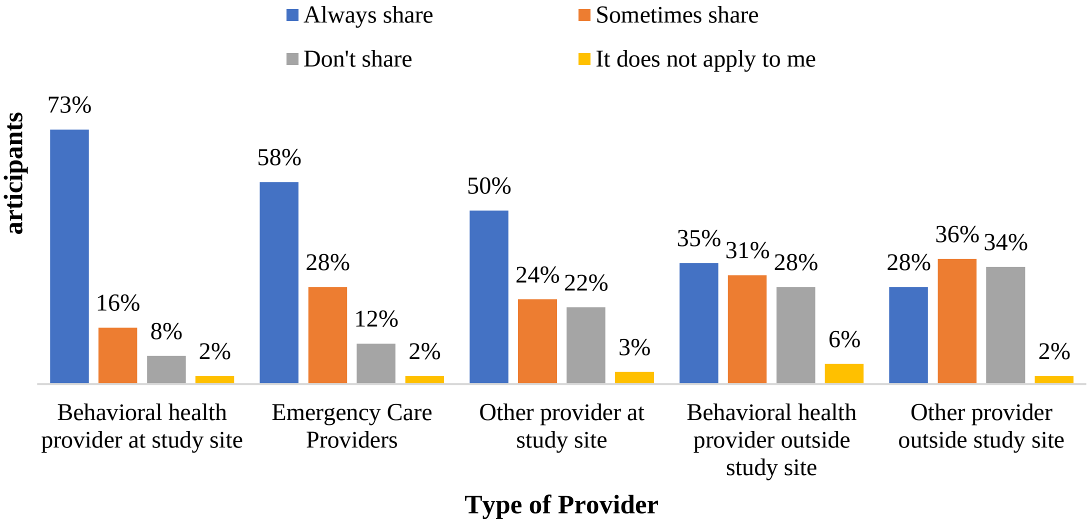


Figure 3. 1 Behavioral Health Data Sharing Preferences, based on the Type of Medical Provider

No significant differences in responses were seen when we divided participants in groups such as, English vs. Spanish speakers ($p=0.8657$, $\chi^2=1.2745$, Chi Square Test), Latino vs. non-Latino participants ($p=0.9409$, $\chi^2=0.7816$, Chi Square Test) and GMH vs. SMI patients ($p=0.9982$, $\chi^2=0.1216$, Chi Square Test).

In assessing participants’ perceptions about how sensitive different types of health information are, we provided them with eight health information categories: mental health, psychotherapy notes, sexual and reproductive health, domestic violence and abuse information, information on sexually transmitted diseases, drug or substance abuse, alcohol abuse, and genetic data. Most participants considered mental health information the most sensitive, followed by psychotherapy notes (Figure 3.2). For several categories, the most common single response was ‘It does not apply to me’. Unfortunately, we did not collect with the survey information that could be used to check if the participant did not have certain types of sensitive medical records.

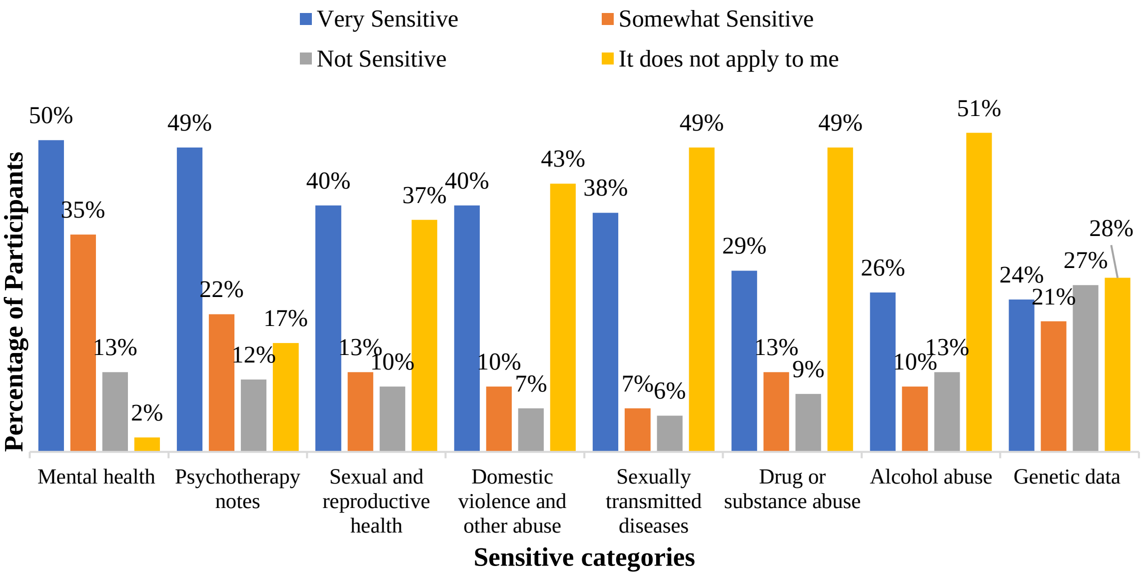


Figure 3. 2 Health Categories and Classification as Sensitive Information

Participants were then asked about the likelihood of sharing sensitive health information with providers outside the study sites (Figure 3.3). We computed the mean percentage of patients who wanted choices regarding sharing their data with different types of providers. On average, when self-reporting having sensitive information in their medical records (the option ‘It does not apply to me’ was not selected), many participants (64.15%) wanted to restrict those records from some or all health care providers.

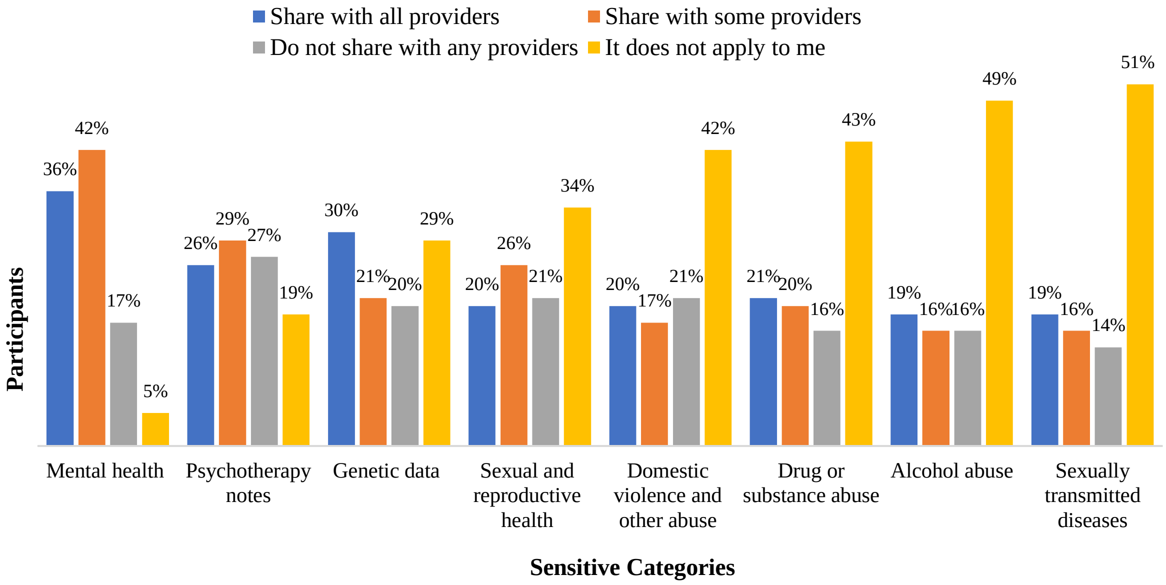


Figure 3. 3 Willingness to Share Sensitive Health Data with Providers Outside Study Sites

In general, we observed a direct correspondence between sensitivity of information and willingness to share (Figure 3.4). The more sensitive the participant thought that the information was, the more willing he/she was to share it with all or some providers. The main exception was genetic data. While participants considered genetic data less sensitive type of information, they ranked it as the third most sharable. Though, no significant associations were found among willingness to share information and sensitivity towards information among all categories except for sexually transmitted diseases ($p<0.05$, Fisher’s Exact Test).

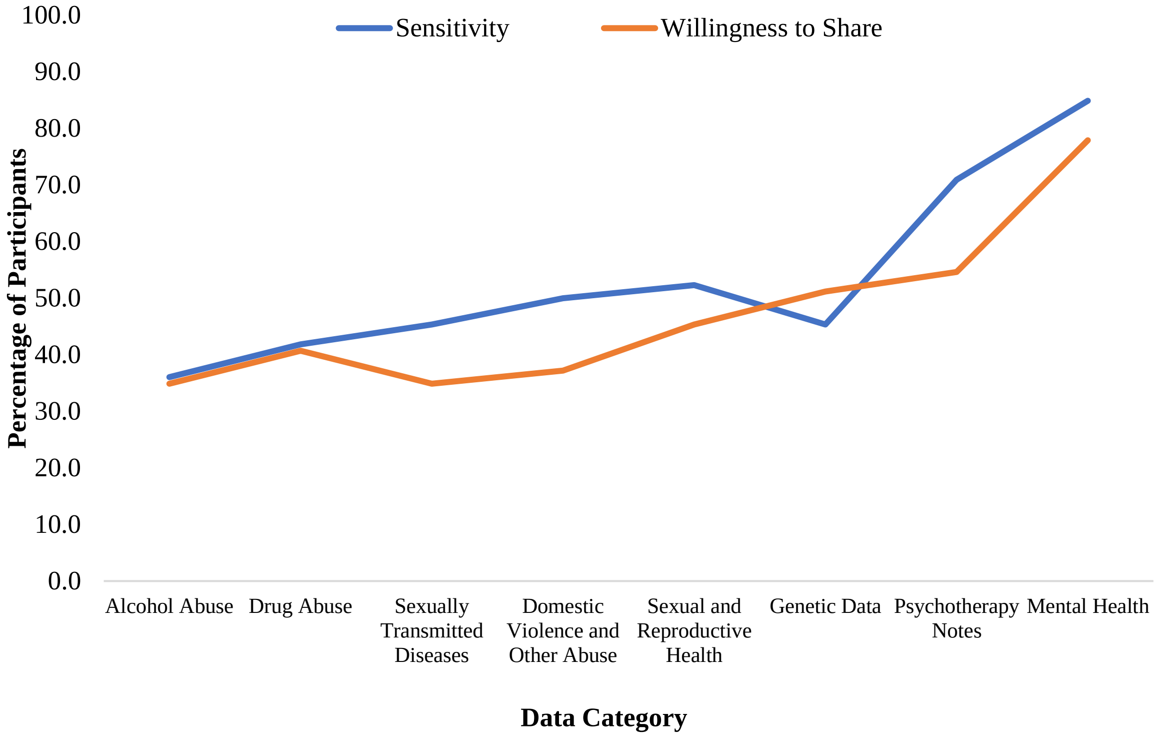


Figure 3. 4 Observed Correspondence Trend between Sensitivity and Willingness to Share

We asked participants about providers’ access to health information when prescribing a new medication. Most participants (78.0%) responded that the providers should have access to all their health data, 12.0% thought that providers should see only the data to which a patient provides the access, and 10.0% indicated that the providers should see all the health data only when the new medication may have any harmful interactions or effects.

Similarly, we asked patients about emergency providers’ access to data in a life-threatening situation. Most of the participants (70.0%), reported that providers should have access to all their data, 19.0% endorsed giving emergency providers access only to data shared by the patients, and 11.0% indicated that providers should have access to all health data only when the emergency may be life threatening.

Participants endorsed sharing their data when it can benefit their own care and treatment (77.8%) or if/when their providers asked them to share their data (61.1%). Large majorities of participants trusted the providers at the study sites overall (87.8%) and trusted them to share only the health data that they consented to share (93.3%). Large majorities also reported that they would be upset if their providers shared their health data without asking them (83.3%) and that they might react by leaving such providers (65.6%). Only 30% of the participants reported worrying about providers knowing that they receive mental health treatment.

3.3.3 Data sharing for Research

Participants were generally willing to share health information with researchers when their own care (91.1%) or care for others (78.9%) could be improved. About half (51.1%) of participants, indicated they would always share their data for research, while 35.6% indicated that they would share their data for research if they were paid for it.

Finally, we asked participants how likely they would be to share their health information with researchers (Figure 3.5). Participants indicated they would be extremely to somewhat willing to share their data for research purposes with their care facilities (96.5%). Participants appeared less willing to share their health information with drug development companies and government agencies.

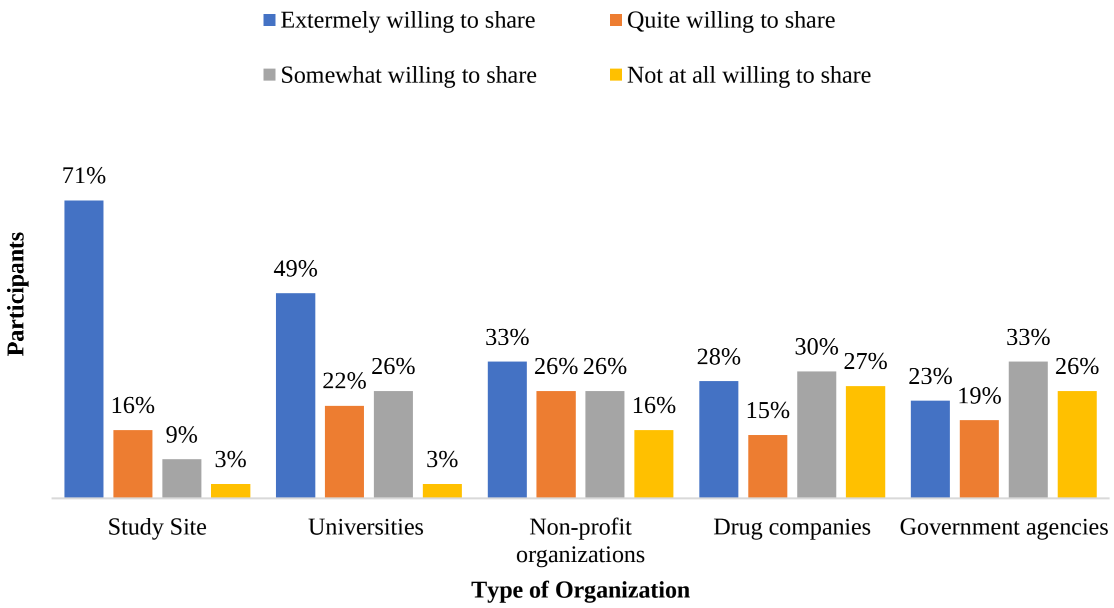


Figure 3. 5 Willingness to Share Data for Research with Different Types of Organizations

For each participant, we looked at if their willingness level varied between different types of organizations. For example, varying willingness to share data with care facility compared to drug companies. Most (78.9%) participants desired control over how they want to share data with different research organizations.

There were no significant differences between data sharing preferences of English vs. Spanish speakers ($p=0.9904$, $\chi^2=0.2913$, Chi Square Test), between Latino vs. non-Latino participants ($p=0.9640$, $\chi^2=0.5913$, Chi Square Test) as well as between GMH vs. SMI patients ($p=0.9928$, $\chi^2=0.2500$, Chi Square Test).

3.4 Discussion

Consistent with previous studies on patients with BHCs, participants wanted control on how to share sensitive health data with health providers.(M. A. Grando et al., 2017) When we contrast our results to studies from patients without behavioral conditions, it has been reported that patients with and without sensitive information prefer to restrict the sharing of sensitive versus less-sensitive EHR information.(Caine & Hanania, 2013; Kim et al., 2017) As reported in the literature, most of the participants appeared to be motivated to share health data unconditionally to avoid medical emergencies or drug-drug interactions.(Caine & Hanania, 2013; Hiestand et al., 2017; Patel et al., 2011) As in previous studies, our participants trusted their providers at the study sites and trust in providers was an important motivation for sharing health information.(M. A. Grando et al., 2017; Ricciardi, 2010; Serenko & Fan, 2013; Teixeira et al., 2011) Additionally, improvement in a patient's own care and treatment was an important motivating factor for sharing health data with providers. As in (M. A. Grando et al., 2017; Kim et al., 2017) patients wanted control on how to share health data with researchers. Consistent with literature, willingness to share data decreases when the recipient is a for-profit research organization.(E. A. Bell et al., 2014; M. A. Grando et al., 2017)

The response 'It does not apply to me' was frequently used when asked to assess the sensitivity of health data and willingness to share sensitive data with providers (34.4% for all types of data, and 29.7% for mental health, psychotherapy notes, drug or substance abuse and alcohol abuse). For some categories, like sexually transmitted disease or substance abuse, it is highly probable that the question did not apply to the participants. Though, participants' lack of understanding of the meaning of certain sensitive data categories or stigma related to disclosing this information could be potential explanations for this response.

For other categories, such as genetic data, the recruiters received frequent requests from participations for clarifications. We also observed that, compared to a direct trend among other sensitive categories, though patients considered genetic data less sensitive, they were very willing to share this information. This could also point to disparity in patient understanding of the category compared to provider interpretations.

Altogether, these results promote the need for better understanding of subjects' varying data sharing preferences and health literacy.

3.4.1 Challenges and Limitations

A limitation of our study is that study participants were sampled from only two outpatient clinics in similar geographic areas with similar social demographics. Additional studies should be conducted on a larger sample of the population to capture more diverse views.

3.4.2 Generalizability and Expansion

We applied the survey to assess data sensitivity and sharing preferences of patients with BHCs. This survey could be employed in understanding data sharing preferences of other population (such as healthy individuals or physical health patients), other types of sensitive categories (such as the NCVHS sensitive categories), types of providers and researchers, etc. with minimal modifications.

Inclusion of more open-ended response options in questions allowing patients choices of adding additional sensitive categories or type of providers could provide better understanding of patient preferences.

3.4.3 Future Work

Further research is needed to better understand survey outcomes, including granularity demands in data sharing as well as evaluate frequent use of ‘It does not apply to me’ responses. The outcomes of this survey guide follow-up card sorting interviews (Aim 3). In the upcoming interviews, data privacy questions are asked while study participants have access to a subset of their own medical records.

3.5 Conclusions

A better understanding of attitudes patients with BHCs towards data sensitivity and sharing is needed. Our findings observed differences in patient perceptions of sensitivity as well as demand for more granular data sharing choices.

The recurrent selection of ‘It does not apply to me’ responses by patients and frequent questions (e.g. what is genetic data?), could reflect lack of knowledge of certain sensitive medical records categories or stigma related to sharing certain information. This calls for a better understanding of patients’ medical records sensitivity perspectives to guide more effective granular informed consent processes.

In doing so, I propose and apply a novel card-sorting interview approach (Aim 3; Chapter 4) personalized to participants’ own medical records to a subset of the surveyed patients.

CHAPTER 4

NOVEL METHOD TO ASSESS MEDICAL RECORD SENSITIVITY PERCEPTIONS

4.1 Introduction

In Aim 1 (Chapter 2), our systematic literature review revealed that few studies have used a patients' own medical record information to explore types of information patients considered sensitive and how such perceptions affected data sharing preferences.(Caine et al., 2015; Caine & Hanania, 2013; Grande et al., 2015; King et al., 2012; Schwartz et al., 2015; Teixeira et al., 2011; Tierney et al., 2015; Weitzman et al., 2012) The outcomes of Aim 2 (Chapter 3) identified the need to better understand attitudes of patients with BHCs towards data sensitivity and sharing. It was assumed that patients might lack of understanding of certain sensitive categories or there is potential stigma of having certain types of sensitive information in their medical records. To further investigate patient preferences and to address the knowledge gaps, I designed personalized card sorting interview approach. The novelty of the approach is that it employs patients' own medical records to personalize the assessment of patients' views on data sensitivity and sharing preferences for care and research.

Patients were asked permission to access their EHRs, including those available through the state's health information exchange (HIE). Our study has been the first to use state's health information exchange data for research. A semi-structured interview script with seven closed card sorting tasks was designed and personalized to each participant's own medical records using thirty items from each patient's medical records. This mixed method combines the quantitative outcomes from the card sorting exercises with themes captured from interview audio recording analysis.

Twenty-five patients with BHCs, English and Spanish-speaking, were recruited. On average, participants recognized 82.7% of the 30 items from their own EHRs. Participants considered mental health (76.0%), sexual and reproductive health sensitive (75.0%) whereas drug abuse (41.1%) and genetic data (40.0%) were considered less sensitive information. Participants were more willing to share information related to other addictions (100.0%), genetic data (95.8%) and general physical health information (90.5%) compared to communicable diseases (77.8%) and sexual and reproductive health (76%). When considering adverse situations such as new medication prescription or emergency, 52.0% and 28.0% participants, respectively, desired choices in sharing data. Preliminary comparison between patient and provider data category classifications led to 66.3% agreements, 14.5% partial agreements, and 19.3% disagreements. Comparison with responses of Aim 2 survey indicated that, of 18 participants who responded that certain categories did not apply to them, 15 (83.3%) had some information in one or more of those sensitive categories.

The interview findings indicated diversity in patient views on EHR sensitivity and data sharing preferences based on type of information, information recipients and information sharing purpose. The interviews identified that patients' survey responses 'It does not apply to me' could be based on stigma related to certain sensitive categories (such as 'drug abuse') or differences in patient perceptions of sensitive medical records classifications compared to standard clinical interpretations (such as patients considering diabetes as 'genetic data' because it "runs in the family"). To further understand rationale for those differences, we compare patients' perspectives with providers, in the next chapter (Aim 4, Chapter 5).

The design and application of this approach have been published in the Journal of Biomedical Informatics-X along with systematic literature review described in Aim 1 (Chapter 2).(Soni et al., 2020)

“**Soni, H.**, Grando, A., Murcko, A., Diaz, S., Mukundan, M., Idouraine, N., Karway, G., Todd, M., Chern, D., Dye, C., & Whitfield, M. J. (2020). State of the art and a mixed-method personalized approach to assess patient perceptions on medical record sharing and sensitivity. *Journal of Biomedical Informatics*, *101*, 103338. https://doi.org/10.1016/j.jbi.2019.103338”

4.2 Methods

Here, I propose a novel approach that uses individual’s own medical records to assess perceptions towards sensitivity of medical records and willingness to share these records for care and research.

4.2.1 Research Team

Subject matter experts from various fields were involved in the development and conduct of this mixed method approach, including biomedical informatics researchers and a statistician. Clinicians reviewed the medical record categorizations and patient education material while study site leadership previewed the materials for appropriateness and compliance.

4.2.2 Study Sites

This study was conducted at two urban outpatient integrated health clinics providing behavioral and physical care to patients with BHCs. Access to additional records from non-behavioral health providers was obtained with permission from the

Arizona HIE. These records contained both structured and unstructured health behavioral and non-behavioral health records.

Integrated clinics: Both Sites 1 and 2 provide physical and behavioral care. Site 1 offers general mental health and social services to children, families and adults of all ages serving approximately 12,000 patients annually. Site 2 offers a range of recovery-focused services to approximately 1,000 adult patients with serious mental illnesses annually. Both sites use a similar proprietary EHR widely used in the US.

HIE: Arizona's statewide physical and behavioral HIE (HealthCurrent) supports nearly 500 participant providers and 8.9 million unique patients.("Network by the Numbers," 2017) Both Sites are members of the HIE. The HIE follows an opt-out consent model for physical health, meaning that data from participating healthcare organizations and providers is automatically shared unless patient explicitly declines to share. An opt-in consent is required for data protected by the 42 CFR Part 2 regulations.

4.2.3 Study Participants

Adult (21 years old or older) English or Spanish-speaking patients diagnosed with a general mental health condition were recruited at Site 1 and those with serious mental illnesses were recruited at Site 2. As part of the larger project, these participants have longitudinally participated in several studies, including the companion survey from Aim 2 (Chapter 3) that served as the formative basis for this research. As part of the original survey (described earlier), the decision-making capacity of the participant was assessed by verbally administering the UBACC test.(Jeste et al., 2007) This study was approved by the ASU IRB (Studies 7514 (2/6/2018) and 7731 (2/12/2018)).

4.2.4 Medical Record Access

Participants from the original data sharing preferences survey were re-contacted and asked permission to access to their personal behavioral and physical health medical records available from their respective study sites and the HIE. As part of the study consent process, participants executed a HIPAA authorization to provide access to their records. Participants were compensated for their time. Patients were also asked permission to be re-contacted for the follow up interview.

4.2.5 Medical Records Sorting and Selection to Create Personalized Cards

We received access to structured and unstructured EHRs (only HIE) from the collaborating sites. This section describes sorting and selection of medical record items for the personalized card sorting tasks. Card sorting is a commonly used approach to understand information architecture views and allows researchers to understand user perceptions and preferences towards categorization of the topic of interest.(*Card Sorting*, 2013) Figure 4.1 summarizes the approach designed to sort and categorize specific medical record items.

Step 1. The first step involves classifying information received from the digital EHRs into sensitive data categories. We only used the structured medical record items for classification. For our study, items were assigned to one of eight data categories. Seven categories were based on the sensitive categories supported by Consent2Share: 1) mental health, 2) drug abuse, 3) alcohol use and alcoholism, 4) other addictions (such as tobacco use disorder), 5) sexual and reproductive health, 6) genetic data and 7) HIV/AIDs and other communicable diseases. Definitions of the classes were adapted based on the standard definitions used in Consent2Share tool by SAMHSA.(*SAMHSA-HRSA Center* *for Integrated Health Solutions. The Current State of Sharing Behavioral Health Information in Health Information Exchanges*, 2014) An additional category, 8) other information, was included to accommodate non-sensitive information or other categories that do not clearly fit any of the above-mentioned categories.

Step 2. The second step consists of classifying each item according to sensitivity. For example, in this study, each item was classified as "sensitive", "not sensitive" or "possibly sensitive". We considered an item "sensitive" if it could be categorized to one or more of the seven sensitive categories by our clinical collaborators. An item was "not sensitive" if classified as 'other information'. An item was "possibly sensitive" if it could be classified as both "sensitive" and "not sensitive". For example, the medication Vicodin (generic: acetaminophen-hydrocodone) is considered "possibly sensitive". Vicodin abuse may be considered sensitive, while the use of Vicodin to manage severe acute pain may be categorized as not sensitive.

Step 3. The third step is defining additional criteria to identify the medical record items for card sorting tasks. To meet the needs of this study, a 2:1 ratio of sensitive to not sensitive EHRs was used to achieve a higher number of sensitive items in the medical record cards. Therefore, we created 30 medical record cards (see section 4.6 for detail): 20 representing potentially sensitive items and 10 corresponding to non-sensitive records. If the structured data from the Site EHR did not include 20 sensitive items, we carefully reviewed the clinical notes received from the HIE (unstructured records) to seek more sensitive items. More than 10 non-sensitive cards were included if there were insufficient sensitive records for any patient. We carefully reviewed patient EHRs to select 20 items representing different sensitive categories to create a diverse set of medical record items, however, patients may not have medical record items belonging to each of the eight data categories. In such cases, we included items from the available categories. As feasible, cards represented medical diagnoses, laboratory results, medications, allergies, procedures, and services.

Item Validation. The process described above was performed by four biomedical informatics student researchers and the outcomes were independently reviewed by two health providers (one internist and one psychiatrist).

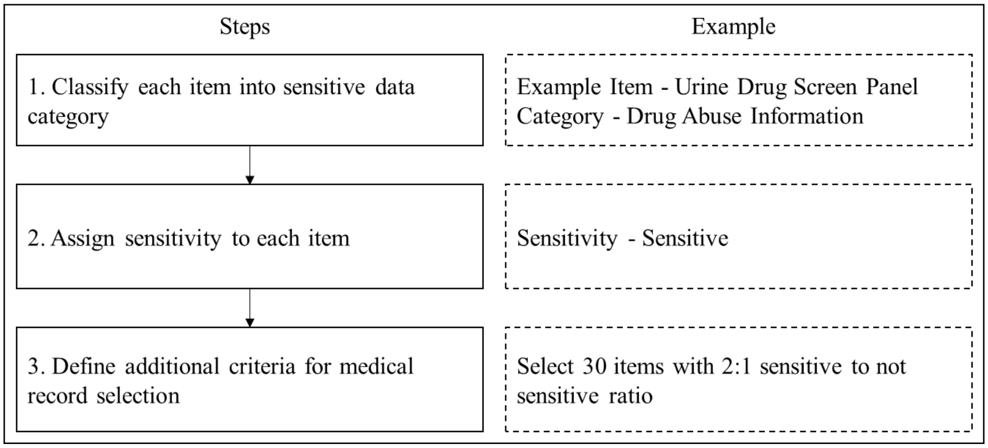


Figure 4. 1 Medical Record Sorting Approach with Example

4.2.6 Personalized Card Sorting Tasks and Interview Script

Card sorting allows researchers to understand user perceptions and preferences towards the topic of interest.(*Card Sorting*, 2013) In closed card sorting, participants are asked to sort content of interest in various predefined categories. With predefined categories, closed card sorting methods provide insight into how users classify the content in various categories.(*Card Sorting*, 2013)

A semi-structured interview script (Appendix E) including seven card sorting tasks (Table 4.1) was developed and personalized to the medical records of the study participants. Best practices for card sorting tasks recommend limiting the cards between 30-40 items to minimize participant fatigue.(*Card Sorting*, 2013) We selected the lower number, 30, based on the cognitive load of the tasks.

The script and cards were available in English and Spanish. English script and cards were translated to Spanish and back translated to English by native Spanish speakers to ensure that the literacy levels were commensurate with patients' educational background and reading ability. An accuracy certificate was presented to the IRB.

Figure 4.2 shows an example of a study question to describe the card sorting components.

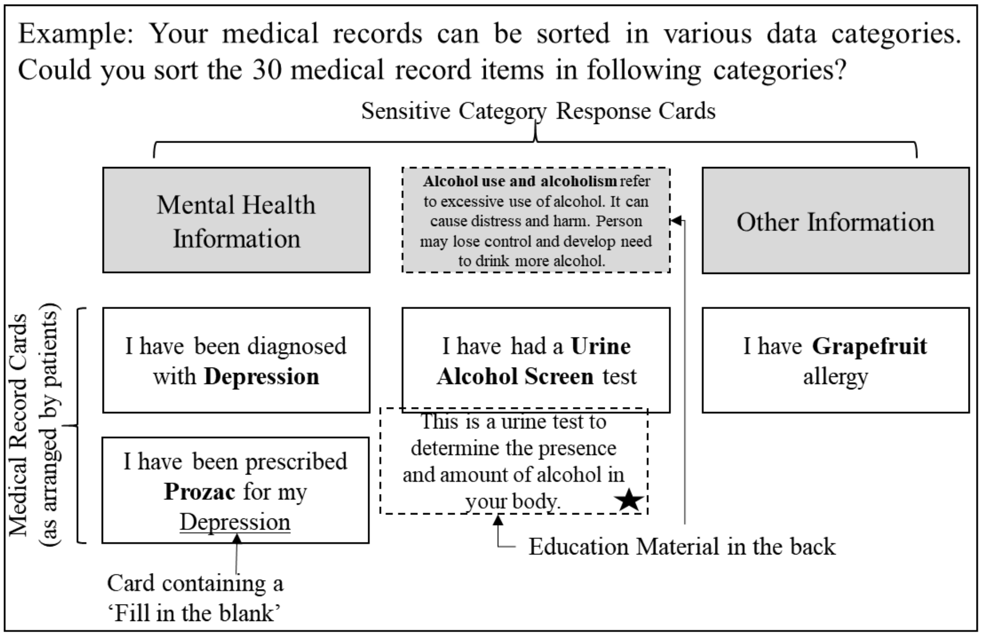


Figure 4.2 Card Sorting Components and Example

Table 4. 1 Interview Sections and Related Questions

Theme	***Questions***
Recognition of own medical records	**Q1:** You may or may not remember the information in the **white card**. But we would like to know how much you remember. Do you recall this information from your present or past medical records? Can you also tell me what do you remember about each? We will go through these cards one by one. There might be some fill in the blanks in cards. We will fill those out as we move forward. *Response Options: Yes; Unsure*
Classification of own medical records into sensitive categories	**Q2:** The medical records can be sorted in different data categories. For example, a card could have a medication related to depression. So, it may relate to the mental health. Could you sort the medical record cards in the data category cards on the table? *Response Options: Drug Abuse; Alcohol Use and Alcoholism; Mental Health; Communicable Diseases; Genetic Data; Sexual and Reproductive Health; Other Addictions; Other Information* [NOTE: After sorting the 30 cards a bundle was created for each category to answer Q3 and Q4]
Sharing of data for care and research	**Q3:** We would like to know your choices of sharing the data in these data category bundles. Would you share information in these bundles with the providers you might see outside Site X? *Response Options: Hospitals; Primary Care Providers; Specialty Care Providers; Nurses; Case Managers; Licensed professional counselors/therapists; Pharmacists; Medical Assistants* **Q5:** Imagine your primary care provider wants to start a new medication. The new medication may have side effects. The primary care provider wants to see your medical records. Which of these 30 medical record cards would you like your doctor to see? Could you tell me some reasons behind your choice? *Response Options: Share This Information; Do not Share This Information* **Q6:** Suppose you have an emergency. And you are unconscious when you come to emergency room. Your emergency care provider wants to see your medical records. But they are unable to ask your permission. Which of these medical record cards would you like your doctor to see? Could you tell me some reasons behind your choice? *Response Options: Share This Information; Do not Share This Information* **Q7:** The next question is related to sharing your medical records for research. There are many organizations that conduct research. For example, I am doing this research at Arizona State University. I will show you different researcher cards. Would you to share all your data for research? Can you please tell me why or why not? *Response Options: Extremely Willing to Share; Quite Willing to Share; Somewhat Willing to Share; Not at All Willing to Share*
Data sensitivity perceptions	**Q4:** We have the medical record in bundles of medical record cards. We also saw how willing you are to share these bundles with your providers. (Q3 below) Now, some of these **bundles** might require special handling. Sharing this information might harm you. A doctor or nurse might treat you differently. Do you think any of the **bundles** are sensitive for you? Could you please say why or why not? *Response Options: Very Sensitive, Somewhat Sensitive; Not Sensitive*

On the front of each medical record card, to increase patient comprehension, standard statements were used to describe the medical record items (Table 4.2).

Table 4. 2 Standard Statements to Describe Medical Record Items

Type of Item	***Standard Statement***
Diagnosis	I have been diagnosed with <medical record item>
Labs	I have had a <medical record item> test
Medications	I have been prescribed <medical record item> medication for my _________
Allergies	I have a <medical record item> allergy
Procedures	I have undergone a <medical record item> procedure for my _________
Services	I have received a <medical record item> service for my _________

For medical record cards pertaining to medications, procedures and services, a *'fill in the blank'* slot was used for the patient to document the reason for the prescription or service. The flip side each medical record card contained pertinent written material curated from reputable resources, such as Medline Plus, to provide patients with standardized, on-demand information about medical record items if needed to help to identify and sort the cards appropriately.(*MedlinePlus—Health Information from the National Library of Medicine*, n.d.) Another purpose of educational material was to assess patient knowledge of their own medical records. The educational material, presented at 6th grade level (using the MS Word Flesch-Kincaid Grade Level) was reviewed by two clinicians.(*How to Find the Readability Score for Your Word Document*, n.d.) For example, education material related to a diagnosis of depression read: "Depression is a serious medical illness. It's more than just a feeling of being sad or "blue" for a few days."

For all interview questions (Table 4.1), response cards were provided. For example, various predefined Likert response options were created for questions Q1 and

Q3-Q7. In Q2, we provided response cards with 8 predefined data categories as detailed in section 2.5. During the study, patients could classify the 30 items in one of the eight data categories.

For Question 2, participants received educational material about sensitive data categories on the flip side, with examples of medical record items classified under each data category. An example of supporting material related to the response card is ‘mental health information’ The flip side states: “Mental health problems affect mood, thinking and behavior. It can make you unhappy and can cause problems in your daily life. There are many causes of mental health problems. Genes, family history and life experiences may have an effect. There are many treatments available. Mental illness examples include Anxiety and Panic Disorders, Depression, Mood and Personality Disorders, Bipolar Disorder, Psychotic Disorder, etc.”

4.2.7 Interviews

Interview recordings were transcribed and coded by two bilingual (Spanish and English) co-authors using MS Excel.(*Microsoft Excel 2016 Spreadsheet Software, Excel Free Trial*, n.d.) The Spanish recordings were first transcribed in Spanish and later translated in English by a Spanish recruiter. Transcriptions were checked by a second translator. All transcriptions were reviewed for accuracy.

The data captured as photographs of card sorting exercises were quantitatively coded and analyzed using MS Excel.(*Microsoft Excel 2016 Spreadsheet Software, Excel Free Trial*, n.d.) Descriptive measures were used to calculate frequency, mean and range. Below, we individually describe the analyses for each of the seven card sorting questions and relevant initial hypotheses.

Responses to the *'fill in the blank'* section for medications, procedures and services cards (Q1) were compared to categorization by clinicians. This approach could help to assess a patient's ability to recognize information from their own EHR. Researchers have previously studied patient comprehension of new medication prescriptions and clinical data, such as laboratory tests.(Reynolds et al., 2018; Tarn & Flocke, 2011) Our hypothesis is that patients data categorizations may differ from provider categorizations and may have difficulties in recognize/remember some types of information related to their medical records.

To assess opinions about sensitivity of medical records, their categorization rationale (Q2) were analyzed. We hypothesize that sensitive data perceptions will be different between patients.(*National Committee on Vital and Health Statistics. Recommendations Regarding Sensitive Health Information*, 2010; Simon P. Cohn, 2008)

To assess variability in patient perceptions of data sensitivity, participants' sensitivity and data categorizations assessed in Q4 were compared to the classifications provided by two clinicians in our research team. We believe that no comparable studies or methods exist for assessing patient perceptions of data sensitivity by category. Considering the open questions from previous survey, the frequent use of 'it does not apply to me' and questions related to the meaning of certain sensitive categories (e.g. genetic data), we hypothesize differences in sensitivity perceptions of patients.

Questions Q3 and Q5-Q7 assessed preferences for data sharing based on information type, information receiver (health provider or research) and purpose of data use (care delivery or research). Based on previous studies, we hypothesize diversity in patient perceptions of sensitivity of EHRs and sharing preferences.(E. Bell et al., 2014;

Caine et al., 2015; Dhopeshwarkar et al., 2012; M. A. Grando et al., 2017; Schwartz et al., 2015; Teixeira et al., 2011; Whiddett et al., 2006)

We used the audio recording to verify accuracy and consistency of asterisks marked by the recruiters regarding patient's reference to education material. Audio and card data were also used to determine instances when participants were uncertain what the card meant and asked for information rather than looking at the back of the card. In case of fill-in-the-blank exercises, agreements between participants' responses were compared against online resources, like Medline Plus, and revised by a clinician in our research team to determine comprehension.(*MedlinePlus—Health Information from the National Library of Medicine*, n.d.)

4.3 Results

4.3.1 Demographics

Thirty-six patients provided access to their EHRs. From these, 25 participants were recruited for the interview study (Table 4.3).

Table 4. 3 Participant Demographics

Participant characteristic	*Medical Records Access (n=36) Freq. (%)*	*Card Sorting Interviews (n=25) Freq. (%)*
Age (Years)		
21-30	3 (8.3)	2 (22.1)
31-40	9 (25.0)	6 (24.0)
41-50	9 (25.0)	7 (28.0)
51-60	7 (19.4)	3 (12.0)
61-70	6 (16.7)	6 (24.0)
>70	1 (2.8)	1 (4.0)
Unknown	1 (2.8)	0 (0)
Gender		
Male	14 (38.9)	10 (40.0)
Female	22 (61.1)	15 (60.0)
Other	0 (0)	0 (0)
Race/Ethnicity		
White Alone, Not Hispanic or Latino	14 (38.9)	10 (40.0)
Black or African American	2 (5.6)	2 (8.0)
Hispanic or Latino	18 (50.0)	12 (48.0)

Native American or Alaskan Native	1 (2.8)	1 (4.0)
Other, Unknown	1 (2.8)	0 (0)
Income		
≤$10000	22 (61.1)	18 (72.0)
$10001-$20000	8 (22.2)	5 (20.0)
$20001-$30000	5 (13.9)	2 (8.0)
>$30001	1 (2.8)	0 (0)
Education		
Middle school (grades 6-8)	7 (19.4)	6 (24.0)
Some high school (no diploma)	4 (11.1)	2 (8.0)
High school graduate (or equivalent)	7 (19.4)	5 (20.0)
Some college (1-4 years, no degree)	10 (27.8)	7 (28.0)
Associate degree (occupation/academic degrees)	7 (19.4)	4 (16.0)
Bachelor's degree (BA, BS, AB, etc.)	1 (2.8)	1 (4.0)
Preferred Language of Study		
English	26 (72.2)	19 (76.0)
Spanish	10 (27.8)	6 (24.0)
Type of Diagnoses		
General mental health	25 (69.4)	15 (60.0)
Serious mental illness	11 (30.6)	10 (40.0)
Patient Diagnoses		
Anxiety or panic disorder	27 (75.0)	19 (76.0)
Bipolar disorder	13 (36.1)	8 (32.0)
Chronic pain or somatic disorder	11 (30.6)	9 (36.0)
Depression	26 (72.2)	18 (72.0)
Drug or alcohol addiction	4 (11.1)	3 (12.0)
Eating disorder	2 (5.6)	1 (4.0)
Identity or memory problems	6 (16.7)	3 (12.0)
Impulse control problems	2 (5.6)	1 (4.0)
Obsessive compulsive disorder	4 (11.1)	4 (16.0)
Personality disorder	6 (16.7)	4 (16.0)
Post-traumatic stress disorder or adjustment disorder	12 (33.3)	8 (32.0)
Schizophrenia or other psychosis	7 (19.4)	5 (20.0)

4.3.2 Recognition of Medical Record Items

On average, participants recognized 82.7% (range:33.3-100.0%) from the 30 items extracted from their own EHRs. Though participants were unsure about 17.3% (range:0.0-66.7%) items, only 4 removed these item (3.3%) from the study. Most (91.7%) unsure items were labs, with representative responses *"I don't remember,"* or *"I don't know what it is but I know it is for blood work"*.

On average, participants referred to the education material for about 32% items (range:3.3-76.7%). Participants frequently checked material related to labs (47.3%) and medications (29.3%). There was very poor correlation between number of times medical records educational material was referred to and age (r= 0.19) or income (r= -0.17). Few participants referred to education material for genetic data (12.0%) and S&R health (8.0%).

Participants completed eight fill-in-the-blank cards on average. Most (95.8%), participants' responses matched with provider classifications/definitions of medication and procedure/service purposes. From the 24% participants who did not recognize medications or services, the unrecognized data was mostly categorized by providers as mental health (83.3%).

4.3.3 Medical Records Classification in Sensitive Data Categories

Participant's categorization was compared against the providers. Tables 4.4 and 4.5 show agreement between participants and providers based on data categories and type of information, respectively.

Participants classified 587 (80.7%) items in agreement. Among 140 (19.3%) disagreements, participants classified 60 (42.9%) items as genetic data. Providers classified most (73.3%) of the 60 items as other information. Participants often disagreed on labs like complete blood count or metabolic panels, classifying them as genetic data, as they evaluate blood components or detect blood-related conditions. They also classified chronic conditions (like diabetes) as genetic. When asked rational behind classifying thyroid labs as genetic data, one participant commented, *"it runs in the family"*. Another mentioned that *"my mom has it [thyroid abnormalities], my sister has it [thyroid abnormalities]"*, so thyroid tests belong to genetic data.

Participants classified possibly sensitive labs related to "communicable diseases S&R health" as S&R health. One participant classified hepatitis labs as S&R health because *"if I have a partner… they know I'm clean and I've been tested [for hepatitis]"*.

Table 4. 4 Agreement of Participant Classification of Medical Records in Eight Primary Data Categories

Data Category	*Agreement Freq. (%)*	*Disagreement Freq. (%)*	*Total*
Drug Abuse	104 (83.9)	20 (16.1)	*124*
Alcohol Use and Alcoholism	11 (73.3)	4 (26. 7)	*15*
Mental Health	210 (91.3)	20 (8.7)	*230*
Communicable Diseases	32 (68.1)	15 (31.9)	*47*
Genetic Data	1 (100.0)	-	*1*
S&R Health	22 (66. 7)	11 (33.3)	*33*
Other Addictions	2 (40.0)	3 (60.0)	*5*
Other Information	204 (75.3)	67 (24.7)	*271*
Total	*586 (80.7)*	*140 (19.3)*	***726***

Table 4. 5 Agreement of Participant Classification of Medical Records based on Medical Information Type

Type of Information	*Agreement Freq. (%)*	*Disagreement Freq. (%)*	*Total*
Allergies	17 (68.0)	8 (32.0)	*25*
Diagnoses	132 (78.6)	36 (21.4)	*168*
Laboratory Tests	223 (77.2)	66 (22.8)	*289*
Medications	170(87.6)	24 (12.4)	*194*
Procedures/Services	44 (88.0)	6 (22.0)	*50*
Total	*586 (80.7)*	*140 (19.3)*	***726***

4.3.4 Medical Records Sensitivity

Most participants concurred with providers considering mental health (76.0%) and S&R health (75.0%) somewhat to very sensitive (Table 4.6). One participant commented that mental health information is very sensitive as *"others do not want to realize how [mental state] you are"*.

Participants appeared to fear stigma and discrimination of mental health (24.0%). A participant commented that *"…it [mental health] is sensitive, for me it's a bother because they treat me very differently… they treat me like an idiot not like a person"*.

Participants frequently considered drug abuse or alcohol use not sensitive perceiving that they do not have a dependency. One participant diagnosed with alcohol dependency commented that *"I don't have a dependency to alcohol. I went to a hospital because I had a few beers after having suicidal thoughts, other than that no".*

Table 4. 6 Participant Perceptions of Sensitivity towards Various Data Categories

Data Category	***# of Participants with Medical Records in Category***	***# of Participants Who Considered Category Sensitive***	***Examples of Participant Perceptions***
Drug Abuse	17	7 (41.1%)	Not Sensitive: "I have nothing to hide because I don’t do drugs." Not Sensitive: *"maybe because I don't use [drugs]"*
Alcohol Use and Alcoholism	8	4 (50.0%)	Not Sensitive: "Because I don't drink."
Mental Health	25	19 (76.0%)	Very Sensitive: "Don't want anyone who's not a doctor to know all my information, especially suicidal stuff.".
Communicable Diseases	9	5 (55.6%)	Very Sensitive: "I don’t want everyone to know what diseases I have or what I've been diagnosed with."
Genetic Data	15	6 (40.0%)	Very sensitive because it's very private to him
Sexuality and Reproductive Health	12	9 (75.0%)	Very Sensitive: "I had to have it because I was sexually abused and I don't want people knowing about that."
Other Addictions	3	2 (66.7%)	Not Available
Other Information	25	10 (40.0%)	Somewhat Sensitive: "Its stuff about my body but medical professionals do need to know history."

4.3.5 Sharing Medical Records for Care and Influence of Sensitivity

All participants desired to share all or some of their EHRs data with providers outside the study sites (such as primary care providers (PCP)) (Table 4.7). Twelve (48.0%) wanted to share all data with all providers. These participants felt that sharing all data would allow them to receive better care and would improve patient-provider and provider-provider communications. A participant mentioned, *"It's easier. Instead of remembering all of this [medical records]"*.

Thirteen (52.0%) participants desired choices in sharing records. When considering the mean willingness to share data with all types of providers, participants appeared very willing to share other addictions (100.0%), genetic data (95.8%) and other information (90.5%) and less willing to share S&R health (76.0%) and communicable diseases (77.8%) information. One participant wanting to share S&R health with only PCPs and specialty providers commented, *"unless, it's affecting something, I don't think they [other providers] need to know"*.

The majority (79.0%) of participants wanted more choices around sharing mental health and were more willing to share with behavioral providers outside the study sites (92.0%) compared to non-behavioral providers. A participant noted, *"I don't think a cardiologist needs to know about it [mental health]"*.

Table 4. 7 Participant Preferences of Sharing Medical Records with Providers Outside Study Sites. All numbers are Represented as Percentages

% of Participants		***Type of Providers***								
		Primary Care Providers	Specialty Care Providers	Hospitals	Medical Assistants	Nurses	Licensed Professional Counselors/Therapists	Case Managers or Social Workers	Pharmacists	*Average*
Data Category	Other Addictions	100	100	100	100	100	100	100	100	*100*
	Genetic Data	100	93.3	100	100	100	93.3	86.7	93.3	*95.8*
	Other Information	96	96	100	88	88	88	84	84	*90.5*
	Alcohol Use	87.5	87.5	75	87.5	87.5	75	87.5	75	*82.8*
	Mental Health	76	80	92	76	76	92	84	76	*81.5*
	Drug Abuse	87.5	87.5	81.3	75	81.3	81.3	81.3	75	*81.3*
	Communicable Diseases	88.9	77.8	77.8	77.8	77.8	77.8	66.7	77.8	*77.8*
	S&R Health	91.7	83.3	75	83.3	75	66.7	66.7	66.7	*76*
Average		*90.9*	*88.2*	*87.6*	*86*	*85.7*	*84.3*	*82.1*	*81*	-

Stigma was cited as an important component of data sharing decisions. A participant commented that *“it [data sharing] might be helpful, it might be detrimental because they see your [mental health] diagnosis and don’t see you as a person. Kind of torn between that."* About sharing drug abuse information, the same participant said, *"I don't want anyone knowing I smoke marijuana because they[providers] look at you differently"*.

We compared the trend between sensitivity and sharing preferences with different providers to identify any direct correspondence between them. Figure 4.3 shows the individual series for sensitivity (dashed series) and different types of providers (solid series). In contrast to the previous survey, no direct correspondence between sensitivity and willingness to share was observed in this study.

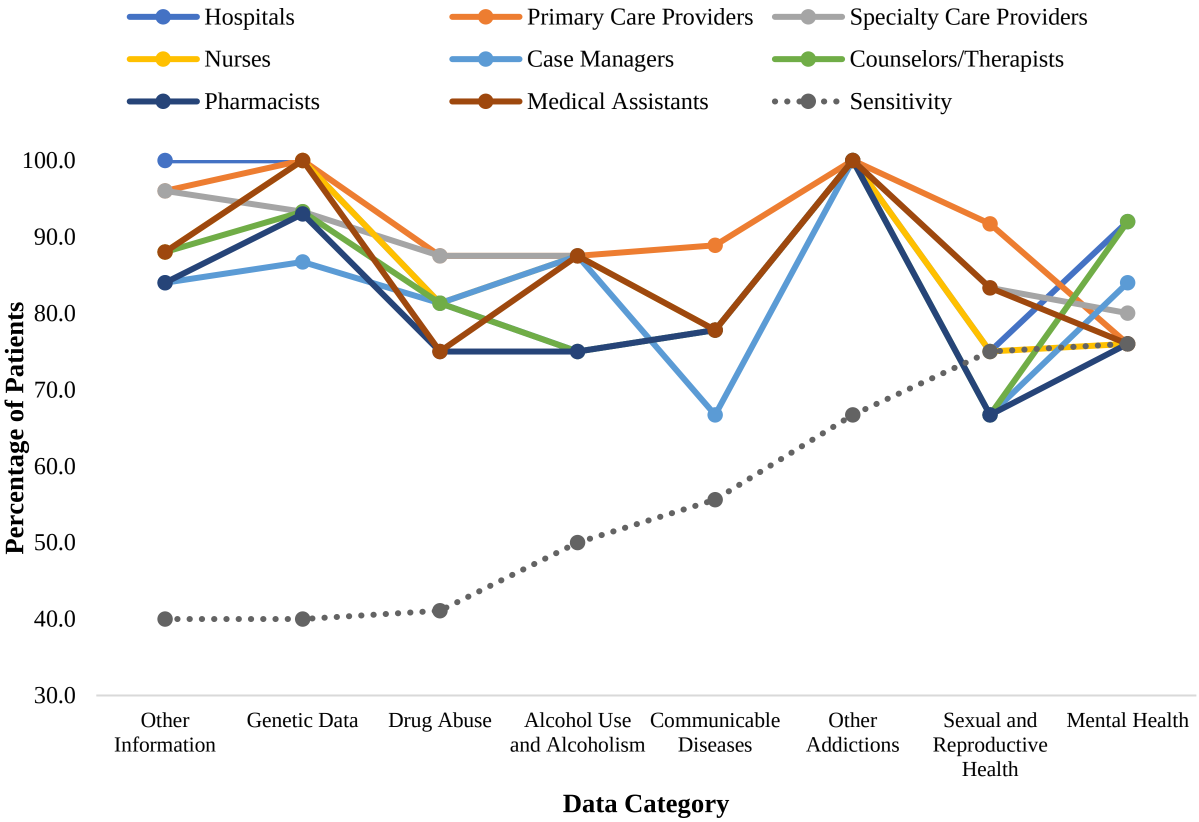


Figure 4. 3 Observed Correspondence Trend between Sensitivity and Willingness to Share

4.3.6 Willingness to Share in Case of Medication Prescription and Emergency

In a hypothetical scenario, we asked participants about their PCP accessing their EHR when prescribing a new medication. Participants were willing to share 85.1% of medical record items. Avoiding adverse drug reactions were a prominent motivation for sharing. A participant mentioned, *"PCP prescribes medication that counteracts medication prescribed by psych [behavioral health] doctor, so they need to be on the same page".* Thirteen (52.0%) participants wanted choices in sharing records. Nine participants chose to restrict some information related to mental health and drug use. One chose to restrict mental health diagnosis and services but opted to share mental health medications commented, *"all my mental health I don't want to share. They [PCP] would know from the medication that it is mental health medication and they [PCP] don't need to know specifics".* Two participants did not want the PCP to know about suicide attempt and physical abuse. Twenty-four percent participants desired to restrict communicable diseases OR S&R health labs and diagnoses perceiving that *"nobody needs to know about this [HIV Antibody Screen Test]"*. Participants (20.0%) chose to restrict S&R health labs and diagnoses (pregnancy (HCG) test, erectile dysfunction diagnoses, etc.) and data pertaining to certain medical conditions (chronic condition tests, obesity diagnosis, etc.).

Another hypothetical scenario asked participants about emergency providers accessing their EHRs in life-threatening situations. Participants wanted to share most (89.1%) EHRs, with 18 participants willing to share 100% records. A common perception was that *"in any emergency situation, they need to see all my data [medical records]."* Seven (28%) participants wanted choices in sharing data. Most (71.4%) wanted to restrict diagnoses, medications and services related to mental health and drug abuse (57.1%). Many (42.6%) participants wanted to share chronic condition labs, urine cultures and metabolic panels. A few (28.6%) preferred to restricted diagnoses and labs for S&R health and communicable diseases.

4.3.7 Sharing Medical Records for Research

We asked participants about sharing the types of data represented by the 30 cards for research study (Figure 4.4). Most (76.0%) participants were extremely willing to share for research conducted by study sites and universities (64.0%). Improvement in own and others' care appeared to be a motivation for many (56%) participants. Almost half (52.0%) of the participants showed willingness to share with non-profit organizations. Participants were less willing to share their EHR data with government agencies (48.0%) and pharmaceutical companies (40.0%). A participant commented, *"I don't know much about them [government agencies]. I don't want someone I don't know much about to know all about me."* Another participant who did not want to share data with drug companies mentioned, *"They [drug companies] don't need to know my personal information and I don't really trust drug companies that much"*.

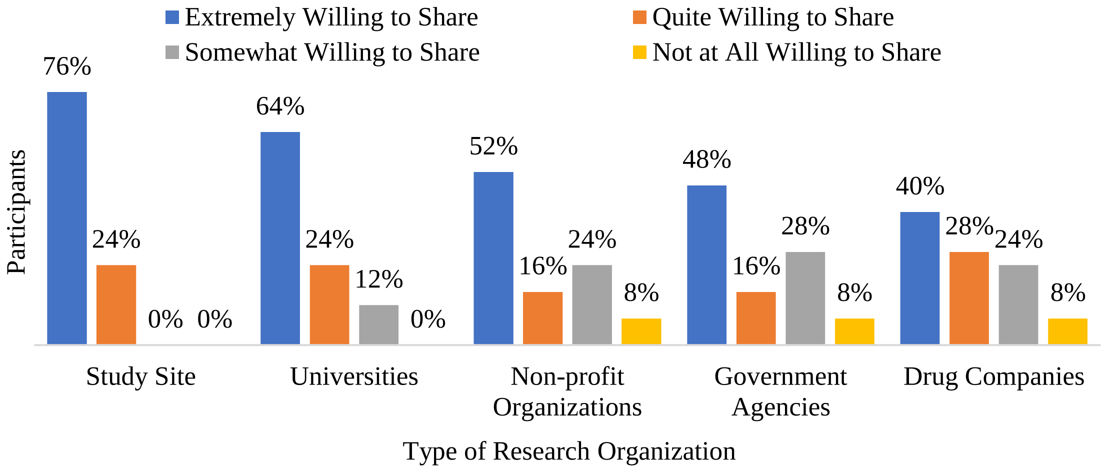


Figure 4. 4 Participant's Preferences for Sharing Medical Records with Different Types of Research Organizations

4.3.8 Comparison of Current and Previous Data Sharing Preferences

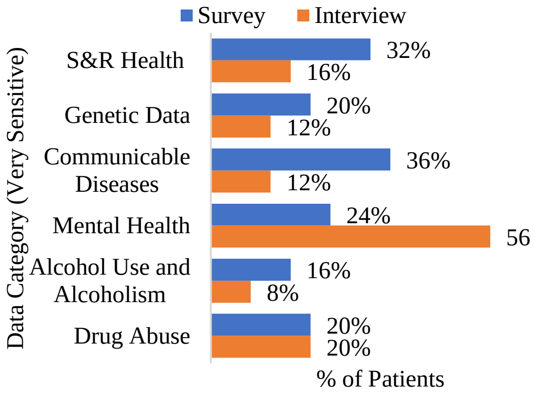
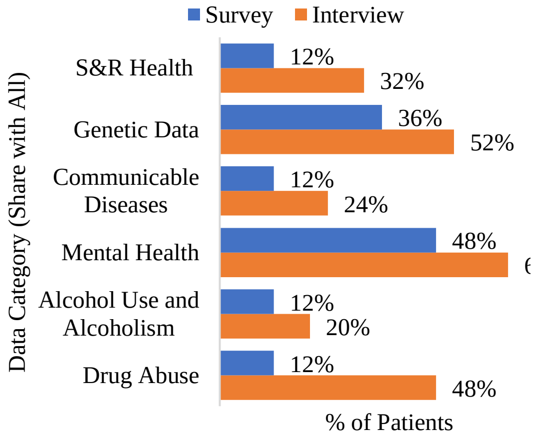
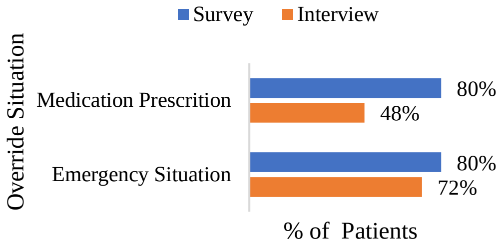
To further investigate for the assumptions made in Aim 2 (Chapter 3) regarding frequent selection of 'It does not apply to me' and assess any changes in patient responses upon access to medical records, we compared 25 participants' survey (Aim 2) and card sorting (Aim 3) responses for five questions (Table 4.8). The major difference being that, during interviews, participants responded to questions considering their own medical records. We compared responses for six common categories: mental health, drug abuse, alcohol abuse, S&R health, communicable diseases and genetic data.

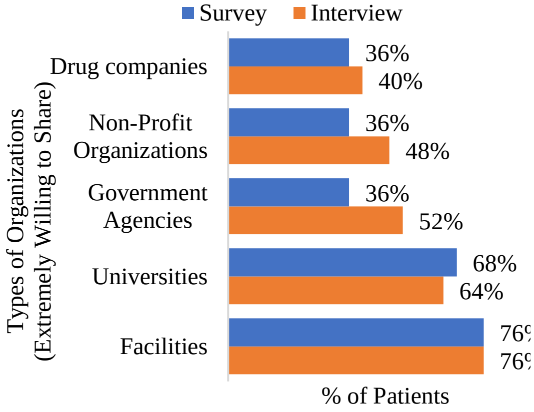
Perceptions of sensitivity varied during both studies. Except for mental health and drug abuse, a decreasing trend was seen in sensitivity towards other categories. Participants appeared to be much more willing to share medical records in all categories during interviews. Interestingly, participants desired more choices in sharing medical records in override situations, such as new medication prescription and emergencies, compared to survey.

In both studies, there was a consensus among participants regarding sharing data for research with their respective sites. Participants seemed more willing to share records with government agencies, non-profit organizations and drug companies during the interviews. Improvement in care was a prominent motivation for sharing in both the studies.

During the survey, 18 of the 25 participants responded to questions with the 'It does not apply to me' response. Interviews determined that 15 of those 18 survey participants' EHRs contained items from one or more of the six data sensitive categories compared: drug abuse (11/15), S&R health (7/15), genetic data (6/15), and communicable diseases (5/15). In interviews, majority patients considered all categories not sensitive (8/15) and chose to share with some or all providers (13/15). These 15 participants referred to education material for 10 items on average during the interviews. Six of the 15 participants had some college education or higher.

Table 4. 8 Comparison of Patient Perspectives of Data Sensitivity and Data Sharing Preferences

<table>
<tr><th>Category</th><th>Survey vs. Interview Responses</th><th>Interview Comments</th></tr>
<tr><td>Perceptions of sensitivity</td><td>
</td><td>"It's [mental health] a lot of stigma."
"Sometimes providers treat you differently if they know about certain mental health disorders."</td></tr>
<tr><td>Data Sharing for Care</td><td>
</td><td>"I have fibromyalgia, so my mental health directly impacts my physical health."
"Almost everything with them [providers] because I need them to know where I need to go"</td></tr>
<tr><td>Data sharing in Override Situations</td><td>
</td><td>"they [medical records] are things that are more important that doctors [PCP] can share with other doctors"
"the [emergency] provider needs my information or else they can't do it [help her]… therefore, it's logical to share information..."</td></tr>
</table>

Data sharing for research		*"I am not willing to share [with drug companies and government agencies] because I can't share all my information regarding my medical records"* *"They [researchers] got my welfare at mind. They [researchers] want to help. Why not make it easier for both."*

4.4 Discussion

Driven by our desire to create a standardized, integrated consent management platform for sharing individual EHR data, we needed to deeply understand the health information sharing preferences and perceptions of patients, particularly those with behavior health conditions.

Sensitivity measurements showed participants were categorizing mental health (76.0%) and S&R health (75.0%) as very to somewhat sensitive, but patients were choosing to place other traditionally perceived sensitive categories such as alcohol use and drug abuse as not sensitive. Interestingly, these specific categories are protected by 42 CFR Part 2 and are legally and clinically considered sensitive.(*42 CFR Part 2—Confidentiality of Substance Use Disorder Patient Records*, n.d.) However, participants who explained their not-sensitive categorizations of these categories appeared to be considering their applicability to their own circumstances. This tendency to consider applicability of a category to how participants viewed its sensitivity was also visible in the Aim 2 survey results.

Our results show that subjects' willingness to control data sharing changes based on the type of health information and perceived sensitivity.(Caine et al., 2015; Caine & Hanania, 2013; Grande et al., 2015; King et al., 2012) The connection between sharing preferences and sensitivity perceptions of own EHRs is especially interesting. There are differences in how patients choose to share categories they deem sensitive. Results showed that S&R health (75.0%) and communicable diseases (76.0%) considered sensitive were less likely to be shared (76.0% and 77.8%, respectively). However, 66.7% of participants classified other addictions as a sensitive category, yet all chose to share. While Whiddett et al. suggested that patients desire to restrict sensitive information, our results showed that while that was true for some categories such as S&R health, it was not true for all.(Whiddett et al., 2006)

Consistent with previous research, our results indicate that willingness to share depends on the type of data recipient. (Caine et al., 2015; Caine & Hanania, 2013; Schwartz et al., 2015; Teixeira et al., 2011; Weitzman et al., 2012) Grando et al. and Schwartz et al. both point to patients potentially choosing not to share information based on their fears of discrimination and lack of trust with a provider.(M. A. Grando et al., 2017; Schwartz et al., 2015) This research showed that fears of stigma and discrimination do play a role in the choice to share data and is prominently visible in the category of mental health. Participants considered this category sensitive (76%) and were considerably willing to share based on whether a provider were a behavioral (share) or non-behavioral (not share) provider. Granular data sharing control by the patient thus may not coincide directly to sensitivity of a category but include a more complex consideration of discrimination fears, trust, and provider relevancy for treatment.(Caine & Hanania, 2013; M. A. Grando et al., 2020; Schwartz et al., 2015)

In our review of the literature in Chapter 1 Caine and colleagues suggest that 100.0% of the patients in their study did not know their own EHR data, but wanted to know more about them to be able to make more informed data sharing decisions.(Caine et al., 2015) We found that patients with BHCs usually recognized their own medical record data (82.7%), though some patterns of recognition difficulty did emerge. For the 17.3% of data that patients found difficulty recognizing as part of their data, laboratory results were predominant (91.7%). Despite this uncertainty, participants consulted the education material only 47.3% times. Therefore, in instances of uncertainty, patients may not seek written educational material. Similarly, participants did not check the definitions of data categorized as genetic (12.0%) or S&R (8.0%). The recognition of genetic data was shown to be imperfectly understood by the original Aim 2 survey. Therefore, there is a need for personalized educational material delivered in different mediums, such as face-to-face explanations or multimedia education, prioritizing high-uncertainty categories.

Interestingly, participants' categorization compared to standard interpretations showed differences in perceptions of certain categories. While 66.4% of the health information was categorized in agreement to our classifications, participants' predominant disagreement in categorization of genetic data (37.5%) and other information (25.0%). For example, a participant classified general physical health laxative medication as Mental Health, even upon recognizing the use of medication but relating it to their general Mental Health regimen: "…This one is for constipation. I say mental health because of medication…if they give you pain pills, they'll give you a

Laxative". This points to incongruity in patient-provider sensitivity perceptions. The 19.3% of overall disagreement and nearly 14.3% partial agreement point to a divergence in patient-provider perceptions that affects how patients categorize and share data with different providers. There is a need to further understand the variations in patient perceptions of sensitivity and medical records classification from standard clinical interpretations and potential factors influencing patient views.

Sensitivity and sharing preferences of participants seemed altered upon access to EHR date in interviews. While most patients (72.0%) indicated that certain sensitive categories did not apply to them in the survey, their EHRs contained data within one or more of those categories. Drug abuse, S&R health and genetic data appeared to prominent categories for which patient views were altered.

Overall, our findings reveal that that there is a diversity in medical records sensitivity and sharing perspectives of patients with BHCs concerning type of information (mental health, sexual and reproductive health, drug abuse information, etc.), recipients (care providers, research organizations, etc.) and purpose of sharing (e.g. care coordination, research, emergency, etc.). Additionally we learned that the differences in patient understanding of data categorizations and sensitivity compared to standard interpretations, stigma and/or difficulty to recognize or remember data from their EHRs could have led to frequent 'It does not apply to me' survey responses.

4.4.1 Challenges and Limitations

The study had limited participants, but their diversity in age, ethnicity/race, and education provides an excellent base for understanding perceptions of sensitivity and sharing. With the inclusion of patients with BHCs as the focus, this study provides a more complete understanding as the emphasis on combining physical and behavioral health data via the HIE continues in the US.(*Bringing Behavioral Health into the Care Continuum*, n.d.; *Challenges in Delivery of Behavioral Health Care—Managing Managed Care—NCBI Bookshelf*, n.d.; *Mental Health By the Numbers | NAMI: National Alliance on Mental Illness*, n.d.; *NIMH » Mental Illness*, n.d.; *The future of behavioral health care*, n.d.)

The proposed method relies on closed card sorting tasks. It is possible that the predefined groups or responses could have biased or restricted patients from other, alternate classification schemes or categories. Patients may have felt stigma related to the experience of sharing information with researchers. It is also possible that patient definitions of sensitivity and data sharing choices may have been altered after exposure to information from their own EHRs. We intend to compare responses of these interviews with our previous survey to explore if patient choices may have been impacted by access to their EHRs.

The process of creating the medical records cards resulted in the separation of some contextual information from medical record items. For example, though available, we did not provide participants with the indication (diagnoses/symptoms) for their psychotropic medications. The availability of this information could have influenced perceptions on sensitivity and sharing.

We received limited data in some sensitive categories. This may be related to legal restrictions on the use or disclosure of certain types of sensitive data. In Arizona, for example, HIE statutes limit the types of use and disclosures of genetic data as well as the general release of data though the HIE.(Health Current, 2017) Lack of sufficient data in all categories could introduce bias and limit the representativeness of data.

EHR records spanning five years were used to create the personalized card sorting tasks. It is possible that patients did not remember details of their medical history (example, prior medications) and therefore not recognize these items. Cognitive impairment and memory loss occur in conditions such as depression, bipolar and personality disorders, obsessive-compulsive disorder, schizophrenia, etc.(Trivedi, 2006) Such factors may have impacted patient perceptions and choices when classifying longitudinal medical record items.

4.4.2 Generalizability and Expansion

Although the proposed method has been piloted with patients receiving care for behavioral health conditions, it is readily applicable to other patient populations and to a wide range of concepts, including alternate sensitive data categories, chronic conditions, criminal justice, abuse and violence, and social parameters (e.g. demographics and socio-economic status, etc.). The differences between perceptions of diverse populations should be studied to better understand variations in data sharing preferences, identify other potentially sensitive data categories and personalized education needs.

Modifying the exercise by substituting the closed card sorting exercise with an open sorting exercise may allow participants to organize and label groups based on what makes sense for each individual.(*Card Sorting*, 2013) Using open card sorting elements, entirely or as an addition to the closed sorting exercise, may yield new insights by providing study participants with more expressive freedom. For example, when classifying their EHRs into sensitive data categories, patients could define additional categories as they see fit. Such design modifications might provide a complementary perspective to explore patient perceptions of sensitive data and identify knowledge gaps.

4.4.3 Future Work

Validation of the proposed methodology with a larger and more diverse population is needed. Caine and Hanania asked patients about data sensitivity and sharing preferences using NCVHS recommended sensitive categories.(Caine & Hanania, 2013) As future work we propose to compare our results with the results from Caine and Hanania studies.

Although they play an integral role in patient care and engagement, healthcare provider views on data sensitivity and data sharing have been rarely studied.(M. A. Grando et al., 2017; Tierney et al., 2015) The outcomes of this study have been used to explore provider views on granular data control.(Tang et al., 2019)

Our findings showed that patients contextualize their medical records based on their own experience and patient's data sensitivity views vary from providers' perspectives. Our follow up study compares patient and providers sensitivity perceptions in more depth. Areas of disagreement, along with patient explanations should provide insights into patient's unique granular data sharing choices.

4.5 Conclusion

This chapter proposes and applies a novel personalized card sorting methodology to gain insights into previously unexplored areas around sensitive data definitions, and patient perceptions and willingness to share sensitive data for care and research.

We identified variations in patients' preferences of sensitivity and sharing with respect to type of information (more willing to share sensitive Mental Health data compared to Sensitive Sexual Health data), type of information recipients (Primary care providers compared to nurses or medical assistants) and purpose of sharing (Care coordination, research, medical emergencies, etc.). The findings show that patients may have responded to survey questions with ‘it does not apply to me’ due to stigma and inconsistencies with providers’ medical records perceptions and classifications (e.g. genetic data).

In addition, we also discovered that patients’ classifications of medical records items and related sensitivity perceptions may vary from standard clinical interpretations. We came across variations in patient understanding and perceptions Consent2Share sensitive categories (for example, perceptions of categories such as genetic data, less perceived sensitivity of federally protected categories such as Drug Abuse, classification of physical health data as Mental Health, etc.) pointing to the further need to examine the areas of disagreements where patients differ from clinical definitions and interpretations of sensitive categories and the rationale for differences in patient views. In the next chapter, we apply a mixed methods approach to compare medical records sensitivity views of patients with providers to explore the differences in patient classifications and identify the reasons behind patient choices.

CHAPTER 5

COMPARISON OF PATIENT AND HEALTHCARE PROVIDER PERSPECTIVES ON MEDICAL RECORD SENSITIVITY AND CATEGORIZATION

5.1 Introduction

Our findings from the Aim 3 (Chapter 4) identified that patients often contextualize medical record sensitivity based on their own experience. Also, preliminary comparisons of patient and provider views showed that patient perceptions of data sensitivity varied from providers. To assess these differences in more depth, we applied a mixed-method approach to compare sensitivity perspectives of patients and providers and identify potential factors influencing patient choices.

Using a four-step systematic approach, we quantified the differences in classification into data categories (e.g. mental health) and information sensitivity. Quantitative analysis was coupled with thematic analysis to explore the rationale for patient views.

The perspectives of 25 English and Spanish-speaking patients with BHCs from the Aim 3 interview study were compared with those of 2 healthcare providers. A total of 726 individual items was extracted from patient medical records. Comparison between patient and provider data categorizations led to 66.3% agreements, 14.5% partial agreements, and 19.3% disagreements. Patients classified their family history of certain conditions (e.g. diabetes) and blood test results (e.g. blood glucose level) as genetic data, while providers categorized as non-sensitive care information. As well, patients considered some physical health medications (e.g. laxatives) to be mental health-related because they were prescribed to augment specific mental health medications or to ameliorate side effects from their mental health regimen. Significant differences were found between sensitivity classifications (χ^2 (2, N = 726) = 36.07, p = < 0.00001). Comparison of sensitivity perspectives resulted in 54.5% agreement, 11.9% partial agreement and 33.6% disagreements. Patient sensitivity classifications were dependent on personal experience and comprehension of sensitive categories, the sense of stigma related to sensitive data category definitions or labels (e.g. alcohol 'abuse') and their own perceptions of applicability of information in their medical records (e.g. having diagnosis of alcohol dependency).

The findings of this comparative study reflect on the desire of patients with BHCs and demand refinements in definitions, labels, and scope of the categories to better manifest patient privacy needs. Knowledge of patient health data sharing understanding and reconciliation of these with providers perspectives can help expedite the development of educational material, granular consent technology and personalized informed consent processes.

The application of this approach and outcomes of the described pilot with 25 patients are under review for publication in the Health Informatics Journal. The approach was further validated by comparing sensitivity perspectives of providers and data segmentations from the Consent2Share.

"Grando, A., Sottara, D., Singh, R., Murcko, A., **Soni, H.**, Tang, T., Idouraine, N., Todd, M., Mote, M., Chern, D., Dye, C., & Whitfield, M. J. (2020). Pilot Evaluation of Sensitive Data Segmentation Technology for Privacy. *International Journal of Medical Informatics*, 104121. https://doi.org/10.1016/j.ijmedinf.2020.104121"

5.2 Methods

5.2.1 Study Setting

As in previous studies, the study was conducted at two outpatient clinics providing integrated behavioral and physical health care in Phoenix, Arizona. Site 1 provides GMH and social services to adults and children serving about 48,000 patients per year. Site 2 provides recovery-focused services to approximately 6,000 adult patients with SMI annually. Both sites are members of Arizona's statewide physical and behavioral HIE.

5.2.2 Study Participants

Patient participants from Aim 3 (Chapter 4) card sorting interview studies consented to this analysis during the interview study (ASU IRB Studies 7514 (2/6/2018) and 7731 (2/12/2018)). Participants' capability to consent was tested via the UBACC test during previous Aim 2 survey study.(Jeste et al., 2007).

5.2.3 Comparison Approach

This section describes the four-step approach employed including: 1) Access and Sorting of Medical Records, 2) Collection of Medical Records Items Classifications from Patients and Providers, 3) Classification Comparison to Compute Type of Agreement, 4) , and 4) Analysis of Rationale behind Patient Choices.

Step 1: Access and Sorting of Medical Records

Access to behavioral and physical EHRs was obtained and a set of 30 EHR items were selected for each participant. Permission to access EHRs from collaborating sites and Arizona's state HIE was asked from participants through HIPAA authorization and consent. This study is the first to use Arizona's HIE data for research.

Step 2: Collection of Medical Records Items Classifications from Patients and Providers

In the interview study (Aim 3), patients were asked to classify each of their own 30 EHRs into one of eight data categories: D_1: Mental Health, D_2: Sexual and Reproductive Health (S&R health), D_3: HIV/AIDS and other Communicable Diseases, D_4: Drug Abuse, D_5: Alcohol Abuse, D_6: Other Addictions, D_7: Genetic Data, and D_8: Other Information. $D_1, \ldots, D_7$ were based on the definitions provided in the Consent2Share tool developed by SAMHSA.(*SAMHSA-HRSA Center for Integrated Health Solutions. The Current State of Sharing Behavioral Health Information in Health Information Exchanges*, 2014) Examples: the medication Vicodin (ingredient: hydrocodone/paracetamol) is categorized by a patient as Drug Abuse. Providers classify Vicodin as Drug Abuse and Other Information. Abuse of Vicodin medication can be considered Drug Abuse information, while the use of Vicodin to manage pain could be categorized as Other Information. Then, patients were asked to classify the data categories as Sensitive or Not Sensitive.

Two providers (an internist and a psychiatrist) independently classified the EHR items classified by patients, into one or more of the data categories $D_1, \ldots, D_8$. Providers were also asked to classify the EHR items into Sensitive, Not Sensitive or Possibly Sensitive categories. Providers chose to classify EHR items as appropriate for multiple data categories $D_1, \ldots, D_8$ or as possibly sensitive, when they did not have access to contextual information needed to more precisely determine the data category or sensitivity. Examples: the medication 'Vicodin' is considered Sensitive by a patient. Providers classify Vicodin as Possibly Sensitive. Abuse of Vicodin medication can be considered Sensitive information, while the use of Vicodin to manage pain could be categorized as Not Sensitive. Finally, discrepancies between the two providers' categorizations were resolved by consensus.

Step 3: Classification Comparison to Compute Type of Agreement

Data and sensitivity classifications of patients and providers were compared to compute agreements, partial agreements, and disagreements. Table 5.1 provides definitions and examples of these terms.

Table 5. 1 Definitions and Examples of Agreements, Partial Agreements and Disagreements

Agreement Type	Description	Data Categorization Examples	Sensitivity Examples
Agreement	Provider and patient assign the same data category or sensitivity to a medical record item.	Both assign Depression to the Mental Health category.	Both assign Depression to the Sensitive category.
Partial Agreement	Provider and patient assign at least one data category or sensitivity in common to a medical record item.	Provider assigns the medication Vicodin to the category Drug Abuse and Other Information. Whereas, the patient categorizes it as Drug Abuse.	Provider assigns the medication Vicodin to the category Possibly sensitive. Whereas, the patient categorizes it as Sensitive.
Disagreement	Provider and patient assign different data categories or sensitivity to a medical record item.	Patient assigns Amnesia to the Other Information category, and the provider assigns it to the Mental Health category.	Patient assigns Amnesia to the Not sensitive category, and the provider assigns it to the Sensitive category.

Data Categorization Comparison

Data categorizations by patients and providers were individually compared (Table 5.2). If an item occurred more than once, each instance was considered in the comparison. For instance, one patient can classify the item Vicodin (ingredient: hydrocodone/acetaminophen) as Other Information, while another as Drug Abuse.

Table 5. 2 Example of Comparison Table Computing Agreements, Partial Agreements and Disagreements between Patients and Providers based on Data Types; Agreements and Partial Agreements are *Highlighted* in the Table

Medical Record Items	Data Classification by Patients	Data Classification by Providers
Depression	***Mental health***	***Mental health***
…	…	…
Vicodin	***Drug abuse***	***Drug abuse***, Other information
…	…	…
Vicodin	***Other information***	Drug abuse, ***Other information***
…	…	…
Complete blood count test	Genetic data	Other information

Sensitivity Classification Comparison

Sensitivity classifications were also individually compared (Table 5.3). Each unique instance was kept in the comparison table. For instance, one patient can classify Vicodin as Not Sensitive, while another patient as Sensitive.

Table 5. 3 Example of Comparison Table with Sensitivity Classifications; Agreements and Partial Agreements are *Highlighted* in the Table

Medical Record Items	***Sensitivity Classification by Patients***	***Sensitivity Classification by Providers***
Depression	**Sensitive**	**Sensitive**
..	..	..
Vicodin	**Sensitive**	**Sensitive, Not Sensitive**
..	..	..
Complete Blood Count test	Sensitive	Not Sensitive

Step 4: Analysis of Rationale behind Patient Choices

Descriptive measures and heatmap matrices were used to reflect frequencies of agreements, partial agreements, disagreements. Mean agreements, partial agreements, disagreements were calculated to serve as threshold. Only cases above threshold were further analyzed, using thematic analysis, to assess patient choices.

Chi Square test was used to test the differences in the sensitivity perceptions. Areas of agreements, partial agreements, disagreements were examined using descriptive measures. Mean agreements, partial agreements, disagreements based on provider classifications were calculated to serve as threshold. Cases above threshold were analyzed employing thematic analysis.

Patient interviews captured opinions of sensitivity and data categorizations. Interview audio recordings were analyzed to identify emerging themes related to patient perceptions and correlate with the quantitative outcomes to draw potential inferences. A set of transcripts were randomly chosen for exploratory analysis of emergent themes and inductive theme analysis from existing literature. Meaningful phrases were the units for transcript coding and analysis. Coding was done using MAXQDA© by one researcher (Julia Ivanova) with definitions of codes continually honed by the research team over three iterations. A second researcher (Adela Grando) reviewed those codes. Discrepancies were resolved through consensus. Themes were then organized to complement quantitative analysis. Each topic was defined in a codebook (Appendix F) to reflect coding reasoning. Further analysis of the main themes was done using complex coding query, allowing analysis of overlapping classifications.

5.3 Results

Twenty-five patients (Table 5.4) and two providers participated in the study.

Table 5. 4 Patient Demographics

Participant characteristic	n=25 Freq. (%)
Age (Years)	
21-30	2 (8.0)
31-40	6 (24.0)
41-50	7 (28.0)
51-60	3 (12.0)
61-70	6 (24.0)
>70	1 (4.0)
Unknown	0 (0)
Gender	
Male	10 (40.0)
Female	15 (60.0)
Other	0 (0)
Race/Ethnicity	
White Alone, Not Hispanic or Latino	10 (40.0)
Black or African American	2 (8.0)
Latinx, Hispanic or Latino	12 (48.0)
Native American or Alaskan Native	1 (4.0)
Other, Unknown	0 (0)
Income	
≤$10000	18 (72.0)
$10001-$20000	5 (20.0)
$20001-$30000	2 (8.0)
>$30001	0 (0)
Education	
Middle school (grades 6-8)	6 (24.0)
Some high school (no diploma)	2 (8.0)
High school graduate (or equivalent)	5 (20.0)
Some college (1-4 years, no degree)	7 (28.0)
Associate degree (including occupation/academic degrees)	4 (16.0)
Bachelor’s degree (BA, BS, AB, etc.)	1 (4.0)
Preferred Language of Study	
English	19 (76.0)
Spanish	6 (24.0)
Type of Diagnoses	
General Mental Health	15 (60.0)
Serious Mental Illness	10 (40.0)

5.3.1 Medical Records Access and Sorting

Table 5.5 describes the EHR information received. A total of 750 items were classified by 25 patients. Patients chose to exclude 24 items in the interviews exercises because these items were “not recognized” as part of their EHRs. The remaining 726 items (Table 5.6) contained 114 repeating and 179 unique items.

Table 5. 5 Specifications of Medical Record Elements Received from Collaborating Sites

Site	Timeframe	Data Elements*	
		All Sites	*Site Specific Elements*
Site 1	2012-17	Demographics, Allergies, Diagnoses, Labs, Medications, Procedures	Services, Health risk assessment data
Site 2	2014-17		Services, Provider information, Insurance providers
HIE	2013-18		Advanced directives, Encounters, Immunizations, Insurance providers, Social history, Vital signs, Family history

* Data received from a site may not contain all data elements for each patient.

Table 5. 6 Distribution of 726 Medical Record Items Included in the Study, As Classified by Providers

Data Category/ies	Sensitivity	Total Items in Category	Frequent Medical Record Items
Drug Abuse	Sensitive	102	**Diagnoses:** Cannabis use disorder, Moderate **Labs:** Prescription Drug Monitoring Panel
Alcohol Abuse	Sensitive	9	**Diagnoses:** Alcohol use disorder, Mild **Labs:** Urine Alcohol Screen
Mental Health	Sensitive	178	**Diagnoses:** Adjustment Disorder with Anxiety; Anxiety Disorder, Unspecified; Bipolar I Disorder Current or Most Recent Episode Depressed, Mild; Borderline Personality Disorder; Suicidal Ideations; Post Traumatic Stress Disorder; Major Depressive Disorder, Recurrent, Moderate **Medications:** Zoloft; Abilify; Lexapro; etc. **Services:** Individual Therapy; Mental Health Assessment; Psychiatric Diagnostic Evaluation
Communicable Diseases	Sensitive	2	**Diagnoses:** Tuberculosis **Lab:** Tb Antigen
Genetic Data	Sensitive	1	**Lab:** Factor V Leiden Mutation Test
Sexual and Reproductive Health	Sensitive	31	**Diagnoses:** Erectile Dysfunction **Procedures:** Cesarean section; Hysterectomy; etc. **Labs:** Prostate Specific Antigen
Other Addictions	Sensitive	3	**Diagnoses:** Nicotine dependence, cigarettes, uncomplicated
Communicable Diseases, Sexual and Reproductive Health	Sensitive	42	**Labs:** Hepatitis B Surface Antigen with Reflex Confirmation; Hepatitis C Ab with Reflex HCV RNA; HIV 1/O/2 Screen with Reflex HIV-1 WB
Drug Abuse, Mental Health	Sensitive	1	**Diagnoses:** Other Substance Use Disorder, Mild
Drug Abuse, Other Information	Sensitive, Not Sensitive	22	**Medications:** Norco; oxycodone hydrochloride

Alcohol Abuse, Other Information	Sensitive, Not Sensitive	6	**Labs:** Aspartate Aminotransferase AST; Hepatic Function Panel; AFP And HCG Tumor Markers
Mental Health, Other Information	Sensitive, Not Sensitive	51	**Diagnoses:** Insomnia **Medications:** trazodone; gabapentin; hydroxyzine pamoate; etc. **Allergies:** phenylephrine hydrochloride; Lamotrigine
Communicable Diseases, Other Information	Sensitive, Not Sensitive	3	**Lab:** Hepatitis A Antibody, IGM
Sexual and Reproductive Health, Other Information	Sensitive, Not Sensitive	3	**Diagnoses:** Acute Prostatitis
Other Addictions, Other Information	Sensitive, Not Sensitive	1	**Medication:** methylnaltrexone bromide;
Other Information	Not Sensitive	271	**Diagnoses:** Hypertension; Calculus of Kidney; Diabetes Mellitus Type 2; etc. **Labs:** Complete Blood Count Test; Comprehensive Metabolic Panel; Thyroid Stimulating Hormone Test **Medications:** ibuprofen; lisinopril; metformin

5.3.2 Data Categorizations Comparison

There were 66.3% agreements, 14.5% partial agreements, and 19.3% disagreements.

Agreements in Data Categorizations

Patients and providers agreed on mutual classification of 481 (66.3%; mean-68.7) items (Table 5.7). There was a high agreement in items classified under Other Information (203 items; 42.2%), Mental Health (161 items; 33.5%), and Drug Abuse (87 items; 18.1%).

Of the 203 Other Information agreements, 94(46.3%) items related to physical health labs, 49(24.1%) diagnoses, 48(23.6%) medications and 6(3.0%) allergies/procedures each. Common patient perceptions were that items did not fit into other categories or best fit in this category.

Total 161 agreements included 66(41.0%) diagnoses, 62(38.5%) medications, 31(19.3%) mental health related services and procedures and 2(1.2%) Mental Health medication allergies.

Patients and providers agreed in classification of 87 Drug Abuse items. Most (94.3%) items were drug testing panel labs. Patients considered items as Drug Abuse based on whether the item had potential for abuse or was socially considered a drug (stigmatization): *“Inability to control this [drug], I can control it. I'm not sure which one this is…which pain killer, but it’s risk of abuse”.*

Table 5. 7 Heatmap Reflecting on Data Categorization Agreements

		Providers							
		Drug Abuse	Alcohol Abuse	Mental Health	Comm. Diseases	Genetic Data	S&R Health	Other Addictions	Other
Patients	Drug Abuse	87							
	Alcohol Abuse		6						
	Mental Health			161					
	Comm. Diseases								
	Genetic Data					1			
	S&R Health						21		
	Other Addictions							2	
	Other								203

Partial Agreements in Data Categorizations

There was a partial agreement for 105 (14.5%; mean-9.5) items (Table 8). Of the 48(45.7%) items classified as Mental Health OR Other Information by providers (Table 5.8) patients classified 31(64.6%) items under Mental Health and 17(36.4%) under as

Other Information. Items classified under Mental Health mostly (93.65%) included medications. When medications may be taken for multiple purposes, patients classified them in category most pertinent to their case: *"I have been prescribed Duloxetine medication for my anxiety and depression, the chronic pain. This falls under mental health…"*.

Of the 17 items classified as Other Information by patients, 16(94.1%) were medications or allergies to medications such as gabapentin and trazodone. Like the Mental Health rationalization, patients chose the category placement based on relevance/importance of symptoms treated: *"I have been prescribed Trazodone medication for sleep. This falls under other information."* The patient perceived the medication specifically for treating ability to sleep rather than a treatment for depression/anxiety.

Thirty (28.6%) items classified by providers as Communicable Diseases OR S&R Health Information were classified as either Communicable Diseases (20; 66.7%) or S&R Health (10; 33.3%) by patients. All 30 items were labs related to conditions such as HIV, Hepatitis B and C, Chlamydia, etc. Some patients were unsure where to place these items; however, common perceptions appeared to be linked to how patients understood sexually transmitted infections (STIs).

Patients classified 15 medications (including allergies to medications) related to Drug Abuse OR Other Information, as classified by providers, as Other Information. Medications often included pain management medications (e.g. morphine). Commonly, patients were considering whether the medication had potential to be abused or were personally abused. One patient noted that the hydrocodone was a prescribed drug for physical health: *"… under physical health…these are all physical health because I take that as needed for physical health."*

Table 5. 8 Heatmap Reflecting on Data Categorization Partial Agreements

		Providers								
		Drug Abuse, Other	Alcohol Abuse, Other	Mental Health, Other	Comm. Diseases, Other	Genetic Data, Other	S&R Health, Other	Other Addictions, Other	Drug Abuse, Mental Health	Comm. Diseases, S&R Health
Patients	Drug Abuse	2							1	
	Alcohol Abuse									
	Mental Health			31						
	Comm. Diseases				2					20
	Genetic Data									
	S&R Health						1			10
	Other Addictions									
	Other	15	5	17			1			

Disagreements in Data Categorizations

There were 140 (19.3%; mean- 5.2) disagreements (Table 5.9). Disagreements were often found in categories classified by providers as Other Information (31.4%).

Table 5. 9 Heatmap Reflecting on Data Categorization Disagreements

		Providers								
		Drug Abuse	Alcohol Abuse	Mental Health	Comm. Diseases	Genetic Data	S&R Health	Other Addictions	Other	Comm. Diseases, S&R Health
Patients	Drug Abuse		2	3					4	
	Alcohol Abuse	2					1	1		1
	Mental Health	5						1	14	
	Comm. Diseases								4	
	Genetic Data	4	1	6			2		44	3
	S&R Health			1	1				1	
	Other Addictions								1	
	Other	9	1	10	2		8			8

Patients classified 44 out of 68(65.7%) items classified by providers as Other Information as Genetic Data. These items often included routine medical tests (e.g. complete blood count), diagnoses, and medication allergies. Patients explained that they considered blood tests as Genetic Data because blood is used to detect blood-related diseases. Another common perception behind classifying chronic conditions data as genetic was that chronic conditions are part of family history. For example, in classifying the diagnosis of hypertension, a patient mentioned, *"Maybe even genetic because it's in the family. I'll put it there because it's in the family."*

Similar misunderstandings occurred with medication and diagnoses classified as Mental Health by providers, but as Other Information by patients (10 items; 7.1%): *"I use this [medication] for pain so I think this is under drug abuse information or other because I don't abuse it. I am just using it. So, I think it goes under other… Yeah, I don't know why they call it a dependence disorder because I could go without it but then I would possibly be stuck in pain and bad with the pain…".*

Vice versa, patients sometimes classified Other Information as Mental Health (14 items: 10.0%). For example, a patient considered diagnosis of obesity as Mental Health because many of the Mental Health medications can cause weight gain.

Nine of 140 (6.4%) instances categorized under Drug Abuse by providers were classified as Other Information by patients. Patients who did not place drug testing under Drug Abuse, reasoned "*I use this for pain, so I think this is under drug abuse information or other because I don't abuse it I am just using it. So, I think it comes under other*". While some patients chose to place items in Drug Abuse because of their potential, others considered their own experiences with the drug and their need for medicine. Five times, patients explained that a drug screen would be categorized under Mental Health rather than Drug Abuse: *"I think [cannabis drug test] under mental health information…Because it's a test to see what* -- *what's wrong with your body and they do all kinds of different tests with it."*

Eight (5.7%) items related to Communicable Diseases OR S&R Health were classified as Other Information by patients. Patients classified or reclassified items with uncertainty in these categories. One patient reclassified a Hepatitis C screening from Other Information to S&R Health as they began providing a rationale: *"Prolactin goes in* *other. No, that goes in sexual health because…too much prolactin impact[s] sexual health."*

Six items classified under Mental Health by providers were classified as Genetic Data by patients. These included Mental Health medication allergies, depression diagnosis and a Mental Health medication. Familial connection was often discussed as rationalization to categorize allergies or depression as Genetic Data.

5.3.3 Sensitivity Classification Comparison

Patient and provider sensitivity classifications were aggregated to create a sensitivity matrix (Table 5.10). Combinations in the matrix include (represented as Patient Classification, Provider Classification): 1) Sensitive, Sensitive, 2) Sensitive, Not sensitive, 3) Sensitive, Possibly Sensitive, 4) Not sensitive, Sensitive, 5) Not Sensitive, Not sensitive, 6) Not sensitive, Possibly Sensitive. For instance, if the Depression item was categorized by a patient as Sensitive and by providers as Not Sensitive, it would be added to the matrix under 2) Sensitive, Not Sensitive.

Significant differences were found between sensitivity classifications of patients and providers (χ^2 (2, N= 726) = 36.07, p= < 0.00001) with 54.5% agreement, 11.9% partial agreement and 33.6% disagreements.

Table 5. 10 Sensitivity Matrix Reflecting Sensitivity Perspectives Comparison

		Providers			*Total*
		Sensitive	*Not Sensitive*	*Possibly Sensitive*	
Patients	*Sensitive*	227	102	41	*370*
	Not Sensitive	142	169	45	*356*
Total		*370*	*271*	*85*	*726*

Agreements in Sensitivity Perspectives

Patients- Sensitive, Providers- Sensitive (227 items; mean- 32.4)

Most often, both patients and providers classified Mental Health (56.4%) and Drug Abuse (18.5%) information as sensitive (Table 5.11). Both topics were often discussed as simply being sensitive and confidential, but participants often included the potential for discrimination and stigma as part of the sensitivity.

Patients- Not Sensitive, Providers- Not Sensitive (169 items)

Providers considered Other Information category containing general physical health information as not sensitive. Of the 169 items classified in agreement, 141(83.4%) items were classified as Other Information by patients as well. Patients classified 18(10.7%) Other Information items as Genetic Data and considered these not sensitive. Categorization was mostly based on familial trends and blood-related testing; however, participants typically appeared to classify genetic data categories based on the sensitivity of the actual items such as medicines, labs, and diagnoses.

Partial Agreements in Sensitivity Perspectives

Patients- Sensitive, Providers- Sensitive, Not Sensitive (41 items; mean- 8.2)

Patients classified 41 possibly sensitive items as sensitive. Common items were classified as Mental Health OR Other Information. Often, Mental Health items were described as sensitive due to the discrimination and stigma within health care: "*Mental Health is very sensitive because "It's the first thing that they [providers] look in the record. "* A theme intertwined with this fear of discrimination was noting that the items were role-specific in how the patient chose to share: "*Only the mental health team should* *handle it [mental health information]... because... they have helped me with so much and I wouldn't want that information to get out from where it is, from here*."

Patients- Not Sensitive, Providers- Sensitive, Not Sensitive (45 items; mean- 9)

Patients classified 45 possibly sensitive items as not sensitive. Common items again included items classified as Mental Health OR Other Information and Drug Abuse OR Other Information. Patients classified items based on contextualization of how it may affect them: *"[This mediation is] Sensitive… because some people, they just have their own opinion, and they can treat you like crap, or they could care less. Sometimes the services, you don't get the services that you need"*.

Disagreements in Sensitivity Perspectives

Patients- Sensitive, Providers- Not Sensitive (102 items)

All 102(41.8%) items classified as not sensitive by providers belonged to general physical health categorized under Other Information (Table 11). Though there was an agreement between patients and providers in data categorization for 62(61.4%) items, sensitivity perspectives did not match for any of the items. Of these 62 items, 28 items were labs related to routine physical health blood tests. Eighteen were diagnoses related to chronic or general physical conditions. Patients considered these items sensitive predominantly due to feelings of privacy (42.0%) and fears of discrimination or stigma (42.0%).

Patients classifying Other Information as Genetic Data, often considered it sensitive. These items included labs (68.0%), diagnoses (16.0%), medication allergies (16.0%), etc. Unanimously, patients explained that Genetic Data is private and sensitive.

Patients- Not Sensitive, Providers- Sensitive (142 items; mean- 15.7)

Patients frequently classified Drug Abuse items (60 items, 42.3%) as not sensitive. Fifty-seven (95.0%) items included drug testing panel labs. The most common patient rationale for this classification was that they did not take drugs (not applicable to patient) and that sensitivity depended on drug type.

Fifty items (35.2%) related to Mental Health, as classified by providers, were also considered as not sensitive by patients. Of which, 22(44.0%) were medications, 18(36.0%) diagnoses and 9(18.0%) Mental Health related services such as therapy. While in some instances, patients determined the Mental Health category not sensitive as it did not include discriminating information, other patients pointed out they wanted to be open about Mental Health.

Table 5. 11 Sensitivity Agreements, Partial Agreements and Disagreements

Sensitivity Views	**Common Provider Classified Categories**	**Total Instances**	**Examples of Patient Classified Categories and Perceptions**
Patients: Sensitive *Providers:* Sensitive *Total Items:* 227	Mental Health	128	*Mental Health: "This is something really personal to me that other people shouldn't know I have, they don't need to know."*
	Drug Abuse	42	*Drug Abuse: “And then drug abuse information like I said if you have the problem it can be very sensitive to you and I'm pretty open about it because I don't have a problem but I can see how it would be very sensitive information.”*
	Communicable Diseases, S&R Health	30	*S&R Health (9 items): “Sensitive okay. Is it like for the same reason that like others should not know, okay?”*
	S&R Health	21	*“And this is sensitive because sexual health has a lot of stigma too.”*
	Communicable Diseases	2	*No Rationale Available*
	Alcohol Use	2	*“I will still put it there [sensitive] too. It’s not as sensitive [as drug abuse] but I guess it is whatever I want to do with it.”*
	Other Addictions	2	*No Rationale Available*
Patients: Not Sensitive	Other Information	169	*Other Information (141 items):” I don’t care about those [other information]. Because I take the, you know, because I*

Providers: Not Sensitive *Total Items: 169*			*take the medications because I need to because I'm in a lot of pain…"*
Patients: Sensitive *Providers:* Sensitive, Not Sensitive *Total Items:* 41	Mental Health, Other Information	29	*Mental Health: "Well more that it [mental health] is sensitive, for me it's a bother because they treat me very differently… they treat me like an idiot not like a person"*
	Drug Abuse, Other Information	7	*Drug Abuse: "Very sensitive because that will have all the people saying she is a tweaker and she is always looking for a tweaker. I will learn when I fall down and then got to get up. I don't like to be dragged through the turf more than once."*
	Communicable Diseases, Other Information	2	*Communicable Diseases: "HIV and AIDS for me was very sensitive very because it was -- I had to have it because I was sexually abused [not] because of any choices I have made, okay and so I don't want a lot of people knowing and I had to have that test done."*
	S&R Health, Other Information	2	*S&R Health:" And this is sensitive because sexual health has a lot of stigma too."*
	Other Addictions, Other Information	1	*No Rationale Available*
Patients: Not Sensitive *Providers:* Sensitive, Not Sensitive *Total Items:* 45	Mental Health, Other Information	22	*Mental Health: "…I share with people around me – with my boss I have shared, hey you know I have a mental illness but I'm recovered now I'm happy to say that you know…I'm open to it, I am not embarrassed you know."*
	Drug Abuse, Other Information	15	*Drug Abuse: "Because, again, I have nothing to hide because I don't do drugs. That's why it's not sensitive because I don't care because I don't do drugs."*
	Alcohol Use, Other Information	6	*Other Information: "I don't have a dependency to alcohol. I went to a hospital because I had a few beers after having suicidal thoughts, other than that no."*
	Communicable Diseases, Other Information	1	*No Rationale Available*
	S&R Health, Other Information	1	*No Rationale Available*

Patients: Sensitive *Providers:* Sensitive, Not Sensitive *Total Items:* 102	Other Information	102	*Other Information (62 items): “Somewhat sensitive… It’s just stuff that needs to be known to certain people.”* *Genetic Data (26 items): “It's very private. I am old now, but there are problems with genes and artificial insemination.”* *Mental Health (6 items): “I don't want a lot of people to know what's happening to me, it's private information. I have experienced discrimination for my mental health."*
Patients: Not Sensitive *Providers:* Sensitive *Total Items: 142*	Drug Abuse	60	*Drug Abuse: “Drug abuse, I don’t think that’s sensitive. That was for* nicotine, *wasn’t it? Oh, the cannabis. No, that’s very sensitive.”*
	Mental Health	50	*Mental Health: “Because it is just… it is not like there is any information about my habits back in the past …”*
	Communicable Diseases, S&R Health	12	*No Rationale Available*
	S&R Health	10	*No Rationale Available*
	Alcohol Use	7	*Alcohol Use: “Not sensitive…because I don’t drink.”*
	Genetic Data	1	*No Rationale Available*
	Other Addictions	1	*No Rationale Available*
	Mental Health, Drug Abuse	1	*See Mental Health or Drug Abuse*

Overall Patient Rationales on Sensitivity

With the use of strict thematic analysis of sensitivity rationales, seven types of patient explanations were found with a total of 59 codes. Rationales explaining increased sensitivity of a category were privacy concern (33.90%), discrimination/stigma (30.51%), specific items within categories (8.47%), and trusting specific providers with certain categories (3.39%). On the other hand, rationales of categories not applicable to a patient (10.17%), sharing for coordination of care (10.17%), and wanting to share information to help others (3.39%) were found when patients classified categories as not sensitive. Results also showed patients may conflate sharing with sensitivity classification as in the cases of privacy, discrimination/stigma, trust in providers, and sharing for coordination of care and to help others.

5.4 Discussion

Our study revealed that patients contextualize health information based on their health history and experience, fear of stigma, as well as perceptions of information applicability in their EHRs often deviating from standard clinical interpretations. Patients similarly contextualized sensitivity as seen with major themes in rationales using privacy concerns (33.90%) and discrimination/stigma (30.51%).

Patients often (65.7%) classified physical health data as Genetic Data, equating genetic information with family history, or any tests related to their blood. Patients categorized information classified by providers as Mental Health OR Other Information, as either Mental Health (64.6%) or Other Information (36.4%) based on their perceptions of personal applicability of the information. Similarly, patients classified physical health information (10.0%), such as hypertension medications as Mental Health, linking these medications being prescribed to support mental health regimens. Furthermore, HIV/AIDS or Hepatitis B and C information was classified as Communicable Diseases OR S&R Health information by clinicians considering that both the categories could be applicable for this type of information. In partial agreement, patients also categorized these as either Communicable Diseases (66.6%), based on their knowledge of STIs, or as S&R Health (33.3%) based on perceptions that HIV/AIDS or Hepatitis related information could impact sexual life.

These examples of classifications based on personal experiences and understanding highlight the flaws in current sensitive categories and subjectivity in patient perspectives, calling for changes in category labels and definitions. For example, a broader classification based on patient perceptions and comprehension may better support patient privacy concerns. King et al. asked 23 Australian adults about their privacy preferences on sharing health information for research.(King et al., 2012) The study included a category ‘family medical history/genetic data’ considered sensitive by the participants. The perceptions of our participants echo the utility of such a broader category. Similarly, merging categories such as Communicable Diseases and S&R Health could be beneficial, as is recommended in categorizations proposed by NCVHS.(*NCVHS*, n.d.) We realize, although these recommendations may improve patient satisfaction, they do not resolve the underlying mismatch between patients and standard clinical definitions. This underscores the need for educational material to enhance patient understanding of sensitive data and guide informed data sharing decisions, such as 42 CFR Part 2 data.

While data categorizations of patients and providers generally agreed (54.5%), there were differences in sensitivity determination. As noted in (M. A. Grando et al., 2020; Soni et al., 2020), sensitivity of categories may be influenced by how patients relate categories to their health. Our results show that sensitivity is also linked to patients’ perceptions of care coordination, concerns over privacy, and feelings of stigma or embarrassment. Incorporating such perspectives about sharing sensitive information such as Mental Health could enhance integrated care.

When patients classified information not sensitive and providers as sensitive, the complexities of patient views is exposed. While some patients linked sensitivity to their willingness to share (coordination of care, not feeling embarrassed, mental health as “nothing serious”), others determined sensitivity based on personal applicability. Patients sometimes considered ‘Alcohol Abuse’ information not sensitive: *"I don't have a dependency to alcohol. I went to a hospital because I had a few beers after having suicidal thoughts, other than that, no"*. Such reactions led us to consider that terminology like ‘Alcohol Dependency’, ‘Alcohol Abuse’ or ‘Drug Abuse’ may be a factor in classification. Hong et al. found that patient-friendly terms could help bridge patient communication gaps.(Hong et al., 2010) Study noted that misunderstandings due to terminology differences could cause communication problems, and result in poor patient satisfaction. It is also possible that previous information from EHRs such as past medications or diagnoses could be less sensitive for patients compared to information related to existing conditions. Whereas, provider views might not be impacted by such a temporal factor and represent rational contextual thinking.

Lastly, the application of certain medical terminology appeared to impact patient’s choices. As 42% patients reported that stigma and discrimination fear impacted their decisions, an emphasis on reducing stigmatizing language could bridge the disparity between patient and provider classifications.(Botticelli & Koh, 2016; M. A. Grando et al., 2017, 2020)

5.4.1 Challenges and Limitations

Though the study had a limited number of participants, it did include a diverse and difficult to reach population. Participants were individuals with behavioral health conditions, including those with serious mental illnesses, at two facilities served by the same HIE. Participants spoke Spanish and/or English. This population allowed us to examine both physical and behavioral health information with a focus on sensitive health records.

Patient perceptions of sensitivity and their sharing choices could have been impacted by the exposure to data from their own medical records. Patients might have experienced stigma or concern sharing information or opinions with researchers. Our larger study will compare patient responses from interviews with a previous survey assessing data sharing preferences to determine if choices are affected by the accessibility of medical records.(Soni et al., 2019)

This study compares sensitivity perceptions using a limited number of medical records items (726 in total) from 25 patients and views of two providers. Furthermore, we received minimal information from certain categories, such as genetic data or other addictions related information which could bias the perception towards these categories. Considering the lack of power due to small population, testing and validation with a larger, more representative patient population that includes healthy individuals is needed. As well, expanding the diversity of provider representation would be helpful.

5.4.2 Generalization and Expansion

Herein we discuss an application of a mixed-methods approach by comparing data sensitivity perceptions of patients with BHCs with those of providers. We believe this approach can be more broadly applied to compare inter-patient perspectives and include other populations, more data types and a variety of sensitive categories (such as the NCVHS sensitive categories). As we did in (A. Grando et al., 2020), the approach can also be used to compare sensitivity perspectives defined by a variety other data categories, such as the data types in an electronic health record (e.g. diagnosis, medications, allergies, etc.) Future studies could further test the robustness of the application in various populations and help develop more patient-friendly definitions of sensitive data categories.

In our application, we used the data gathered from a formative card-sorting interview study. To accommodate patient comprehension, modulate cognitive load and adhere to best practices for card sorting, we limited the number of medical record items to 30.(*Card Sorting*, 2013) Other methods, such as surveys or interviews, could be used to capture an entity's (here, patients) perceptions towards own medical records with the inclusion of more than 30 items.

5.4.3 Ongoing and Future Work

In this chapter, we applied the mixed-method approach to compare provider and patient data sensitivity perspectives. We have also applied this method to compare provider data sensitivity categorizations with the data segmentation outcomes produced by the software tool, Consent2Share.(A. Grando et al., 2020) Providers and Consent2Share sensitivity categorizations resulted in 56.5% agreements, 29.8% disagreements, and 13.7% partial agreements. Most (92.5%) of the disagreements resulted from information being classified as not sensitive by Consent2Share and sensitive by providers. Further validation of Consent2Share was recommended before its deployment and use in a health care setting. The combined outcomes from both studies will be used to develop educational materials to support the medical record sharing decision process and to improve the accuracy of the available data segmentation technology.

Better understanding of patient views on data sensitivity and concerns regarding data sharing will further inform recommendations and policies on granular data sharing.

5.5 Conclusion

This chapter presents an application of a systematic mixed methods approach to compare data sensitivity and categorization perspectives patients with BHCs and healthcare providers. The findings provide insights on variations in patient perceptions of medical records sensitivity and classifications compared to clinical interpretations as well as factors influencing patients' mental models.

Along with the areas of disagreements between patients and providers, we identified that the key factors influencing patient determination of sensitivity were comprehension of sensitive categories, own experience, stigma towards certain category definitions or labels (e.g. drug abuse) and self-perception of category applicability to own records (e.g. alcohol dependency). Refinements in existing sensitive category definitions (broader definition of Genetic Data category to accommodate family history, merging of categories HIV/AIDS and other Communicable Diseases with Sexual and Reproductive Health, etc.), modifications in category labels to reduce stigmatizing language (such as replacing Drug Abuse for 'Drug Use') and better educational resources explaining sensitive categories and their scope (e.g. classification of physical health items as Mental Health, benefits of sensitive data sharing, etc.) could help manifest patient privacy needs and help patients make more informed sensitive data sharing decisions.

Further, knowledge of patients' sensitivity preferences and reconciliation of these with provider data sensitivity definitions can help expedite the development of granular consent technology and personalized informed consent processes.

CHAPTER 6

CONCLUSION

Sensitive health data demands special attention and handling to avert unauthorized disclosure. Patients with BHCs, who often receive treatments at multiple behavioral and physical care organizations and are at a higher risk of stigma and discrimination, could benefit from granular cross-organizational data sharing.(California Healthcare Foundation, 2008; *SAMHSA-HRSA Center for Integrated Health Solutions. The Current State of Sharing Behavioral Health Information in Health Information Exchanges*, 2014) Though, how these patients perceive sensitive data and their preferences of sharing it are rarely studied.(M. A. Grando et al., 2017) Moreover, methods to assess such perceptions and compare those with standard clinical interpretations to get a better understanding of patient views are needed.

The hypotheses of this work are that 1) there is a diversity in medical record sensitivity and sharing preferences of patients with BHCs with respect to type of information, recipients and purpose of sharing and 2) there is a mismatch between the existing sensitive data categories and the desires of patients with BHCs. This thesis proposes and applies two mixed methods approaches to assess and contrast medical records sensitivity and sharing preference of patients with BHCs to inform the development of patient-centered sensitive data sharing technologies.

6.1 Main Findings

The underlying aim of this thesis has been to propose and pilot novel informatics approaches to better understand patient data privacy views. The outcomes from patient surveys and interviews demonstrate variations in how patients perceive different sensitive categories as well as their preferences of sharing medical records. Based on patients' own experience and perceptions, they often considered categories such as mental health, communicable diseases, and sexual health as sensitive. Whereas patients frequently considered federally protected information, such as drug or alcohol abuse, as not sensitive. Accordingly, willingness to share the records for care and research varied based on types of recipients and purpose. Patients also demanded choices when sharing medical records for scenarios such as medication prescription and medical emergencies.

We also found that patients contextualized health information and its perceived sensitivity based on their own understanding and recollection of medical records. Patient classifications and perceptions of sensitive data categories often varied from standard clinical interpretations. Our comparison of patient and provider classifications of medical records revealed the differences in patient and provider perspectives and attitudes towards data categorizations and sensitivity views. This comparison exposed that even when patients and providers agree on data category classifications, patients' sensitivity classifications could vary from routine clinical definitions based on their own experiences (perceiving blood related information as genetic data), patients' perceptions of applicability of the data category to them (sensitivity determination based on own perceptions of having Drug Abuse problems) and the way how certain categories/medical record items were labeled (Having 'Alcohol Dependency'). Refinements in existing sensitive category definitions (what is genetic data?), modifications in category labels to reduce stigmatizing language (such as replacing Drug Abuse for 'Drug Use') and better educational resources explaining sensitive categories and their scope (explanation of medical records classification in various categories based on standard clinical definitions) could accommodate for patient privacy needs and aid patients in making more informed sensitive data sharing decisions.

6.2 Dissemination of Research Outcomes

The outcomes of this research have been published through journal and conference papers and posters. Below, we provide details of resultant publications.

The outcomes of the literature review discussed in Chapter 2 (Aim 1) were published in the Journal of Biomedical Informatics- X along with the personalized card sorting approach developed to understand the data sensitivity perspectives of patients with BHCs (Chapter 4; Aim 3).

Soni, H., Grando, A., Murcko, A., Diaz, S., Mukundan, M., Idouraine, N., Karway, G., Todd, M., Chern, D., Dye, C., & Whitfield, M. J. (2020). State of the art and a mixed-method personalized approach to assess patient perceptions on medical record sharing and sensitivity. *Journal of Biomedical Informatics, 101*, 103338. https://doi.org/10.1016/j.jbi.2019.103338

A poster discussing the design and reliability testing of the survey discussed in chapter 3 (Aim 2) was presented at the 17th World Congress of Medical and Health Informatics (MEDINFO) 2019 conference. Alongside, a full conference paper discussing the findings of the survey was also presented at the conference.

Aliste Gomez, M., Grando, M. A., Murcko, A. C., **Soni, H.**, Todd, M., Mukundan, M., Saks, M., Horrow, C., Sharp, R., Dye, C., Chern, D., Whitfield, M. J., & Callesen, M. (2019). *Design and Pilot Testing of an English and Spanish Behavioral Health Patient Survey on Data Privacy. - PubMed—NCBI. 264*, 1891–1892. https://doi.org/10.3233/SHTI190699

Soni, H., Grando, A., Aliste, M. P., Murcko, A., Todd, M., Mukundan, M., Saks, M., Horrow, C., Sharp, R., Dye, C., Chern, D., Whitfield, M. J., & Callesen, M. (2019). Perceptions and Preferences About Granular Data Sharing and Privacy of Behavioral Health Patients. *Studies in Health Technology and Informatics*, *264*, 1361–1365. https://doi.org/10.3233/SHTI190449

The method focusing on the comparison of patient and provider perspectives and its findings are under review for the Health Informatics Journal.

In addition, another conference paper was published at the American Medical Informatics Association (AMIA) 2017 Annual Symposium discussing outcomes of an ethnographic study on observing the behavioral health consent processes, existing challenges in behavioral health consent processes and recommendations for improvement.

Soni, H., Grando, A., Murcko, A., Bayuk, M., Chandrashekar, P., Mukundan, M., Abrams, M., Aliste, M. P., Hiestand, M., Varkey, J., Zhou, W., Horrow, C., Saks, M., Sharp, R., Whitfield, M. J., Callensen, Mark, Dye, C., & Chern, D. (2017, 77/07). Current State of Electronic Consent Processes in Behavioral Health: Outcomes from an Observational Study. *American Medical Informatics Association 2017 Annual Symposium*.

Along with understanding patient perspectives on data sensitivity and sharing, this research also supported research focusing on healthcare provider views on data sensitivity and data sharing. Such as, the outcomes of the card sorting patient interviews study (Chapter 4; Aim 3) have been used to explore provider views on granular data control. Below is a list of relevant publications.

Grando, M. A., Ivanova, J., Hiestand, M., **Soni, H.**, Murcko, A., Saks, M., Kaufman, D., Whitfield, M. J., Dye, C., Chern, D., & Maupin, J. (2020). Mental Health Provider Perspective on Health Data Sharing: Mixed Methods Study. *Health Informatics Journal*, 1–16. https://doi.org/10.1177/1460458219893848

Ivanova, J., Grando, A., Murcko, A., Saks, M., Whitfield, M. J., Dye, C., & Chern, D. (2020). Mental health professionals' perceptions on patients control of data sharing. *Health Informatics Journal*, 1460458219893845. https://doi.org/10.1177/1460458219893845

Lastly, the method proposed in Chapter 5 (Aim 4) to compare data sensitivity perspectives was also applied to compare provider data sensitivity categorizations with the data segmentation outcomes produced by the software tool, Consent2Share.(A. Grando et al., 2020) The outcomes of this study have been summarized as a journal paper.

Grando, A., Sottara, D., Singh, R., Murcko, A., **Soni, H.**, Tang, T., Idouraine, N., Todd, M., Mote, M., Chern, D., Dye, C., & Whitfield, M. J. (2020). Pilot Evaluation of Sensitive Data Segmentation Technology for Privacy. *International Journal of Medical Informatics*, 104121. https://doi.org/10.1016/j.ijmedinf.2020.104121

6.3 Generalizability of Proposed Methodologies and Findings

We focused on a specific population of patients with BHCs, but our proposed approaches can be readily applied to other clinical environments with minimal modifications. Along with behavioral and physical health patients, healthy individuals and legal guardians of children and adult patients are often involved in consent decisions.

The proposed methods could be adapted and applied in understanding their perspectives on medical records sensitivity and sharing.

The card sorting interview approach proposed in Aim 3 as well as comparative analysis in Aim 4 can be applied independent of the type of EHR technology or source of EHR data. The medical records items included in our study were collected from a similar EHR system used at two different clinical sites and an HIE engine.

Our studies aimed to test the sensitive data categories proposed by SAMHSA in the tool Consent2Share. Individuals' perspectives towards other sensitive data categories (such as the NCVHS sensitive categories) or different types of information can be readily explored using proposed card sorting interview and comparison methods.

We proposed a comparative analysis approach (Aim 4) to contrast sensitivity and data segmentation views of patients and providers (our gold standard). This approach can be broadly used to explore relative inter-patient (such as differences in views of physical health patients and patients with behavioral health conditions), inter-provider variations, include other populations and compare classifications on granular data segmentation consent technologies towards of any set of sensitive data categories. In a concurrent research, we tested the proposed comparison approach to contrast data classifications by providers and Consnt2Share tool.(A. Grando et al., 2020) The application of the method resulted significant differences in Consent2Share and Provider classifications ($\chi 2$ (2, N = 584) = 114.74, p = <0.0001) and led to 56.0% agreements, 31.2% disagreements, and 12.8% partial agreements. As discussed in the previous section, the outcomes of this research have been published in the International Journal of Medical Informatics.(A. Grando et al., 2020)

Anyhow, the survey proposed in Aim 2 and the methodologies proposed in Aims 3 and 4 should be further evaluated with a larger, diverse population to test their reliability, validity, and applicability in assessing the views of a variety of individuals as well as to determine the generalizability of the findings.

Our population included patients with BHCs from two out-patients integrated behavioral and physical health clinics in Phoenix, Arizona. Although participants represented both GMH and SMI population, all participants did not have a legal guardian and were able to consent for their care related decisions assessed using the UBACC test. These participants received a score of 15 or higher out 20 suggesting their qualifications for making consent-related decisions. Most of our population included White Latino or non-Latino participants with a high school degree or higher and annual income of lower that $10,000. Additionally, our studies included small number of participants. Considering the homogeneity of patient population and the small study population, the results may not be generalizable.

We identified that patients' sensitivity decisions were often influenced by factors such as stigma towards certain sensitive data categories, their own comprehension and experience. Additionally, motivations behind sharing or restricting information based on types of providers and purpose of sharing seemed to influence patients' willingness to share sensitive information. Often patients made sharing decisions based on their trust in information recipients, knowledge about receiving individuals or organizations, and the self-perceptions of recipients' 'need to know' the health information. Despite, in this research, we did not explore the variations in motivations behind information sharing in detail to analyze the aspects impacting patient motivations. Therefore, these findings, potentially specific to our study population, might not echo the desires and motivations of other patient populations or healthy individuals and raise questions related to exploring not only the diversity in sensitive data sharing but also the elements affecting the decisions. For example, how motivations of data sharing may differ from culture to culture? How patients' conditions or diagnoses impact their sensitivity and sharing decisions? How the perceptions of legal guardians or fiduciaries making decisions for individuals influence these decisions? Does the socio-economic status or topography impact individuals' decisions?

In future, exploring the diversity in sharing preferences, relevant motivations and additional factors or stereotypes influencing sensitive data sharing decisions of individuals from different health conditions, geographic locations, societal and cultural ecosystems, socio-economic statuses, etc. could help determine the extensive heterogeneity in sensitivity views and sharing decisions.

6.4 Broad Impact

This research could contribute on a variety of facets, especially informatics, healthcare delivery and healthcare policies.

We test the sensitive data categories taxonomy proposed by SAMHSA with patients with behavioral health conditions. It could be adopted to further test and validate sensitive data taxonomies to identify a set of comprehensive, patient-focused sensitive data categories allowing patients granular control over data sharing, also ensuring compliance and regulatory requirements. The findings of this research can also influence the design of more effective, granular consent mechanisms to better meet patient expectations. It could support creation of embedded on-demand educational materials for patients (such as discussing benefits and barriers of sensitive data sharing, definitions and scope of sensitive data categories, etc.) to improve patient comprehension and bridge existing knowledge gaps.

Furthermore, this research introduces the concept of contextual sensitivity or possibly sensitive data. Here, we refer to the medical records data which could be potentially sensitive or not-sensitive based on the context of reference, as classified by providers. Our comparisons of providers' views with patients (Aim 4, Chapter 5) and Consent2Share data segmentation technology, revealed the need to further test and accommodate the notion of possibly sensitive data to satisfy privacy concerns.(A. Grando et al., 2020) The application of our methodology and its outcomes could help direct improvements in data segmentation logic of e-consent tools such as Consent2Share and possibly set a stage for more personalized consent engines. A related, practical implication of this research is discussed in section 6.5.

In the last decade, in addition to technologies such as consent tools and HIE engines supporting consent-based sharing, health record banking concepts and initiatives have come forward to promote patient-authorized data sharing for primary (e.g. sharing for care) and secondary (e.g. sharing data for research) purposes.(Gold, 2007) Health record banks (HRBs) are repositories of patients' medical records that allow providers permission-based access to reliable and authenticated copies of patients' health records with the key focus on patient-controlled, granular access to achieve coordination in care.(Gold, 2007; *Health Record Banking Alliance*, n.d.) Whereas data sharing via HIEs might often be restricted due to regulatory or compliance requirements (for e.g. restrictions on HIEs sharing genetic data in Arizona), HRBs as patient-controlled data access tools, could potentially serve as resources allowing further granularity in health data sharing.(Health Current, 2017) Though, the patient privacy aspects, technical and architectural challenges and compliance affairs should be further explored.(Gold, 2007) This research could prove useful in assessing patient perceptions towards sharing data via HRBs, patient concerns and motivations, possible factors influencing patient desires, etc. to guide development and dissemination of the HRBs.

Supporting ONC recommendations, this research digs deeper in identifying the areas where patients with BHCs desire control and granularity.(*Health IT policy committee, privacy and security tiger team, letter to David Blumenthal, Chairman of the Office of National Coordinator for Health IT*, 2010) By comparing patients' views with providers' medical records sensitivity views, we expose the differences in understanding, desires and factors influencing the subjectivity in patients with BHCs' decisions related to sensitivity. These factors, potentially unique to patients with BHCs, include patients' own experiences, perceptions of applicability of information or category in their own medical records as well as stigma towards definition or labels in sensitive categories and medical record items. Identification of these factors and perceived sensitivity could aid in developing better educational resources to inform patients in making better consent decisions. In addition, knowledge of patients' contextualization of medical records sensitivity could help clinicians in implementing more informed data sharing consent processes, educating patients, and increasing patient engagement, while accommodating patient's data sharing desires and stigma concerns.

Our findings suggest that current "All or None" data sharing models do not accommodate for patient's specific medical records sensitivity and sharing needs. Saks and colleagues reported on the importance and need of understanding federal and state laws to construct patient-driven granular control mechanisms.(Saks et al., 2018) Our findings could serve as a basis to support the development of future policies and recommendations on sensitive data sharing to increase patient convenience, lessen privacy concerns, enhance patient's understanding of sensitive categories and guide informed data sharing decisions, such as sharing of 42 CFR Part 2 data. As our research identifies the gaps in patients' perspective of sensitivity compared to healthcare providers' views (or standard clinical interpretations) including the factors influencing patients' decisions, this knowledge of patient desires could inform and assist health policy makers and officials when developing such sensitive data sharing recommendations.

6.5 Future Work

This research was funded by the My Data Choices grant. The outcomes of this research will guide the refinement of sensitive data categories proposed by SAMHSA and design of a granular, patient-centered electronic consent tool, My Data Choices.

Using the outcomes of this research, concurrent studies are focusing on understanding provider views on patient perceptions of data sensitivity and granular control over sharing as well as granular segmentation logic of existing consent technology, Consent2Share. Collectively, we aim to refine the existing Consent2Share sensitive data categories to better reflect patient desires while considering aspects such as provider views on patient control over sensitive data sharing, technology adherence and segmentation capabilities as well as compliance with state and federal regulations on sensitive data sharing. The collective research will support the development of My Data

Choices tool as an extension of Consent2Share. The My Data Choices tool will employ the refined Consent2Share sensitive data categories and tailored patient education material validated by healthcare providers and patients with BHCs. For further validation, the tool and educational material will be pilot tested with patients with BHCs and their legal representatives in a prospective study to further assess their data privacy needs and the expediency of using refined granular sensitive data categories to support their desires of granular control.

Within the scope of the grant, this research will also guide development of recommendations for SAMHSA related to enhancing Consent2Share electronic consent tool and SAMHSA’s sensitive data category taxonomy.

Altogether, the research carried out as a part of My Data Choices grant will inform the future development of e-consent technologies, educational materials, recommendations, and protocols to better support granular medical records sharing.

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APPENDIX A

PUBLISHED JOURNAL PAPERS

State of the Art and a Mixed-Method Personalized Approach to Assess Patient Perceptions on Medical Record Sharing and Sensitivity

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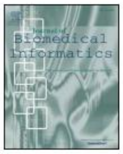

Special Report

State of the art and a mixed-method personalized approach to assess patient perceptions on medical record sharing and sensitivity

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ABSTRACT

Objective: Sensitive health information possesses risks, such as stigma and discrimination, when disclosed. Few studies have used a patient's own electronic health records (EHRs) to explore what types of information are considered sensitive and how such perceptions affect data sharing preferences. After a systematic literature review, we designed and piloted a mixed-method approach that employs an individual's own records to assess content sensitivity and preferences for granular data sharing for care and research.

Methods: A systematic literature review of methodologies employed to assess data sharing willingness and perceptions on data sensitivity was conducted. A methodology was designed to organize and categorize sensitive health information from EHRs. Patients were asked permission to access their EHRs, including those available through the state's health information exchange. A semi-structured interview script with closed card sorting was designed and personalized to each participant's own EHRs using 30 items from each patient record. This mixed method combines the quantitative outcomes from the card sorting exercises with themes captured from interview audio recording analysis.

Results: Eight publications on patients' perspectives on data sharing and sensitivity were found. Based on our systematic review, the proposed method meets a need to use EHRs to systematize the study of data privacy issues. Twenty-five patients with behavioral health conditions, English and Spanish-speaking, were recruited. On average, participants recognized 82.7% of the 30 items from their own EHRs. Participants considered mental health (76.0%), sexual and reproductive health (75.0%) and alcohol use and alcoholism (50.0%) sensitive information. Participants were willing to share information related to other addictions (100.0%), genetic data (95.8%) and general physical health information (90.5%).

Conclusion: The findings indicate diversity in patient views on EHR sensitivity and data sharing preferences and the need for more granular and patient-centered electronic consent mechanisms to accommodate patient needs. More research is needed to validate the generalizability of the proposed methodology.

1. Introduction

Protected health information is considered sensitive if it carries high personal risks when disclosed [1]. Information autonomy allows patient control over private information, such as physical and behavioral health records [2]. When disclosure of sensitive data leads to stigma and discrimination, there can be a ripple effect on family and friends [1]. These factors could impact health data sharing and sensitive information determination.

Data sensitivity, therefore, is often subjective and varies based on patient preferences and context of information use. Cultural and social factors, individual life situations and emotional and health status could impact such choices [2]. There is a lack of agreement as to what types of information patients may consider sensitive [3]. Identification and categorization of such data and approaches to satisfy patient diversity in privacy needs requires substantial attention.

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To satisfy patient privacy rights and exercise information autonomy, federal and state laws and policies regulate health information sharing [4]. The Health Information Portability and Accountability Act (HIPAA) rules provide special protections for some health information, such as psychotherapy notes, based on their very sensitive nature [5]. Another example is the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 Code of Federal Regulations 2 (42 CFR Part 2), which guarantees confidentiality for individuals seeking substance use disorder treatment from federally assisted programs [4].

In 2008, the National Committee on Vital and Health Statistics (NCVHS) identified five potentially sensitive data categories: mental health, sexual and reproductive health, domestic violence, substance abuse and genetic information [6]. The Committee acknowledges the need to better understand which specific sensitive categories require special handling to satisfy patient privacy needs [3,7]. The Office of National Coordinator of Health Information Technology (ONC) recommends allowing patients to exercise granular control over what information to share, with whom and for what purpose, to achieve higher patient satisfaction and active patient engagement [6].

The Substance Abuse and Mental Health Services Administration (SAMHSA) developed an open source consent technology to support granular consent options that align with federal and state data sharing requirements [8]. The software, known as Consent2Share, uses the following sensitive data categories: mental health, drug use, alcohol use and alcoholism, other addictions, sexual and reproductive health (S&R), genetic data and HIV/AIDS and other communicable diseases. While this software has been pilot tested using electronic health record (EHR) data, it has not been field validated with individuals at the point of care [9].

Researchers have also acknowledged the need to study patient opinion on data privacy to compile a more comprehensive list of sensitive data categories and related concepts [10,11]. Health data privacy research supports the recommendations from the ONC [12–18]. In contrast, consent processes and technologies currently in widespread use generally employ broad consent choices, such as 'share all or none' or offer limited consent granularity.

Concurrently, there has been a movement towards understanding individual's perspectives towards privacy and sharing preferences in the last decade [8,10,15,16,19–25]. To the best of our knowledge, no reviews have been carried out to understand and summarize the existing methods or approaches employed in assessing such perceptions.

The work described herein supports a multi-year National Institute of Mental Health grant focusing on the development of a granular electronic informed consent tool (known as My Data Choices) built as an extension of the SAMHSA Consent2Share software. The outcomes of this research will help to define sensitive data categories supporting patient preferences and the development of educational material to guide informed choices.

In the context of the My Data Choices project, we conducted a systematic literature review on studies related to methodological approaches to evaluate an individual's willingness to share data and data sensitivity perceptions. In the light of the need for more formal methods to assess data privacy preferences, this literature review informed the creation of a systematic approach to sort and categorize sensitive information from structured EHRs. This method uses categorized EHRs in a card sorting exercise guided by a semi-structured interview script, and combines qualitative and quantitative analytics techniques to assess a participant's (1) ability to recognize or remember information from their own EHRs, (2) opinions about sensitivity of EHRs, and (3) preferences on data sharing based on type of information, type of information receiver (healthcare providers or researchers) and purpose of data use (care delivery or research).

We have applied the proposed method to study the data sharing preferences of English and Spanish-speaking patients with behavioral health conditions. In a previous study, we asked patients about data sensitivity and privacy. Eighty-six patients were surveyed on their perceptions regarding stigma, quality of life, data sensitivity and preferences for data sharing [26]. The results of this formative survey revealed that participants wanted granular control over sharing sensitive data. Most patients (82.5%) considered mental health information as sensitive and many (64.1%) wanted choices over sensitive record sharing with health care providers. The survey also revealed that participants often indicated 'it does not apply to me' when asked about perceptions of certain sensitive categories and data sharing preferences (34.4% for all types of data, and 29.7% for behavioral health data). This response was most often reported for questions related to sharing sexual and reproductive health information, genetic data, substance and alcohol abuse, and communicable diseases. Moreover, the recruiters were frequently asked to clarify the meaning of categories such as psychotherapy notes, sexual and reproductive health and genetic data.

Insights on individuals' privacy needs could help the development of educational material to inform data sharing decisions, and the design of data sharing consent processes and tools to permit patient-driven granular consent models. Understanding individual perceptions of sensitivity can also be valuable in the development of policies or recommendations related to data sharing and granular consent mechanisms.

2. Literature search methods

2.1. Search strategy

Preliminary narrative searches were conducted to identify keywords and candidate search terms. Based on this, the following standard search string containing generalized keywords was used to avoid potential bias in searching for studies representing the state of the art:

(Share OR Sharing) AND (Sensitive OR Private) AND (Health Record OR EHR OR Medical Record OR EMR)

Synonyms of the candidate terms were included using Boolean operator 'OR' to maximize the efficiency. As a first step, *electronic* searches were performed using five electronic databases: PubMed, Scopus, Elsevier, BioMed Central and IEEE Xplore. In addition, database specific criteria were defined to refine the search as explained in Table 1. Next, titles and abstract of each article were *independently* and *manually* scanned by two co-authors. The articles meeting inclusion criteria were included for the full text review. Full text for each article was reviewed to select potentially relevant articles. Next, using the snowballing method, the reference lists of each article included in the full text review were manually scanned to find additional relevant articles. Full text of each selected article was reviewed for inclusion in the final review (Fig. 1). Disagreements between the two reviewers were resolved by consensus. Final outcomes were revised by a third reviewer.

2.2. Inclusion and exclusion criteria

This study focuses on reviewing the state of the art with a concentration on design, assessment or evaluation of willingness to share data and/or data sensitivity perceptions of patients, legal guardians or surrogates of the patients, healthy individuals and health providers.

Table 1
Literature search strategy and database specific criteria.

Database	Included Journals/Conferences	Other Criteria
Biomed Central	BMC Medical Informatics and Decision Making	–
Elsevier	International Journal of Medical Informatics Journal of Biomedical Informatics Patient Education and Counselling	–
IEEE Xplore	All	–
PubMed	All	Species: Human
Scopus	All	–

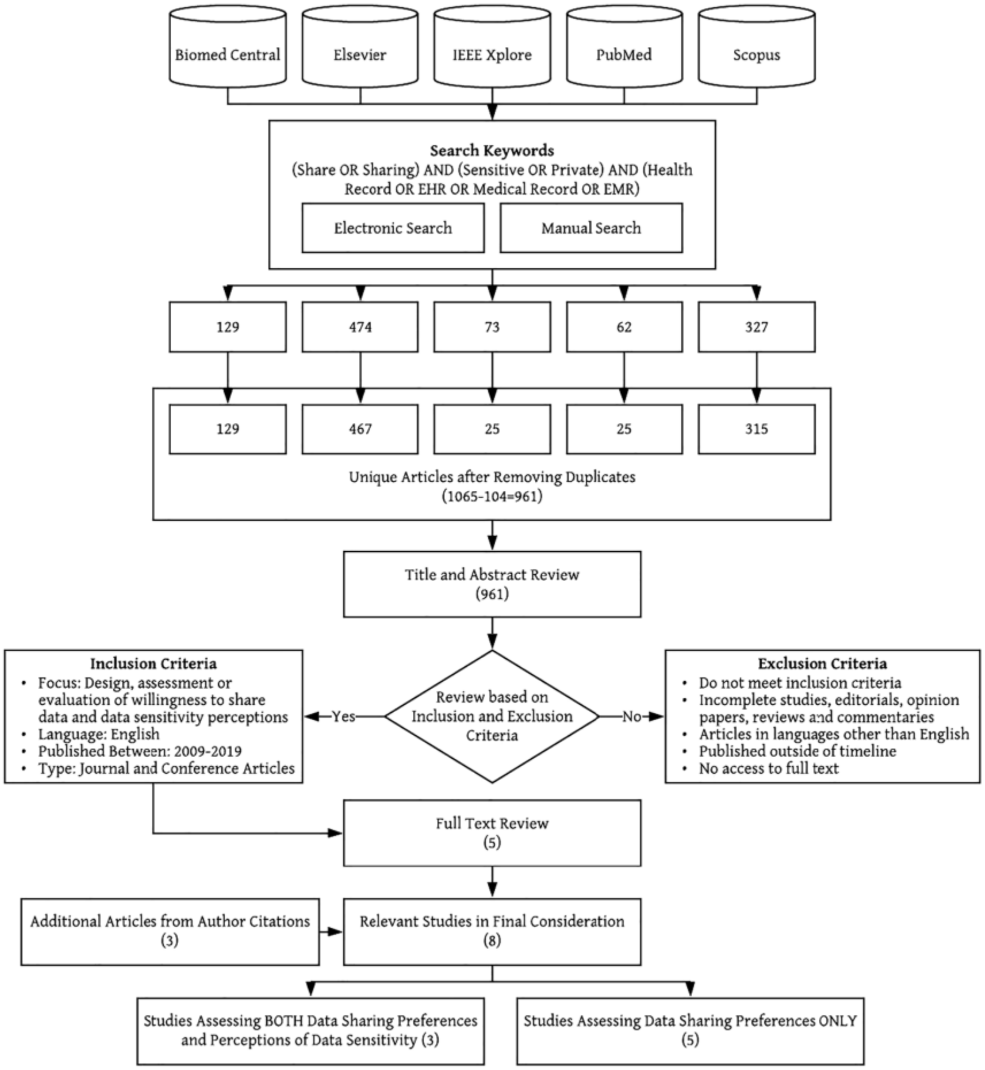

Fig. 1. Literature search strategy and process.

Only English language studies were included. Research, journal and conference articles from 2009 and 2019 were used. Incomplete studies, editorials, opinion papers, reviews and commentaries were excluded from consideration.

3. State of the art on individual perceptions of data sensitivity and sharing preferences

Electronic searches resulted in a total of 1,065 articles of which 104 articles appeared in the multiple databases. Upon de-duplication, we manually screened titles and abstracts of 961 unique articles. Applying the inclusion and exclusion criteria, 956 articles were excluded after screening; *five* were included in the full text review. Table 2 outlines the primary objectives of the excluded articles. We also identified *three* additional articles through forward snowballing. The snowballing process was iterated until no more relevant articles were found in the author citations. *Three* of the *eight* articles were found to be related to assessing, both individuals' preferences of sharing healthcare data and data sensitivity perceptions. Given the scarcity of research, we also included five articles with a focus on willingness to share healthcare data. Fig. 1 depicts the literature search strategy and process.

3.1. Main findings

Various qualitative and quantitative methods have been employed in understanding individuals' perspectives of sensitive data sharing. In

Table 2
Objectives of excluded of articles based on title and abstract review.

Objectives of Excluded Articles	# of Articles
Big data and blockchain in healthcare	9
Clinical workflow and communications	11
Conference summary and recommendations	2
Data reuse in care and research	7
Development/discussion of technology for data sharing	56
Development/discussion of other healthcare technology, databases, models, frameworks, etc.	454
Discussion of health status	19
Ethical and legal considerations of health data and sharing	11
Ethical and legal considerations of health information technology	5
Health information management and practices	5
Impact of cultural barriers	1
Integrated and patient-centered care	7
Patient and family engagement in health care and related decisions	29
Patient experiences related to health	1
Patient and provider interaction	29
Patient or provider education	11
Preferences or attitudes towards electronic health records	42
Preferences or attitudes towards health information exchange	18
Preferences or attitudes towards health information technology	42
Preferences or barriers in using and/or sharing data	11
Review of existing technology/solutions	16
Security and privacy concerns of sharing data	16
Security and privacy of health data	93
Security and privacy of health information technology	23
Shared decision making in healthcare	8
Storage and/or management of health data	22
Use and management of health information technology	8
Total	**956**

our review, three studies [19–21] provided insight into perceptions of health data sensitivity as well as preferences for sharing the data for care and/or research. Five studies [10,14–16,25] focused on evaluating preferences towards sharing health data. We read the eight selected papers to determine population and main objectives, methods and findings (Table 3).

3.1.1. Assessment of both sensitivity perceptions and sharing preferences

In a semi-structured web-based survey, Weitzman et al. captured attitudes and practices related to sharing health information of patients and parents/guardians using the personally controlled health records (PCHR) system [19]. As a part of the survey, authors asked participants about willingness to share data from PCHR, conditions and context of sharing and sensitivity towards a list of items allowing multiple selections from the predefined response options. The list included categories such as contagious illness, violence, sexually transmitted diseases, tobacco, alcohol, other substances, genetic disorders, mental illness, family information and financial information.

King et al. focused on discovering Australian adults' (18 years or older) attitudes towards privacy in health care via focus groups and a social survey [20]. The focus groups asked participants about their views on privacy of health information used for research and a social survey of 700 adults asked about privacy concerns towards certain types of health record items including sexually transmitted disease, abortion and infertility, family medical history/genetic disorders, mental illness, drug/alcohol incidents, list of previous operations/procedures/dates and current medications. The survey also asked participants' concerns about sharing their information for research. The study did not focus on participant's willingness to share information for care and treatment purposes.

Lastly, a comparative study by Grande et al. administered an online survey with embedded conjoint experiments to understand the differences in willingness to share health information and sensitivity of health information of individuals with and without history of cancer [21]. Using scenario-based conjoint experiments, the authors compared three attributes related to information use including who will access the information, for what purpose and sensitivity of the information. The participants were randomly assigned six scenarios created by the researchers and were asked to rate their willingness to share personal health information.

3.1.2. Assessment of data sharing preferences

Caine and Hanania conducted a study to assess desires of adult patients receiving healthcare in central Indiana regarding granular privacy control of their health information and diversity in preferences based on the sensitivity of electronic medical record information [10]. As a part of a larger study, two card sorting tasks were designed to understand patient preferences for sharing medical records with potential participants (for example, providers, researchers, family members, etc.). The authors introduced the five NCVHS sensitive categories during the study and assessed preferences of sharing high and low sensitive items, though sensitivity perceptions were not captured In [14], Caine et al. reported on the outcomes of the semi-structured interviews designed to identify user needs to inform the design of an interface recording individual choices regarding EHR access. The interviews assessed selected aspects of an individual's knowledge about their EHR contents and desire for granular control over this data.

Schwartz et al. studied primary care patients' willingness to share EHR data by allowing patients to restrict EHR access to various providers via a computer-based program.[15] In a demonstration project, patients could exert granular control and restrict access to all data or specific NCVHS sensitive categories and for a specified time period. Additionally, a follow-up Likert-style survey partially assessed control over access to information. In a concurrent study, Tierney et al. asked providers their opinions about patients controlling the access to their EHR data [25]. If patients in [15] restricted access to EHR for any providers, relevant data was redacted for the providers whose access was restricted. However, if providers felt that important information might be being redacted, they could "break the glass" to view the redacted data during that EHR use session.

Providers in [25] participated in the demonstration project, as well as completed a post-study semi-structured survey containing Likert-style and open-ended questions partly focusing on their opinions and comfort level regarding patient control over EHR data access, the effect of such restrictions and related concerns.

Teixeira et al. conducted a survey study to understand attitudes of persons with HIV towards their personal health information storage and sharing [16]. Authors assessed individual's willingness to share their personal health information with various recipients.

3.2. Summary

With the exception or Tierney et al, the other seven papers focus on the populations of patients and/or parents/guardians of patients [25]. The outcomes from our literature review suggest that the type and sensitivity of the health information, [10,14,20,21] the type of data recipient [10,14–16,19] and the purpose of data use [19–21] may influence subjects' attitudes towards sharing medical data. Subjects are less willing to share information that is highly personal, such as sensitive information about sexually transmitted diseases, abortions and infertility, family medical history/genetic disorders, mental illness, drug/alcohol related incidents, operations/procedures/dates and current medications. Subjects' willingness to share decreases when the research is done by commercial or for-profit entities and the purpose of data use is different from treatment. Caine et al. found that subject's lacked of knowledge of what data is in their EHRs and with to know more to make better informed data sharing decisions [14].

Qualitative methods such as surveys and interviews have emerged as prominent methods to assess individuals' views of sensitive data and pertinent sharing preferences [10,14–16,19–21,25]. In conjunction with qualitative methods, other approaches, such as conjoint

Table 3
Summary of findings.

#	Reference	Year	Population	Objective	Methods	Findings
Assessment of both Sensitivity Perceptions and Sharing Preferences						
1	Weitzman et al. [19]	2012	Patients, parents or guardians of patients	Assess willingness to share health information	Cross-sectional Web-based survey	63.3% of 261 reported they would be more willing to share all information with the state/local public health authority than with an out-of-hospital provider (54.1%) (OR 1.5, 95% CI 1.1, 1.9; $p = .005$); few would not share any information with these parties (respectively, 7.9% and 5.2%). For public health sharing (ORs 4.9 to 1.4, all p-values < 0.05) and provider sharing (ORs 6.3 to 1.5, all p-values < 0.05), reticence was higher for most topics compared to contagious illness.
2	King et al. [20]	2012	Adults 18 years or older	Discover privacy concerns towards sharing data for research	Focus groups; Social survey	Great support for medical research (98%), and concern about privacy of health information (66%) was found. Participants preferred to be asked for their permission before their health information was used for any purpose other than medical treatment (92%). There was a concern (42–60%) about any possibility of linking patient's name with sensitive data (such as sexually transmitted diseases) in a situation not related to medical treatment.
3	Grande et al. [21]	2015	Individuals with and without history of cancer	Compare willingness to share data between individuals with and without history of cancer	Online survey;Conjoint experiments	Participants with and without a diagnosis of cancer had similar willingness to share health information (0.27; $P = .42$). Both cancer and noncancer participants rated the purpose of information use as the most important factor (importance weights, 67.1% and 45.6%, respectively). Cancer participants were more willing to share their health information when the information included more sensitive genetic information (0.48; $P = .015$).
Assessment of Data Sharing Preferences						
4	Teixeira et al. [16]	2011	Adults 21 years or older living with HIV	Assess attitudes towards personal health information storage and sharing	Survey	The majority (84%) of individuals were willing to share their personal health information (PHI) with clinicians involved in their care. Fewer individuals (39%) were as willing to share with non-clinical staff. Willingness to share PHI was positively associated with trust and respect of clinicians.
5	Caine and Hanania [10]	2013	Adults receiving healthcare in central Indiana	Assessment of desire towards granular control and sharing preferences	Card sorting tasks	No patients reported that they would prefer to share all records with all potential recipients. Sharing preferences varied by type of information and recipient. Overall sharing preferences varied by participant. Patients with and without sensitive records preferred less sharing of sensitive versus less-sensitive information.
6	Caine et al. [14]	2015	Adults receiving healthcare in central Indiana	Derive user needs for an interface recording granular sharing choices	Semi-structured interviews	Patients rarely knew what data were in their EHRs but would have liked to know. They also wanted to be able to control who could access what information in their EHR and wanted to be notified when their data were accessed.
7	Schwartz et al. [15]	2015	Adults 18 years or older	Assess patient's willingness to share EHR data	Demonstration project; Likert-style survey	Sixty patients (57%) did not restrict access to EHRs for any providers. Thirty-four (32.3%) patients blocked access to all personal information by all doctors, nurses, and/or other staff, 26 (24.8%) blocked access to all doctors and/or nurses, and five (4.8%) denied access to all doctors, nurses, and staff.
8	Tierney et al. [25]	2015	Physicians, nurses and other clinic staff	Assess provider views on patient control over EHR access	Demonstration project; Likert-style survey	Providers "broke the glass" for 14% of 43 patients with redacted data vs. zero among 49 study patients without redactions ($p = 0.01$); 54% agreed that patients should have control over who see their EHRs, 58% believed restricting EHR access could harm provider-patient relationships and 71% felt quality of care would suffer.

experiment and hands-on project demonstrations have been used [15,21,25].

In general, most of the studies attempted to understand individual's perspectives of health record sensitivity or sharing preferences as part of a larger study [14,16,19-21,25]. Except for Schwartz and Tierney et al., none of the studies identified used own patient's EHRs [15,25].

Previously, individuals have been asked about their preferences towards NCVHS recommended sensitive date categories for care and research [10,15]. Individuals ' preferences towards a broader list of potentially sensitive categories have been explored [19,20]. Researchers and policy makers have advocated for better understanding of patient perception and the need for identifying sensitive data categories [3,10].

Overall, there is a need for methodologies to study medical record sensitivity and willingness to share various types of sensitive and non-sensitive data personalized to the individual's own EHRs. In the next section, we propose a novel mixed-method approach that uses individuals' own EHRs to assess perceptions of the sensitivity of medical records and willingness to share these records for care and research.

The completed systematic literature review informed the development of the proposed method. Similar to Schwartz and Tierney et al., we focus on better understanding patient views by employing elements from their own EHRs [15,25]. Like Caine and Hanania, our study utilizes card sorting as a central technique in understanding patient perceptions of sensitivity and sharing [10]. However, our method also incorporates tasks using patient's own EHRs and supplemental audio-recorded interviews of the rationale behind patient choices. Lastly, though we adapt sensitive categories based on SAMHSA's Consent2-Share tool, these categories overlap with multiple studies [10,15,19,20].

4. A novel approach to evaluate medical record sensitivity perceptions

4.1. Research team

Subject matter experts from various fields were involved in the development and conduct of this mixed method approach, including biomedical informatics researchers and a statistician. Clinicians reviewed the medical record categorizations and patient education material while study site leadership previewed the materials for appropriateness and compliance.

4.2. Study sites

This study was conducted at two urban outpatient integrated health clinics providing behavioral and physical care to patients with behavioral health conditions. Access to additional records from non-behavioral health providers was obtained with permission from the Arizona health information exchange (HIE). Ours is the first study to use EHRs available through the state's HIE for research. HIE records contained both structured and unstructured health behavioral and non-behavioral health records.

Integrated clinics: Both Sites 1 and 2 provide physical and behavioral care. Site 1 offers general mental health and social services to children, families and adults of all ages serving approximately 12,000 patients annually. Site 2 offers a range of recovery-focused services to approximately 1,000 adult patients with serious mental illnesses annually. Both sites use a similar proprietary EHR widely used in the US.

HIE: Arizona's statewide physical and behavioral HIE (Health Current) supports nearly 500 participant providers and 8.9 million unique patients [27]. Both Sites are members of the HIE. The HIE follows an opt-out consent model for physical health, meaning that data from participating healthcare organizations and providers is automatically shared unless patient explicitly declines to share. An opt-in consent is required for data protected by the 42 CFR Part 2 regulations.

4.3. Study participants

Adult (21 years old or older) English or Spanish-speaking patients diagnosed with a general mental health condition were recruited at Site 1 and those with serious mental illnesses were recruited at Site 2. As part of the larger project, these participants have longitudinally participated in several studies, including the companion survey that served as the formative basis for this research [26,28]. As part of the original survey (described earlier), the decision-making capacity of the participant was assessed by verbally administering the University of California, San Diego Brief Assessment of Capacity to Consent [29]. This study was approved by the Arizona State University Institutional Review Board (IRB).

4.4. Medical record access

Participants from the original data sharing preferences survey were re-contacted and asked permission to access to their personal behavioral and physical health EHRs available from their respective study sites and the HIE [26]. As part of the study consent process, participants executed a HIPAA authorization to provide access to their records. Participants were compensated for their time. Patients were also asked permission to be re-contacted for the follow up interview.

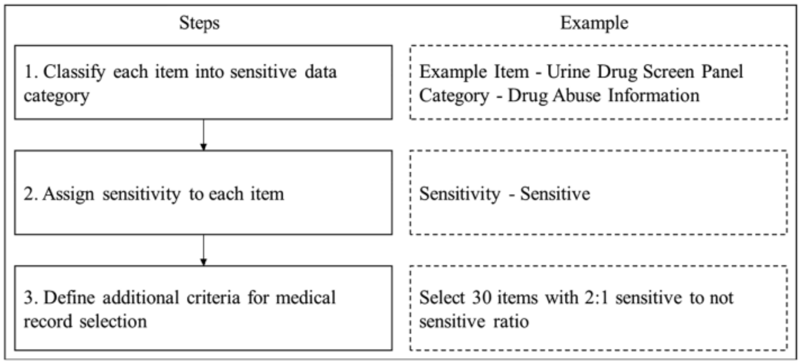

Fig. 2. Medical record sorting approach with example.

4.5. Medical records sorting and selection to create personalized cards

We received access to structured and unstructured EHRs (only HIE) from the collaborating sites. This section describes sorting and selection of medical record items for the personalized card sorting tasks. Fig. 2 summarizes the approach designed to sort and categorize specific medical record items.

Step 1. The first step involves classifying information received from the digital EHRs into sensitive data categories. We only used the structured medical record items for classification. For our study, items were assigned to one of eight data categories. Seven categories were based on the sensitive categories supported by Consent2Share: (1) mental health, (2) drug abuse, (3) alcohol use and alcoholism, (4) other addictions (such as tobacco use disorder), (5) sexual and reproductive health, (6) genetic data and (7) HIV/AIDs and other communicable diseases. Definitions of the classes were adapted based on the standard definitions used in Consent2Share tool by SAMHSA [8]. An additional category, (8) other information, was included to accommodate non-sensitive information or other categories that do not clearly fit any of the above-mentioned categories.

Step 2. The second step consists of classifying each item according to sensitivity. For example, in this study, each item was classified as "sensitive", "not sensitive" or "possibly sensitive". We considered an item "sensitive" if it could be categorized to one or more of the seven sensitive categories by our clinical collaborators. An item was "not sensitive" if classified as 'other information'. An item was "possibly sensitive" if it could be classified as both "sensitive" and "not sensitive". For example, the medication Vicodin (generic: acetaminophen-hydrocodone) is considered "possibly sensitive". Vicodin abuse may be considered sensitive, while the use of Vicodin to manage severe acute pain may be categorized as not sensitive.

Step 3. The third step is defining additional criteria to identify the medical record items for card sorting tasks. To meet the needs of this study, a 2:1 ratio of sensitive to not sensitive EHRs was used to achieve a higher number of sensitive items in the medical record cards. Therefore, we created 30 medical record cards (see section 4.6 for detail): 20 representing potentially sensitive items and 10 corresponding to non-sensitive records. If the structured data from the Site EHR did not include 20 sensitive items, we carefully reviewed the clinical notes received from the HIE (unstructured records) to seek more sensitive items. More than 10 non-sensitive cards were included if there were insufficient sensitive records for any patient. We carefully reviewed patient EHRs to select 20 items representing different sensitive categories to create a diverse set of medical record items, however, patients may not have medical record items belonging to each of the eight data categories. In such cases, we included items from the available categories. As feasible, cards represented medical diagnoses, laboratory results, medications, allergies, procedures and services.

Item Validation. The process described above was performed by four biomedical informatics student researchers and the outcomes were independently reviewed by two health providers (one internist and one psychiatrist).

4.6. Personalized card sorting tasks and interview script

Card sorting allows researchers to understand user perceptions and preferences towards the topic of interest [30]. In closed card sorting, participants are asked to sort content of interest in various predefined categories. With predefined categories, closed card sorting methods provide insight into how users classify the content in various categories [30].

A semi-structured interview script (Appendix) including seven card sorting tasks (Table 4) was developed and personalized to the EHRs of the study participants. Best practices for card sorting tasks recommend limiting the cards between 30 and 40 items to minimize participant fatigue [30]. We selected the lower number, 30, based on the cognitive load of the tasks.

The script and cards were available in English and Spanish. English script and cards were translated to Spanish and back translated to English by native Spanish speakers to ensure that the literacy levels were commensurate with patients' educational background and reading ability. An accuracy certificate was presented to the IRB.

Fig. 3 shows an example of a study question to describe the card sorting components.

On the front of each medical record card, to increase patient comprehension, standard statements were used to describe the medical record items (Table 5).

For medical record cards pertaining to medications, procedures and services, a *'fill in the blank'* slot was used for the patient to document the reason for the prescription or service. The back of each medical record card contained pertinent written material curated from reputable resources, such as Medline Plus, to provide patients with standardized, on-demand information about medical record items if needed to help to identify and sort the cards appropriately [31]. Another purpose of educational material was to assess patient knowledge of their own EHRs. The educational material, presented at 6th grade level (using the MS Word Flesch-Kincaid Grade Level) was reviewed by two clinicians [32]. For example, education material related to a diagnosis of depression read: "Depression is a serious medical illness. It's more than just a feeling of being sad or "blue" for a few days."

For all interview questions (Table 4), response cards were provided. For example, various predefined Likert response options were created for questions Q1 and Q3-Q7. In Q2, we provided response cards with eight predefined data categories as detailed in section 2.5. During the study, participants could classify the 30 items in one of the eight data categories. When responding to Q2, participants could indicate that they did not recognize/remember having in their EHR some of the 30 items and choose to exclude them when responding Q3-Q7.

For Q2, participants received educational material about sensitive data categories on the back of the card, with examples of medical record items classified under each data category. An example of supporting material related to 'mental health information' is "Mental health problems affect mood, thinking and behavior. It can make you unhappy and can cause problems in your daily life. There are many causes of mental health problems. Genes, family history and life experiences may have an effect. There are many treatments available. Mental illness examples include; Anxiety and Panic Disorders, Depression, Mood and Personality Disorders, Bipolar Disorder, Psychotic Disorder, etc."

4.7. Interviews

After consent, participants completed interviews in English or Spanish, according to the interview script. While thinking aloud, participants were asked to sort their personalized medical record cards while answering a series of questions. As part of the sorting process, recruiters asked the participant to explain rationale for their choices. For example, when classifying medical record items into sensitive data categories, recruiters asked, *"why do you think this card (*e.g. *medical record item) belongs to this sensitive data category?"* The recruiters recorded each time a patient referred to the education material by marking an asterisk (*) sign in the back of the record card.

Each interview session was also documented by an audio recording and digital photographs of the card arrangements for each question. Participants were compensated for their time.

4.8. Data analysis

Interview recordings were transcribed and coded by two bilingual (Spanish and English) co-authors using MS Excel [33]. The Spanish recordings were first transcribed in Spanish and later translated in English by a Spanish recruiter. Transcriptions were checked by a second

Table 4
Interview sections and related questions.

Theme	Questions
Recognition of own medical records	**Q1:** You may or may not remember the information in the **white card**. But we would like to know how much you remember. Do you recall this information from your present or past medical records? Can you also tell me what do you remember about each? We will go through these cards one by one. There might be some fill in the blanks in cards. We will fill those out as we move forward. *Response Options: Yes; Unsure*
Classification of own medical records into sensitive categories	**Q2:** The medical records can be sorted in different data categories. For example, a card could have a medication related to depression. So, it may relate to the mental health. Could you sort the medical record cards in the data category cards on the table? *Response Options: Drug Abuse; Alcohol Use and Alcoholism; Mental Health; Communicable Diseases; Genetic Data; Sexual and Reproductive Health; Other Addictions; Other Information* [NOTE: After sorting the 30 cards a bundle was created for each category to answer Q3 and Q4]
Sharing of data for care and research	**Q3:** We would like to know your choices of sharing the data in these data category bundles. Would you share information in these bundles with the providers you might see outside Site X? *Response Options: Hospitals; Primary Care Providers; Specialty Care Providers; Nurses; Case Managers; Licensed professional counselors/therapists; Pharmacists; Medical Assistants* **Q5:** Imagine your primary care provider wants to start a new medication. The new medication may have side effects. The primary care provider wants to see your medical records. Which of these 30 medical record cards would you like your doctor to see? Could you tell me some reasons behind your choice? *Response Options: Share This Information; Do not Share This Information* **Q6:** Suppose you have an emergency. And you are unconscious when you come to emergency room. Your emergency care provider wants to see your medical records. But they are unable to ask your permission. Which of these medical record cards would you like your doctor to see? Could you tell me some reasons behind your choice? *Response Options: Share This Information; Do not Share This Information* **Q7:** The next question is related to sharing your medical records for research. There are many organizations that conduct research. For example, I am doing this research at Arizona State University. I will show you different researcher cards. Would you to share all your data for research? Can you please tell me why or why not?*Response Options: Extremely Willing to Share; Quite Willing to Share; Somewhat Willing to Share; Not at All Willing to Share*
Data sensitivity perceptions	**Q4:** We have the medical record in bundles of medical record cards. We also saw how willing you are to share these bundles with your providers. (Q3) Now, some of these **bundles** might require special handling. Sharing this information might harm you. A doctor or nurse might treat you differently. Do you think any of the **bundles** are sensitive for you? Could you please say why or why not? *Response Options: Very Sensitive, Somewhat Sensitive; Not Sensitive*

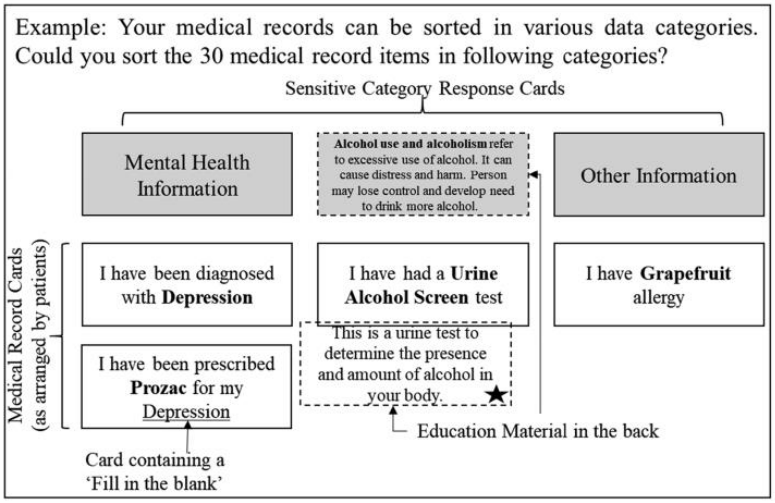

Fig. 3. Card Sorting Components and Example.

translator. All transcriptions were reviewed for accuracy.

The data captured as photographs of card sorting exercises were quantitatively coded and analyzed using MS Excel [33]. Descriptive measures were used to calculate frequency, mean and range. Below, we individually describe the analyses for each of the seven card sorting questions and relevant initial hypotheses.

Responses to the *'fill in the blank'* section for medications, procedures and services cards (Q1) were compared to categorization by clinicians. This approach could help to assess a patient's ability to recognize information from their own EHR. Researchers have previously studied patient comprehension of new medication prescriptions and clinical data, such as laboratory tests [34,35]. Our hypothesis is that

Table 5
Standard statements to describe medical record items.

Type of Item	Standard Statement
Diagnosis	I have been diagnosed with < medical record item >
Labs	I have had a < medical record item > test
Medications	I have been prescribed < medical record item > medication for my _____
Allergies	I have a < medical record item > allergy
Procedures	I have undergone a < medical record item > procedure for my _____
Services	I have received a < medical record item > service for my _____

patients data categorizations may differ from provider categorizations and may have difficulties in recognize/remember some types of information related to their medical records.

To assess opinions about sensitivity of medical records, their categorization rationale (Q2) were analyzed. We hypothesize that sensitive data perceptions will be different between patients [3,7].

To assess variability in patient perceptions of data sensitivity, participants' sensitivity and data categorizations assessed in Q4 were compared to the classifications provided by two clinicians in our research team. We believe that no comparable studies or methods exist for assessing patient perceptions of data sensitivity by category. Considering the open questions from previous survey, the frequent use of 'it does not apply to me' and questions related to the meaning of certain sensitive categories (e.g. genetic data), we hypothesize differences in sensitivity perceptions between patients and providers [26].

Questions Q3 and Q5-Q7 assessed preferences for data sharing based on information type, information receiver (health provider or research) and purpose of data use (care delivery or research). Based on previous studies, we hypothesize diversity in patient perceptions of sensitivity of EHRs and sharing preferences [12–18].

We used the audio recording to verify accuracy and consistency of asterisks marked by the recruiters regarding patient's reference to education material. Audio and card data were also used to determine instances when participants were uncertain what the card meant and asked for information rather than looking at the back of the card. In case of fill-in-the-blank exercises, agreements between participants' responses were compared against online resources, like Medline Plus, and revised by a clinician in our research team to determine comprehension [31].

5. Results

5.1. Demographics

Thirty-six patients provided access to their EHRs. From these, 25 participants were recruited for the interview study (Table 6).

5.2. Ability to recognize medical record items

On average, participants recognized 82.7% (range: 33.3–100.0%) from the 30 items extracted from their own EHRs. Though participants were unsure about 17.3% (range: 0.0–66.7%) items, only 4 removed these item (3.3%) from the study. Most (91.7%) unsure items were labs, with representative responses ***"I don't remember"*** or ***"I don't know what it is but I know it is for blood work"***.

On average, participants referred to the education material for about 32% items (range:3.3–76.7%). Participants frequently checked material related to labs (47.3%) and medications (29.3%). There was very poor correlation between number of times medical records educational material was referred to and age (r = 0.19) or income (r = -0.17). Few participants referred to education material for genetic data (12.0%) and S&R health (8.0%).

Table 6
Participant Demographics.

Participant characteristic	Medical Records Access n = 36 Freq. (%)	Card Sorting Interviews n = 25 Freq. (%)
Age (Years)		
21–30	3 (8.3)	2 (22.1)
31–40	9 (25.0)	6 (24.0)
41–50	9 (25.0)	7 (28.0)
51–60	7 (19.4)	3 (12.0)
61–70	6 (16.7)	6 (24.0)
greater than70	1 (2.8)	1 (4.0)
Unknown	1 (2.8)	0 (0)
Gender		
Male	14 (38.9)	10 (40.0)
Female	22 (61.1)	15 (60.0)
Other	0 (0)	0 (0)
Race/Ethnicity		
White Alone, Not Hispanic or Latino	14 (38.9)	10 (40.0)
Black or African American	2 (5.6)	2 (8.0)
Hispanic or Latino	18 (50.0)	12 (48.0)
Native American or Alaskan Native	1 (2.8)	1 (4.0)
Other, Unknown	1 (2.8)	0 (0)
Income		
≤$10000	22 (61.1)	18 (72.0)
$10001-$20000	8 (22.2)	5 (20.0)
$20001-$30000	5 (13.9)	2 (8.0)
> $30001	1 (2.8)	0 (0)
Education		
Middle school (grades 6–8)	7 (19.4)	6 (24.0)
Some high school (no diploma)	4 (11.1)	2 (8.0)
High school graduate (or equivalent)	7 (19.4)	5 (20.0)
Some college (1–4 years, no degree)	10 (27.8)	7 (28.0)
Associate degree (occupation/ academic degrees)	7 (19.4)	4 (16.0)
Bachelor's degree (BA, BS, AB, etc.)	1 (2.8)	1 (4.0)
Preferred Language of Study		
English	26 (72.2)	19 (76.0)
Spanish	10 (27.8)	6 (24.0)
Type of Diagnoses		
General mental health	25 (69.4)	15 (60.0)
Serious mental illness	11 (30.6)	10 (40.0)
Patient Diagnoses		
Anxiety or panic disorder	27 (75.0)	19 (76.0)
Bipolar disorder	13 (36.1)	8 (32.0)
Chronic pain or somatic disorder	11 (30.6)	9 (36.0)
Depression	26 (72.2)	18 (72.0)
Drug or alcohol addiction	4 (11.1)	3 (12.0)
Eating disorder	2 (5.6)	1 (4.0)
Identity or memory problems	6 (16.7)	3 (12.0)
Impulse control problems	2 (5.6)	1 (4.0)
Obsessive compulsive disorder	4 (11.1)	4 (16.0)
Personality disorder	6 (16.7)	4 (16.0)
Post-traumatic stress disorder or adjustment disorder	12 (33.3)	8 (32.0)
Schizophrenia or other psychosis	7 (19.4)	5 (20.0)

Participants completed eight fill-in-the-blank cards on average. Most (95.8%), participants' responses matched with provider classifications/definitions of medication and procedure/service purposes. From the 24% participants who did not recognize medications or services, the unrecognized data was mostly categorized by providers as mental health (83.3%).

Table 7
Agreement of Participant Classification of Medical Records in Eight Data Categories.

Data Category	Agreement Freq. (%)	Disagreement Freq. (%)	Total
Drug Abuse	105 (84.7)	19 (15.3)	*124*
Alcohol Use and Alcoholism	11 (73.3)	4 (26. 7)	*15*
Mental Health	210 (91.3)	20 (8.7)	*230*
Communicable Diseases	32 (68.1)	15 (31.9)	*47*
Genetic Data	1 (100.0)	–	*1*
S&R Health	22 (66. 7)	11 (33.3)	*33*
Other Addictions	2 (40.0)	3 (60.0)	*5*
Other Information	204 (75.3)	67 (24.7)	*271*
Total	*587 (80.9)*	*139 (19.1)*	***726***

Table 8
Agreement of Participant Classification of Medical Records based on Medical Information Type.

Type of Information	Agreement Freq. (%)	Disagreement Freq. (%)	Total
Allergies	17 (68.0)	8 (32.0)	*25*
Diagnoses	132 (78.6)	36 (21.4)	*168*
Laboratory Tests	223 (77.2)	66 (22.8)	*289*
Medications	171 (88.1)	23 (11.9)	*194*
Procedures/Services	44 (88.0)	6 (22.0)	*50*
Total	*587 (80.9)*	*139 (19.1)*	***726***

5.3. Medical records classification in sensitive data categories

Participant's categorization was compared against the providers. Tables 7 and 8 show agreement between participants and providers based on data categories and type of information, respectively.

Participants classified 587 (80.7%) items in agreement. Among 140 (19.3%) disagreements, participants classified 60 (42.9%) items as genetic data. Providers classified most (73.3%) of the 60 items as other information. Participants often disagreed on labs like complete blood count or metabolic panels, classifying them as genetic data, as they evaluate blood components or detect blood-related conditions. They also classified chronic conditions (like diabetes) as genetic. When asked rational behind classifying thyroid labs as genetic data, one participant commented, *"it runs in the family"*. Another mentioned that *"my mom has it [thyroid abnormalities], my sister has it [thyroid abnormalities]"*, so thyroid tests belong to genetic data.

Participants classified possibly sensitive labs related to "communicable diseases S&R health" as S&R health. One participant classified hepatitis labs as S&R health because *"if I have a partner… they know I'm clean and I've been tested [for hepatitis]"*.

5.4. Medical records sensitivity

Most participants concurred with providers considering mental health (76.0%) and S&R health (75.0%) somewhat to very sensitive (Table 9). One participant commented that mental health information is very sensitive as *"others do not want to realize how [mental state] you are"*.

Participants appeared to fear stigma and discrimination of mental health (24.0%). A participant commented that *"…it [mental health] is sensitive, for me it's a bother because they treat me very differently… they treat me like an idiot not like a person"*.

Participants frequently considered drug abuse or alcohol use not sensitive perceiving that they do not have a dependency. One participant diagnosed with alcohol dependency commented that *"I don't have a dependency to alcohol. I went to a hospital because I had a few beers after having suicidal thoughts, other than that no"*.

5.5. Sharing medical records for care and influence of sensitivity

All participants desired to share all or some of their EHRs data with providers outside the study sites (such as primary care providers (PCP)) (Table 10). Twelve (48.0%) wanted to share all data with all providers. These participants felt that sharing all data would allow them to receive better care and would improve patient-provider and provider-provider communications. A participant mentioned, *"It's easier. Instead of remembering all of this [medical records]"*.

Thirteen (52.0%) participants desired choices in sharing records. When considering the mean willingness to share data with all types of providers, participants appeared very willing to share other addictions (100.0%), genetic data (95.8%) and other information (90.5%) and less willing to share S&R health (76.0%) and communicable diseases (77.8%) information. One participant wanting to share S&R health with only PCPs and specialty providers commented, *"unless, it's affecting something, I don't think they [other providers] need to know"*.

The majority (79.0%) of participants wanted more choices around sharing mental health and were more willing to share with behavioral providers outside the study sites (92.0%) compared to non-behavioral providers. A participant noted, *"I don't think a cardiologist needs to know about it [mental health]"*.

Stigma was cited as an important component of data sharing decisions. A participant commented that *"it [data sharing] might be helpful, it might be detrimental because they see your [mental health] diagnosis and don't see you as a person. Kind of torn between that."* About sharing drug abuse information, the same participant said, *"I don't want anyone knowing I smoke marijuana because they [providers] look at you differently"*.

5.6. Willingness to share in case of medication prescription and emergency

In a hypothetical scenario, we asked participants about their PCP accessing their EHR when prescribing a new medication. Participants were willing to share 85.1% of medical record items. Avoiding adverse drug reactions were a prominent motivation for sharing. A participant mentioned, *"PCP prescribes medication that counteracts medication prescribed by psych [behavioral health] doctor, so they need to be on the same page"*. Thirteen (52.0%) participants wanted choices in sharing records. Nine participants chose to restrict some information related to mental health and drug use. One chose to restrict mental health diagnosis and services but opted to share mental health medications commented, *"all my mental health I don't want to share. They [PCP] would know from the medication that it is mental health medication and they [PCP] don't need to know specifics"*. Two participants did not want the PCP to know about suicide attempt and physical abuse. Twenty-four percent participants desired to restrict communicable diseases OR S&R health labs and diagnoses perceiving that *"nobody needs to know about this [HIV Antibody Screen Test]"*. Participants (20.0%) chose to restrict S&R health labs and diagnoses (pregnancy (HCG) test, erectile dysfunction diagnoses, etc.) and data pertaining to certain medical conditions (chronic condition tests, obesity diagnosis, etc.).

Another hypothetical scenario asked participants about emergency providers accessing their EHRs in life-threatening situations. Participants wanted to share most (89.1%) EHRs, with 18 participants willing to share 100% records. A common perception was that *"in any emergency situation, they need to see all my data [medical records]."* Seven (28%) participants wanted choices in sharing data. Most (71.4%) wanted to restrict diagnoses, medications and services related to mental health and drug abuse (57.1%). Many (42.6%) participants wanted to share chronic condition labs, urine cultures and metabolic panels. A few (28.6%) preferred to restricted diagnoses and labs for S&R health and communicable diseases.

Table 9
Participant Perceptions of Sensitivity towards Various Data Categories.

Data Category	Participants with Medical Records in Category	Participants Who Considered Category Sensitive Freq. (%)	Examples of Participant Perceptions
Drug Abuse	17	7 (41.1)	Not Sensitive: "I have nothing to hide because I don't do drugs." Not Sensitive: *"maybe because I don't use [drugs]"*
Alcohol Use and Alcoholism	8	4 (50.0)	Not Sensitive: "Because I don't drink."
Mental Health	25	19 (76.0)	Very Sensitive: "Don't want anyone who's not a doctor to know all my information, especially suicidal stuff.".
Communicable Diseases	9	5 (55.6)	Very Sensitive: "I don't want everyone to know what diseases I have or what I've been diagnosed with."
Genetic Data	15	6 (40.0)	Very sensitive because it's very private to him
Sexuality and Reproductive Health	12	9 (75.0)	Very Sensitive: "I had to have it because I was sexually abused and I don't want people knowing about that."
Other Addictions	3	2 (66.7)	Not Available
Other Information	25	10 (40.0)	Somewhat Sensitive: "Its stuff about my body but medical professionals do need to know history."

Table 10
Participant Preferences of Sharing Medical Records with Providers Outside Study Sites. All numbers are represented as percentages. The order of the data categories and providers is organized based on percentages.

		Type of Providers (%)								*Average*
		Primary Care Providers	Specialty Care Providers	Hospitals	Medical Assistants	Nurses	Licensed Professional Counselors/Therapists	Case Managers or Social Workers	Pharmacists	
Data Category (%)	Other Addictions	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	*100.0*
	Genetic Data	100.0	93.3	100.0	100.0	100.0	93.3	86.7	93.3	*95.8*
	Other Information	96.0	96.0	100.0	88.0	88.0	88.0	84.0	84.0	*90.5*
	Alcohol Use	87.5	87.5	75.0	87.5	87.5	75.0	87.5	75.0	*82.8*
	Mental Health	76.0	80.0	92.0	76.0	76.0	92.0	84.0	76.0	*81.5*
	Drug Abuse	87.5	87.5	81.3	75.0	81.3	81.3	81.3	75.0	*81.3*
	Comm. Diseases	88.9	77.8	77.8	77.8	77.8	77.8	66.7	77.8	*77.8*
	S&R Health	91.7	83.3	75.0	83.3	75.0	66.7	66.7	66.7	*76.0*
Average		*90.9*	*88.2*	*87.6*	*86.0*	*85.7*	*84.3*	*82.1*	*81.0*	–

5.7. Sharing medical records for research

We asked participants about sharing the types of data represented by the 30 cards for research study (Fig. 4). Most (76.0%) participants were extremely willing to share for research conducted by study sites and universities (64.0%). Improvement in own and others' care appeared to be a motivation for many (56%) participants. Almost half (52.0%) of the participants showed willingness to share with non-profit organizations. Participants were less willing to share their EHR data with government agencies (48.0%) and pharmaceutical companies (40.0%). A participant commented, *"I don't know much about them [government agencies]. I don't want someone I don't know much about to know all about me."* Another participant who did not want to share data with drug companies mentioned, *"They [drug companies] don't need to know my personal information and I don't really trust drug companies that much".*

6. Discussion

Driven by our desire to create a standardized, integrated consent management platform for sharing individual EHR data, we needed to deeply understand the health information sharing preferences and perceptions of patients, particularly those with behavior health conditions. When our systematic literature review produced a dearth of studies and methods, we devised this new mixed-methods methodology to fill the gap. Our study reviews the current state of the art and proposes a novel mixed-methods approach using an individual's own EHRs.

Our literature review revealed that while there are methods to study

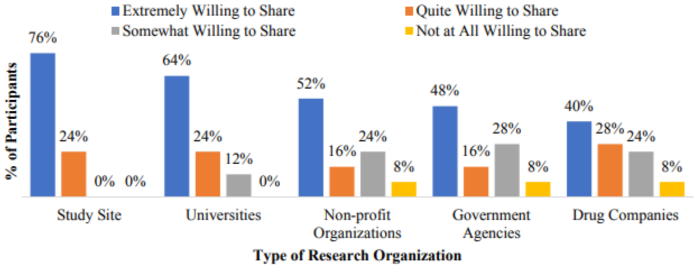

Fig. 4. Participant's Preferences for Sharing Medical Records with Different Types of Research Organizations.

data sharing preferences and perceptions, patient's own EHRs are rarely involved in the process. Gaps in patient knowledge of their own EHRs could influence their choices related to sensitivity and sharing. As in Schwartz et al. and Tierney et al., our method aims to quantify how individuals perceive and prefer to share sensitive health data from their actual EHRs [15,25].

Our literature review shows that subjects' willingness to control data sharing changes based on the type of health information and perceived sensitivity [10,14,20,21]. Participants' categorization compared to providers' showed differences in perceptions of certain categories. While 66.4% of the health information was categorized in agreement to provider classifications, participants' predominant disagreement in categorization of genetic data (37.5%) and other information (25.0%). This points to incongruity in patient-provider sensitivity perceptions supporting Soni et al. suggested differences [26]. The 19.3% of overall disagreement and nearly 14.3% partial agreement point to a divergence in patient-provider perceptions that affects how patients categorize and share data with different providers.

Sensitivity measurements showed participants were categorizing mental health (76.0%) and S&R health (75.0%) as very to somewhat sensitive, but patients were choosing to place other traditionally perceived sensitive categories such as alcohol use and drug abuse as not sensitive. Interestingly, these specific categories are protected by 42 CFR Part 2 and are legally and clinically considered sensitive [4]. However, participants who explained their not-sensitive categorizations of these categories appeared to be considering their applicability to their own circumstances. This tendency to consider applicability of a category to how participants viewed its sensitivity was also visible in the Soni et al. survey results [26].

The connection between sharing preferences and sensitivity perceptions of own EHRs is especially interesting. There are differences in how patients choose to share categories they deem sensitive. Results showed that S&R health (75.0%) and communicable diseases (76.0%) considered sensitive were less likely to be shared (76.0% and 77.8%, respectively). However, 66.7% of participants classified other addictions as a sensitive category, yet all chose to share. While Whiddett et al. suggested that patients desire to restrict sensitive information, our results showed that while that was true for some categories such as S&R health, it was not true for all [13].

Our literature review indicates that willingness to share depends on the type of data recipient [10,14–16,19]. Grando et al. and Schwartz et al. both point to patients potentially choosing not to share information based on their fears of discrimination and lack of trust with a provider [15,17]. We showed that fears of stigma and discrimination do play a role in the choice to share data and is prominently visible in the category of mental health. Participants considered this category sensitive (76%) and were considerably willing to share based on whether a provider were a behavioral (share) or non-behavioral (not share) provider. Granular data sharing control by the patient thus may not coincide directly to sensitivity of a category but include a more complex consideration of discrimination fears, trust, and provider relevancy for treatment [10,15,36].

Our literature review found that Caine et al. study suggested that 100.0% of patients did not know their data but wanted to know more about them to take more informed data sharing decisions [37]. We found that patients with behavioral health conditions usually recognized their own medical record data (82.7%), though some patterns of recognition difficulty did emerge. For the 17.3% of data that patients found difficulty recognizing as part of their data, laboratory results were predominant (91.7%). Despite this uncertainty, participants consulted the education material only 47.3% times. Therefore, in instances of uncertainty, patients may not seek written educational material. Similarly, participants did not check the definitions of data categorized as genetic (12.0%) or S&R (8.0%). The recognition of genetic data was shown to be imperfectly understood by the original survey by Soni et al. [26]. Therefore, there is a need for personalized educational material delivered in different mediums, such as face-to-face explanations or multimedia education, prioritizing high-uncertainty categories.

Sensitivity and sharing preferences of participants seemed altered upon access to EHRs in interviews. While most patients (72.0%) indicated that certain sensitive categories did not apply to them in the survey, their EHRs contained data within one or more of those categories. Drug abuse, S&R health and genetic data appeared to prominent categories for which patient views were altered.

Overall, our findings reveal that differences between patient and provider understanding of data categorizations, stigma concerning these categories and/or difficulty to recognize or remember data from their EHRs could have led to frequent 'It does not apply to me' survey responses and the validation of our initial hypotheses.

6.1. Limitations and challenges

The study had limited participants, but their diversity in age, ethnicity/race, and education provides an excellent base for understanding perceptions of sensitivity and sharing. With the inclusion of patients with behavioral health conditions as the focus, this study provides a more complete understanding as the emphasis on combining physical and behavioral health data via the HIE continues in the US [38–42].

The proposed method relies on closed card sorting tasks. It is possible that the predefined groups or responses could have biased or restricted patients from other, alternate classification schemes or categories. Patients may have felt stigma related to the experience of sharing information with researchers. It is also possible that patient definitions of sensitivity and data sharing choices may have been altered after exposure to information from their own EHRs. We intend to compare responses of these interviews with our previous survey to explore if patient choices may have been impacted by access to their EHRs.

The process of creating the medical records cards resulted in the separation of some contextual information from medical record items. For example, though available, we did not provide participants with the indication (diagnosis/symptoms) for their psychotropic medications. The availability of this information could have influenced perceptions on sensitivity and sharing.

We received limited data in some sensitive categories. This may be related to legal restrictions on the use or disclosure of certain types of sensitive data. In Arizona, for example, HIE statutes limit the types of use and disclosures of genetic data as well as the general release of data though the HIE [43]. Lack of sufficient data in all categories could introduce bias and limit the representativeness of data.

EHR records spanning five years were used to create the personalized card sorting tasks. It is possible that patients did not remember details of their medical history (example, prior medications) and therefore not recognize these items. Cognitive impairment and memory loss occur in conditions such as depression, bipolar and personality disorders, obsessive-compulsive disorder, schizophrenia, etc. [44]. Such factors may have impacted patient perceptions and choices when classifying longitudinal medical record items.

6.2. Generalizability and expansion

Although the proposed method has been piloted with patients receiving care for behavioral health conditions, it is readily applicable to other patient populations and to a wide range of concepts, including alternate sensitive data categories, chronic conditions, criminal justice, abuse and violence, and social parameters (e.g. demographics and socio-economic status, etc.). The differences between perceptions of diverse populations should be studied to better understand variations in data sharing preferences, identify other potentially sensitive data categories and personalized education needs.

Modifying the exercise by substituting the closed card sorting exercise with an open sorting exercise may allow participants to organize and label groups based on what makes sense for each individual [30]. Using open card sorting elements, entirely or as an addition to the closed sorting exercise, may yield new insights by providing study participants with more expressive freedom. For example, when classifying their EHRs into sensitive data categories, patients could define additional categories as they see fit. Such design modifications might provide a complementary perspective to explore patient perceptions of sensitive data and identify knowledge gaps.

6.3. Future work

In addition to addressing questions such as why patients felt some categories '*did not apply to me*' and whether access to their EHRs affect data sharing choices, this study developed a foundation for upcoming studies. A follow up study will compare patients' sensitivity views with providers. Areas of disagreement and along with patient explanations, the study will develop knowledge of how sensitivity affects patients' choices to share EHRs.

Validation of the proposed methodology with a larger and more diverse population is needed. Caine and Hanania asked patients about data sensitivity and sharing preferences using NCVHS recommended sensitive categories [10]. We are considering comparing our outcomes with their results as an initial validation.

Although they play an integral role in patient care and engagement, healthcare provider views on data sensitivity and data sharing have rarely been studied [17,25]. We will use the outcomes of this study to explore provider views on granular data control.

Study outcomes will guide the future development of our electronic consent tool, My Data Choices, and the on-demand, personalized patient education material to be embedded into this patient-facing application.

Finally, the identification of other data categories defined as sensitive by patients and related privacy concerns shared by patient and provider participants will help guide the development of regulations and policies related to sensitive data sharing.

7. Conclusion

Based on a comprehensive state of the art review on data sensitivity and sharing perceptions, we proposed a novel, personalized card sorting methodology using an individual's own EHR to explore sensitive data definitions, perceptions, comprehension and willingness to share categories of health information for care and research. We identified diversity in patient perceptions of data sensitivity and desire for granular health records sharing. These outcomes provide new information about patient attitudes towards sensitive data and sharing preferences that will inform policy formation and guide the ongoing development of an electronic, patient-driven, informed consent platform for granular data sharing with personalized on-demand education.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jbi.2019.103338.

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Mental health professionals' perceptions on patients control of data sharing

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Abstract

Integrated mental and physical care environments require data sharing, but little is known about health professionals' perceptions of patient-controlled health data sharing. We describe mental health professionals' views on patient-controlled data sharing using semi-structured interviews and a mixed-method analysis with thematic coding. Health information rights, specifically those of patients and health care professionals, emerged as a key theme. Behavioral health professionals identified patient motivations for non-sharing sensitive mental health records relating to substance use, emergency treatment, and serious mental illness (94%). We explore conflicts between professional need for timely access to health information and patient desire to withhold some data categories. Health professionals' views on data sharing are integral to the redesign of health data sharing and informed consent. As well, they seek clarity about the impact of patient-controlled sharing on health professionals' roles and scope of practice.

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data privacy, data sharing, electronic medical records, interview, mental health, thematic analysis

Introduction

Mental illness is defined as a condition affecting thinking, feeling, mood, or behavior of an individual that may be occasional or chronic,[1] while mental health is a broader term that includes a person's emotional, psychological, and social well-being over the course of life.[1] Individuals requiring additional assistance due to a mental illness may be designated as having a serious mental illness (SMI).[2] The term behavioral health is the most encompassing, as its definition considers any behaviors that affect an individual's physical and mental health.[3] Mental health is a rising health care worry in the United States, with an estimated one in five individuals experiencing some type of mental illness each year[4] and over 10 million people in the United States having an SMI designation.[5] Therefore, the integration of mental health and behavioral health into physical health care is integral to providing high quality of care to individuals.[6,7]

The integration of behavioral and physical health care[8,9] affects all aspects of health care delivery, including the sharing of protected health information (PHI). Research demonstrates that when patients have more control over their health data, they are more likely to adhere to treatments and express higher satisfaction with their care.[10,11] Unfortunately, individuals who suffer from a mental illness face higher levels of stigma and discrimination not only in their lives but also in their health care.[12] Such evidence has motivated medical educators to incorporate instruction on non-discriminatory treatment of patients with mental health problems.[13] Since patients have increasingly more control over their information,[14] the fear of discrimination and privacy may lead to lack of sharing pertinent information during care.[7,15] As such, it is crucial to consider not only how patients with behavioral health data want to share information but also what health professionals perceive as necessary information for treatment.

The preponderance of literature focuses on perceptions of patients receiving general medical care. Kim et al. performed a 394-participant pilot of an informed, tiered consent tool focusing on whether participants would make changes to record access. Of all the participants, 31.9 percent made changes. Using the National Committee on Vital and Health Statistics' (NCVHS)[16] sensitive categories, the study found no significant relationship between data categories and how patients chose to share their NCVHS-designated sensitive data. They concluded that patients preferred granular data control and that having options increased their confidence in data sharing decisions.[17] Another survey study of over 200 participants also found that patients wanted to choose who sees their health information; however, the study also noted 90 percent of patients had incomplete or no knowledge of how their health information was being currently shared.[18] A recent study by Wass et al.[19] paired survey (n = 56) and interviews (n = 9) to examine the impact of electronic health records (EHRs) on patient engagement and the patient–provider relationship. They concluded that while patient EHR access increased engagement and constructive communication with providers, accessibility must be coupled with education to explain the clinical content of the EHR.[19,20] As more health care information is placed under patient control, Woods et al.[21] note that mutual education and perspectives must be incorporated for successful health care and communication. Generally, the current literature demonstrates that patients prefer more transparency and granular data control, but there is a disconnect between patient and provider perspectives.[19,18,22–26]

A survey-based study of over 1600 participants concluded that patients are most influenced by privacy concerns (significant negative path coefficient $\beta PC = -0.160$, $p < .001$) when deciding whether to share their health information.[27] Other studies showed that trust in providers is the motivating factor to share health data, including highly sensitive information, such as HIV.[26,28] Furthermore, while patient perception of higher cultural sensitivity of their health professionals appear to increase adherence to regimens and overall quality of care,[10,29] information sharing requires a communicative relationship between patients and their health professionals.[30]

Studies on patients receiving general medical care are consistent with findings from behavioral health-related studies. A recent paper on the privacy and sensitivity perceptions of 86 behavioral health patients found that 82.5 percent identified their mental health information as sensitive.[31] In this study, perceived sensitivity of information corresponded to patients' willingness to share information with providers.[31] Another recent study focusing on patient perspectives in behavioral health found that the sensitivity of information was not consistently correlated to patient sharing choices.[32] Grando et al. reported that behavioral health patients and providers both believe that intended use affects record-sharing choices. In this study, patients (75%) felt quality of care and trust in providers (45.8%) was a reason to share information, while providers (75%) worried about reduced quality if patients restrict relevant clinical information.[22] These results correspond to findings that communication in the patient–provider relationship is crucial in record sharing as well as care quality.

While these studies focus on patient perspectives, understanding the health professional perspective is integral to a beneficial system redesign. On one hand, patients have rights controlling the access to their health information[18,19]; on the other hand, health professionals need to have the necessary information to treat and care for patients.[20] Such a dynamic was considered by Tierney et al. as they allowed 105 patients to redact all sensitive information in their EHR. These data were accessed by 31 clinicians with "break the glass" rights to view the information withheld. Of the 126 times patient EHRs were viewed, clinicians broke the glass on 14 percent of EHRs with redacted information and 0 percent of non-redacted EHRs.[33] Tierney et al. concluded that while clinicians (54%) feel that patients should have granular data control of their EHRs, 58 percent consider that restrictions could harm the patient–provider relationship. In fact, 71 percent believed quality of care would decline with granular data sharing.[33] Patients knowledgeable about the contents of their personal health record have a better understanding of their ongoing health and are generally more active in decision-making and communicating with their health care team.[34] Thus, increasing communication and understanding of granular data sharing may lead to patients' better understanding of who has access to their information and why.[35]

While patients may withhold information due to fear of discrimination or stigma,[7,36,37] a trusting patient–health professional relationship and proper communication may counteract this trend of non-adherence to treatment and withholding of health information.[35,38–40] An impediment to clear communication and strong patient–professional relationships has been regulations and policies devoted to protecting patient privacy and control over data. Indeed, health professional–centered studies have shown that regulations meant to protect patients from discrimination and stigma such as 42 CFR (Code of Federal Regulations) Part 2 can actually create concern and worry. As Campbell et al.[41] pointed out in their interview-based study, health professionals have to choose between patient privacy rights and patient safety in care. Furthermore, the literature has consistently focused on general health professionals' perceptions of an integrated health information exchange (HIE)[10,42–44] but the view of behavioral health professionals regarding necessary information to share and why has not been explored.[37,45]

In this article, we refer to individuals providing behavioral health care (BHC) as behavioral health professionals. This term includes several roles ranging from social worker to psychiatrist.

The legal definition of the term provider refers to individuals who are able to provide health care services in a prescribing role such as psychiatrists, psychiatric nurse practitioners, and primary care providers.[46]

In our previous study, we interviewed 20 behavioral health professionals to understand the perceptions of mental health professionals on granular data sharing, patients' fear of stigma, patients' desire to protect sensitive health information, and opportunities and challenges in the development of electronic consent tools that support patient-driven granular control.[35] Thematic analysis revealed seven emergent topics of significance—patient motivation, coordination of care, patient knowledge, stigma, trust, sociocultural understanding, and professionals' frustration with the forms/system—relating to patient granular data sharing. While 70 percent of health professionals agreed that patients should have control over who sees their health information, they (75%) also believed that their patients did not fully comprehend the consent forms for sharing information. The theme of patient motivation for sharing or not sharing exposed areas requiring further analysis.

In this article, we used the interview data previously collected[35] to elucidate behavioral health professionals' perspectives on (1) patient motivations when deciding to share sensitive medical records, (2) types of information viewed as necessary for care, and (3) differences between provider and patient views on what information is shared. By focusing on these objectives, this article also considers themes behavioral health professionals view as positive and negative motivators for patients to share information. In addition, there is a need to understand what health information types are considered mandatory by behavioral health professionals to safely and confidently deliver care. These requirements are dictated by the professionals' roles. Thus, there is a need to consider the effective roles of behavioral health professionals in any analysis that is done. Ultimately, the professionals' perceptions are needed to highlight areas of concern that may arise in granular data sharing and to develop effective educational resources and data sharing tools for alleviating such concerns.

Methods

Study design

With institutional review board (IRB) approval, Arizona behavioral health professionals were recruited from two urban behavioral health outpatient clinics. One facility provides general mental health care for individuals of all ages while the second facility focuses on treatment for adult patients with SMI. Both clinics use similar EHR systems that include electronic consent forms and e-signatures.

All health professionals were at least 21 years old and involved in the process of patient consent to release health information at the facilities. Health professionals were also required to have current or recent BHC experience during the year prior to the interview date. Health professionals were compensated for their participation.

A consent form was signed by participating health professionals that included permission to audio record and analyze interviews. All interviews were in person and solo, conducted at a meeting room provided by the facility.

Health professionals' interviews script

The semi-structured interview script was created after workflow observations were done in the two facilities[47] (see Supplementary Material). An interdisciplinary research team of experts in biomedical informatics, law, ethics, and physical and mental health fields developed and finalized the

Table 1. Types of questions asked in semi-structured interview, how they relate to objectives, and examples of prompts used.

Question type	Relevant objectives	Example prompt
Roles and duties	Demographic data for correlation analyses	Are you involved in the consent process for releasing medical records at this facility?
Consent form knowledge	Types of information viewed as necessary for treatment of patients	What kind of education (verbal, written, flyers, video, online, etc.) does this facility provide to patients and legal guardians before or during their appointment?
Types of data withheld or shared	Divergence with patients' views on information shared.	Do patients tend to share/withhold certain types of information more than others?
General health professional perceptions of patient data sharing	Patient motivations when deciding to share sensitive medical records	From you experience, do you think patients want to have more control over their health data and how it is shared?
Patient motivations to share or withhold information	Patient motivations when deciding to share sensitive medical records	What do you think are the main motivations or reasons that your patients choose to share or not share their health information?
Perceptions of patient fears	Patient motivations when deciding to share sensitive medical records	Do you think patients would be afraid if providers outside of this facility knew about their behavioral health conditions?
Perceptions of a granular data sharing tool	Types of information viewed as necessary for treatment of patients, and divergence with patients' views on information shared.	What are your thoughts about a tool like this?

script, covering health professional demographics and perceptions of consent practices and patient data sharing (see Table 1).

Data analysis

All interview recordings were transcribed using Transcribe® software and reviewed by two members of the team for accuracy and reliability. Braun and Clarke's[48] guidelines and Bernard's[49] steps for thematic analysis were utilized to identify emergent themes via repetition and frequency of codes from the interviews.

Three transcripts were chosen for exploratory analysis of emergent themes and for inductive theme analysis from existing literature. Meaningful phrases were the units for coding and analysis of transcripts. Coding was done using MAXQDA© by one team member with definitions of codes (themes) iteratively honed by the research team over four iterations. Themes were then organized from broadest to most specific definitions. Further analysis of the seven main themes found in Grando et al.[35] was done using quote matrices, complex coding query, and simple similarity analysis. The themes of patient motivation and coordination of care were emphasized based on prior results.

Two co-authors categorized health professional responses based on the semi-structured interview script. Inter-rater agreement was computed using three transcripts with very good initial agreement (unweighted kappa: 0.82) followed by final agreement of 100 percent. Descriptive and inferential statistical methods were used on the categorized response. A regression using Microsoft

Excel data analysis package was used to identify significant correlation among health professional answers to prompts. Quote matrices and multidimensional analysis were used to provide frequency and distribution of all themes, including the seven main themes previously reported and subthemes found via qualitative analysis methodology.[35]

Demographics

The 20 recruited health professionals (10 from each facility) spoke English during the consent and interview process. Health professionals were asked to share their credentials and training. Participants represented 11 distinct roles. The research team classified participants into two groups using the Prescriptive Authority of Health Professionals[50] chart. Health professionals defined as *prescribers*—any health professional able to prescribe medication to a patient—included three psychiatrists, three psychiatric nurse practitioners, and one primary care health professional. Health professionals without prescribing authority did not meet the criteria were classified as *non-prescribers*: three case managers, three counselors, two registered nurses, two therapists, one clinical nurse manager, one integrated treatment specialist, one operations coordinator, and one discharge specialist.

Results

Hierarchy of themes

Seven main themes emerged from thematic analysis of health professionals perceptions: patient sharing motivations (54%), coordination of care (15%), patient knowledge (15%), stigma (7%), trust (5%), sociocultural understandings (3%), and professional frustration with the system or forms (1%).[35] Further categorization of codes within patient sharing motivation was performed due to the complexity of issues noted. These were topics within BHC that health professionals identify as affecting patients' decisions to share or not share information.[20]

After creating a multidimensional scale of subthemes, further analysis of patient sharing motivations yielded another main theme. Behavioral health professionals consistently noted patient rights as a process driver, so categorized initially as patient sharing motivations. However, with multidimensional analysis, provider rights surfaced as a theme. When discussing patient rights, participants included their rights as professionals, including a right to certain information to provide care to individuals:

> If they're choosing to withhold information, they need to be honest with the provider and let the provider know "I'm choosing to withhold information from you." . . . just like the patient has rights, the providers have their rights. They have a license, they [health professionals] have the right to make that decision as well. (Prescriber)

Participants' discussions of their own perceived "rights" referred not to legally enforceable privileges or power, but to community standard, that is, their responsibilities, privileges, and authorized powers bestowed or desired because of the relationship.

"Rights," reflecting discussion of the legal rights of both parties to a care encounter (466 codings), was elevated to a main theme (see Figure 1 and Table 2). From 1727 codes, eight themes were identified: rights (27%), patient sharing motivations (27%), coordination of care (15%), patient knowledge (14%), stigma (6%), trust (5%), sociocultural understandings (4%), and professional frustrations with the forms/system (~2%).

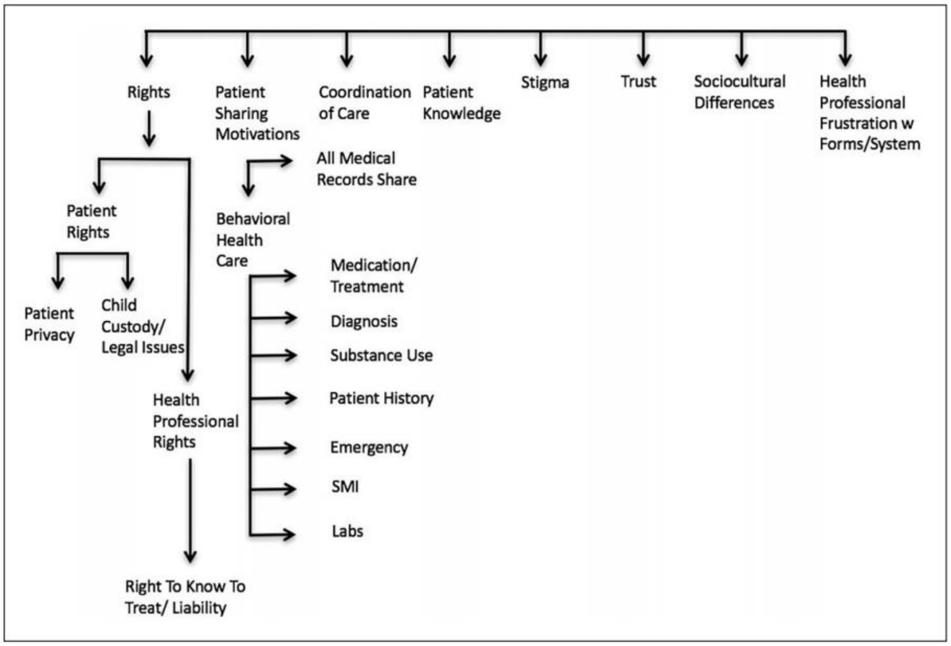

Figure 1. Themes discussed by health professionals.
Themes identified then structured into a hierarchy of themes and subthemes by health professional perceptions of patient data sharing.

More participants discussed patient rights (78%) than health professional rights (22%). From patient rights, two further subthemes emerged: patient privacy (85 times) and child custody/legal issues (55 times). Similarly, one health professional rights subtheme, right to know to treat/liability had 75 mentions. While participants tended to discuss patient rights as motivators to not share information, they noted that health professional rights should be considered as part of the sharing justification: ". . . that means if you [patients] want to control, you can't pick and choose . . . That's part of your control, your acknowledgment that you're going to take our healthcare" (prescriber). This theme emerged as a way for health professionals to discuss the tension between patient rights and health professional rights in relation to granular data sharing.

Within the conversation of health professional rights, there was concern over liability (Table 2). As one prescriber considers the topic of patient data sharing with the responsibility to treat a patient:

> Because they're saying we can't share that . . . I'm using meth and alcohol, but I'm getting my opiates from this [other] doctor. So from a safety standpoint, I'm less conservative with that because I think this information needs to be shared, especially as the liability for healthcare providers in this country is always increasing.

Prescribers and non-prescribers expressed significant concerns. This prescriber added that he was not confident that he knew current consent requirements:

> I know drug and alcohol and HIV status have always needed an additional consent, even amongst the AHCCCS [Arizona's Medicaid] providers. I take that back, I don't really know that anymore. Because maybe it has changed over the years.

Table 2. Rights subthemes: definitions for codes and exemplars.

Themes	Definition	Examples
Patient rights	Any discussion of patient/guardians rights, including signing release forms and consent forms	We give them the option that they can sign up, that they can change their mind later on. They can opt out on it if they want to later on. But most of the clients don't mind they feel like it's, it's fine.
Health professional rights	Any discussion of health professional rights, directly or indirectly, that considers their right to share or not share patient information or see a patient. Also includes discussion of signing forms to treat patient	And it's for our eyes only, because the client will misconstrue what was written, and they won't understand why we wrote what we did, they will take it negatively.
Patient privacy	Discussion of issues of privacy such as patient wanting privacy specifically or worry over others knowing their health information; discussing HIPAA	Well some of the things that they don't want to, is like releases of information. Who the information get to. Like, for example, if they have a new med, and maybe the client has a mom who is considered a liability to the clients or not supportive of the clients' treatment.
Right to know to treat/liability	Any type of discussion where the health professional wants information for treating the patient. Includes discussion of thoughts or fears on liability issues directly or in an obtuse fashion of handling confidentiality, licensure, HIPAA-related issues, and legal/health ramifications for themselves or the patient	I've had patients come in and say, "I'm not going to choose . . . I choose not to tell you everything that's going on." And I say, "I'm also going to choose not to see you." Because it's not safe for someone to take care of somebody without knowing all of your medical history, all the medicines that you're taking, all the surgeries that they had.
Child custody/ legal issues	Any discussion of custody or legal issues as it relates to the patient sharing or not sharing information	I guess, the biggest concern would be who out there is going to receive any of this information, meaning Child Protection Services or Department of Child Safety or legal or the courts, that seems to be the reason why anyone would hold back is because they're afraid if they're too honest with me sometimes that I may be telling them things that could have some bad consequences for them are telling others.

HIPAA: Health Insurance Portability and Accountability Act.
Themes are ordered based on frequency.

Subthemes within patient sharing motivations (461 thematic analysis codings) focused on two distinct categories of BHC (94%) and all medical records share (6%). BHC was a special focus due to its relative complexity.[35] Thematic analysis results were further analyzed with quote matrices to further categorize the BHC subthemes into whether patients share, should share, or do not share data. There were 514 instances that fit within these three categories: medication/treatment (29%), diagnosis (23%), emergency (12%), substance use (12%), patient history (12%), SMI (6%), and labs (6%). The similarity in percentages of codes total per subtheme and the percentages of instances these subthemes are discussed within share, not share, and should share is notable and is considered during the coding process (Table 3).

Table 3. Behavioral health care subthemes: definitions for codes and exemplars.

Themes	Definition	Examples
Medication/ treatment	Discussion of medication or treatment in relation to patient–health professional needs, so medications and treatments can be prescribed.	That's basically what we want to make sure we're, I guess we've found medications conflicting, that the medical doctor was giving and with our psych meds they don't go together, or the patient's, you know even the nurse practitioner will have a question even though she is a nurse practitioner.
Diagnosis	Discussion of a patient's diagnosis and/or symptoms using the *Diagnostic Statistical Manual of Mental Disorders* (*DSM-5*)-type language[33] used by behavioral health professionals in the United States	I am thinking one particular gentleman, schizophrenic, that I have. He lives with his family, but he's pretty high functioning, he's high functioning in the sense he fits my criteria, the criteria for my team, so I would say it doesn't matter to him.
Substance use	Discussion of substance use (alcohol, prescription or non-prescription drugs) for patients	If they had a substance use and they may not have told the doctor, or they don't want us to get too involved with that.
Patient history	Discussion of patient's medical or health experiences, including illness both in physical and in mental health[32]	They usually don't want their other providers to know some things about their social life and sometimes about substance use or recreational use of street drugs.
SMI	Discussion of SMI specifically as a designation or a patient with SMI	They're in an SMI program, serious mental illness, with the state. They're kind of labeled, they feel labeled.
Emergency	Discussion of a perilous situation that arises suddenly and threatens the life or welfare of a patient or a group of people, as a natural disaster, medical crisis, or trauma situation[32]	Like I said, the obvious ones of self-harm and danger to self and threatening others because we also have that duty to protect their life and the community's life and everything else. So yes, in that sense, yes.
Labs	Any discussion of lab work, including blood or urine analysis	They are getting used to it, because we do the blood work here but then I have a lot they're saying, I don't need it here anymore. I go to my primary care and they're doing it. We'll send you a copy.

SMI: serious mental illness.
Themes are ordered based on frequency.

Themes within BHC were coded as to whether health professionals believed patients were sharing their health information with them. Professionals who noted patients choose to share their entire record provided two major rationales overall. According to health professionals, patients share all data due to a want/need (36%) from provider (e.g. medication refill) or to accelerate time to receiving care (25%). Other reasons mentioned by health professionals included ambivalence and/or perceived obligation:

> I just think it's time. They want to get out of here, especially when they know that they're not going to get their medication on their first visit. It just depends on the situation. (Non-prescriber)

The identification of emergent themes is fundamental to identifying why providers think patients decide to share or withhold data and related areas important to behavioral health professionals.

Table 4. Frequency of codings within behavioral health care themes as classified by behavioral health professionals with justifications.

Themes	Codes (n)	How themes are discussed (%)[a]			Health professionals' main justification
		Share	Should share	Not share	
Emergency	60	17	57	27	Professional need info for care (32%); staff/patient/other safety (21%)
Patient history	63	13	52	35	Professional need info for care (36%); patients' fear of disclosure (17%)
Medication/ treatment	148	22	46	32	Professional need info for care (52%); patients' fear of disclosure (13%)
Labs	29	48	41	10.34	Professional need info for care (34%); professional need info on medications (32%)
Diagnosis	118	15	38	47	Professional need info for care (29%); patient fear of disclosure (31%)
Substance use	63	14	38	48	Professional need info for care (38%); professional need info on medications (21%)
SMI	33	30	30	39	Patients' fear of disclosure (50%); professional need info for care (22%)

SMI: serious mental illness.
Themes are ordered based on frequency of should share. Themes in bold show that there is a larger than/equal to 20% difference between share and should share perceptions.
[a]Rounded data do not always add to 100.

Furthermore, data sharing motivations subthemes were generally expressed as agree or disagree. This binary expression demonstrates the importance of this issue.

Health professional perceptions on medical records sharing

The topics discussed under the theme of BHC are of special significance because they are directly linked to care. An interactive quote matrix was used to classify all codings within the seven subthemes of BHC (see Table 4). Any time a health professional specifically mentioned a patient sharing or not sharing information, the code *share* or *not share* was considered: "They usually don't want their other providers to know some things about their social life and sometimes about substance use or recreational use of street drugs" (prescriber, *not share*). When a health professional noted that a patient should share a type of information, the coding was classified as *should share*: "That should never be restricted? Okay, so labs, and substance abuse history, and medication logs, and even from other psychiatric providers, I need psych evals, I need progress notes . . . even from the primary care provider" (prescriber, *should share*). Whereas the *should share* category is determinate of what professionals want to see shared by patients (necessary information), the share and not share categories indicate how behavioral health professionals view their patients' decisions to use the information. In cases where a health professional noted that certain information should be shared while also noting that a patient does not or does share that information, the case was classified as all that applied.

Of all the codes discussed within *share/not share/should share* (514), the highest perceived rates of *not share* appeared within substance use (48%) and diagnosis (47%). These topics had patients' fear of disclosure as a major element in how health professionals discuss these topics. Health professionals noted labs as a category most shared (48% of coded instances), followed by SMI (30%) and medication/treatment (22%).

Interestingly, the two dominant themes under BHC, comprising over half (52%) of categorized instances, are medicine/treatment and diagnosis. We note that medicine/treatment, a most shared topic, was often discussed within substance use. This was raised as not shared—especially regarding prescription medication being used outside of a healing context:

> But we're pretty much obligated to use CSPMP, the controlled substance prescription monitoring program, so that all the controlled substances show up on that document. So, you know what other controlled substances [are] being prescribed anyway even if they don't want us [the health professionals] to communicate. (Prescriber)

Therefore, the context of certain topics as well as topic combinations affected how sharing was perceived and coded.

Behavioral health professionals discussed all seven subthemes, most as *should share*. Specifically, the majority of emergency (57%) and patient history (52%) themes were felt by participants to be data necessary for providing care. Health professionals emphasized that they need this information to provide effective care for the patient.

While health professionals focused on emergency, patient history, and medication/treatment as data types patients *should share*, labs were considered to be the data predominantly *shared* and *should be shared* by patients. Though health professionals noted that diagnosis, substance use history, and SMI-related patient health information are *not shared*, professionals did not emphasize it *should be shared* in the same way that they focused on emergency, patient history, and medication/treatment data.

Prescribers emphasize that the entire care team needs to be aware of certain information, such as medication history: ". . . what medicines they're taking, their diagnosis, their past medical history those types of things that should be shared with everybody who's taking care of the patient." Non-prescribers discuss the topic similarly: "So I think at least you know the medication should be shared between doctors, because, like I said, some can say I need clonopin, and they could be getting it from somewhere else and go to another [provider]."

The most common justification from health professionals when explaining types of data that *should be shared* was information needed for care. The justification of a patient fearing to disclose information often touched on themes of discrimination and stigma: "Some people, and this is very prevalent, they feel that the moment their medical provider finds out that they see a psychiatrist the treatment will change. And unfortunately, we have seen that happen" (prescriber). Such examples show the trust in the provider is a factor that influences fear of disclosing information and ultimately a patient's choice to share information. The importance of a complete medication history for safe care justified access.

Justification based on staff/patient/other safety was consistently cited:

> [A patient] had hypertrophic cardiomyopathy. He also had conned his psychiatrist into prescribing much over the recommended amount of Adderall, because he had an Adderall addiction. So, this is now a risk to him, and it's a risk to the psychiatrist who doesn't know about this condition. So, certain types of medical conditions need to be disclosed to us, and it cannot be hidden, especially if there's a substance abuse issue. (Prescriber)

This discussion leads to exploration of information types necessary for successful patient treatment. In the *should share* category, health professionals are considering motivators to share and not

Table 5. Frequency of codings within BHC as classified by NPs and Ps.

Themes	NP% from NP totals[a]			P% from P totals[b]		
	Share	Should share	Not share	Share	Should share	Not share
Emergency	21	51	28	10	67	24
Patient history	14	50	36	10	57	33
Medication/treatment	22	45	33	20	47	32
Labs	47	37	16	50	50	0
Diagnosis	13	38	50	21	39	39
Substance use	12	36	52	17	40	43
SMI	29	29	43	33	33	33

BHC: behavioral health care; NP: non-prescriber; P: prescriber; SMI: serious mental illness.
Themes are ordered based on frequency of should share. Themes in bold show where there is a difference in perceptions (share, should share, or not share) between Ps and NPs by more than or equal to 10%.
[a,b]Rounded data do not always add to 100.

share as well as what type of information they require to help a patient. Participants imply that their caring needs (*should share*) may not meet with how patients actually allow access to types of information (*not share*).

Health professional groups and perceptions

Using the interactive quote matrix, participants were assigned as prescriber or non-prescriber[35] (Table 5). There were clear differences in how these groups viewed patients' data sharing, considered notable if equal to or more than 10 percent difference in *share, should share*, and *not share*. The topics of diagnosis, emergency, labs, and SMI had the greatest difference in how prescribers and non-prescribers discussed sharing of data. While non-prescribers had somewhat similar rates of patients' sharing (21%) and not sharing (28%) data for emergency, prescribers emphasized that patients do not share (23%) for emergency more so than share (10%).

When discussing SMI, non-prescribers talked about the topic most as related to patients not sharing data (43%), while prescribers were equally divided among the categories on the topic (33% for *share, should share*, and *not share*). Similarly, while non-prescribers perceived patients mostly sharing (47%) data pertaining to labs, prescribers discussed labs as something that should be shared and are shared equally (50% each). Finally, non-prescribers talked about diagnosis as something not shared by patients (50%) with only about 13 percent discussing the topic as information that is shared. Prescribers, on the contrary, seem to view more instances of patients sharing this information (21%) as they only discuss patients not sharing diagnoses 39 percent of the instances.

Overall, the justifications to support participant perceptions remained the same between prescribers and non-prescribers (Table 5). While there were some differences in how the two groups discuss BHC themes, thematic analysis yielded a key distinction. Prescribers used examples from their own direct care experiences, for example, prescribing, assigning diagnoses, and dealing with emergencies, while non-prescribers tended to consider the team: "We need to let the emergency room [know that] this is what the client's on, this is their diagnosis . . . What if they give them the wrong medication? What if they're allergic to something?" (non-prescriber).

While there were differences in specific subtopics, needing certain information for care of the individual patient is a consistent concern for all behavioral health professionals, prescribers, and non-prescribers. These results are necessary for understanding what types of information behavioral health professionals view as necessary for successful treatment of patients and how certain information relates to role-specific needs.

Discussion

This study, a continuation of our prior work,[20] focuses on health professionals' perspectives on patient data sharing motivations and desire to share health data and contrasted them with professionals' own perspectives on negative consequences of providing care in the absence of relevant clinical data. By delving further into patient sharing motivations, new themes emerged and underlining dimensions of motivation discovered.

Particularly within the BHC subtheme, professionals noted information shared, not shared, and should be shared. Using such organization, this study reveals why providers think patients share information and what types of information is perceived integral for care. This structure of comparison also allows to identify information sharing gaps. While this process was utilized to address the study objectives, our methodology identified novel topics, requiring further consideration, such as behavioral health professionals' perceptions of their rights.

How health professionals discuss data sharing is significant. Reviewing the themes and subthemes, it is evident that health professionals discuss data sharing in terms of specifics and clinical use such as medications, diagnoses, and labs—and substance use information as it relates to drug–drug interactions. In contrast, studies on patient data privacy, data sharing policies/laws, and proposed sensitive data types mostly target broad, cross-cutting sensitive data groups such as mental health, substance use, sexual and reproductive health, HIV/AIDS and communicable diseases, genetic information, and others.[18,27,33–35,51] As a result, comparisons between health professional, patient, and policy/law data sharing views are difficult. However, there is a clear distinction between behavioral health professionals and patients' perceptions of what constitutes BHC data. These differences were visible in categorization and substance of the hierarchy of themes. Such differences in perception may be a cause of professionals' divergence with patients' views on what information should be shared.

While some patients consent to share all records, health professionals emphasized that patients were most motivated to do so if they were seeking something, such as a prescription refill. These findings from the health professionals' perspectives bolster results in Grando et al. where 70 percent of behavioral health patients in the study wanted to share all information but also wished to restrict who has access to the information.[22] Furthermore, health professionals' perspectives in Table 4 affirm the prior study's outcome regarding fear of disclosure of certain topics impedes sharing of patient data.[22]

Studies show that trust and communication between the health professional and patient affect data sharing positively[35,28] and may be used to reduce fear of disclosure. While Abdelhamid et al.[27] found that trust in providers was the least influential factor in how patients shared data, their study did not include behavioral health data. We found that behavioral health professionals reflected increased patient sharing with increased trust, and results from other studies in behavioral health support such a conclusion.[22,35] Throughout interviews, health professionals noted that educating their patients about the importance of sharing specific information is a first step in having patients understand the importance of data sharing: ". . . let's say their PCP is giving them something that depresses their respiratory system or would interact with anything I'm going to prescribe now this is dangerous. They might not understand the implications of that especially for prescribing" (prescriber). Trust and communication are integral to how patients choose to share information.

Behavioral health professionals want patients to share medical history, emergency, and medication/treatment, while patients are less likely to want to share that information. When considering the differences between what health professionals request to support best practices and what patients want to share, information from a trusted source may help bridge this gap.[51,52] Studies outside BHC have arrived at similar conclusions regarding the need for patient education, especially in the cases of emergency.[44] Patients were perceived as willing to share labs, SMI, and medication/treatment information; however, behavioral health professionals emphasized all seven subtheme topics should be shared. Professionals emphasized safety, and as illustrated in Table 4, health professionals believe that some data types, especially medications, should always be shared to optimize the safety and quality of care. Trust and improved communication can allay fear of disclosure and increase patients' understanding of why information is necessary for care. We identified areas to prioritize those demonstrating divergence in perceptions.

Trust and improved communication are especially significant for prescribers, who may need access to different types of health information. Prescribers focused on information that they specifically should know for prescription of medicine or treatment such as patient history, medication, labs, in the time of emergency. Meanwhile, non-prescribers focused on the team. With the rise of care integration, all health care professionals must be knowledgeable about consent and confidentiality policies, regulations, and laws relating to patient care.[53] The resulting trust and communication are key to the patient–professional relationship.[54]

The analysis of the patient sharing motivation theme led the new theme of "rights." While there are elements of this theme that affect patient sharing motivations, this is an area that requires future consideration.

Health professionals appear to lack clarity on data sharing responsibilities and resultant liability. Specifically, prescribers are concerned about adverse drug interactions that may result from incomplete sharing. However, health professionals are not liable for harm to a patient that is caused by the patient's choice to withhold relevant information so that the health professionals did not have access to data.[1] Although health professionals may not be legally liable, the duty and integrity espoused by health professional includes ensuring the safety of the patient[55] compels them to feel responsible for negative consequences.[56] While a health care professional provides "essential services that promote health, prevent diseases and deliver health care services to individuals, families and communities," they can only do so with what they, themselves, have access to in terms of patient data.[55] As one prescriber demonstrated,

> I'm against it [patient data control] . . . Because I don't think that if the liability is ultimately going to fall back on us . . . We have to have that level of control to be able to communicate to said doctor that this is what I'm looking at, this is why I wouldn't recommend this medication, and not to let the patient be the filter as to what information is going to be provided to them. Because that puts the providers at a disservice, at a disadvantage, where we need to be at the top of controlling the treatment that we're providing. And that includes communication with other providers. (Prescriber)

Behavioral health professionals and facilities may benefit from education on legal duty and related liabilities.[1] Health professionals have a variety of roles in patient care, so tailored education is needed. Ethical, policy, and legal standards differ and may even conflict among fields of social work, medicine, nursing, and other health care.[57,58] There is, however, an emphasis on developing cohesive, harmonized guidelines across all health care professionals.[59] While a prescriber may have access to a patient's medicine records via tools such as the CSPMP, other care team members do not have such access. The complexity of the integrated health care setting is resulting in the need to review and modernize rules, regulations, policies, and ethical guidelines for different behavioral health professional roles.[57] As one health professional notes the confusion,

> For our facility I think we need clarification, and I've asked for clarification on the consent forms that go to the specialists or the primary care physician. I don't understand why when we get the consent signed, they have told me we that we need a separate consent just to do a verbal consult and it makes no sense to me. (Prescriber)

To keep health professionals best informed of policy and procedural changes, a process of education within the facilities may be most helpful. Though assembling, monitoring, and maintaining such an robust educational program and process will be resource-intensive, facilities may find efficiency and cost reduction overall due to effective use and sharing of EHRs.[60,61] Health care managers have been highlighted as a population who requires more in-depth understanding of contract liability and insurance law—to name only a couple—but a move toward broader health team education may be necessary.[62]

Patient and health professional education on law and policies will benefit BHC, overall. For patients and health professionals to communicate effectively, policies and laws may need to be broken down into usable information for both parties during the consent process. For example, a policy on HIE access may be difficult to understand regarding who may have access to the information within an HIE system and how Health Insurance Portability and Accountability Act (HIPAA) and issues of substance use records[63] work to protect and benefit the patient.[14] Adherence to 42 CFR Part 2 with respect to HIE is still considered a source of confusion for health care professionals as integration between substance use treatment and primary care services is becoming more prominent.[41,64] McCarty et al.[64] showed that 42 CFR Part 2 was found to be in conflict with integration and coordination of care initiatives in Oregon: 76 interviewed stakeholders revealed concerns over confusion with the regulations and worry on the effect of information sharing and communication among patients and health professionals. Indeed, such concerns over balancing patient safety and patient privacy have been voiced by health care professionals when it comes to regulations and policies such as 42 CFR Part 2.[41]

BrintzenhofeSzoc and Gilbert[53] illustrated the possible confusion by providing potential conflicts between 42 CFR Part 2 and other laws and regulations such as the privacy rule, the Affordable Care Act (ACA), and certain state laws: "Although many professionals believe that the integration of services [ACA] would provide better patient care and outcomes, they avoid integration for fear of increased risk and liability [42 CFR Part 2]." By providing continued education on the policies and laws to both health professionals and patients, there may be a better understanding of who would need access to information during treatment and why the information is needed for care. Thus, education on this topic may also increase the level of trust and communication among patients and health professionals. Furthermore, by developing greater trust and communication in the patient–professional relationship, there would be an alleviation of differences in their perceptions of what information should be shared for positive patient care.[14,18,22,23,35,42]

This study employed a diverse sample of 20 behavioral health professionals. A larger sample size with an equal distribution of prescribers and non-prescribers is needed for comparison of the groups. The two facilities are in urban centers with a patient demographic that may not be representative of the local or the national population. Further research is needed to understand how applicable conclusions may be across the United States and across all health care, especially in understanding how education of patients and health professionals benefits the quality of care for behavioral health patients.

The outcomes of this study on health professionals' views on data sharing will be combined with perspectives on data privacy from patients from the same sites[47] to guide the development of supportive educational material. The education resources will be embedded in an electronic tool that supports granular data sharing and will be pilot tested in a prospective randomized control trial.[65]

Conclusion

Behavioral health professional views on patient-controlled granular data sharing are needed to inform procedural modernization and the development of consent-based tools and processes. This study provides insights on the sensitive health data types health professionals consider necessary for care safety and quality optimization while acknowledging some may be data that patients do not want to share. Furthermore, the analysis of patient sharing motivations surfaced a need for education among health professionals to understand law and policy surrounding care, treatment, and consent processes in behavioral health. Behavioral health professionals need continuing education to minimize misperceptions about patients' rights and professional liability. The outcomes from this study will be compared to previous studies on patients' data privacy perspectives conducted at the same behavioral health facilities[47] and used for the development of multimedia educational material and an electronic consent-based data sharing tool.

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Supplemental material

Supplemental material for this article is available online.

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Mental health professional perspectives on health data sharing: Mixed methods study

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Abstract

This study explores behavioral health professionals' perceptions of granular data. Semi-structured in-person interviews of 20 health professionals were conducted at two different sites. Qualitative and quantitative analysis was performed. While most health professionals agreed that patients should control who accesses their personal medical record (70%), there are certain types of health information that should never be

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restricted (65%). Emergent themes, including perceived reasons that patients might share or withhold certain types of health information (65%), care coordination (12%), patient comprehension (11%), stigma (5%), trust (3%), sociocultural understanding (3%), and dissatisfaction with consent processes (1%), are explored. The impact of care role (prescriber or non-prescriber) on data-sharing perception is explored as well. This study informs the discussion on developing technology that helps balance provider and patient data-sharing and access needs.

Keywords

consent, data privacy, health professional perceptions, interview, mental health

Introduction

There is a need to integrate mental and physical health care to improve care of the total person.[1,2] In integrated healthcare systems dedicated to delivering both behavioral and physical health care, sharing of electronic medical records (EHR) opens new questions about data privacy and data-sharing needs to effectively coordinate care.

The National Institute of Mental Health (NIMH)[3] estimates over 40 million Americans, roughly one in five individuals, experience mental illness every year.[4] Approximately 9.8 million of these individuals suffer a serious mental illness (SMI),[5] indicating an impairment severely interfering with daily life activities.[6] Nationally, one in five patients with a diagnosed mental illness has unmet needs, while in some states this care shortfall is four times as great.[4] Individuals with mental illness experience severely fragmented care. Individuals receive care in the inpatient and outpatient settings, but often without clear communication and coordination among treating health professionals.[7] Mental healthcare delivery is dynamic and becoming better integrated with the other aspects of health care, especially primary care.[7]

Mental illness has its inherent complexities requiring specially trained individuals and practices. However, mental health and physical health are interdependent, so their care should be as well. Over 34 million adults, or 17 percent of the US population, have a co-morbid mental illness and medical condition.[7] These co-occurring conditions each worsen the other, requiring specialized and complex care.[7] This societal recognition has led to mental and physical care integration initiatives to decrease healthcare costs while increasing quality of care.[8,9] If health professionals had more complete access to health information across the care continuum, we might expect better communication among and between health professionals, enhanced coordination of care, improved efficiency of health concern identification, more comprehensive patient education and increased patient satisfaction.[9,10]

With the shift to integrated delivery models and a rise in the sharing of information through health information exchanges (HIEs), physical care professionals have increasing access to mental health information, including data that a patient may consider highly sensitive and stigmatizing. Patients with mental health disorders face a higher level of stigma and discrimination related to their diagnosed condition in work environments, personal relationships, and healthcare settings.[7] This fear often results in a lack of data sharing.[11] The process for sharing health data in an integrated environment demands careful consideration. Beyond Health Insurance Portability and Accountability Act (HIPAA) protections, patients have certain rights to control access to specific types of sensitive information.[12] For instance, 42 Code of Federal Regulations Part 2 protects an individual's records related to substance abuse treatment provided by federally subsidized programs. The health information on substance abuse cannot be shared unless the patient provides specific consent. In addition, the Office of the National Coordinator for Health Information Technology (ONC) recommends patients have greater control of their personal health information by specifying what information may be disclosed and to whom.[1] Such mechanisms should be sufficiently detailed to address patient concerns about privacy and security.

A consideration of different professionals' roles may provide a deeper understanding of mental health data sharing.[13] Existing literature uses the term provider to refer to an entire healthcare institution[14] or to individual clinicians[15]—with little or no definition of the term or its inclusivity.[16,17] For our purpose, we use the terms mental health professional, or health professionals, to refer to all clinical healthcare roles within a behavioral health facility, including social work and counseling. The term provider refers to a specific set of health professionals determined by the Secretary of Labor as capable of providing healthcare services, coinciding with the ability to prescribe.[18] Providers, therefore, include psychiatrists, psychiatric nurse practitioners, and primary care providers for the purposes of this article.

Studies have considered patient perceptions on data-sharing control, sensitivity, and knowledge.[19,20] These studies find the majority of patients are interested in granular data sharing and control[19–21] and that patients (90% of 200 participants) are not well informed as to how their information is shared and/or used.[20] Caine et al.[22] found that 100 percent of the 30 patients participating were not fully aware of the contents of their own EHRs. Whereas studies have reported on provider and patient views on granular data sharing and data sensitivity, little is known about the perspectives of patients with mental health disorders and the respective health professionals on those topics.[5,7,14,23]

Health professionals play a critical role in the treatment outcomes, yet they are often not part of the data-sharing narrative. While studies exist on general health professional perspectives of HIE conveying their beliefs that this integration of information would decrease costs, increase quality of care, increase efficiency of care, and increase privacy issues for patients,[24,25] few consider mental health professionals. Shank[26] shows mental health professionals may be lagging in their use of HIEs due to two major, perceived barriers: (1) security and vulnerability of health information, especially in behavioral health, where confidentiality is of utmost importance and (2) increase of time spent and cost due to HIE use. Indeed, security/vulnerability of information, along with quality of care, appears to be a central issue for all mental health professionals.[26–28] Themes affecting professional perceptions of the HIE include stigma of mental illness, quality of the health record, and release of information.[27,29] However, these studies focused on the greater integration of health care rather than granular data sharing by patients within such systems.

One study by Tierney et al.[30] examines 31 professionals' responses to granular data sharing by patients. Professionals in the study include physicians, physician assistants, nurse practitioners and staff, specifically nurses, clinical nurse assistants, and medical assistants. While 54 percent of professionals agreed that patients should have control over their EHR, 58 percent considered that restriction of information could harm patient–provider relations, and 71 percent believed the quality of health care may suffer due lack of access to pertinent information.[30] When professionals were given the opportunity to "break the glass" to display potentially redacted information, they did so 102 times. Reasons for access included concerns about substance use, prevention of unnecessary testing, and confirmation of vital information needed prior to treatment planning.[30] While the study provides a window into how health professionals handle granular data–sharing physical healthcare data–sharing system, focused work is needed to understand behavioral health professionals' perspectives on the topic.

One study considered professional perspectives on health data–sharing control by surveying eight behavioral health professionals.[31] The study examines professionals' opinions about patients' control over their data. The majority (87.5%) felt patients should have more control over their preferences in sharing data, but 75 percent of these professionals also indicate that such control could negatively affect patient care. While the sample size was small, this study shows there is a conflict of perceptions when it comes to HIE and granular data sharing within behavioral health. Further work is needed to understand where these disagreements stem from in behavioral health.

This study looks to address the limitations of prior work, specifically by focusing on behavioral health professionals' perceptions on patient granular data sharing. Considering the existing literature and prior work,[19,20,22,31,32] the goals of the project include exploring health professionals' perceptions on granular data sharing for care and research, and perceived experiences of patients, specifically self-stigma, fear of discrimination, desire to protect sensitive health information, and opportunities and challenges in the development of electronic consent tools supporting patient-driven granular control.

Methods

Study sites

Face-to-face interviews were conducted in an office or a private meeting room at two study sites. Facility 1 is an outpatient clinic offering general mental health and social services to children, families, and adults of all ages. Facility 2 is an outpatient clinic that provides psychiatric treatment and recovery-focused services to adult patients with SMI. The facilities use a similar proprietary EHR system that supports electronic consent forms with e-signatures. The EHR system used in both facilities is widely used in the United States and includes customizable behavioral health modules.

Study participants

All participants met the following inclusion criteria: 21 years old or older, work at one of the study sites, be involved in the process of obtaining patient consent to release health information, and work closely with patients with a mental health disorder within the last year (either at the study site or during previous employment).

Each interview was attended by a single health professional. Participants signed a consent form before the interview and were compensated for their time at the end of the interview.

Interview script design

An interdisciplinary research team with expertise in biomedical informatics, law, ethics, and physical and mental health designed a semi-structured interview script (see Appendix). Semi-structured interviews were chosen to allow participants to elaborate on their answers and present new ideas throughout—all while ensuring main concepts are discussed for analysis.[33]

The interview script is based on prior studies[21,31,34] and aims to elucidate key concepts identified in these studies. Foci include the effects of stigma, fear of discrimination, and culture on patient consent; differences in patient populations (SMI and general mental health); the current state of consent processes; and health professionals' opinions on consent process tools. Interview prompts were tailored to specific processes within the behavioral health field and facilities. Specifically, prompts guided mental health professionals to explore their experience and opinions toward data sharing as it affects patient care, patient understanding of consent processes, patient–professional relationships, patient outcomes, and challenges related to the consent process.

The interview script captured participants' demographic information (Q1–2), the current consent practices at their facility (Q3–4, Q6), patient involvement in consent processes (Q5, Q7), patient motivations to share or restrict health information (Q8), patient willingness to share data for care (Q9–11) and research (Q12), and health professionals' perceptions of use of electronic consent tools supporting granular patient control over data sharing (Q13–15).

Data analysis

Study participants were categorized as prescribers or non-prescribers, based on the Prescriptive Authority of Health Professionals.[35] A prescriber is any professional with the legal authority to prescribe medication, while non-prescriber refers to those who do not meet the prescriber definition.

For the quantitative analysis, two co-authors categorized participants' responses. For a subset of three transcripts, inter-rater agreement was computed. A very good agreement was found between two coders (unweighted kappa: 0.82). Discrepancies were resolved by consensus to reach an agreement of 100 percent. Descriptive and inferential statistical methods were used to obtain frequencies, means, and related measures. Fisher's exact tests were used to identify correlations between mental health professional roles in a facility (prescribers versus non-prescribers) and emergent themes and interview responses. Fisher's exact test was chosen over Pearson chi-square analysis due to the small samples.[33] All the statistics were analyzed using Excel and SPSS.

Interviews were audio recorded and transcribed using Transcribe® software.[36] Transcriptions were reviewed by two members of the team for accuracy. For the thematic analysis, the team followed the six phases of Braun and Clarke's[37] thematic analysis guidelines and was further guided by anthropological methodology.[33] Two co-authors identified emergent themes and defined them through four iterations using MAXQDA©. Three transcripts were randomly chosen for exploratory analysis of themes expected from previous literature.[19,21,30,31,34]

Thematic analysis themes were identified through repetition and frequency in the transcripts.[33] Meaningful segments of conversation considered were the units for coding and analysis. Due to the complexity of the topics, the units were several sentences to a paragraph in length. One co-author coded for themes using a set of definitions that were iteratively improved by the team.

Complex coding query and quote matrices were developed to map how participants discussed prompts and themes. Quote matrices were created to determine participant reasoning and identify why certain themes were more salient or relevant in certain prompts[38,39]. Outcomes from the complex coding query and quote matrices were used to make comparisons within the participant sample.[39]

Results

Demographics

Ten professionals from each facility participated, 20 in total. All spoke English during the consent process; five were also qualified to speak in Spanish with patients. The mean work experience in mental health was 6.88 years (minimum 3 months, maximum 25 years).

Health professionals included the following roles: three psychiatrists, three psychiatric nurse practitioners, one primary care provider, three case managers, two counselors, two registered nurses, two therapists, one clinical nurse manager, one integrated treatment specialist, one operation coordinator, and one discharge specialist.

When participants were categorized into prescriber and non-prescriber groups, there were a total of seven prescribers (psychiatrists, psychiatric nurse practitioners, and primary care provider) and 13 non-prescribers (case managers, counselors, registered nurses, therapists, clinical nurse manager, integrated treatment specialist, operations coordinator, and discharge specialist).

Emergent, interrelated themes

Overarching themes appeared that overlap topics from previous literature and observations.[14,21,40,41] The seven principal themes in order of overall frequency are patient motivations for sharing data (65%), coordination of care (12%), patient comprehension (11%), stigma (5%), trust (3%), sociocultural understanding (3%), and health professional dissatisfaction with consent processes (1%). All the themes, except for health professional dissatisfaction and patient comprehension, were coded from the perspective of whether professionals believed patients were or should be sharing their health information in relation to the theme (see Table 1). This extra layer of coding was performed after exploratory analysis found participants appeared to routinely discuss these five themes in a binary fashion.

Complex coding query reveals patient motivation is discussed in context of the other themes, but in highest frequency with coordination of care (201 instances) and patient comprehension (145 instances). However, when more than two sets are introduced, the results show that coordination of care, trust, and patient comprehension are discussed together most frequently (50 instances with three themes).

The resulting seven themes are used by participants to discuss current consent practices, the use of an electronic consent tool, patient involvement in the consent practice, sensitivity of patients' health data, and data sharing for care.

Current consent practices and use of an electronic consent tool

Overall, health professionals find the consent process burdensome and time consuming. They recommend simplifying and standardizing consent processes including combining consent forms, reducing reading levels, and decreasing the length of consent forms.

On average, health professionals report completing 4.25 consent-related forms with each patient, ranging between 1 and 12 forms during a single encounter.[21] Professionals' opinions on the current consent process vary, with half (50%) reflecting satisfaction, 30 percent dissatisfaction. There is generally an agreement (67%), however, that changes to the content of the consent documents could improve the process. One non-prescriber noted "there is a lot of duplication. I think it would make the process go much faster if we had someone literally really read through these documents and really understand [that] this could be eliminated, that could be eliminated."

A third of participants (33%) recommend improvements to their facility's digital consent capture process and tool. One non-prescriber states that

> right now I am one of two people out of 10 people on my team whose computer actually can use the signature pad [. . .] So, we literally print out the electronic forms and print every single page and have to take it to people's houses.

Health professionals were also asked about the use of an electronic consent tool allowing patients to choose which sensitive health information to share. Most (80%) agree that using the tool could bring benefits such as saving all parties time, giving patients more control and background on sharing purpose, improving coordination of care, and conserving paper. All agreed that the main barriers to implementing such electronic tools include the lack of patient access to computers, language barriers, and an increase in provider burden.

Overall, the discussion of current consent practices by interviewees elicited dissatisfaction. Codings demonstrated that 57 percent of prescribers and 54 percent of non-prescribers experienced dissatisfaction with the current process. No significant coding differences are found between the

Table 1. Identified themes with definitions and exemplar quotes.

Themes	Definition	Examples
Patient motivations for sharing data	Topics that health professionals feel impact patients' decisions to share or not share information	Some of the things that they don't want to do is releases of information . . . For example, if they have a new med, and maybe the client has a mom who is considered a liability to the clients or not supportive of the client's treatment.
Coordination of care	How provider role impacts sharing perceptions	I explained it's a coordination of care, so everybody would be on the same page. So, we want to make sure we're not giving you medications conflicting with what the medical doctor is giving you . . .
Patient comprehension	Informal and formal knowledge of patient ability to digest information, familiarity with process, questions asked of professionals	I have to say, all the clients know about the HIPAA standard, at least mine . . . They are very aware of HIPAA, and if they are not, I explain that to them, and it's like 4 pages.
Stigma	Statements about fear or the abnormality/marginalization of an individual or group. Includes factors of stigma (fear of disclosure, discrimination, etc.)	I've personally seen outside providers stigmatize these people. They treat them differently. Across the street is one example. They're so bad to our patients.
Trust	Trust between patient and health professional(s) including comfort/discomfort with a health professional	I think over time, with trust, they will share more, but I don't think they are going to be sharing that much in the beginning.
Sociocultural understanding	Socio-economic status, discussion of different cultures, ethnicities, or group understandings	And there's a couple Asian cultures that were that way, that I had experienced, that don't open. Kind of proud, "We don't talk about certain things."
Professionals' dissatisfaction with forms/system	Aspects of dissatisfaction with the process, his or her involvement in process, and how it impacts patients	I find these forms cumbersome . . . I'm very familiar with reading extensive text and yet with some of the patients who are not very familiar with reading this much information at once . . . I'm making a guess that they will not understand everything.

HIPAA: Health Insurance Portability and Accountability Act.

two groups, although prescribers cite other themes along with their dissatisfaction, namely, 50 percent of instances and non-prescribers only 27 percent.

Patient involvement in consent processes

The majority (75%) of professionals agree that patients do not fully comprehend the consent forms—particularly at the time of initial document execution. A non-prescriber compares the consent process with the experience of signing papers for buying a house: "[At the end of the process,] you just start signing to get done instead of trying to understand."

Participants also note that patients are not consistently engaged in the lengthy consent process and rarely ask questions related to the consent forms. Half (50%) state that the questions asked by patients during the process are unrelated to the consent form content, for example, "how long will this process take?" or "when will I receive the medications?"

Our analysis demonstrated that the third most frequent theme in this category was linked to patient involvement. Health professionals expressed a lack of certainty regarding patient comprehension of the consent forms they sign. As well, patients may not use the educational information currently provided.

> I did an intake yesterday . . . [then]realized they had left their handbook and all these forms here. I went to see if he was here so I could go chase him down but he wasn't. I don't think they are too concerned, I doubt that many of them even take it home with them or read them carefully. Some, but not all. (non-prescriber)

Prescribers were responsible for 37 percent of the total coded instances related to patient comprehension, while the majority (63%) were from non-prescribers. Considering the higher number of non-prescribers represented, both groups discuss patient comprehension with similar frequency, and qualitative analysis shows participants also discussed this theme similarly in context.

Sensitivity of health data

Participants identified the types of data they felt patients would perceive as highly sensitive and shared their rationale.

Over half (55%) of the professionals agreed that certain types of information correspond with the theme of patient motivation, for example, substance abuse, SMI designation, certain diagnoses, and communicable diseases (such as HIV.) One prescriber points out that

> I think in many cases they don't necessarily give the same information to all of their providers and there have been cases where some of the patients use opioids, for example, and they don't want their doctor to talk to me . . . So they might not sign the consents for that type of information . . .

A common reason suggested by participants for this behavior is to conceal "doctor shopping" for narcotic prescriptions.

Quantitative analysis reveals 40 percent of participants feel that patients express a desire to protect information that is not specified by the current consent forms—specifically, social life patterns/habits and legal history. Some patients fear losing child custody if certain sensitive information is shared. These aspects of sensitive data are more thoroughly discussed within the theme of patient data–sharing motivations to share or withhold their data. Quantitative analysis demonstrates a similar frequency after standardization across prescriber and non-prescriber groups (2.6 codes per prescriber and non-prescriber), and quote matrices show that both groups discussed the context similarly. Non-prescribers (69%) and prescribers (86%) both discuss coordination of care and stigma when discussing patients' legal reasons to share or not share. Two non-prescribers separately note themes of trust and sociocultural understanding briefly when discussing the topic.

Views on patient motivations for sharing data

Many health professionals (70%) indicate that their patients are willing to always or sometimes share their health information with physical care providers outside their mental health facility. When asked whether patients would be fearful if health providers outside of their mental health facility knew about the patient's mental health conditions, 55 percent of participants responded yes,

Table 2. How non-prescriber and prescriber groups discuss major themes.

Theme	Total codings per theme	Subcoding theme	% all professionals (no. codes)	% non-prescribers (no. codes)	% prescribers (no. codes)
Patient motivation	895	Share	42 (379)	40 (224)	47 (155)
		Not share	58 (516)	60 (340)	53 (176)
Coordination of care	249	Share	71 (178)	69 (120)	77 (58)
		Not share	29 (71)	31 (54)	23 (17)
Patient comprehension	250	n/a	n/a	158	92
Stigma	111	Share	0 (0)	0 (0)	0 (0)
		Not share	100 (111)	100 (66)	100 (45)
Trust	81	Share	100 (81)	100 (64)	100 (18)
		Not share	0 (0)	0 (0)	0 (0)
Sociocultural understanding	46	Share	17 (8)	12 (4)	29 (4)
		Not share	83 (38)	88 (28)	71 (10)
Professionals' dissatisfaction with forms/system	23	n/a	n/a	(15)	(8)

25 percent responded no, and 20 percent had a mixed opinion, depending on specific details about the patient. As identified in the theme of patient motivations, participants consider everything from behavioral health care (e.g. medicine, labs, patient history) to the issue of rights (e.g. liability, privacy) to be motivators for sharing/not sharing.

Fisher's exact test was performed to compare prescribers and non-prescribers on questions Q7, Q11, Q13, and Q15a, relating to how patients share or should share their data (see Appendix). The results show no visible correlation or significance (Q7 $p=0.082$, Q11 $p=0.218$, Q13 $p=0.052$, and Q15a $p=0.095$). For greater depth, quote matrices for themes were examined between prescriber and non-prescriber. While some sharing themes were clearly discussed, (see Table 2), many had a more nuanced response. For example, the in-depth quantitative analysis of Q11 revealed a large change in significance. We observe that adding nuance to health professionals' answers for Q11 presented with a p value $=0.171$ and bolsters the need for analysis using quote matrices.

Patient motivation for sharing was the theme associated with the greatest ambiguity, most variation, and lowest agreement (56% share, 44% not share). One non-prescriber shared an example used during this discussion, "I explained it's a coordination of care, so everybody would be on the same page. So, we want to make sure we're not giving you medications conflicting with what medical doctor is giving you." Others focused on patients not sharing, for example, due to doctor shopping for prescription opioids (prescriber, see above section, sensitivity of health data). Finally, there was agreement in the characterization of stigma as a factor that decreases patient sharing, while trust is associated with increased patient sharing of information.

Data sharing for care

While 70 percent of participants support patient-centered granular data–sharing control, 65 percent of participants also note there are certain types of health information that should never be withheld. Health professionals express strong concern about the potential impact on patient safety and care coordination that may result from allowing patients more control over sharing medical records. Overall, participants appear to support patient-centered granular data–sharing control but are wary of patients choosing to conceal information that professionals find necessary to provide quality care.

Regarding the types of health data needed, health professionals underscored the importance of having their patients' treatment plans, medications, history of harm to themselves or others, and child abuse. However, some professionals (35%) disagree, suggesting that patients should have the right to share or withhold whatever information they choose. While accessibility to data for care is discussed similarly in context and frequency by both prescribers and non-prescribers, we observed a difference in what constitutes adequate data for care. Prescribers discuss this topic more frequently (43%) than other topics. Contextually, quote matrices demonstrate distinct differences in how prescribers and non-prescribers discuss the topic.

One prescriber highlights the related issues of patient safety and professional liability:

> . . . I've had patients come in and say, ". . . I choose not to tell you everything that's going on." And I say, "I'm also going to choose not to see you." Because it's not safe for someone to take care of somebody without knowing all of your medical history, all the medicines that you're taking, all the surgeries that they had.

In contrast, a non-prescriber emphasizes patient rights and privacy when discussing data sharing:

> Again the stigma and I think that some patients are more private than others and it would depend on the reason. I don't think they would just want information out there just because it would be on a need to know basis.

Quote matrices and complex coding query provide a common thread across discussions. Greater patient comprehension and trust will increase the likelihood of patients sharing information: "When the client understands, counts on the case management and knows them really well, they become a little bit more open" (non-prescriber). Some participants linked trust with patient comprehension as it impacts coordination of care and information sharing:

> I'm writing a therapy note about a trauma that they've never told anybody about. They don't want that shared. They had a hard time sharing it with me, and I've spent six months building rapport to get them to the point where they're able to start trauma processing. (prescriber)

Discussion

Our study provides unique insights into the data sensitivity and granular data–sharing perceptions of behavioral health professionals. While a number of studies have been published on these topics, they rarely represent perceptions of individuals with a mental health diagnosis.[40,42–45] Patient surveys and/or interviews have been conducted to identify the positive impact of patients education on sharing and the effects of stigma on an individual's healthcare experience.[43,44] While some of these studies include patients with mental health disorders, few include patients with SMI.[31,44,34]

We found that the majority of mental health professionals supported patient-centered granular data sharing control for care and research (70%). Regarding the impact on coordination of care, many feel patients should be allowed to restrict access to sensitive data in justified contexts, such as to avoid discrimination from professionals outside the mental health care system. However, participants were concerned about patients restricting access to critical information, such as treatment plans and medications. A lack of information could affect safety and quality of care, for which health professionals are responsible. Nearly two-thirds (65%) believe there are certain types of health information that should never be withheld and doing so could cause a decrease in the quality of care. Prescription data were the most commonly cited example, with drug–drug interactions as an issue of concern. Our findings are consistent with those of Tierney et al.[30] study that found 54 percent of physical care providers agree patients should have control over who sees their medical records, 58 percent believe restricting medical record access could harm provider–patient relationships, and 71 percent feel quality of care would suffer.

Our results show the majority (75%) of mental health professionals feel their patients do not thoroughly understand the release of record consent process and forms. These results complement the Caine et al.[22] conclusion that patients are not aware of the content of their EHRs so that when agreeing to share health data, they are not fully informed.

Our study highlights areas of agreement among participants (prescriber and non-prescriber groups), such as trust and stigma. Our results also show differences in the opinions of prescribers and non-prescribers in two important areas: coordination of care and patient motivations to share. The two groups present contextual differences of these themes in how data are and should be shared during the consent process. Prescribers focus on having information to successfully treat patients. Meanwhile, non-prescribers are more likely to defer to patients having the ultimate decision over what they can see or share with others. Our results complement and add further understanding of conclusions of Hiestand et al., where health professionals discuss the impact of HIE and granular health information sharing on patient preferences.[31] Our spotlight on the differences in discussion of coordination of care and patient motivations to share requires further analysis as to the root of the variances.

In our study, the use of complex coding theory revealed a deep interrelationship of the seven themes. Participants explicitly or implicitly acknowledged these complex concept relationships and were aware of the eventual themes that impact data-sharing decisions. While the complexity of the consent process and granular data–sharing issues have been reported,[11,46–50] our study provides additional depth about the influence of these concepts on information-sharing decisions. Behavioral health professionals are also aware patient perceptions of sensitivity of their data and process comprehension might significantly impact the design of a granular data–sharing tool.

We also found that the themes of trust and patient comprehension are perceived to increase the likelihood of patient data sharing, while stigma, sociocultural understandings, and dissatisfaction with consent processes reduce sharing prospects. The remaining themes of patient motivations and coordination of care provide mixed outcomes. Based on complex coding query and quote matrices, further work within patient motivation and coordination of care to explain these varied outcomes.

Even within the complexity of our theme relationships, trust played major role. More trust between the provider–patient relationship will lead to increased information sharing. While published studies find that judgment and stigma weaken the patient–provider relationship,[46,51] our study shows that providers actively use relationship-enhancing measures to increase patient comprehension and trust, thereby improving the likelihood of data sharing. Understanding and considering the sensitivity of mental health data, the complexity of current consent practices, and the need for better consent processes and tools are key recommendations. Our findings about the impact of sociocultural understandings, stigma, trust, and sensitive information on patients' decision to share or not share clinical data are consistent with those of previous studies[42,44–45,48,49,52,53] Consistent with observations at the same study sites,[21] professionals also express the need for better processes and tools for data sharing. Emphasis on patient comprehension and trust related to promoting necessary data sharing has emerged as a key in developing an effective electronic tool that aids in patient granular data sharing.

This study is limited to a small sample of mental health professionals and two health facilities in Arizona. Although the small sample size makes certain quantitative methods difficult, the qualitative analysis allows us to find patterns and significant themes. Within the small sample, we included experienced professionals from all phases of the consent process and took care to represent general mental health and SMI. Size, geography, and focus on behavioral health care in

Arizona may limit generalizability. Our study represents the two categories of mental health care, general mental health and SMI, allowing comparisons between professionals caring for these two populations. Future studies should employ larger sample sizes and include more study locations, in Arizona and in other states.

This mixed methods study opens a variety of future research directions. With the evolution of integrated care systems, data sharing becomes paramount.[54] Future work should focus on understanding the connections between and among emerging themes that most impact data sharing, why certain themes are appropriate to both sharing and not sharing health information, and why health professionals have differing views of perceived patient motivation. Further analysis is necessary to understand health professionals' perceptions of the relationship between quality of care and patients' granular data sharing as well.

Conclusion

Our study is one of the first to provide insights into patient-driven granular data sharing from the perspective of health professionals who care for individuals with mental health disorders, including those with SMI. We found health professionals agreed that while patients should have control over who sees their medical records (70%), there are certain types of health information that should never be withheld (65%), mainly to avoid patient safety issues. Interconnected themes emerged were perceived patient data-sharing motivations (65%), care coordination (12%), patient knowledge (11%), stigma (5%), trust (3%), sociocultural understanding (3%), and health professional dissatisfaction with consent processes (1%). Clear differences related to a health professional's role (prescriber vs non-prescriber) emerged. Finally, health professionals agreed that fear of stigma makes sharing less likely, while trust in the provider increases the likelihood of health data sharing.

Outcomes from this study will inform the design of software and systems for data sharing that permit greater granularity while balancing patient safety and privacy concerns, namely, stigma and discrimination. The goals are a digital consent tool to support patients with mental health conditions when releasing records to behavioral and physical care professionals.

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Appendix 1

Provider interview script

1. What is your role at this facility and how long have you worked here?
2. Please, tell us something about your professional career.
   a. Training and experience
   b. Current roles and responsibilities at this FACILITY
   c. Time at this FACILITY
   d. Types of patients you see at this FACILITY. Non-English speakers or other populations (e.g. refuges)
3. Are you involved in the consent process for releasing medical records at this FACILITY? (If not involved with consent for releasing medical records, which other consent types are you involved with?)
4. Currently patients/legal guardians in this FACILITY can choose types of health information to be shared with providers outside the FACILITY (Show FORMs packet in logical sequence. Present forms one at a time to see if provider is familiar with each one.)
   a. What kind of education (verbal, written, flyers, video, online, etc.) does this facility provide to patients and legal guardians before or during their appointment?
   b. Do you think these materials help patients and legal guardians decide what information to share with providers?
   c. Are there differences in how you educate patients compared to legal guardians?
5. When patients/legal guardians are provided the consent (show FORM) to decide what information to share with providers, how do they respond?
   a. Do patients tend to share/withhold certain types of information more than others?
   b. Have patients expressed any desire to protect types of information that are not covered in the form?
   c. What kinds of questions/concerns do patients have when being presented with this consent form?
   d. Do you think patients or legal guardians fully understand all the consent forms they are signing?
6. What do you think about the current consent processes at this FACILITY? Are there improvements you might suggest?
7. From your experience, do you think patients want to have more control over their health data and how it is shared?
8. What do you think are the main motivations or reasons that your patients choose to share or not share their health information?

    a. Care will be improved if information is shared
    b. It is an emergency
    c. The patient trusts the provider
    d. The provider suggests sharing of information
    e. The guardian/advocate suggest sharing of information
    f. Stigma/discrimination, being treated differently
    g. Provider might share information with others
    h. Information might be unsafe

9. Do you think patients want to share their mental health information with providers outside this FACILITY? Why?
10. Do you think patients would be afraid if providers outside of this FACILITY knew about their mental health conditions?
    a. Is there a difference for SMI versus mental health?
    b. Are there cultural differences?
11. What do you think about allowing patients to control the sharing of their health information based on the type of provider? Example: Not sharing information about drug abuse with their Primary Care Provider.
12. Right now, this FACILITY consent process does not include sharing medical information for research purposes. What are your perceptions about patients sharing medical information for research? (for example: patients giving permission for Arizona State University to use their data in a research study)
    a. Risks and benefits of sharing medical information for research
    b. Do you think it makes a difference if patients knew what the research/study was about?
13. Arizona State University is developing an electronic consent tool which could provide patients and their legal guardians more control over what specific information is shared. This tool would help patients to choose which specific types of providers or researchers they want to share specific data with. Example: I don't want my PCP to access any information on my mental health diagnosis, or I want to share my information only with non-profit researchers. What are your thoughts about a tool like this?
14. If such a tool was developed, what do you think could be the main barriers and benefits to using it in this FACILITY? Read only if they ask for clarification (example: time, patient education, workflows, etc.)
15. Imagine that a patient/legal guardian uses such tool to choose to restrict your access to a certain type of information.
    a. Should you be notified when accessing the medical record that some information from the patient/legal guardian was not shared and is missing? Why or why not?
    b. Do you think there are certain situations when you should be permitted to override the choices of a patient/legal guardian and gain access to all their medical data? (If interviewee is confused, give examples of emergency or potential drug interaction.)
    c. Do you think there are types of health information that should never be restricted from you as a provider? If yes, which ones? Why?

APPENDIX B

PUBLISHED CONFERENCE PAPERS

Perceptions and preferences about granular data sharing and privacy of behavioral health patients

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Perceptions and preferences about granular data sharing and privacy of behavioral health patients

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Abstract

Little is known about data sharing preferences for care and research of behavioral health patients. Eighty-six behavioral health patients (n =37 Latinos; n = 32 with serious mental illness) completed questionnaires, in either English or Spanish, with items assessing their views on privacy and sensitivity of health record information. Most patients (82.5%) considered mental health information as sensitive. In general, there was a direct correspondence between perceived sensitivity of information and willingness to share with all or some providers. A main motivation for sharing data with providers was improving the patient's own care (77.8%). Most participants (96.5%) indicated they would be extremely to somewhat willing to share their data for research with their care facilities and universities. Follow-up patient interviews are being conducted to further elucidate these findings.

Keywords:

Privacy, Electronic Health Records, Surveys

Introduction

Behavioral health problems include substance use disorders, serious psychological distress, suicide, and mental disorders.[1] In the U.S., behavioral health conditions affect over 44 million (18.3%) adults, including 10.4 million (4.2%) adults who have a serious mental illness (SMI) such as major depression.[2] On average, SMI patients have 3.5 times higher emergency room visits, 4 times higher primary care visits, and 5 times higher specialist visits than the general population.[3] It is estimated that 17.8% of the U.S. population is Latino or Hispanic.[4] Of those, 15.6% (over 8.9 million) had a diagnosable mental illness in the past year. The rate of illicit drug use for Hispanic individuals ages 12 and up was 8.9%, while the national average was 10.2%.[5]

The growth of health information exchanges (HIEs) and healthcare technologies have stimulated interest in integrated care and data sharing. Behavioral health patients often visit multiple health care providers when receiving behavioral and physical health treatments, and care coordination among those providers could be advantageous.[3] While data sharing among care providers may improve care, it may also impact patient privacy.[6,7] Privacy concerns may lead patients to avoid discussing their problems with providers, delay care and withhold information from providers.[8–10] Additionally, patients with behavioral health conditions frequently experience social stigma, employment and insurance discrimination, legal concerns, and worry regarding disclosing information to others.[11,12]

The Office for the National Coordinator for Health Information Technology (ONC) recommends giving patients more granular level control over how and with whom their health record information is shared.[13] Granular control could include giving patients more authority over with which providers, under which circumstances, and for which purposes their data are shared. For example, ability to make decisions over whether or not to share alcohol abuse-related information with a physical health provider. Studies indicate that patients desire more control over their health data for care and research.[11,14,15] A recent study of 394 patients indicated that they were reluctant to share clinical data with for-profit research organizations, and that 32% of them expressed a desire for choices regarding the data sharing category (for example, mental health, substance abuse history, etc.) and data recipient when sharing medical records for care.[14] Understanding the level of granularity that individuals desire is still an open question.

Little is known about data sharing preferences for care and research of behavioral health patients. Grando et al. surveyed 50 English speaking behavioral health patients with no SMI concerning their data sharing preferences.[11] The study showed that behavioral patients may wish granularity over who can access their personal health data for care and research. Understanding patients' data sharing preferences and perceptions may improve education and consent processes that influence their decisions to release or withhold health information.

The purpose of this study was to survey English and Spanish speaking behavioral health patients, including those with SMIs, on their perceptions regarding data sensitivity, willingness to share health data for care and research and related motivations.

Methods

Study Sites

Study site 1 is a community clinic in Arizona providing general mental health (GMH) treatment and social services to adults of all ages. Site 2, also in Arizona, offers case management services to adult patients with SMI.

Survey

We found validated English surveys, such as [16], developed to assess patients' data sharing choices. But there was a lack of bilingual (English and Spanish) data sharing questionnaires validated with behavioral health patients.

Our survey was based on [11]. Demographic information was categorized based on U.S. Census Bureau classifications, except diagnoses, which were adapted per National Institute of Mental Health categorization.[17,18] The sensitive categories used in our instrument to ask questions related to sensitive data were based on those used by the National Committee on Vital and Health Statistics.[19] The resulting survey was translated to Spanish and back-translated to English by native Spanish speakers.

Survey Reliability Testing

Reliabilities of questionnaire items were examined using a test-retest approach with 31 Spanish and English-speaking adult behavioral health patients from study sites 1 and 2. Participants completed the questionnaire, in either English or Spanish, on two occasions, 14-21 days apart. Questionnaire items were revised based on the outcomes of the reliability analyses. The revised questionnaire was used in the current study.

Study Participants

Participants for the study described here were recruited from the same study sites where the reliability study was conducted. Potential participants were identified by study site staff members during routine clinical visits and referred to the recruiters. After the recruiter met with the prospective participant at the facility and explained the study to him/her (in either English or Spanish), the recruiter assessed the participant's decision-making capability (using the UBACC test)[20]. We excluded participants with low consent comprehension (i.e., with UBACC scores < 15). Adult patients (21 years old or older) diagnosed with GMH or SMI who agreed to complete the questionnaire in English or Spanish and were deemed capable of giving informed consent were considered eligible to participate.

Study Design

After initial screening and consenting of eligible participant, the recruiter offered the participant the option of completing the questionnaire either in English or Spanish, and either electronically or on paper. The recruiter was present to help the participant with any questions or technical difficulties. Participants were compensated for their time.

Data Analysis

We used univariate statistics (e.g., frequencies, means, standard deviations, percentages) and plots to summarize the data. Parametric inferential statistical methods were used to analyze perceptions of data sensitivity and willingness to share data among English and Spanish-speaking, Latino and non-Latino participants from GMH and SMI populations.

Results

Demographics

Of the 88 participants recruited, 2 were excluded because of inability to understand and follow the study protocol, as measured by the UBACC test. Table 1 shows the demographics of participants included in the sample. The majority (n = 54; 62.8%) of patients had a GMH condition, while the rest were patients with SMI diagnoses. Most participants (n = 71; 82.5%) opted to have the questionnaire administered in English; the remainder opted for Spanish.

Table 1: Demographic of participants

Participant characteristics (n=86)	*Freq. (%)*
Age (Years)	
21-30	19 (22.1)
31-40	24 (27.9)
41-50	16 (18.6)
51-60	15 (17.4)
61-70	9 (10.5)
>70	2 (2.3)
Unknown	1 (1.2)
Gender	
Male	26 (30.2)
Female	59 (68.6)
Other	1 (1.2)
Race/Ethnicity	
White Alone, Not Hispanic or Latino	34 (39.5)
Black or African American	11 (12.8)
Hispanic or Latino	37 (43.0)
Native American or Alaskan Native	3 (3.5)
Other, Unknown	1 (1.2)
Income	
≤$10000	50 (58.2)
$10001-$20000	23 (26.7)
$20001-$30000	10 (11.6)
>$30001	3 (3.5)
Education	
No Schooling	1 (1.2)
Middle school (grades 6-8)	9 (10.5)
Some high school (no diploma)	14 (16.3)
High school graduate	19 (22.1)
Some college (1-4 years, no degree)	24 (27.9)
Associate degree	14 (16.2)
Bachelor`s degree	5 (5.8)
*Diagnoses**	
Anxiety or panic disorder	65
Bipolar Disorder	34
Depression	65
Impulse Control Problems	10
Identity or memory problems	22
Eating disorder	5
Obsessive compulsive disorder	9
Personality disorder	13
Schizophrenia or other psychosis	14
Drug or alcohol addiction	18
Post-traumatic stress disorder or adjustment disorder	36
Chronic pain or somatic disorder	24
Other	1

** As participants may have more than one diagnosis, the percentages are not reported.*

Data Sharing for Care

We asked questions to understand participants' desire for granular data sharing control based on type of information, information recipient and purpose of data usage. We asked participants how likely they were to share their behavioral health data with different behavioral and non-behavioral providers (Figure 1). Participants were most willing to always or sometimes share their health information with the behavioral providers at the study sites, followed by emergency providers, other non-behavioral providers at the study sites (e.g., primary and specialty care providers, pharmacists), behavioral providers outside the sites, and lastly with other non-behavioral providers outside the study sites. No significant differences in responses were seen in comparisons of English vs. Spanish speakers (χ^2=1.27, p=0.866), Latino vs. non-Latino participants (χ^2=0.78, p=0.941), or GMH vs. SMI patients (χ^2=0.12, p=0.998).

In assessing participants' perceptions about how sensitive different types of health information are, we provided them with eight health information categories: mental health, psychotherapy notes, sexual and reproductive health, domestic violence and abuse information, information on sexually transmitted diseases, drug or substance abuse, alcohol abuse, and genetic data. Most participants considered mental health information the most sensitive, followed by psychotherapy notes (Figure 2). For several categories, the most common single response was *'It does not apply to me'*. Unfortunately, we did not collect with the survey information that could be used to check if the participant did not have certain types of sensitive medical records.

Participants were then asked about the likelihood of sharing sensitive health information with providers outside the study sites (Figure 3). We computed the mean percentage of patients who wanted choices regarding sharing their data with different types of providers. On average, when self-reporting having sensitive information in their medical records (the option *'It does not apply for me'* was not selected), many participants (64.15%) wanted to restrict those records from some or all health care providers.

In general, we observed a direct correspondence between perceived sensitivity of information and willingness to share. The main exception was genetic data. While participants considered genetic data the eighth most sensitive type of information, they ranked it as the third most sharable. However, with the exception of sexually transmitted diseases ($p<.05$, Fisher's exact test), none of the associations between willingness to share a particular category of information and perceived sensitivity of the information).

We asked participants about providers' access to health information when prescribing a new medication. Most participants (78.0%) responded that the providers should have access to all their health data, 12.0% thought that providers should see only the data to which a patient provides the access, and 10.0% indicated that the providers should see all the health data only when the new medication may have any harmful interactions or effects.

Similarly, we asked patients about emergency providers' access to data in a life-threatening situation. Most of the participants (70.0%), reported that providers should have access to all their data, 19.0% endorsed giving emergency providers access only to data shared by the patients, and 11.0% indicated that providers should have access to all health data only when the emergency may be life threatening.

Participants endorsed sharing their data when it can benefit their own care and treatment (77.8%) or if/when their providers asked them to share their data (61.1%). Large majorities of participants trusted the providers at the study sites overall (87.8%) and trusted them to share only the health data that they consented to share (93.3%).

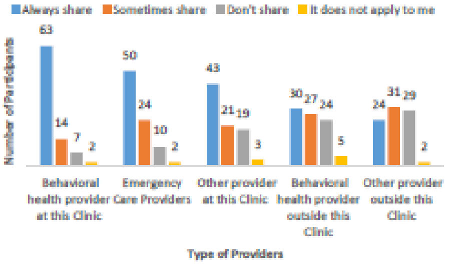

Figure 1: Behavioral health data sharing preferences, based on the type of medical provider

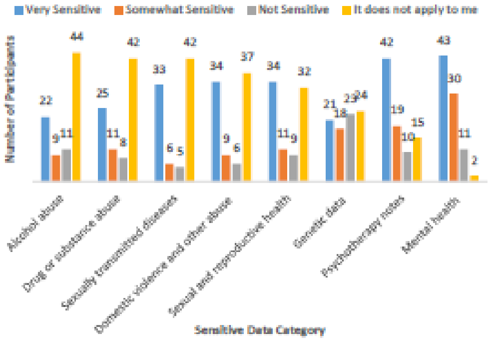

Figure 2: Health categories classification as sensitive information

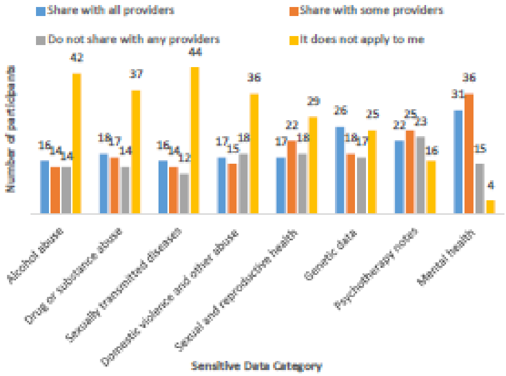

Figure 3: Willingness to share sensitive health data with providers outside study sites.

Figure 4: Willingness to share data for research with different types of organisations.

Large majorities also reported that they would be upset if their providers shared their health data without asking them (83.3%) and that they might react by leaving such providers (65.6%). Only 30% of the participants reported worrying about providers knowing that they receive mental health treatment.

Data sharing for Research

Participants were generally willing to share health information with researchers when their own care (91.1%) or care for others (78.9%) could be improved. About half (51.1%) of participants, indicated they would always share their data for research, while 35.6% indicated that they would share their data for research if they were paid for it. Finally, we asked participants how likely they would be to share their health information with researchers (Figure 4). Participants indicated they would be extremely to somewhat willing to share their data for research purposes with their care facilities (96.5%). Participants appeared less willing to share their health information with drug development companies and government agencies. For each participant, we looked at whether their willingness level varied between different types of organizations. For example; varying willingness to share data with care facility compared to drug companies. Most (78.9%) participants desired control over how they want to share data with different research organizations.

There were no significant differences in data sharing preferences between English vs. Spanish speakers (χ^2=0.29, p=0.990), Latino vs. non-Latino participants (χ^2=0.59, p=0.964), or GMH vs. SMI patients (χ^2=0.25, p=0.993).

Discussion

Consistent with previous studies on behavioral health patients, participants wanted control over how to share sensitive health data with health providers.[11] In general, there was a direct correspondence between perceived sensitivity of information and willingness to share with all or some providers. When we contrast our results to studies from patients without behavioral conditions, it has been reported that patients with and without sensitive information prefer to restrict the sharing of sensitive versus less sensitive EHR information.[14,15] As reported in the literature, most of the participants appeared to be motivated to share health data unconditionally to avoid medical emergencies or drug-drug interactions.[15,21,22] As in previous studies, our participants trusted their providers at the study sites and trust in providers was an important motivation for sharing health information.[11,16,23,24] Additionally, improvement in a patient's own care and treatment was an important motivating factor for sharing health data with providers.

As in previous studies [11,14], patients wanted control over how to share health data with researchers. Consistent with literature, willingness to share data decreases when the recipient is a for-profit research organization and important motivations to share health information for research were benefiting own care or improving care for others.[11,25]

The *'It does not apply to me'* response was frequently used when asked to assess the sensitivity of health data and willingness to share sensitive data with providers (34.4% for all types of data, and 29.7% for mental health, psychotherapy notes, drug or substance abuse and alcohol abuse). Participants' lack of understanding of the meaning of certain sensitive data categories, inability to form opinions regarding sensitive categories, or stigma related to disclosing this information could be potential explanations for this response. For some categories, like sexually transmitted disease or substance abuse, it is highly probable that the question did not apply to the participants. For other categories, such as genetic data, the recruiters received frequent requests from participants for clarifications. These results highlight the need for better on-demand education material to address patients' varying data sharing preferences and levels of health literacy.

A limitation of our study is that study participants were sampled from only two outpatient clinics in similar geographic areas with similar social demographics. Additional studies should be conducted on a larger sample of the population to capture more diverse views.

The outcomes of this survey and previous formative studies will guide follow-up card sorting interviews.[11,25] Thirty-six survey participants have given access to their health medical records available through the HIE. In the upcoming interviews, data privacy questions will be asked while study participants have access to a subset of their medical records.

Outcomes from that study will influence the design of an e-consent tool based on the Consent2Share software developed by the Substance Abuse and Mental Health Services Administration (SAMHSA).[26] The My Data Choices tool will support patient-driven data access based on data sharing interoperability standards. Patient data will be shared in compliance with federal and state confidentiality laws, including protection of confidentiality of substance use disorder (42 CFR Part 2).[27] On-demand multimedia patient education material will be embedded in the tool to illustrate risks and benefits of cross-organizational data sharing. We aim to pilot test the tool with 270 behavioral health patients in a prospective study.

Conclusions

A better understanding of behavioral health patients' attitudes towards data sharing is needed. The outcomes of this survey indicate consistency between the perspectives on data sharing and privacy of behavioral health patients and other previously surveyed populations of patients with or without sensitive medical records.

In future work, we plan to apply lessons learned from the completed survey to conduct follow-up interviews with a subset of the surveyed patients. The knowledge gained from the interviews will be used for the development of an e-consent tool that will support patient-driven data sharing control and on-demand educational resources to better inform data sharing choices.

Acknowledgements

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Current State of Electronic Consent Processes in Behavioral Health: Outcomes from an Observational Study

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Abstract

An integral element of value-based care is care team access to both physical and behavioral health data. Data release processes in both environments are governed by federal and state statutes. The requirements for obtaining consent are complex and often confusing. Little is known about the consent processes and practices in the behavioral health setting, specifically how patients and surrogates engage in the process and their interactions with electronic consent tools. This study analyzes the consent processes from the patient perspective at two community behavioral health clinics. Outcomes include description of the processes using electronic consent, workflows and consenter-provider interactions. Conclusions include need to streamline and standardize consent technologies and improve consenter engagement. This study supports the development of an electronic consent tool, My Data Choices (MDC), funded by the National Institute of Mental Health, that offers individuals with behavioral health conditions more control over their medical records.

Introduction

Behavioral health conditions affect nearly 46 million American adults, a quarter of whom have a serious mental illness[1]. Substance Abuse and Mental Health Services Administration (SAMHSA) defines behavioral health as the mental/emotional well-being and/or actions that affect wellness. Behavioral health problems include substance use disorders; alcohol and drug addiction; and serious psychological distress, suicide, and mental disorders[2].

Caring for the total person is important. Patients with behavioral health conditions are more likely to have a chronic medical condition, with nearly 70% of adults with a behavioral health condition having at least one medical condition. Individuals suffering from a serious mental illness (SMI) have higher emergency room, primary care and specialist visit rates[1]. Patients receiving both behavioral health and physical health treatment often see multiple providers and thereby benefit from integrated care amongst a variety of providers and organizations[1]. Sharing health data between providers requires obtaining informed consent from the patient or legal guardian of the patient, when the patient is physically, mentally or legally not capable of providing consent[3]. Informed consent is the most widely recognized ethical safeguard in research and clinical care used to protect patient rights[3,4]. Patients use informed consent to decide what health information to share and with whom.

Patients with behavioral health conditions often suffer social stigma, fear of losing employment, insurance discrimination or legal concerns[5]. Such fears might influence their care and related data-sharing decisions[6]. Studies have shown that patients want more control over their data and the Office for the National Coordinator for Health Information Technology recommends that patients be given more choices at a granular level[7,8]. Granular control could afford patients more control over how personal health information is shared, with whom, and why. The consent decisions pertaining to sharing health data for care can affect treatment and care coordination, compelling the need for meaningful consent. Meaningful consent involves key components such as patient engagement, education and ensuring alignment with laws and regulations[9].

Understanding the quality of provider-consenter interaction and patient and legal guardian comprehension and involvement is vital. Studies rating the quality of informed consent and related tools exist to guide the design of

consent processes for clinical research[10]. Our review of the state of the art indicates lack of studies about the quality and effectiveness of informed consents for treatment, and studies focusing on patients with behavioral health conditions and legal guardians.

The conventional means to obtain the informed consents has been paper based hard copy forms. Nevertheless, these forms could be long, verbose and monotonous and retrieving information could be time consuming and cumbersome[11,12]. With advancements and increased adoption of electronic health records (EHR), over the last decade, studies documenting the introduction and development of electronic consent technologies to support the transition from paper-based to electronic consents have been published. Many universities and organizations have contributed to developing multiplatform open-source consent systems for research and treatment. Apple's ReseachKit provides an open source framework to create visual consent templates[13]. Similarly, in its early stages, 'Consent2Share' is an open source web-based consent tool developed by SAMHSA which supports a patient facing interface with granular and dynamic consent choices[1]. Electronic consents could be more convenient, less time consuming, more informed and interoperable with EHR systems[14,15]. Studies and pilots have noted improved comprehension, better patient awareness, reduced provider workload, improved patient and provider satisfaction and more effective consent management with the transition to electronic consent systems[15-20].

The main objective of this paper is to observe, capture and report on the current state of consent tools and processes for treatment and care at two community behavioral health clinics in Phoenix, Arizona to better understand behavioral health consent workflows and challenges and to identify improvement opportunities related to electronic consent technologies. The outcomes presented in this paper will contribute to the broader goal of deploying a patient-centered electronic consent tool, *My Data Choices* (MDC), that supports more granular data access for patients with behavioral health conditions and surrogates based on interoperability standards.

Methods

Study Participants

Following Institutional Review Board (IRB) approval, subjects were recruited from two outpatient behavioral health clinics in Phoenix, Arizona. Patients and legal guardians of patients diagnosed with general mental health illness or SMI and providers involved in the consent process, were enrolled. Patients and legal guardians were required to be 21 years old or older and English speakers. Participants were identified by facility staff during routine clinical visits and referred to recruiters. Participating providers at each facility were 21 or older, certified behavioral health professionals with experience as case managers and/or behavioral therapists. Patients, legal guardians and providers to be observed were consented by recruiters before the observation sessions. Participating patients and legal guardians were compensated for their participation with gift cards.

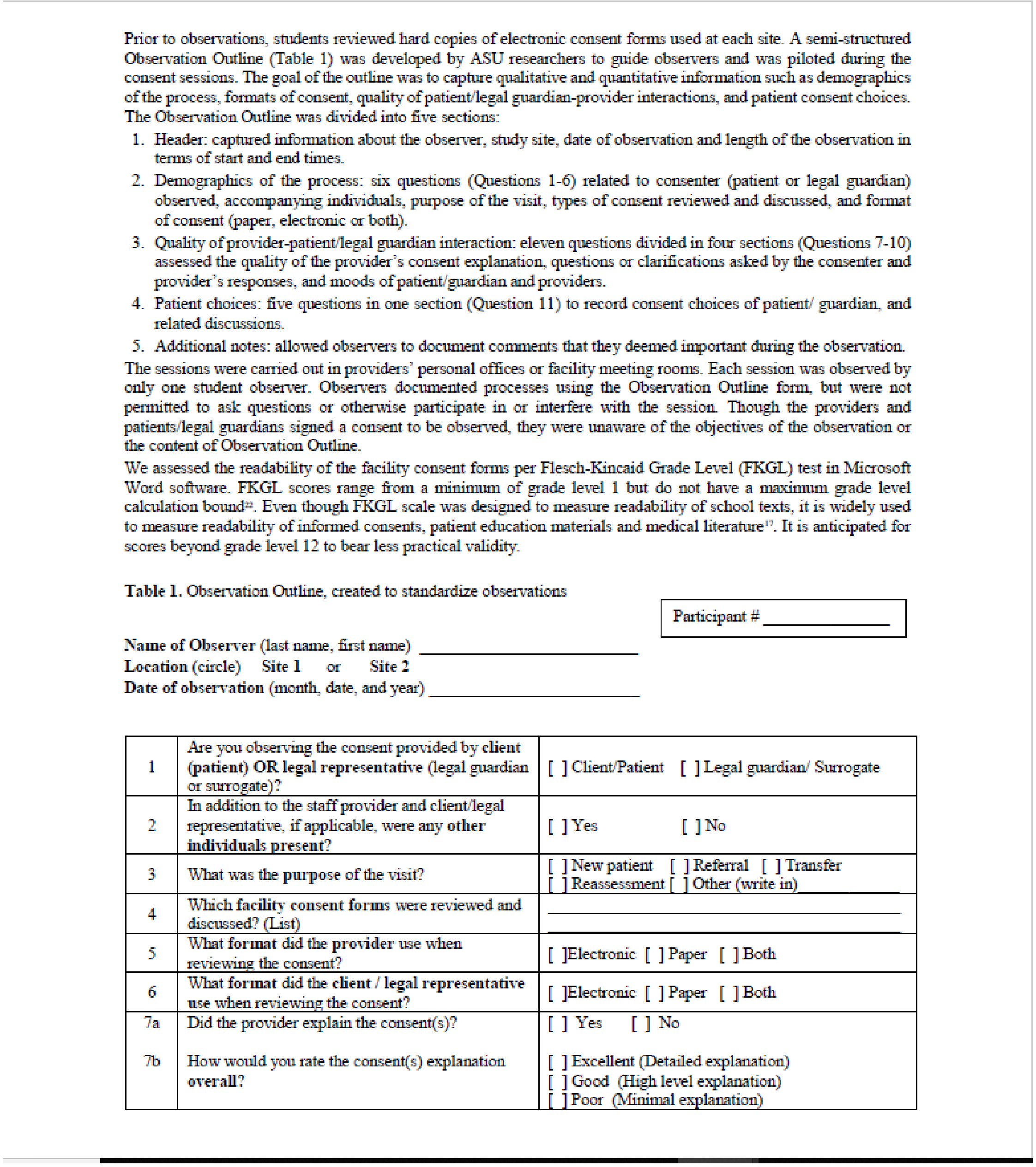
Study Sites

Our study sites include one clinic (Site 1) which offers general behavioral health and social services to children, families and adults of all ages. Licensed clinicians are responsible for treating and consenting the patients at Site 1. Study site 2 offers a range of recovery-focused services to adult patients with SMI. Providers consenting the patients at Site 2 are case managers. Both the study sites use a similar proprietary EHR system with embedded consent management and e-signature systems. The EHR system used in both facilities is widely used in the US, including customizable behavioral health modules. Use of the same EHR system in these two different care environments aided in the capture of comparable and contrastable workflow processes at both sites.

The Network: Arizona's statewide physical and behavioral health information exchange, also known as 'The Network', follows an opt-out consent model where patient data is automatically shared unless explicitly declined to share. About 6.7 million Arizona patients receiving care from 246 participating providers are enrolled in the state. Physical and behavioral health information is shared automatically, except the alcohol and drug abuse records protected under 42 CFR Part 2 regulations, accessible only if the explicit opt-in consent is obtained which requires a patient consent to share personal health information[21].

Consent Observations

For this non-participatory qualitative study, seven graduate students and one undergraduate student, all from the Department of Biomedical Informatics at Arizona State University (ASU) completed IRB and facility requirements, including Human Subject Protection and HIPAA training, completion of required documents from the study sites and compliance with Level 1 fingerprint security clearance.



Prior to observations, students reviewed hard copies of electronic consent forms used at each site. A semi-structured Observation Outline (Table 1) was developed by ASU researchers to guide observers and was piloted during the consent sessions. The goal of the outline was to capture qualitative and quantitative information such as demographics of the process, formats of consent, quality of patient/legal guardian-provider interactions, and patient consent choices. The Observation Outline was divided into five sections:

1. Header: captured information about the observer, study site, date of observation and length of the observation in terms of start and end times.
2. Demographics of the process: six questions (Questions 1-6) related to consenter (patient or legal guardian) observed, accompanying individuals, purpose of the visit, types of consent reviewed and discussed, and format of consent (paper, electronic or both).
3. Quality of provider-patient/legal guardian interaction: eleven questions divided in four sections (Questions 7-10) assessed the quality of the provider's consent explanation, questions or clarifications asked by the consenter and provider's responses, and moods of patient/guardian and providers.
4. Patient choices: five questions in one section (Question 11) to record consent choices of patient/ guardian, and related discussions.
5. Additional notes: allowed observers to document comments that they deemed important during the observation.

The sessions were carried out in providers' personal offices or facility meeting rooms. Each session was observed by only one student observer. Observers documented processes using the Observation Outline form, but were not permitted to ask questions or otherwise participate in or interfere with the session. Though the providers and patients/legal guardians signed a consent to be observed, they were unaware of the objectives of the observation or the content of Observation Outline.

We assessed the readability of the facility consent forms per Flesch-Kincaid Grade Level (FKGL) test in Microsoft Word software. FKGL scores range from a minimum of grade level 1 but do not have a maximum grade level calculation bound[22]. Even though FKGL scale was designed to measure readability of school texts, it is widely used to measure readability of informed consents, patient education materials and medical literature[17]. It is anticipated for scores beyond grade level 12 to bear less practical validity.

Table 1. Observation Outline, created to standardize observations

Participant # _______________

Name of Observer (last name, first name) ________________________

Location (circle) **Site 1** or **Site 2**

Date of observation (month, date, and year) ________________________

1	Are you observing the consent provided by **client (patient) OR legal representative** (legal guardian or surrogate)?	[ ] Client/Patient [ ] Legal guardian/ Surrogate
2	In addition to the staff provider and client/legal representative, if applicable, were any **other individuals present?**	[ ] Yes [ ] No
3	What was the **purpose** of the visit?	[ ] New patient [ ] Referral [ ] Transfer [ ] Reassessment [ ] Other (write in) ________
4	Which **facility consent forms** were reviewed and discussed? (List)	______________________________ ______________________________
5	What **format** did the **provider** use when reviewing the consent?	[ ]Electronic [ ] Paper [ ] Both
6	What **format** did the **client / legal representative** use when reviewing the consent?	[ ]Electronic [ ] Paper [ ] Both
7a	Did the provider explain the consent(s)?	[ ] Yes [ ] No
7b	How would you rate the consent(s) explanation **overall?**	[ ] Excellent (Detailed explanation) [ ] Good (High level explanation) [ ] Poor (Minimal explanation)

8a	Did the provider ask the client/legal representative if he/she had **questions or needed clarification**?	[ ] Yes [ ] No
8b	Did the **client/legal representative ask questions** about consent? *If answered YES to above question:*	[ ] Yes [ ] No
8c	Did the client ask questions related to what **specific health information would be shared or with whom?**	[ ] Yes [ ] No
8d	Did the client/legal representative have questions related to **how consent would affect his/her care?**	[ ] Yes [ ] No
8e 8e	How would you **rate provider's answers** to these questions?	[ ] Excellent (Detailed answer) [ ] Good (High level answer) [ ] Poor (Minimal answer)
8f	**Was the client receptive** to the consent explanation provided by the provider in response to the questions?	[ ] Receptive [ ] Non-receptive
9a	What was the **mood of the client** during the consent process? (Choose all that apply)	[ ] Angry/Frustrated [ ] Sad [ ] Uninterested/bored [ ] Overwhelmed [ ] Other: ____________________
9b	*If a legal representative was present*, what was the **mood of the legal representative** during the consent process? (Choose all that apply)	[ ] Not applicable [ ] Angry/Frustrated [ ] Sad [ ] Uninterested/bored [ ] Overwhelmed [ ] Other:
10	What was the **mood of the provider** during consent process? (Choose all that apply)	[ ] Angry/Frustrated [ ] Sad [ ] Uninterested/bored [ ] Overwhelmed [ ] Other: ____________________
11a	**Was consent given?** (Did the client/legal representative give permission for information to be shared?)	[ ] Yes, agreed to share ALL information [ ] Yes, agreed to share SOME information and to restrict access other information [ ] No, refused to consent share ALL information
11b	If the client/legal representative **initially refused to share specific information**, did the provider then provide a **discussion or explanation?**	[ ] Yes [ ] No
11c	If YES, how would you **rate the discussion** by provider?	[ ] Excellent (Thorough discussion) [ ] Good (High level discussion) [ ] Poor (Minimal discussion)
11d	Was the consent provided after the above discussion?	[ ] Yes [ ] No
Additional Notes		

Workflow Analysis

After completing the observations, ASU students created mental models of the consent workflows at Sites 1 and 2. Discrepancies were resolved through consensus. The purpose of this process was to identify similarities and differences of consent processes between the facilities. A generalized workflow was created using a free, web-based workflow modeling tool, LucidChart[23].

Results

Consent Observations

Of the 20 observed consenters, 19 (95%) were patients and one (5%) was a legal guardian. Participants at Site 1 included 10 patients with general mental health conditions and 7 providers. At Site 2, participants included 9 patients with SMI, 1 legal guardian of a patient with SMI, and 7 providers. In one case, other individuals (such as family, care takers, etc.) who were not legal guardians accompanied patients during the session.

The average length of sessions at Site 1 was 10 minutes (range 5 - 20). An average of 3 forms (range 1-5), were discussed during the process. At Site 1, the readability of the forms ranged between grade level 10.6 to 12.1. At Site 2, the average length of session was 23.1 (range 3- 36) minutes. An average of 6.1 (range 1-11) forms, were discussed. Readability of the consent forms at Site 2 ranged between grade level 7.0 and 15.0.

At both sites, observers identified a variety of consent forms covered during respective processes. Site 1 used electronic consents exclusively, while Site 2 providers used both paper and electronic consents based on patient preference. In all sessions, providers referenced their computer (desktops or laptops) screens to explain electronic consents. In 20% of sessions, providers referred also to paper-based materials to explain consents. Observers rated the explanations provided by the providers at both sites while categorizing the explanations into three categories: 'Excellent' (40%), 'Good' (40%) and 'Poor' (20%).

The number and type of consent forms discussed per session were based on the purpose of the appointment. Of the 10 appointments at Site 1, 9 (90%) appointments were for new patients, followed by 1 (10%) appointment for yearly reassessment. On average, new patients completed 2.6 (range 1-5) forms and the reassessment patient completed 3 forms. At Site 2, 5 (50%) appointments were for new patients and 5 (50%) for transfer patients. The new patients at Site 2 completed an average of 6.4 (range 2-10) forms, whereas the transfer patients completed 5.8 (range 1-11) forms.

Each site had unique consent forms. Table 2 provides a summary of the types of consent forms observed at both sites. Most of the forms, except forms 3a-3e, supported broad consent models. Forms 3a-3e provided consenters with granular consent opportunities to share or restrict specific health information (such as medications, assessments, diagnosis, substance abuse and HIV related information, treatment and discharge records and psychotherapy notes) and to direct the information to and from specific entities such as patients' primary care provider (PCP) or other specialty providers, family members, living facilities (such as group homes) and any federal or state government agencies (e.g. Department of Child Safety or data protected under 42 CFR Part 2 regulations), as necessary.

Table 2. Types of consent forms observed at both sites

#	Type of Consent		Purpose
1	Consent to Treatment		To request permission to provide the patient care
2	Advance Directive		To request patient to appoint someone else for making health care or mental health decisions in the event the patient becomes incapable of making decisions related to treatment
3a	Release of Information	a. Facility to PCP	To request permission to share patient's information, including treatment and medical records, with a PCP
3b		b. PCP to Facility	To request permission to receive patient's information, including treatment and medical records, from other PCPs
3c		c. To Family	To request permission to share patient information with family members
3d		d. To Care Facility	To request permission to share patient information with their care facility
3e		e. To Government Agencies	To request permission to share patient information with required government agencies
4	Communication via Email/ Voicemail		To request permission for provider to leave a voicemail or send email pertaining to treatment

In most sessions (75%), providers asked consenters if they had any questions. Overall, among all the sessions, only two (10%) of the consenters had any questions. One of the two consenters asked questions pertaining to what type of personal health information to share and with whom. No consenters had any questions about how consents would affect their care. Further, observers noted the quality of provider responses to questions by the consenters. One response was rated ‘Excellent’ and one was rated ‘Good’. Only one of the two consenters who asked questions was found receptive to the provided explanations.

Observers rated the mood of the consenters and providers during the process. The response options for this section were: a) Angry/Frustrated, b) Sad, c) Uninterested/bored, d) Overwhelmed, e) Other. The researchers subjectively categorized the responses in category ‘Other’ as: ‘Interested’, ‘Happy’, ‘Depressed’, ‘Confused’, ‘Annoyed’, ‘Optimistic’, ‘Nervous’ and ‘Neutral’. The most common response for the mood of the consenters between both facilities was ‘Interested’ (40%), followed by ‘Neutral’ (20%) and ‘Happy’ (20%). Some of the less common responses were: ‘Uninterested’ (5%), ‘Depressed’ (5%), ‘Confused’ (5%) and ‘Annoyed’ (5%). When it comes to the providers’ overall mood, the common response was ‘Interested’ (45%) followed by ‘Happy’ (30%) and ‘Neutral’ (20%). One (5%) provider each was rated as ‘Annoyed’, ‘Optimistic’ or ‘Nervous’.

Lastly, observers noted the consent choices of the consenters. Most participants (90%) chose to consent and share all personal health information with one or more entities (for e.g. PCP, family, care facility, etc.). Two (10%) participants chose to provide consent to share some information (such as restrict medications from PCP and treatment records from family) and restrict certain information. No explanations or information were provided by the providers to the consenter regarding decision to restrict the health information and any consequences.

Issues with the consent processes were reported as free text. We identified seventeen free text notes related to five themes: a) education methods, b) consenter-provider interaction, c) consent interruptions, d) use of electronic consent technology, and e) use of paper-based consents. In 6 (35.3%) sessions, no visual guide was provided for consenters during explanation referencing screen. In 4 (23.5%) sessions, observers recorded lack of interaction such as eye contact between consenters and providers. There were also interruptions due to location-based noise and distractions by persons accompanying the patients (17.6%). In 3 (17.6%) sessions, problems with the function of the electronic consent technology were noted. Lastly, in 1 (5.9%) session, a provider left the meeting space to print consent documents requested by the patient.

Discovered Workflow:

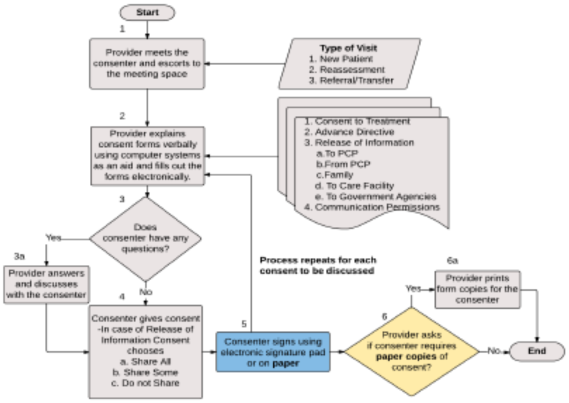


Fig. 1 Generalized Consent Process Workflow, from observations at behavioral health Sites 1 and 2. In color Yellow, workflow step sometimes observed at Site 1, in color Blue workflow step (printing the filled consent forms when patient/legal guardian prefers signing paper-based consents) only observed at Site 2.

The students observed ten consent processes at each site and created a generalized workflow to describe the steps involved in the observed consent process (Figure 1). Any observed differences in consent workflows between Sites were noted in the workflow. Below we provide a step-by-step description of the observed consent workflows:

Step 1: The consent process starts with provider meeting the patient/guardian and accompanying members, if any, in 'Patient Waiting Areas' and escorting them to the meeting space.

Step 2: In the meeting space, the provider chooses one consent form from a potential set of forms and verbally explains it with the aid of their computer systems, based on the type of appointment and requirements.

Step 3: The consenter is asked if s/he has questions about the specific consent form.

Step 3.a: If the consenter has questions, the providers clarifies consenter's doubts or concerns.

Step 4: The consenter makes consent choices. In case of release of information forms (Forms 3a-3e from Table 2), the consenter can choose whether to provide consent to share all, some or none of their information and with whom.

Step 5: The provider either requests the consenter to provide an electronic signature or requests to sign the paper copies of the consent form (only observed at Site 2).

The described process (steps 2-5) is repeated for each consent form, based on the set of consent forms to be discussed.

Step 6 and 6a: Consenter is offered and provided a printed copy of the signed consent form/s, as per their preference (sometimes at Site 1).

Site 1 consenting sessions were performed before the therapeutic treatment sessions, instead of after the session, to better accommodate student observations. This modification could have introduced changes in the workflow and consent session length.

Discussion

Literature describing the use of electronic consent technologies is increasing. Much of the research has focused on consent for clinical research and patient recruitment. These have identified increased flexibility and interest, greater comprehension and patient engagement, reduced provider workload and higher satisfaction among patients and providers as potential benefits of electronic consent[15,17-19,24]. As well, the transition from paper consent forms to tablet or web-based consent tools is noted to be feasible, effective and preferred by users[18,24]. However, we identified no studies that analyzed the consent process in the routine ambulatory environment using electronic consent tools.

Informed consent for patients with behavioral health conditions is complicated by comprehension and decision-making issues[3]. Disorders and treatments that impair cognitive and intellectual functioning interfere with the comprehension and retention needed to make informed decisions. Similarly, certain conditions may produce declines in intellectual processes, compromised judgement and insight impairment. These factors can contribute to increased cognitive load and result in confusion for some individuals, especially those with behavioral health conditions.

The lack of preexisting studies on consent processes and the effect of electronic consent tools on behavioral health patient and surrogate engagement convinced us of the importance of this research. It is particularly important for behavioral health patients that the consent process is understandable and low burden, but our study findings contradict this expectation. Below we provide a **summary of our observations** during the consent using electronic tools at two outpatient behavioral health clinics, Site 1 and Site 2:

The consent forms offer granular choice: Both study sites currently offer patients a certain level of granular choices to share/restrict health information (Table 1, forms 3a-3e), specifically medications, assessments, diagnosis, substance abuse and HIV related information, treatment and discharge records and psychotherapy notes. This is consistent with the recommendation from the Office for the National Coordinator for Health Information Technology and with patients' desires for more control over data sharing and in compliance with regulations[7,8].

The consent process is burdensome and time consuming: The consent process duration ranged from 3 to 36 minutes between both sites. Consenters completed multiple forms electronically (desktop or laptop) or paper-based forms during the process, with average of 5 forms and 2.25 pages of written information. In the worst case, one consenter was asked to complete 11 forms; this process consumed 34 minutes during which 15 pages were discussed. The length of the consent process and number of forms covered, in part reflect the distinct patient populations (general mental health vs. SMI) they serve. However, within each site we observed variation in the process based primarily on the type of visit, i.e. new or established and the nature of the presenting problem. Such variation reflects the necessity of personalizing the consent process for each patient within the structure of a standardized protocol and process.

The reading level of consent documents is high: An average American reads at an eighth-grade level[25]. This was affirmed by Doak and Doak who studied the average reading level of patients in a public hospital and found that despite reporting high school education, most patients read at a seventh-grade level[26]. A 2007 review of 154 informed consent forms from mental health studies in Massachusetts that found the consents were written at an average of 12-14.5 grade level[22]. This is consistent with our study where the mean reading level ranged from grade 7.0 to 15.0. To accommodate patients with low reading levels or low health literacy, Paasche-Orlow and Taylor suggest the target reading levels of grade 4 to 6[27].

The terminology and layout of consent forms are variable: Study Sites 1 and 2 use consent forms which serve similar purpose but are titled differently. For example, the Release of Information form is known as 'Consent for Disclosure of Confidential Information' at Site 1 and 'Consent to Release Protected Health Information (PHI)' at Site 2. There also appears to be an effort towards consolidation of some related forms, as exhibited in Site 2 (Table 2, forms 3a-3e and 4). An additional issue results from different titles for a similar process. Site 1 refers to the consent process as 'Intake' while Site 2, calls this segment the 'Welcome Packet'. Such variations may cause confusion for the patient, especially as they visit other medical facilities and execute similar documents.

The physical space was not organized optimally: Effective patient-provider communication and shared decision making can improve the efficacy of the informed consent process[28]. However, we observed that the seating arrangement and the location of the consent technologies (i.e. desktop computers and signature pads) could be improved. Observers noted lack of eye contact and the absence of visual aids. Combined, these issues in setup can interfere with the consent interaction, affect consenter comprehension and may lead to a lack of shared decision-making between patient and provider.

Though the sample size was small and the observations limited to two clinics, we have identified the following areas **for improvement, that could guide the development of the MDC electronic consent tool**:

Standardize the consent processes, forms and terminology, where possible: With the involvement of the behavioral health facilities, attempts could be made to understand if some of the observed processes, forms and terminology could be standardized to reduce variability, though we acknowledge that the differences in patients' demographics (general behavioral health vs. SMI), provider's roles and relationships with patients, and types of services could impose constraints in the standardization process.

Combine consent forms: When possible, multiple consent forms should be combined (as it was observed at Site 2, when 'Release of Information' and 'Consent for Email/Voicemail Communication' forms were consolidated), to streamline the consent process.

Reduce reading levels and length of consent forms: Embedded consent forms written in an average sixth-grade level and dividing the content of the consents into smaller thematic sections, in consent tools, might help to increase patient focus, understanding and reduce the cognitive load on patients compared to being exposed to all material at once.

Address challenges in provider-consenter interaction related to physical space and technology arrangements: As consents are embedded in the EHRs used by providers, providers take an active role and consenters are the passive entities during the consent process. Electronic consent tools supporting multiplatform interface could allow providers and consenters to interact with the tool on any stationary (such as desktops) or mobile (such as tablets or smartphones) device. Potential use of handheld mobile devices can provide mobility to the providers in the meeting space, which could lead to better quality of provider-consenter interaction and allow consenters to take direct control of the process.

Incorporate multimedia educational material: Multimedia education has shown promises among physical and behavioral health patients with increased understanding, comprehension and interest towards treatment and care[29-32]. Embedding on-demand educational material relevant to consents, health data sharing and any related consequences, into the electronic consent forms would help enhance direct patient engagement and involvement in the process.

Personalize consenter experience: Consent tools could be personalized based on the type of patient (general behavioral health diagnosis vs. SMI), patient appointment type (such as new, referral/transfer, reassessment), preferred language (English or Spanish) and past user experience (such as providing instructions when using the tool for first time). Personalized experiences and flexibility to virtually access the tool any time (inside or outside care facilities), could encourage patient engagement and help reduce the complexity and time taken to complete the consent process in one session, as it was observed to happen now.

In terms of **methodological improvements**, the free text notes from observers helped to identify a need to amend the Observation Outline (Table 1) to reflect some consistent observations, including the lack of visual guides for patients, lack of eye contact between patient and provider and interruptions during the process. Revisions to the Observation Outline include questions related to quality of the interaction, such as eye contact, conversation, etc., number and nature of interruptions such as environmental noise, disturbances by accompanying member or other staff, etc., technology arrangement and physical space, such as sitting arrangements, direction of computer screens, etc. Furthermore, observers noted challenges related to the use and absence of electronic technologies, such as issues with signature pads or absence of printers in provider meeting space. Observers often subjectively noted consenter or provider moods as 'Interested' or 'Happy'. Certain positive moods can be accommodated in the revised outline. Such revisions could enhance future data acquisition using the proposed Observation Outline instrument.

An important **limitation** of our study is the number of observations. We observed ten consent processes for each site and included only one legal guardian. Also, each site has multiple providers responsible for the consent execution, but we observed limited number of providers. Another limitation is the lack of diversity within the observed population. Only English-speaking consenters and providers were included in the study. Differences in culture, lack of familiarity with the U.S. health care system or the use of translators could greatly affect the dynamics of the consent process. Similar studies should be conducted on a larger and more diverse sample of patients with behavioral health conditions, surrogates, and providers. Companion studies in the physical health environment will also be useful as technology permits greater data granularity.

Conclusions and Future Work

Informed consent establishes ethical safeguards for care and research and protects patient rights. Such protections are particularly important for individuals being treated for behavioral health conditions. Based on our observations of consent processes at two community behavioral health clinics, we identified several challenges and highlighted areas for improvement. These include standardizing the consent protocol and process; applying quality improvement techniques to minimize variation; redesigning consent artifacts to a reading level of grade six; re-imagining the physical space to include technology hardware; and upgrading the electronic consent software. More research is needed to better understand how electronic consent technologies and educational support will impact the informed consent practices and preferences of patients with behavioral health conditions, their surrogates and providers.

The outcomes from this observational study will be supplemented with semi-structured provider interviews and a survey of patients with behavioral health conditions and legal guardians to guide the development of the electronic consent tool, *My Data Choices*.

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APPENDIX C

PUBLISHED POSTERS

Design and Pilot Testing of an English and Spanish Behavioral Health Patient Survey on Data Privacy

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Design and Pilot Testing of an English and Spanish Behavioral Health Patient Survey on Data Privacy

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Abstract

We piloted a Spanish and English survey on data privacy. Thirty-one Latino behavioral health patients completed the survey in person with a preference for paper (78%) over electronic questionnaire. Dialect variations across Latino countries and the lack of tools to assess reading level in Spanish affected comprehension. Our experience will help others address similar tasks more effectively and encourage inclusion of Latino populations in future research.

Keywords:

Health Surveys, Privacy, Behavior, Latinos

Introduction

In the US, behavioral health conditions affect 44 million adults, a quarter of whom suffer from a serious mental illness (SMI).[1] About 17.8% of the US population is Latino or Hispanic, and of those, 15.6% had a diagnosable mental illness in the past year compared to an overall past year prevalence of 18.3%.[2] The rate of illicit drug use for Hispanic individuals ages 12 and up was 8.9%, while the national average was 10.2%.[3]

Latino patients often do not seek mental health treatment due to stigma. [4] We are moving towards more integrated care models where electronic data exchange is being facilitated by the electronic health records and health information exchanges. This means non-behavioral care providers might gain access to sensitive health information. Understanding the perceptions of Latino patients with behavioral health conditions relating to privacy and data sharing is vital to better inform and guide successful transitions to integrated care models.

The purpose of this study was to design, pilot test and refine Spanish and English surveys to elicit behavioral health patients' perspectives on data privacy.

Methods

Sample

Inclusion criteria were: 1) speak either English or Spanish; 2) no legal guardian; 3) receive care at the partnering outpatient facilities; 4) have a diagnosis of a behavioral health condition; and 5) be 21 years or older. This study was approved by the Arizona State University Institutional Review Board (IRB).

Procedures

Initial questionnaire design and organization

A 17-item English-language survey was designed to collect patient demographics (Q1-5) and behavioral health diagnoses (Q6), experience and willingness to share medical information for care (Q7-10, Q12-15), sensitivity perceptions of the information in those records (Q11) and willingness and motivation to share data for research (Q16-17).

Translation of questionnaire from English to Spanish

Two researchers, both native Spanish speakers with graduate degrees and academic knowledge of the subject, translated the survey. Back-translations were performed by a third native Spanish speaker to ensure that literacy levels commensurate with the patient's educational background and reading ability. An accuracy certificate was presented to the IRB.

Questionnaire administration

After consenting, participants completed the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) test.[5] Patients scoring lower than 15 were excluded. Eligible participants completed the survey in English or Spanish, using a paper survey or electronic tablet. The participants completed the survey twice (test-retest), 14-21 days apart. The time taken to complete the survey was recorded.

Survey revision

Questionnaire items were revised in response to reliability testing and recruiter feedback. Review of the Spanish versions of the revised items was performed by two native Spanish speakers born in Mexico. During the revision, we had access to behavioral health-specific vocabulary used by a Spanish-speaking behavioral health academy in Arizona.

Data analyses

Test-retest reliability was assessed using Cohen's Kappa and intra-class correlations (ICCs). Frequencies and percentages of item responses were tabulated.

Results

Sample characteristics

Threre were 31 (16 Spanish and 15 English) participants; 11 SMI; most were women (74%), aged 21-50 years (65%), completed high school (74%) with an annual income of ≤$20,000 (74%). Most participants presented with depression (75%) and/or anxiety or panic disorder (71%). The average UBACC score was 17.3. The paper format was preferred (78%) over electronic.

Reliability testing and revision of questionnaire

Questions yielding low ICCs < .50 and/or kappas < 0.40 were revised. Highlights below.

Q9 *"Which providers do you see outside this Clinic?"* yielded a poor kappa (-0.07 to 0.51). Response "*Yes, primary care providers. Such as a family doctor, nurse practitioner (NP), physician assistant (PA) or PCP*" was revised to: "*Primary care providers. Such as a family doctor.*"

In Q10 with kappa (-0.03 to 0.52), we replaced *"Has anyone at the facility explained to you the benefits and risks of sharing your data outside of the facility?"* with the less complex question: *"Have you been asked if you want to share your data with providers outside this Clinic?"*

Q12, ICC satisfactory, (0.53–0.86), "*Extremely willing to share*" was replaced with "*Always share.*" A new response ("*It does not apply to me*") was added for when participants did not receive care from certain types of providers. In Q13 (ICC: 0.41–0.75) and Q14 (ICC: 0.56–0.79; kappa: 0.19–0.54), difficulties in answering questions related to sharing drugs or alcohol use data, sexual transmitted diseases, etc., were noted. Recruiters reported that participants had difficulties when they did not feel a diagnosis or problem applied to them. To avoid hypothetical questions, a new option *"It does not apply to me"* was included.

Q15 and Q16 yielded poor kappa (0.13 and 0.12, respectively) and were simplified to more direct questions, e.g. Q15, *"Suppose that you don't share data with your provider. You have an emergency. Your provider wants to see all your data. Do you want your provider to see the missing data?"* to *"You have an emergency. What do you want your emergency provider to see when he looks at your data?".*

Q17 (ICC: 0.24–0.93) and Q18 (ICC: 0.37–0.95) were simplified. In Q19 when participants were asked with whom they would share data for research, the option *"State, county, or federal agencies. Such as the Arizona Department of Health Services"* was not well understood. We changed it to *"government agencies."*

Discussion

Valuable lessons learned in designing and pilot testing a bilingual data privacy survey included the following:

Tools to assess the reading level for Spanish documents are not easily accessible: Though limited methods are available to measure readability in Spanish, there is insufficient evidence of reliability or correlation to English reading levels.

Differences between Mexican and South American Spanish affected survey comprehension: Translations did not target the ancestry of the Latino population of Arizona. In response, the survey was reiwritten in Mexican Spanish and reviewed by three Mexican Spanish speakers.

Information to better characterize Latino subjects was not captured by the survey: The survey did not ask for country of origin or descent, years in the US, birth and immigration status, etc. which could healp acount for differences in culture between immigrants and the children of minorities born in the US.

Technology adoption barriers encountered when offered the electronic survey: Most of the participants preferred paper surveys and were more familiar with the term "tablet" compared to "iPad".

On-demand educational material could enhance explanation of data types: Participants often asked for clarifications on topics such as genetic data. On-demand education material could have improved comprehension.

Conclusions

The design and revision of the Spanish and English survey was complex and resource-intensive, involving a multidisciplinary team as well as native Spanish and English speakers. The result was a Spanish survey at a 6th grade reading level, high understandability, culutrally-correct behavioral health-specific vocabulary, accurate translations, and adaptation to a more Mexican-friendly Spanish. We have shared the lessons learned to help others address similar tasks more effectively and facilitate the inclusion of Latino behavioral health patients in future research.

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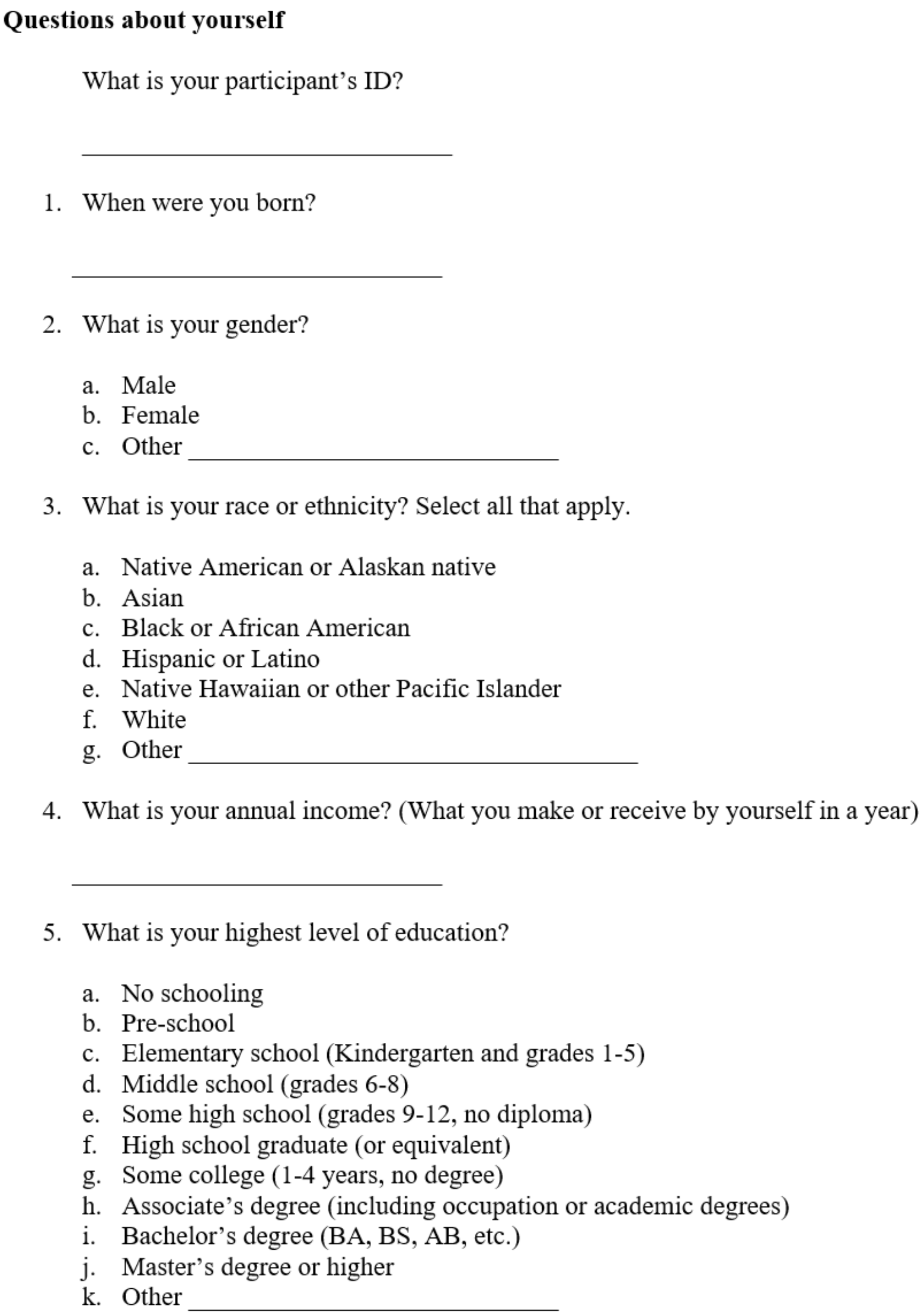
APPENDIX D

DATA SHARING SURVEYS (AIM 2)

D.1 English Survey



Questions about yourself

What is your participant's ID?

____

1. When were you born?

   ____

2. What is your gender?

   a. Male
   b. Female
   c. Other ______________________________

3. What is your race or ethnicity? Select all that apply.

   a. Native American or Alaskan native
   b. Asian
   c. Black or African American
   d. Hispanic or Latino
   e. Native Hawaiian or other Pacific Islander
   f. White
   g. Other ____________________________________

4. What is your annual income? (What you make or receive by yourself in a year)

   ____

5. What is your highest level of education?

   a. No schooling
   b. Pre-school
   c. Elementary school (Kindergarten and grades 1-5)
   d. Middle school (grades 6-8)
   e. Some high school (grades 9-12, no diploma)
   f. High school graduate (or equivalent)
   g. Some college (1-4 years, no degree)
   h. Associate's degree (including occupation or academic degrees)
   i. Bachelor's degree (BA, BS, AB, etc.)
   j. Master's degree or higher
   k. Other ______________________________

6. Mark the <u>one</u> box that best fit your thoughts and feelings during the past week, including today.
   How would you describe:

	Very good	Good	Neither good nor bad	Bad	Very Bad
Quality of Life?	☐	☐	☐	☐	☐
Mental (intellectual) well-being?	☐	☐	☐	☐	☐
Physical well-being?	☐	☐	☐	☐	☐
Emotional well-being?	☐	☐	☐	☐	☐
Level of social activity?	☐	☐	☐	☐	☐
Ability to function in daily life?	☐	☐	☐	☐	☐
Your level of support from friends and family?	☐	☐	☐	☐	☐
Your financial concerns?	☐	☐	☐	☐	☐
Your legal concerns?	☐	☐	☐	☐	☐
Life satisfaction and contentment during the past week?	☐	☐	☐	☐	☐

7. Mark the <u>one</u> box that best fits your thoughts and feelings.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I have been discriminated against because of my mental health problems. For instance, by employers, school or police	☐	☐	☐	☐	☐
Sometimes I feel that I am being talked down to because of my mental health problems	☐	☐	☐	☐	☐
I feel bad about having had mental health problems	☐	☐	☐	☐	☐
I worry about telling people I receive mental health treatment	☐	☐	☐	☐	☐
Very often I feel alone because of my mental health problems	☐	☐	☐	☐	☐
I am scared of how other people will react if they find out about my mental health problems	☐	☐	☐	☐	☐
I would have had better chances in life if I had not had mental health problems	☐	☐	☐	☐	☐
I mind people in my neighborhood knowing I have had mental health problems	☐	☐	☐	☐	☐
I would say I have had mental health problems if I was applying for a job	☐	☐	☐	☐	☐
I worry about telling people that I take medicines/tablets for mental health problems	☐	☐	☐	☐	☐
People's reactions to my mental health problems make me keep to myself	☐	☐	☐	☐	☐
I am angry with the way people have reacted to my mental health problems	☐	☐	☐	☐	☐
I had some trouble with people because of my mental health problems	☐	☐	☐	☐	☐
I have been discriminated against by health professionals because of my mental health problems	☐	☐	☐	☐	☐
People have insulted or avoided me because of my mental health problems	☐	☐	☐	☐	☐
I avoid telling people about my mental health problems	☐	☐	☐	☐	☐
I feel embarrassed because of my mental health problems	☐	☐	☐	☐	☐
Having had mental health problems makes me feel that life is unfair	☐	☐	☐	☐	☐
Continued to next page					

Continued from Question 8…	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I feel the need to hide my mental health problems from my friends	☐	☐	☐	☐	☐
I find it hard telling people I have mental health problems	☐	☐	☐	☐	☐

8. Do you have any of the following health conditions? Select all that apply.

   a. Anxiety or panic disorder
   b. Bipolar disorder
   c. Depression
   d. Impulse control problem. Such as with gambling, sex or stealing
   e. Identity and memory problem. Such as amnesia.
   f. Eating disorder. Such as anorexia or bulimia.
   g. Obsessive compulsive disorder. Such as OCD or hair pulling.
   h. Personality disorder. Such as borderline, sociopath or antisocial
   i. Schizophrenia or other psychosis. Such as hearing voices.
   j. Drug or alcohol addiction
   k. Post-traumatic stress disorder, PTSD or adjustment disorder
   l. Chronic pain or somatic disorder
   m. Other ____________________________

Questions about your choices on data sharing for care

9. Which providers do you see **outside this Clinic?** Select all that apply.

    a. Primary care providers. Such as family doctor
    b. Behavioral health providers. Such as psychiatrist or case manager
    c. Specialty care providers. Such a cardiologist or orthopedist
    d. I don't see other providers
    e. Other ___________________________

10. Have you been asked if you want to share your data with providers **outside this Clinic**? Select all that apply.

    a. Yes, I have been asked
    b. No, I haven't been asked
    c. I am not sure
    d. Other _____________________________

11. Has a provider ever shared your data without asking you?

    a. Yes
    b. No
    c. I am not sure
    d. Other _____________________________

12. Behavioral health data relates to your mental health, substance use disorders or other addictions. If asked, how likely are you to share your **behavioral health data** with the following types of providers? Choose <u>one</u> box for each provider type.

	Always share	Sometimes share	Don't share	It does not apply to me
Behavioral health provider **at this Clinic**	☐	☐	☐	☐
Other provider **at this Clinic**	☐	☐	☐	☐
Behavioral health provider **outside this Clinic**	☐	☐	☐	☐
Other provider **outside this Clinic**	☐	☐	☐	☐
Other provider, in case of emergency	☐	☐	☐	☐

13. Sensitive health data may have harmful effects if known. Do you consider any of the following types of data to be sensitive? Choose <u>one</u> box for each data type.

	Very Sensitive	Somewhat Sensitive	Not at all Sensitive	**It does not apply to me**
Mental health	☐	☐	☐	☐
Drug or substance abuse	☐	☐	☐	☐
Alcohol abuse	☐	☐	☐	☐
Psychotherapy notes	☐	☐	☐	☐
Domestic violence and other abuse	☐	☐	☐	☐
Sexual and reproductive health. Such as pregnancy, abortion or sexual preference	☐	☐	☐	☐
Sexually transmitted diseases. Such as syphilis, HIV and AIDS	☐	☐	☐	☐
Genetic data	☐	☐	☐	☐

14. If asked, how likely are you to share the following types of data with **providers outside this Clinic**? Choose <u>one</u> box for each data type.

	Share with all providers	Share with **some** providers	**Do not share** with any provider	It does not apply to me
Mental health	☐	☐	☐	☐
Drug or substance abuse	☐	☐	☐	☐
Alcohol use	☐	☐	☐	☐
Psychotherapy notes	☐	☐	☐	☐
Domestic violence and other abuse	☐	☐	☐	☐
Sexual and reproductive health. Such as pregnancy, abortion or sexual preference	☐	☐	☐	☐
Sexually transmitted diseases. Such as syphilis, HIV or AIDS	☐	☐	☐	☐
Genetic data	☐	☐	☐	☐

15. Your provider wants you to start taking a new medication. What do you want your provider to see when he looks at your data?

    a. My provider should see **all** my data.
    b. My provider should **only** see the data I want to share.
    c. My provider should see all my data **only** if the new medication could harm me.
    d. Other ______________________________

16. You have an emergency. What do you want your emergency provider to see when he looks at your data?

    a. The emergency provider should see **all** my data.
    b. The emergency provider should **only** see the data I want to share.
    c. The emergency provider should see all my data **only** if the emergency is life threatening
    d. Other ______________________________

17. How much do you agree or disagree with each statement below? Mark the one box for each statement.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I trust providers will share **only data that** I allow to share.	☐	☐	☐	☐	☐
Sharing all my data with my providers would improve my care.	☐	☐	☐	☐	☐
I worry about providers knowing that I receive mental health treatment.	☐	☐	☐	☐	☐
I trust providers at this Clinic.	☐	☐	☐	☐	☐
If my provider asks me to share all my data, I would share it.	☐	☐	☐	☐	☐
I would be upset if a provider shares my data without my permission.	☐	☐	☐	☐	☐
I might leave this Clinic if they share my data without asking me.	☐	☐	☐	☐	☐

Questions about your choices on data sharing for research

18. Research helps to find new treatments and medications. Mark the <u>one</u> box that best matches how much you agree or disagree with each statement.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
I would **always** share my data	☐	☐	☐	☐	☐
If better care for **me** can be found, I would share my data	☐	☐	☐	☐	☐
If better care for **others** can be found, I would share my data	☐	☐	☐	☐	☐
If I am paid, I would share my data	☐	☐	☐	☐	☐
I would **never** share my data	☐	☐	☐	☐	☐

19. Different types of organizations do research. How likely are you to share your data for research with the following organizations? Choose <u>one</u> box for each organization type.

	Extremely willing to share	Quite willing to share	Somewhat willing to share	Not at all willing to share
Jewish Family and Children's Services	☐	☐	☐	☐
Universities or academic institutions. Such as Arizona State University	☐	☐	☐	☐
Government agencies	☐	☐	☐	☐
Non-profit organizations. Such as the American Diabetes Association	☐	☐	☐	☐
Drug companies	☐	☐	☐	☐

D.2 Spanish Survey

Encuesta
Información personal

¿Cuál es su identificador como participante de esta encuesta?

____

1. ¿En qué año nació?

   ____

2. ¿Cuál es su sexo?
   a. Masculino
   b. Femenino
   c. Otro ____

3. ¿Cuál es su raza o grupo étnico? Seleccione todas las que correspondan.
   a. Nativo Americano o nativo de Alaska
   b. Asiático
   c. Afroamericano o Afro estadounidense
   d. Latino o Hispánico
   e. Nativo del Hawái o de otras islas del Pacifico
   f. Blanco
   g. Otro ____

4. ¿Cuál es su ingreso anual? (Dinero ganado o recibido en un año)

   ____

5. ¿Cuál es su máximo nivel de educación?
   a. No fui a la escuela
   b. Preescolar
   c. Escuela Elemental (Kindergarten y grados 1 al 5)
   d. Escuela Intermedia (grados 6 al 8)
   e. No completé la Preparatoria (grados 9 al 12, sin diploma)
   f. Preparatoria (o equivalente)
   g. No completé la Universidad (1 a 4 años, sin diploma)
   h. Grado Asociado o Técnico Superior (incluyendo diploma académico u ocupacional)
   i. Bachiller (BA, BS, AB, etc.)
   j. Maestría o título superior
   k. Otro ____

6. Elija una casilla que mejor describa lo que ha pensado o sentido durante esta semana pasada, incluyendo hoy. ¿Cómo describe su …

	Muy Buena(o)	Buena(o)	Ni buena(o), ni mala(o)	Mala(o)	Muy mala(o)
¿Calidad de vida?	☐	☐	☐	☐	☐
¿Bienestar mental (intelectual)?	☐	☐	☐	☐	☐
¿Bienestar físico?	☐	☐	☐	☐	☐
¿Bienestar emocional?	☐	☐	☐	☐	☐
¿Nivel de actividad social?	☐	☐	☐	☐	☐
¿Capacidad de funcionar en su vida diaria?	☐	☐	☐	☐	☐
¿Nivel de apoyo de sus amigos y familia?	☐	☐	☐	☐	☐
¿Preocupaciones financieras?	☐	☐	☐	☐	☐
¿Preocupaciones legales?	☐	☐	☐	☐	☐
¿Satisfacción y felicidad con su vida durante la semana pasada?	☐	☐	☐	☐	☐

7. Elija una casilla que mejor describa lo que usted piensa o siente

	Muy de acuerdo	De acuerdo	Ni de acuerdo, ni en desacuerdo	En desacuerdo	Muy en desacuerdo
He sido discriminado porque tengo problemas de salud mental. Por ejemplo, por empleadores, escuela o policía	☐	☐	☐	☐	☐
A veces siento que la gente es condescendiente conmigo porque tengo problemas de salud mental	☐	☐	☐	☐	☐
Me siento mal por tener problemas de salud mental	☐	☐	☐	☐	☐
Me preocupa decirle a la gente que recibo tratamiento por problemas de salud mental	☐	☐	☐	☐	☐
Muy a menudo me siento solo por causa de mis problemas de salud mental	☐	☐	☐	☐	☐
Tengo miedo de cómo reaccionarán otras personas si descubren mis problemas de salud mental	☐	☐	☐	☐	☐
Tendría mejores oportunidades en la vida, si no hubiera tenido problemas de salud mental	☐	☐	☐	☐	☐
Me molesta que la gente del barrio sepa que tengo problemas de salud mental	☐	☐	☐	☐	☐
Diría que tengo problemas de salud mental cuando estoy buscando trabajo	☐	☐	☐	☐	☐
Me preocupa decirle a la gente que tomo medicinas para tratar mis problemas de salud mental	☐	☐	☐	☐	☐
La reacción de la gente a mis problemas de salud mental hace que me mantenga aislado	☐	☐	☐	☐	☐
Me enoja la forma en que la gente reacciona cuando conoce mis problemas de salud mental	☐	☐	☐	☐	☐
He tenido problemas con alguna gente a causa de mis problemas de salud mental	☐	☐	☐	☐	☐
He sido discriminado por personal médico a causa de mis problemas de salud mental	☐	☐	☐	☐	☐
Algunas personas me han insultado o evitado porque tengo problemas de salud mental	☐	☐	☐	☐	☐
Evito decirle a la gente que tengo problemas de salud mental	☐	☐	☐	☐	☐
Continúa en la siguiente página					

Continuación de pregunta 7…	Muy de acuerdo	De acuerdo	Ni de acuerdo, ni en desacuerdo	En desacuerdo	Muy en desacuerdo
Me da vergüenza tener problemas de salud mental	☐	☐	☐	☐	☐
El tener problemas de salud mental me hace sentir que la vida es injusta	☐	☐	☐	☐	☐
Siento la necesidad de ocultarle a mis amigos que tengo problemas de salud mental	☐	☐	☐	☐	☐
Me resulta difícil decirle a la gente que tengo problemas de salud mental	☐	☐	☐	☐	☐

8. ¿Sufre de alguna de estas condiciones médicas? Seleccione todas las que correspondan.

   a. Ansiedad o pánico
   b. Bipolaridad
   c. Depresión
   d. Comportamiento compulsivo. Por ejemplo, adicción al juego o al sexo, o impulso de robar
   e. Problemas de memoria o de identidad. Por ejemplo, amnesia.
   f. Trastornos alimentarios. Por ejemplo, anorexia o bulimia.
   g. Obsesión compulsiva. Por ejemplo, TOC u obsesión de arrancarse el cabello.
   h. Trastornos de personalidad. Por ejemplo, trastorno límite de la personalidad, sociópata o antisocial
   i. Esquizofrenia u otras psicosis. Por ejemplo, oír voces.
   j. Adicción a drogas o alcohol
   k. Trastorno de estrés post- traumático (TEPT) o depresión reactiva.
   l. Hipocondría u otros trastornos psicosomáticos
   m. Otro ______________________________________

12. Salud de la conducta se refiere al uso de drogas o alcohol, u otras adicciones. Si se le pregunta, ¿compartiría información sobre su salud mental o de conducta con el siguiente personal médico? Elija <u>una</u> casilla por cada tipo de personal médico.

	Compartir siempre	Compartir a veces	No compartir	No me aplica
Personal de esta Clínica que trata la salud mental o de conducta	☐	☐	☐	☐
Otro personal de esta Clínica	☐	☐	☐	☐
Personal fuera de esta Clínica que trata la salud mental o de conducta	☐	☐	☐	☐
Otro personal fuera de esta Clínica	☐	☐	☐	☐
Otro personal, en caso de emergencia	☐	☐	☐	☐

13. Información médica confidencial puede tener efectos negativos cuando es conocida. ¿Considera a los siguientes tipos de información confidencial? Elija <u>una</u> casilla por cada tipo de información.

	Muy confidencial	Algo confidencial	Nada confidencial	No me aplica
Salud mental	☐	☐	☐	☐
Adicción a las drogas	☐	☐	☐	☐
Adicción al alcohol	☐	☐	☐	☐
Notas del psicoterapeuta	☐	☐	☐	☐
Violencia doméstica y otros abusos	☐	☐	☐	☐
Sexualidad y salud reproductiva. Por ejemplo, embarazo, aborto o preferencia sexual	☐	☐	☐	☐
Enfermedades de transmisión sexual. Por ejemplo, sífilis, VIH o SIDA.	☐	☐	☐	☐
Información genética	☐	☐	☐	☐

14. ¿Compartiría la siguiente información con personal médico fuera de la Clínica? Elija <u>una</u> casilla por cada tipo de personal médico.

	Compartiría con todo el personal médico	Compartiría con parte del personal médico	No compartiría con personal médico	No me aplica
Salud mental	☐	☐	☐	☐
Adicción a las drogas	☐	☐	☐	☐
Adicción al alcohol	☐	☐	☐	☐
Notas del psicoterapeuta	☐	☐	☐	☐
Violencia doméstica y otros abusos	☐	☐	☐	☐
Sexualidad y salud reproductiva. Por ejemplo, embarazo, aborto o preferencia sexual	☐	☐	☐	☐
Enfermedades de transmisión sexual. Por ejemplo, sífilis, VIH o SIDA.	☐	☐	☐	☐
Información genética	☐	☐	☐	☐

15. Su médico quiere que comience un tratamiento nuevo. Cuando su médico mira su información, ¿qué desea que vea?
    a. Mi médico debería ver toda mi información
    b. Mi médico debería ver sólo la información que quiero compartir.
    c. Mi médico debería ver toda mi información sólo si el tratamiento pudiera hacerme daño.
    d. Otro ____

16. Usted tiene una emergencia. Cuando el personal médico de emergencia mira su información, ¿qué desea que vea?
    a. El personal médico debería ver toda mi información.
    b. El personal médico debería ver sólo la información que quiero compartir.
    c. El personal médico debería ver toda mi información sólo si la emergencia pudiera llevarme a la muerte.
    d. Otro ____

17. ¿Está de acuerdo con las siguientes frases? Elija una casilla por cada frase.

	Muy de acuerdo	De acuerdo	Ni de acuerdo, ni en desacuerdo	En desacuerdo	Muy en desacuerdo
Confío que el personal médico comparte mi información sólo cuando lo permito	☐	☐	☐	☐	☐
Compartir toda mi información con los médicos mejorará mi cuidado médico	☐	☐	☐	☐	☐
Me preocupa que el médico sepa que recibo tratamiento por problema de salud mental	☐	☐	☐	☐	☐
Confío en el personal médico de esta Clínica	☐	☐	☐	☐	☐
Compartiría mi información, si mi médico me lo pide	☐	☐	☐	☐	☐
Me molestaría si el médico compartiera mi información sin mi permiso	☐	☐	☐	☐	☐
Dejaría de venir a esta Clínica si compartieran mi información médica sin mi permiso	☐	☐	☐	☐	☐

Preguntas sobre sus preferencias sobre compartir información médica para la investigación

18. A través de la investigación se descubren nuevos tratamientos médicos y drogas. Elija una casilla que mejor describa cuanto está de acuerdo o no con cada frase.

	Muy de acuerdo	De acuerdo	Ni de acuerdo, ni en desacuerdo	En desacuerdo	Muy en desacuerdo
Siempre compartiría mi información	☐	☐	☐	☐	☐
Compartiría mi información, si pudiera ayudar a mejorar el cuidado médico que yo recibo	☐	☐	☐	☐	☐
Compartiría mi información, si pudiera ayudar a mejorar el cuidado médico que otros reciben	☐	☐	☐	☐	☐
Compartiría mi información, si me ofrecen dinero	☐	☐	☐	☐	☐
Nunca compartiría mi información	☐	☐	☐	☐	☐

19. Diferentes tipos de organizaciones realizan investigación. ¿Cuán probable es que usted comparta su información para investigación con las siguientes organizaciones? Elija una casilla por cada tipo de organización.

	Muy dispuesto a compartir	Dispuesto a compartir	Algo dispuesto a compartir	Nada dispuesto a compartir
Jewish Family and Children's Services	☐	☐	☐	☐
Universidades o instituciones académicas. Por ejemplo, Arizona State University	☐	☐	☐	☐
Agencias del gobierno	☐	☐	☐	☐
Organizaciones sin fines de lucro. Por ejemplo, Asociación Americana para la Diabetes	☐	☐	☐	☐
Compañías farmacéuticas	☐	☐	☐	☐

APPENDIX E

CARD SORTING INTERVIEW SCRIPT (AIM 3)

203

Thank you for participating. For this study, we are using your medical records. We received the records from Site X after you gave us permission to share your medical records in a previous study (show their previously signed consent form including Title of the Study and Sign).

We have selected 30 medical record items. We wrote each item in a white card. Each white card is a medication, lab, allergy, diagnosis, etc. (show white cards) The information could be from your present or past medical records. For example, you may be taking a medication in past but have stopped now.

This study is very similar to a survey you took a few months back (show their previous consent form with Title of the Study and provided Re-Contact Information) on paper or iPad.

This is an interactive study. We will complete 7 questions. For example, "Did you have corn for dinner?". You could answer "Yes" or "I am unsure". We will represent possible answers with colored cards. If you are unsure about eating corn, you will place the corn white card to the "I am unsure" colored card (show to participant). Is this clear? This was an example. The questions in the study will not relate to your meals, but to your medical records. We will ask questions about these 30 (show white cards) and your choices for sharing this data. There are no right or wrong answers.

I will also ask you some questions when you are sorting the white cards. I will audio record your answers. I request you to please think aloud. This will help us to capture your thoughts. I will also take pictures of how you arranged cards after each question. The photos will not have your face or any feature that can identify you.

Please let me know if you would like to take a short break anytime in between. I am happy to answer any questions you might have during the study.

(Instructions for recruiters:

Recruiters should sit down when patient is answering questions unless needed.

Recruiters will have snacks and water for patients and offer them in the beginning

Recruiters will have plaques for each question, so that patients can read along and refer while answering the question. These plaques should be placed on table such that patients can read them with ease.)

1. You may or may not remember the information in the white card. But we would like to know how much you remember. Do you recall this information from your present or past medical records? Can you also tell me what do you remember about each? We will go through these cards one by one. There might be some fill in the blanks in cards. We will fill those out as we move forward.

Question Description

We will provide the participant will all the 30 white cards at once. The information in the white card will be taken from patient's medical records. The top right corner of the white card will specify the information category (such as medication, diagnosis, allergy, etc.). Each white card will contain participant ID in the back. The examples are as below:

- Diagnosis: I have been diagnosed with <medical record information>
- Labs: I have had a <medical record information> test

- Medications: I have been prescribed <medical record information> medication for my __________
- Patient allergies: I have a <medical record information> allergy
- Procedures: I have undergone a <medical record information > procedure for my _________

As depicted in Figure 1, the colored cards are coded as follows:

- Green: Yes
- Blue: Unsure

(If the patient classifies information in 'Unsure' category, the recruiter will provide personalized patient education material giving more information about the medical record.

If the patient verbalizes that the card does not correspond to any information from his/her medical record, the interviewer will be trained to not to disagree with the patient, keep notes of that concern, and proceed as for the 'Unsure' response. The patient will receive information on the medical record card and will be asked to classify that information as it were part of his/her medical record. For example, the recruiter can mention, 'Let's assume that these cards have information from your medical records.')

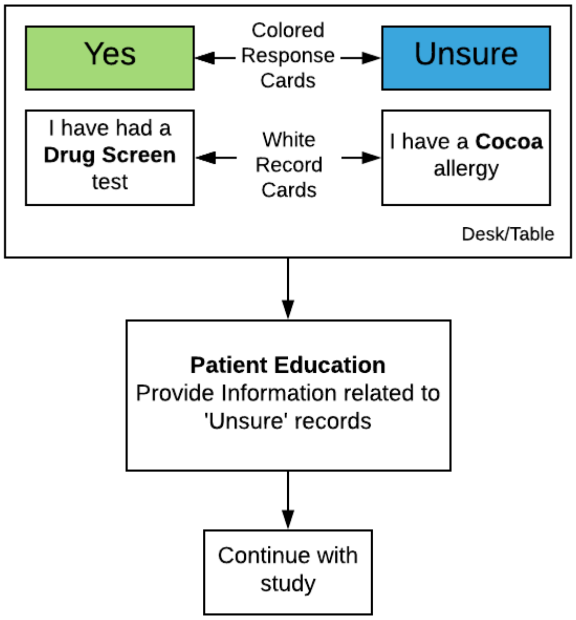


Figure E.1 Representation of task 1

2. The white cards can be sorted in different colored cards. For example, a white card could have a medication related to depression. So, it may relate to the mental health colored card. Could you sort the white cards in the colored cards on the table?

(If a patient is unsure about a white card allow then to classify that information to closest group possible. For example, the recruiter can mention, ‘please classify the information into the closest group you think they belong.’)
Question Description
We will provide participants will all the white cards at once. There will be 8 different blue colored cards. Each blue colored card will contain a label from below:

- Drug Abuse
- Alcohol use and alcoholism
- Mental health
- HIV/AIDS and other communicable disease
- Genetic disease
- Sexuality and Reproductive health
- Other addictions
- Other

At the end of the task, all the white cards will be bundled with corresponding colored card. For instance, all the white cards categorized as Mental Health Information will be pinned with colored card with that label.

3. Next, we would like to know your choices of sharing the data in these bundles. Would you share information in these bundles with the providers you might see outside Site X?

The providers may include;(show provider cards)

- hospitals
- primary care providers,
- specialty care providers; for example: a cardiologist or a dermatologist ,
- nurses; for example: RNs, LPNs,
- case managers or social workers,
- licensed professional counselors/therapists,
- pharmacists,
- medical assistants

Can you please tell me why would you like to share?
Question Description
We will provide the participant with all the bundles at once. We will place in the table the following colored cards:

- Green: Share with all providers
- Yellow: Share with some providers
- Red: Do not share with any provider

When patients select the yellow card “share this information with some providers”, recruiters will hand over provider cards and ask participants to identify which of those providers the participant wants to share information with.

4. We have the white cards in bundles. We also saw how willing you are to share these bundles with your providers. Now, some of these bundles might require special handling. Sharing this information might harm you. A doctor or nurse might treat you differently. Do you think any of the bundles are sensitive for you? Could you please say why or why not?

Question Description
We will provide participants will all the bundles at once. We will also place in the table the following colored cards:

- Green: Very Sensitive
- Yellow: Somewhat Sensitive
- Red: Not Sensitive

5. For next question, we will separate the white cards from these bundles. Imagine your primary care provider wants to start a new medication. The new medication may have side effects. The primary care provider wants to see your medical records. Which of these white cards would you like your doctor to see?

Question Description
We will provide participants will all the white cards at once. We will place on the table the following colored cards:

- Green: Share this information
- Red: Do not share this information

For the next question, I will hand you again the white cards.

6. Suppose you have an emergency. And you are unconscious when you come to emergency room. Your emergency care provider wants to see your medical records. But they are unable to ask your permission. Which of these white cards would you like your doctor to see? Could you tell me some reasons behind your choice?

Question Description
We will provide participants will all the white cards at once. We will place on the table the following colored cards:

- Green: Share this information
- Red: Do not share this information

Now, I will place all the white cards into one bundle. The next question is related to sharing your medical records for research. There are many organizations that conduct research. For example, I am doing this research at Arizona State University. I will show you different researcher cards. Would you to share the data in the bundle for research? Can you please tell me why or why not?

Question Description
The bundle will be labeled “All your medical records”.
The researcher cards given to the participant will be:

- Site X
- Universities, like Arizona State University
- Government Agencies, like Department of Health Services
- Non-Profit Organizations, like American Diabetes Association
- Drug Companies, like a company that makes a medication you are taking

The following colored cards will be also placed in the table:

- Green: Extremely Willing to Share
- Purple: Quite Willing to Share
- Yellow: Somewhat Willing to Share
- Red: Not at All Willing to Share

APPENDIX F

THEMATIC ANALYSIS CODEBOOK DEFINITIONS AND EXEMPLARS OF MAJOR CATEGORIES (AIM 4)

Code	Definition	Exemplar
Type of Information	Information found on patient flashcards. This section includes groupings of the specific information	No coding done
Communicable Disease	Illnesses from infection, presence, and growth of pathogenic biological agents in an individual. Includes interviewee discussing communicable disease in non-standard (medically incorrect) fashion.	"Because Hepatitis C, if you're sitting there like a male partner or female partner and you have that, you know, you that's something I think you should tell your, you know, your significant other."
DSM-5 Disorders	Illness listed in *DSM–5*	"I have been diagnosed with depression disorder. This falls into under mental health."
Physical Health Information	Health diagnoses related to all excepting mental health (physical ailments)	"So, this allergy, Phenylephrine. This is a medication for cold and sinus congestion and stuff."
Labs	Any type of bodily fluid testing in medical records	Male Speaker: "Other." Interviewee: "Like your gene and blood tests." Interviewer: "No, this is just a blood test to check maybe for you like, know all the type of chemicals in your body."
Medication	Any mention of medications	"I have been prescribed Medrol dose pack medication…"
Sensitivity of Info	Interviewee categorized sensitivity of the classifications and/or on flashcard	Codes based directly on instructions from interview as "-sensitive", "not sensitive" or "possibly sensitive"
Classifications	Interviewee classified flashcards into one of eight categories based on interview	Eight subsections based on flashcard exercise
Patient Unsure	Interviewee indicates unsure meaning of item on flashcard or how to categorize it	Interviewer: "What do you think? Yeah, it's not necessary that you might have or you can look at it in the back what belongs to, you know, possibly they're screening for drug abuse. So, it is definitely not necessary that you have that

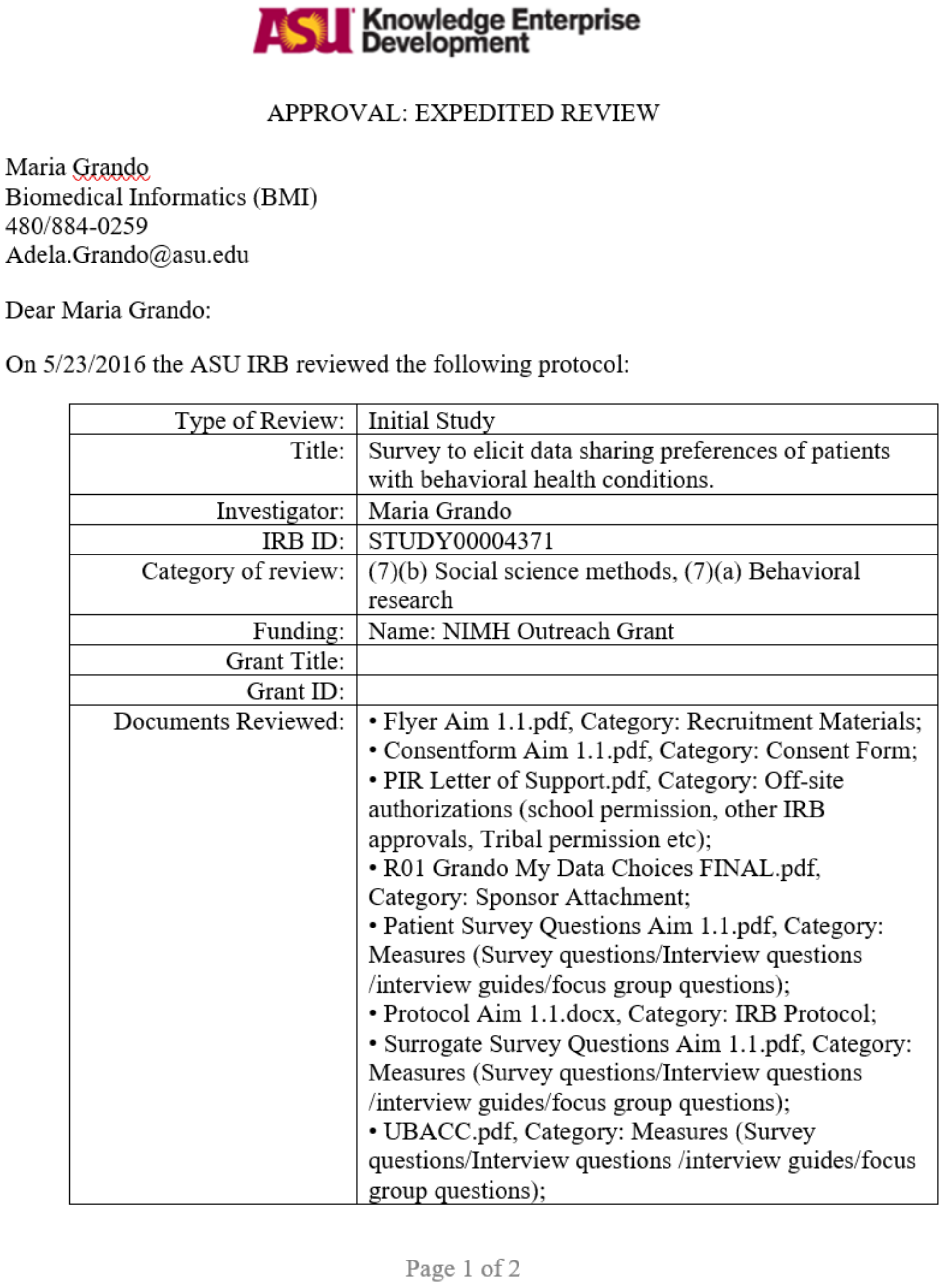
		problem. You know, but it might belong to some like that category." Interviewee: "I don't know."
Reclassification	Interviewee reclassifies flashcard	No coding done
Final Classification	In instances when interviewee changed the categorization of the flashcard, the first categorization is coded here	Interviewee: "I have been diagnosed with…" Interviewer: "Drug abuse." Interviewee: "...drug abuse, this falls under alcohol use and alcoholism." Interviewer: "So, why do you think it?" Interviewee: "Oh no." Interviewer: "Drug, okay."

APPENDIX G

IRB AAPPROVALS

Survey to elicit data sharing preferences of patients with behavioral health conditions

(ASU IRB #4371)



ASU Knowledge Enterprise Development

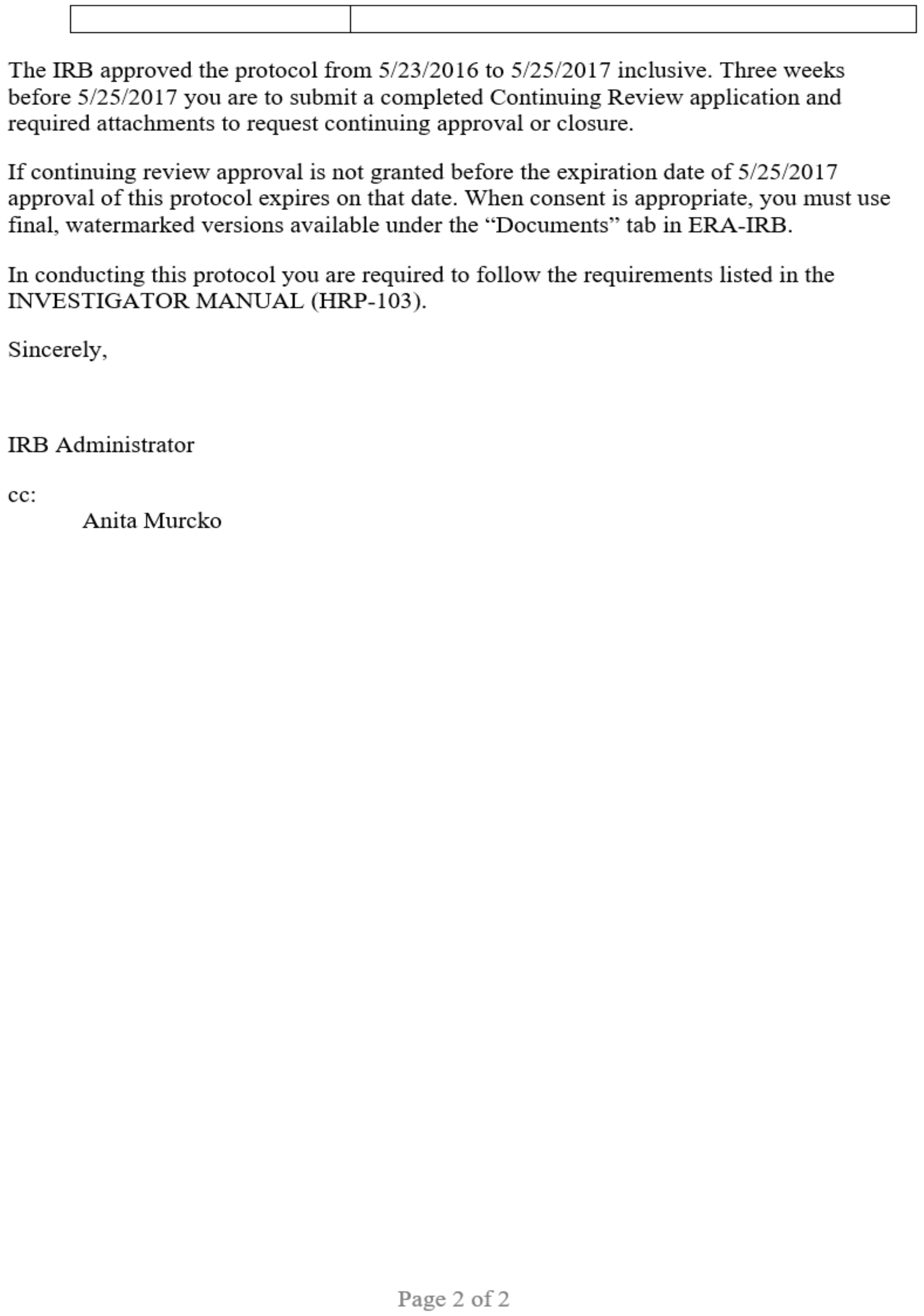
APPROVAL: EXPEDITED REVIEW

Maria Grando
Biomedical Informatics (BMI)
480/884-0259
Adela.Grando@asu.edu

Dear Maria Grando:

On 5/23/2016 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Survey to elicit data sharing preferences of patients with behavioral health conditions.
Investigator:	Maria Grando
IRB ID:	STUDY00004371
Category of review:	(7)(b) Social science methods, (7)(a) Behavioral research
Funding:	Name: NIMH Outreach Grant
Grant Title:	
Grant ID:	
Documents Reviewed:	• Flyer Aim 1.1.pdf, Category: Recruitment Materials; • Consentform Aim 1.1.pdf, Category: Consent Form; • PIR Letter of Support.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); • R01 Grando My Data Choices FINAL.pdf, Category: Sponsor Attachment; • Patient Survey Questions Aim 1.1.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Protocol Aim 1.1.docx, Category: IRB Protocol; • Surrogate Survey Questions Aim 1.1.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • UBACC.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);



The IRB approved the protocol from 5/23/2016 to 5/25/2017 inclusive. Three weeks before 5/25/2017 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 5/25/2017 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

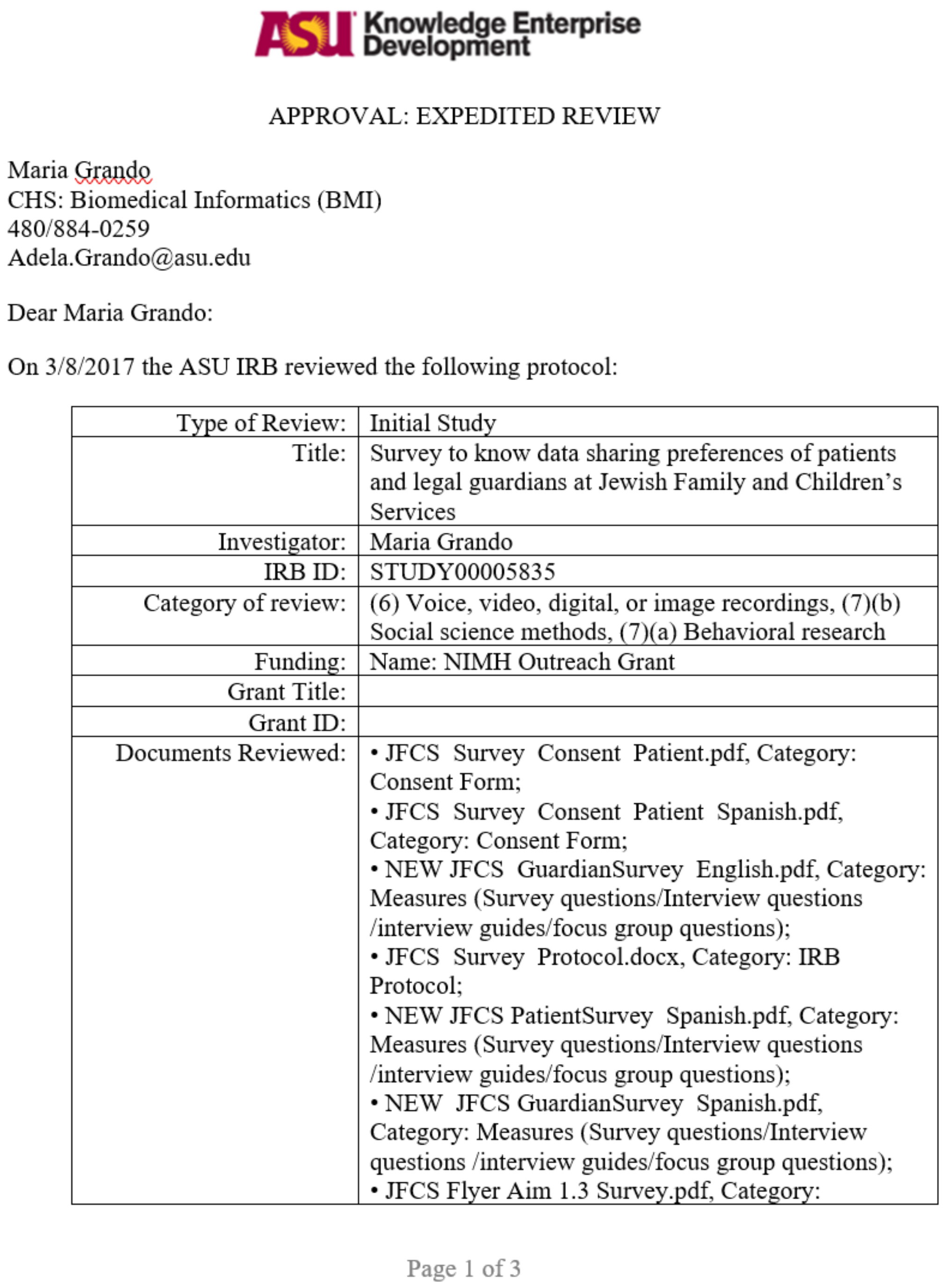
In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc:
Anita Murcko

Survey to know data sharing preferences of patients and legal guardians at Jewish Family and Children’s Services (ASU IRB #5835)



ASU Knowledge Enterprise Development

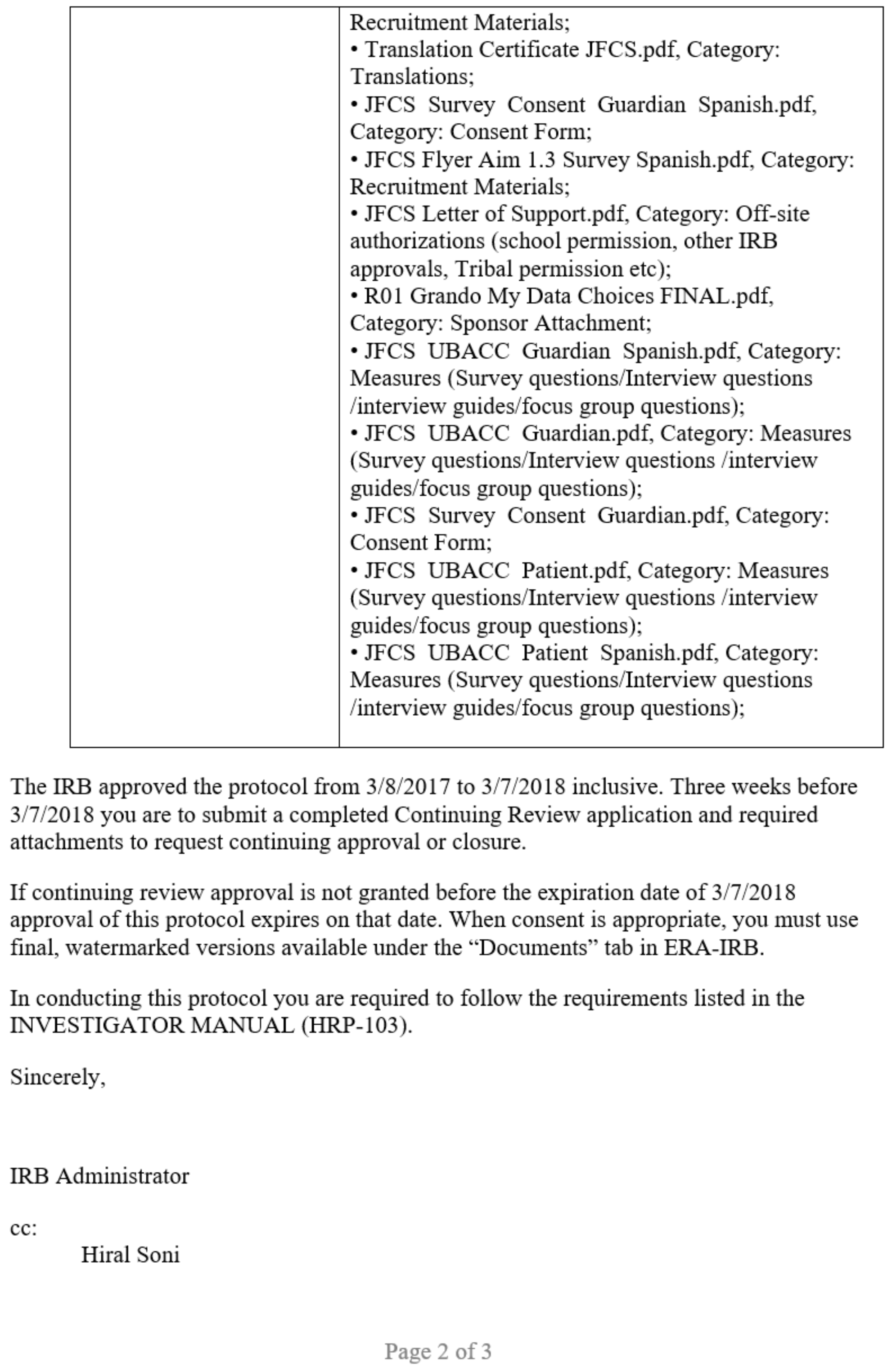
APPROVAL: EXPEDITED REVIEW

Maria Grando
CHS: Biomedical Informatics (BMI)
480/884-0259
Adela.Grando@asu.edu

Dear Maria Grando:

On 3/8/2017 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Survey to know data sharing preferences of patients and legal guardians at Jewish Family and Children’s Services
Investigator:	Maria Grando
IRB ID:	STUDY00005835
Category of review:	(6) Voice, video, digital, or image recordings, (7)(b) Social science methods, (7)(a) Behavioral research
Funding:	Name: NIMH Outreach Grant
Grant Title:	
Grant ID:	
Documents Reviewed:	• JFCS Survey Consent Patient.pdf, Category: Consent Form; • JFCS Survey Consent Patient Spanish.pdf, Category: Consent Form; • NEW JFCS GuardianSurvey English.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • JFCS Survey Protocol.docx, Category: IRB Protocol; • NEW JFCS PatientSurvey Spanish.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • NEW JFCS GuardianSurvey Spanish.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • JFCS Flyer Aim 1.3 Survey.pdf, Category:



	Recruitment Materials; • Translation Certificate JFCS.pdf, Category: Translations; • JFCS Survey Consent Guardian Spanish.pdf, Category: Consent Form; • JFCS Flyer Aim 1.3 Survey Spanish.pdf, Category: Recruitment Materials; • JFCS Letter of Support.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); • R01 Grando My Data Choices FINAL.pdf, Category: Sponsor Attachment; • JFCS UBACC Guardian Spanish.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • JFCS UBACC Guardian.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • JFCS Survey Consent Guardian.pdf, Category: Consent Form; • JFCS UBACC Patient.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • JFCS UBACC Patient Spanish.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);

The IRB approved the protocol from 3/8/2017 to 3/7/2018 inclusive. Three weeks before 3/7/2018 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 3/7/2018 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

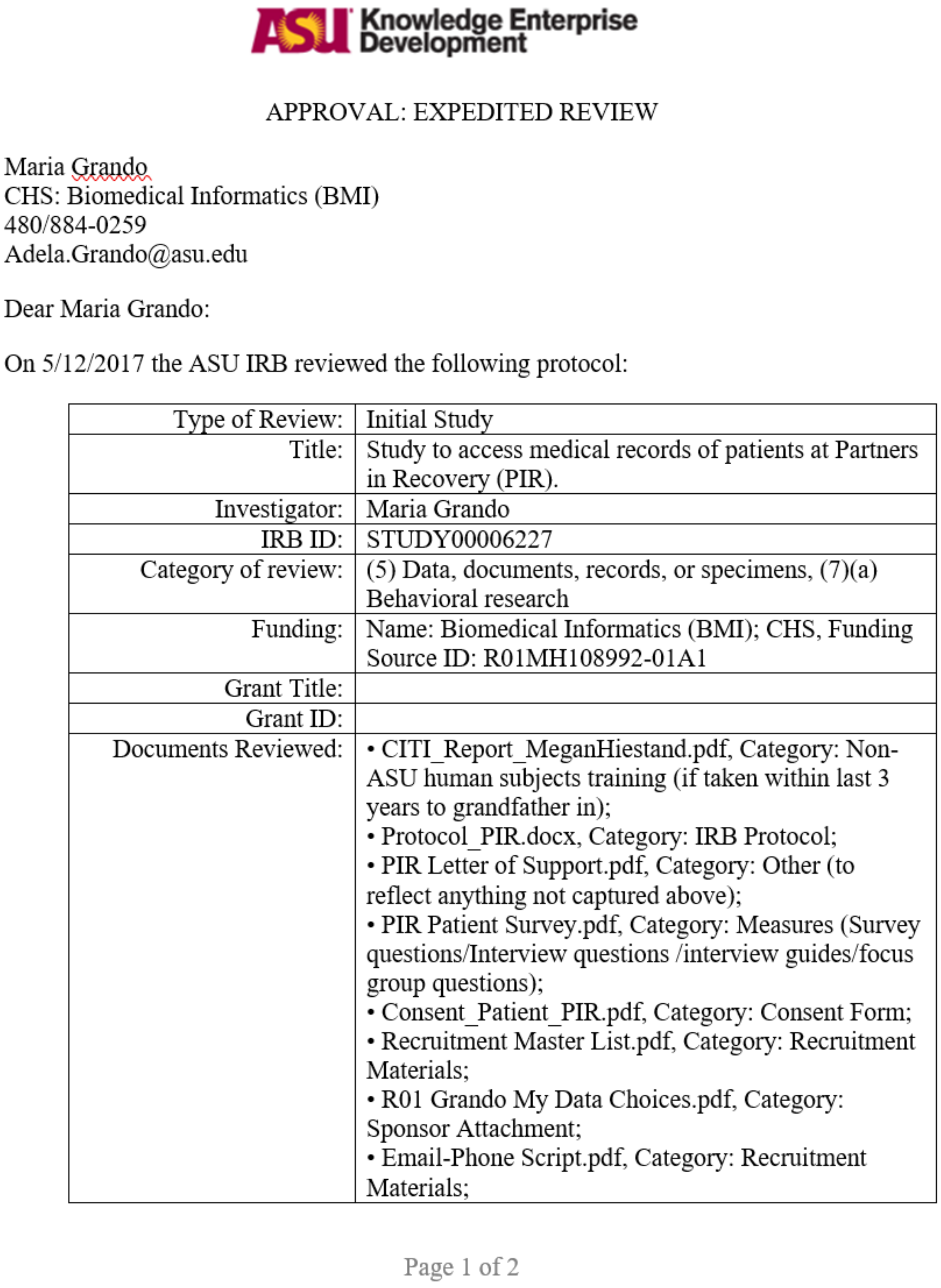
Sincerely,

IRB Administrator

cc:
Hiral Soni

Madhumita Mukundan
Anita Murcko
Julia Varkey

Study to access medical records of patients at Partners in Recovery (PIR) (ASU IRB #6227)



ASU Knowledge Enterprise Development

APPROVAL: EXPEDITED REVIEW

Maria Grando
CHS: Biomedical Informatics (BMI)
480/884-0259
Adela.Grando@asu.edu

Dear Maria Grando:

On 5/12/2017 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Study to access medical records of patients at Partners in Recovery (PIR).
Investigator:	Maria Grando
IRB ID:	STUDY00006227
Category of review:	(5) Data, documents, records, or specimens, (7)(a) Behavioral research
Funding:	Name: Biomedical Informatics (BMI); CHS, Funding Source ID: R01MH108992-01A1
Grant Title:	
Grant ID:	
Documents Reviewed:	• CITI_Report_MeganHiestand.pdf, Category: Non-ASU human subjects training (if taken within last 3 years to grandfather in); • Protocol_PIR.docx, Category: IRB Protocol; • PIR Letter of Support.pdf, Category: Other (to reflect anything not captured above); • PIR Patient Survey.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Consent_Patient_PIR.pdf, Category: Consent Form; • Recruitment Master List.pdf, Category: Recruitment Materials; • R01 Grando My Data Choices.pdf, Category: Sponsor Attachment; • Email-Phone Script.pdf, Category: Recruitment Materials;

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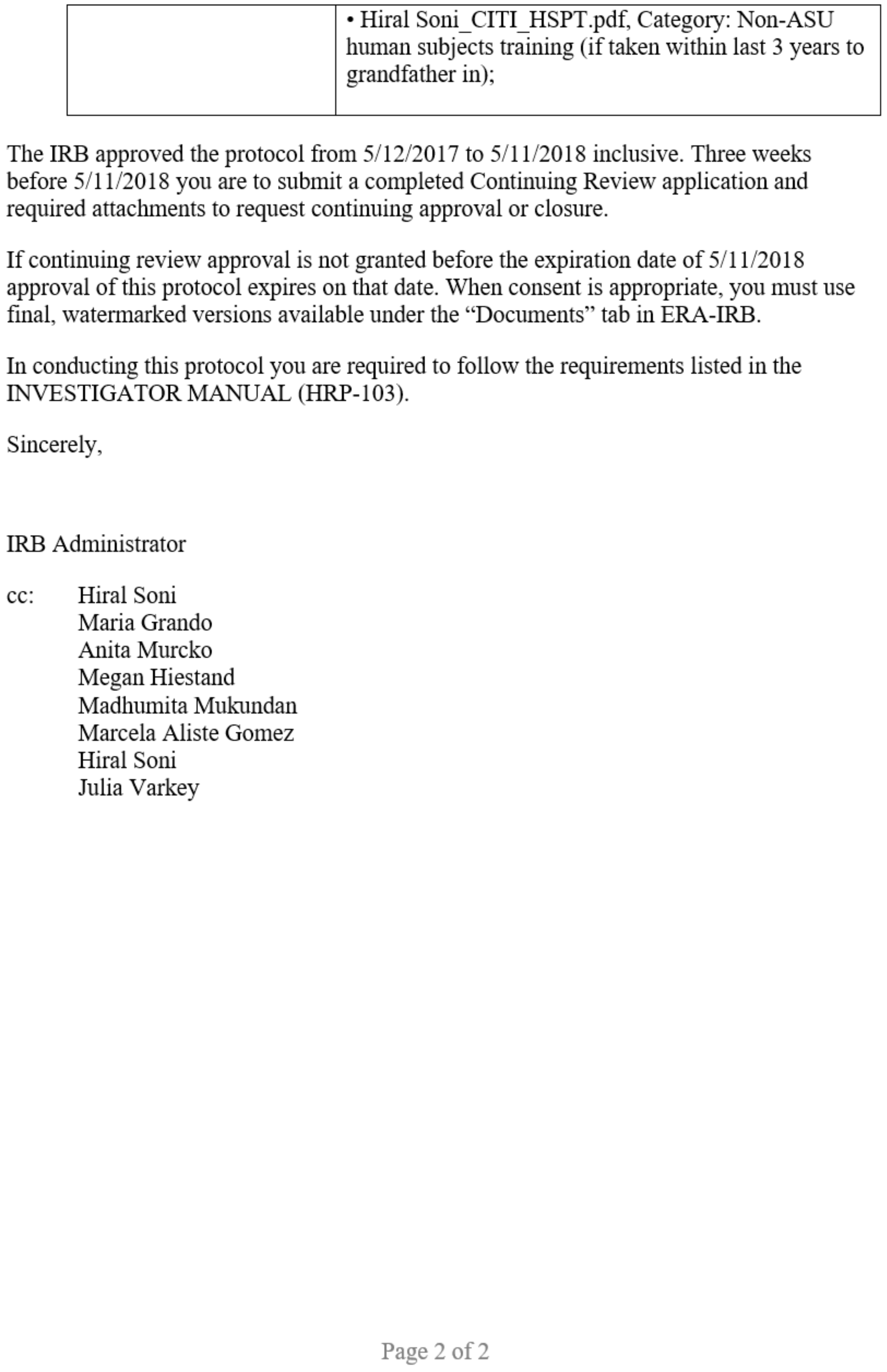


	• Hiral Soni_CITI_HSPT.pdf, Category: Non-ASU human subjects training (if taken within last 3 years to grandfather in);

The IRB approved the protocol from 5/12/2017 to 5/11/2018 inclusive. Three weeks before 5/11/2018 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 5/11/2018 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

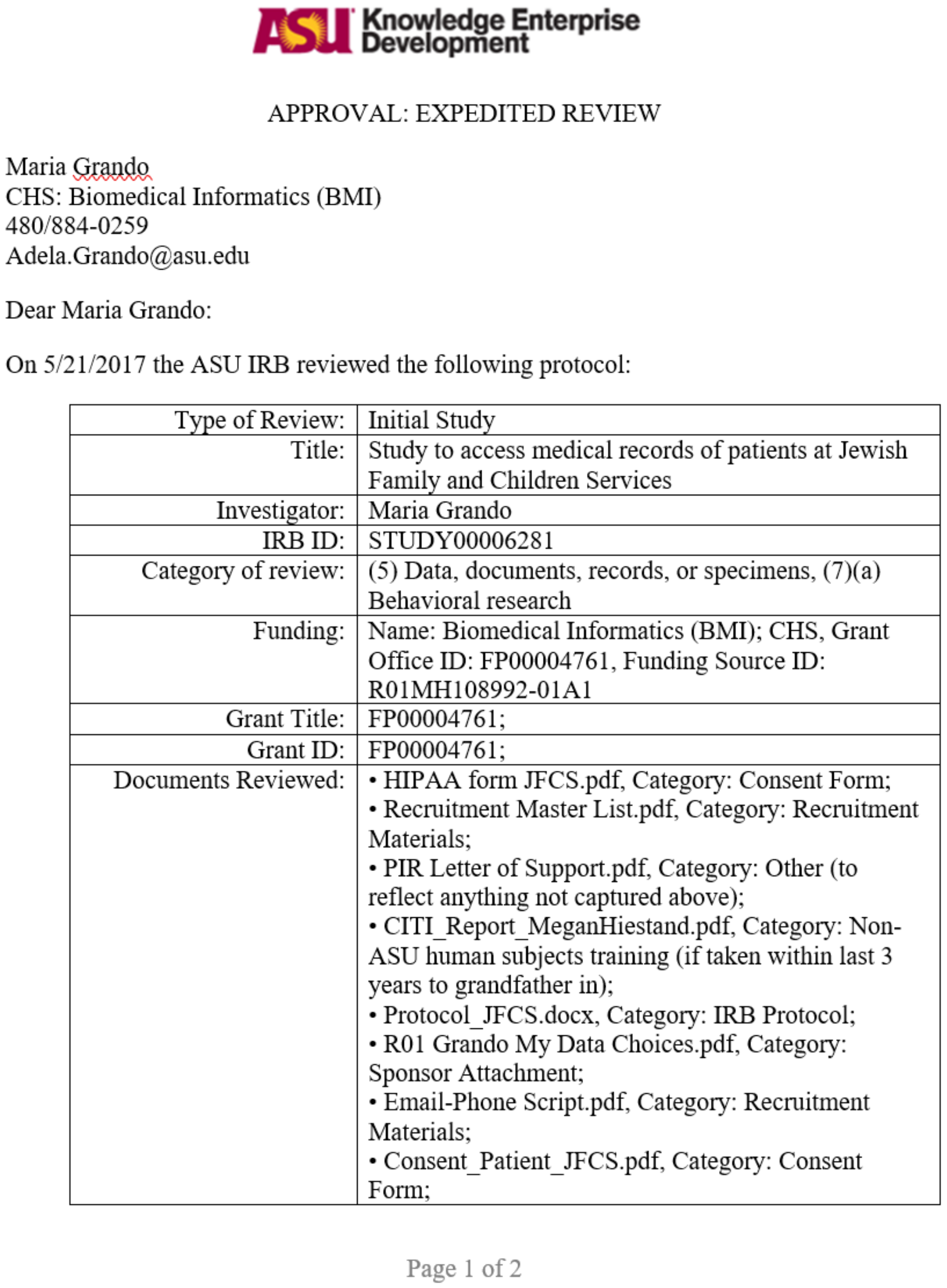
In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Hiral Soni
Maria Grando
Anita Murcko
Megan Hiestand
Madhumita Mukundan
Marcela Aliste Gomez
Hiral Soni
Julia Varkey

Study to access medical records of patients at Jewish Family and Children Services (ASU IRB #6281)



ASU Knowledge Enterprise Development

APPROVAL: EXPEDITED REVIEW

Maria Grando
CHS: Biomedical Informatics (BMI)
480/884-0259
Adela.Grando@asu.edu

Dear Maria Grando:

On 5/21/2017 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Study to access medical records of patients at Jewish Family and Children Services
Investigator:	Maria Grando
IRB ID:	STUDY00006281
Category of review:	(5) Data, documents, records, or specimens, (7)(a) Behavioral research
Funding:	Name: Biomedical Informatics (BMI); CHS, Grant Office ID: FP00004761, Funding Source ID: R01MH108992-01A1
Grant Title:	FP00004761;
Grant ID:	FP00004761;
Documents Reviewed:	• HIPAA form JFCS.pdf, Category: Consent Form; • Recruitment Master List.pdf, Category: Recruitment Materials; • PIR Letter of Support.pdf, Category: Other (to reflect anything not captured above); • CITI_Report_MeganHiestand.pdf, Category: Non-ASU human subjects training (if taken within last 3 years to grandfather in); • Protocol_JFCS.docx, Category: IRB Protocol; • R01 Grando My Data Choices.pdf, Category: Sponsor Attachment; • Email-Phone Script.pdf, Category: Recruitment Materials; • Consent_Patient_JFCS.pdf, Category: Consent Form;

	• Hiral Soni_CITI_HSPT.pdf, Category: Non-ASU human subjects training (if taken within last 3 years to grandfather in); • AzHeC_ASU%20Agreement%2009_02_16-2.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); • Card Example.pdf, Category: Other (to reflect anything not captured above);

The IRB approved the protocol from 5/21/2017 to 5/20/2018 inclusive. Three weeks before 5/20/2018 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 5/20/2018 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

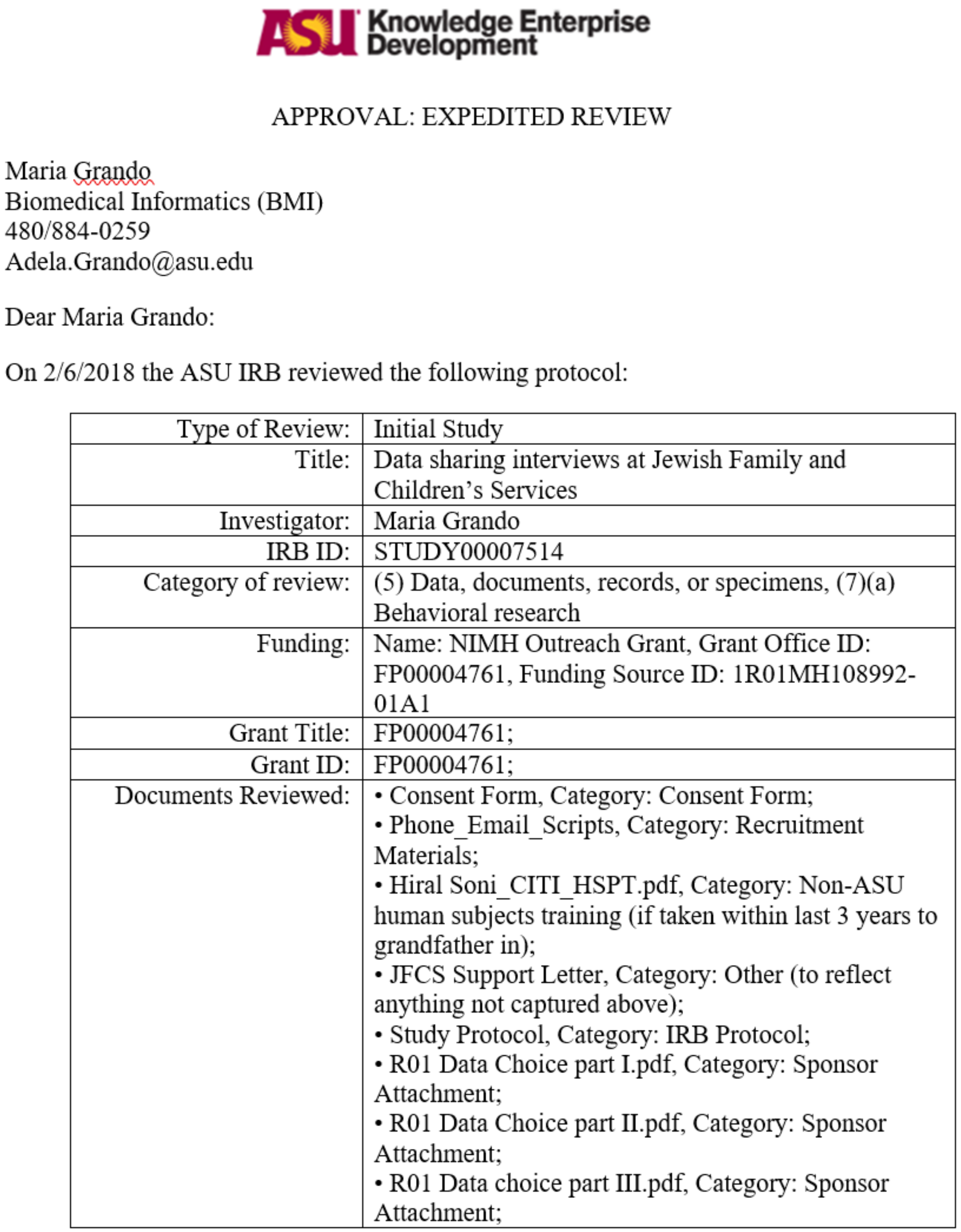
In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Hiral Soni
Maria Grando
Megan Hiestand
Hiral Soni
Madhumita Mukundan
Julia Varkey
Marcela Aliste Gomez
Anita Murcko

Data sharing interviews at Jewish Family and Children's Services (ASU IRB #7514)



ASU Knowledge Enterprise Development

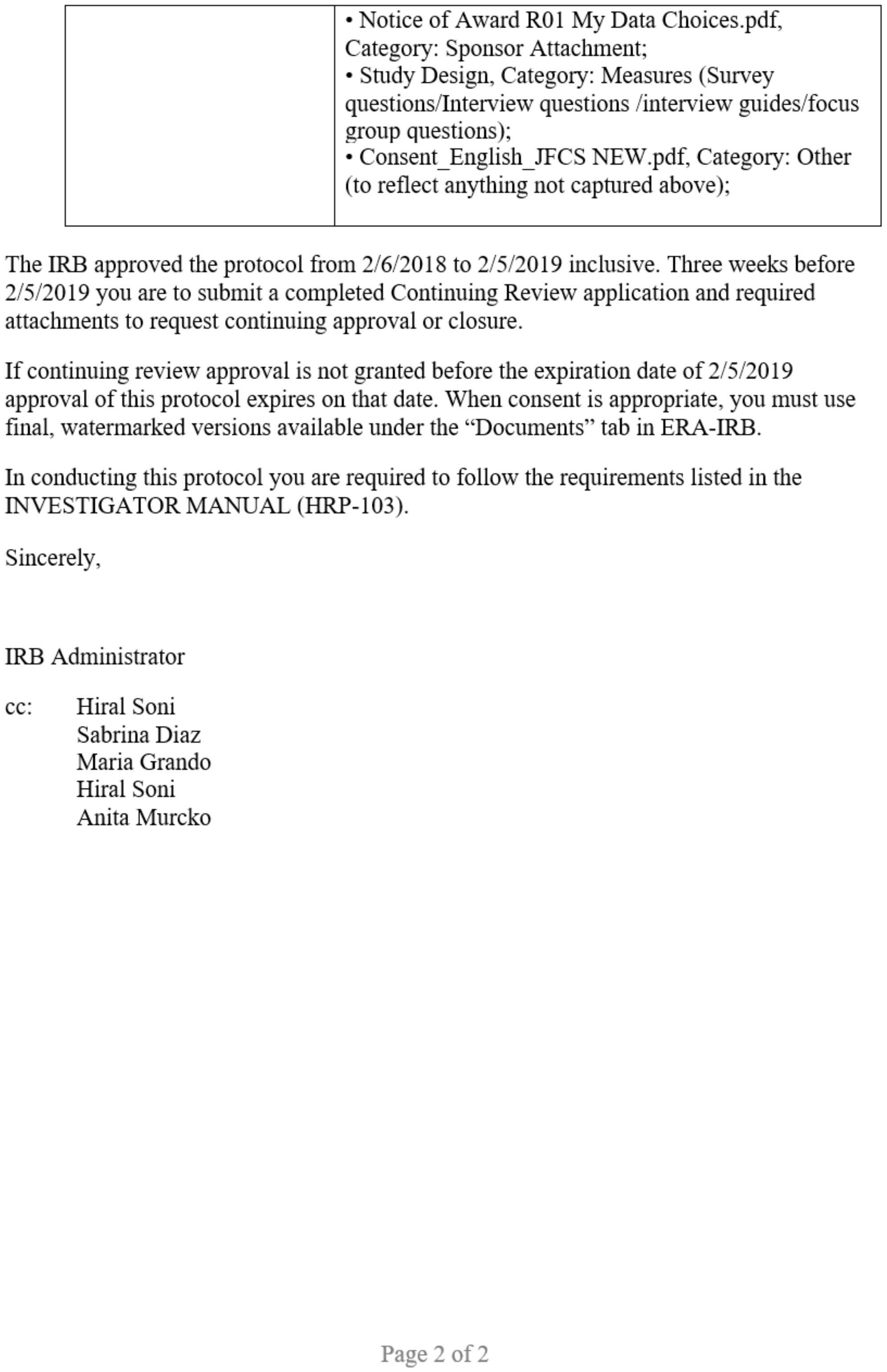
APPROVAL: EXPEDITED REVIEW

Maria Grando
Biomedical Informatics (BMI)
480/884-0259
Adela.Grando@asu.edu

Dear Maria Grando:

On 2/6/2018 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Data sharing interviews at Jewish Family and Children's Services
Investigator:	Maria Grando
IRB ID:	STUDY00007514
Category of review:	(5) Data, documents, records, or specimens, (7)(a) Behavioral research
Funding:	Name: NIMH Outreach Grant, Grant Office ID: FP00004761, Funding Source ID: 1R01MH108992-01A1
Grant Title:	FP00004761;
Grant ID:	FP00004761;
Documents Reviewed:	• Consent Form, Category: Consent Form; • Phone_Email_Scripts, Category: Recruitment Materials; • Hiral Soni_CITI_HSPT.pdf, Category: Non-ASU human subjects training (if taken within last 3 years to grandfather in); • JFCS Support Letter, Category: Other (to reflect anything not captured above); • Study Protocol, Category: IRB Protocol; • R01 Data Choice part I.pdf, Category: Sponsor Attachment; • R01 Data Choice part II.pdf, Category: Sponsor Attachment; • R01 Data choice part III.pdf, Category: Sponsor Attachment;



	• Notice of Award R01 My Data Choices.pdf, Category: Sponsor Attachment; • Study Design, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Consent_English_JFCS NEW.pdf, Category: Other (to reflect anything not captured above);

The IRB approved the protocol from 2/6/2018 to 2/5/2019 inclusive. Three weeks before 2/5/2019 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 2/5/2019 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

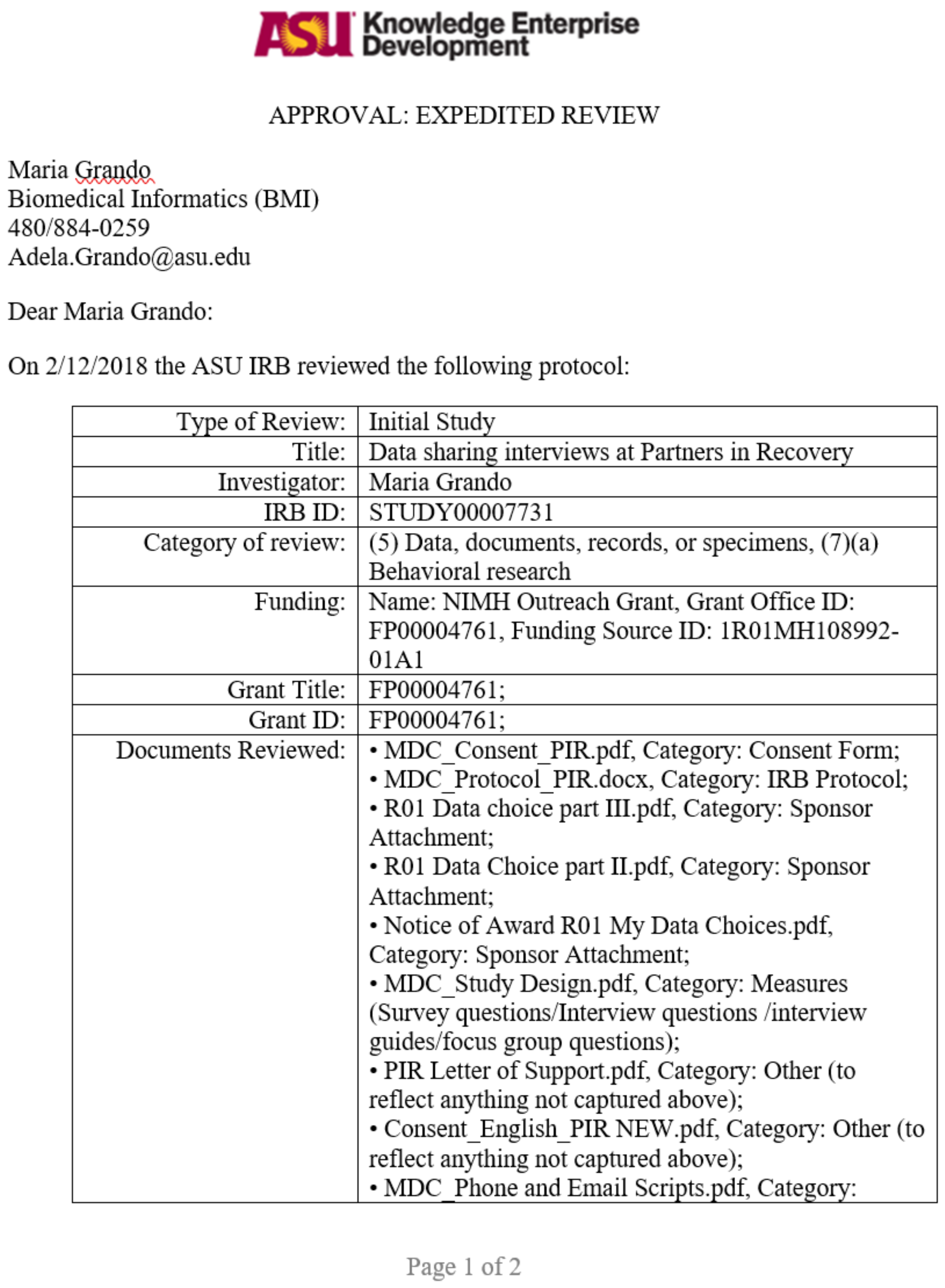
In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Hiral Soni
Sabrina Diaz
Maria Grando
Hiral Soni
Anita Murcko

Data sharing interviews at Partners in Recovery (ASU IRB #7731)



ASU Knowledge Enterprise Development

APPROVAL: EXPEDITED REVIEW

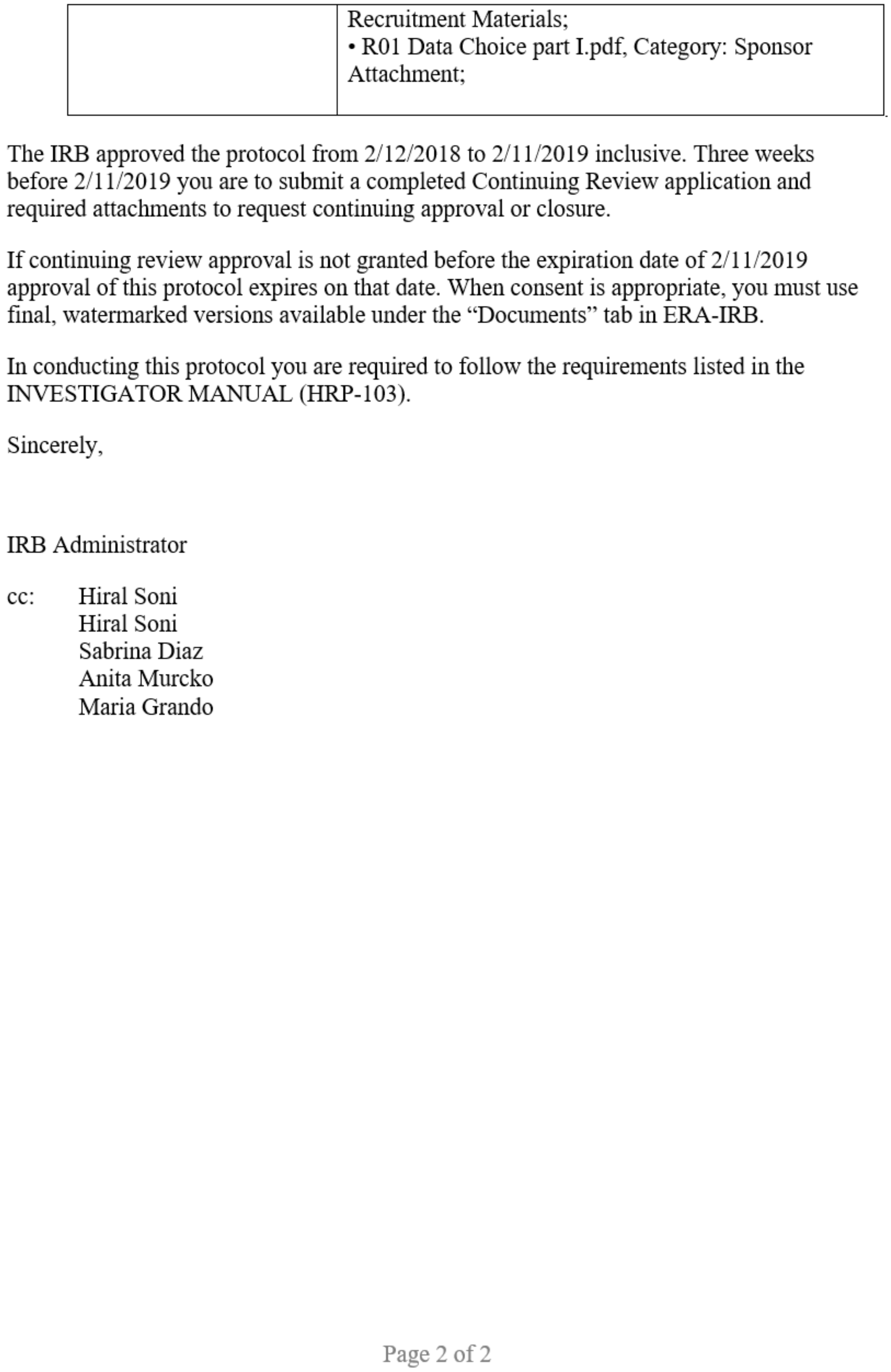
Maria Grando
Biomedical Informatics (BMI)
480/884-0259
Adela.Grando@asu.edu

Dear Maria Grando:

On 2/12/2018 the ASU IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Data sharing interviews at Partners in Recovery
Investigator:	Maria Grando
IRB ID:	STUDY00007731
Category of review:	(5) Data, documents, records, or specimens, (7)(a) Behavioral research
Funding:	Name: NIMH Outreach Grant, Grant Office ID: FP00004761, Funding Source ID: 1R01MH108992-01A1
Grant Title:	FP00004761;
Grant ID:	FP00004761;
Documents Reviewed:	• MDC_Consent_PIR.pdf, Category: Consent Form; • MDC_Protocol_PIR.docx, Category: IRB Protocol; • R01 Data choice part III.pdf, Category: Sponsor Attachment; • R01 Data Choice part II.pdf, Category: Sponsor Attachment; • Notice of Award R01 My Data Choices.pdf, Category: Sponsor Attachment; • MDC_Study Design.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • PIR Letter of Support.pdf, Category: Other (to reflect anything not captured above); • Consent_English_PIR NEW.pdf, Category: Other (to reflect anything not captured above); • MDC_Phone and Email Scripts.pdf, Category:

Page 1 of 2



	Recruitment Materials; • R01 Data Choice part I.pdf, Category: Sponsor Attachment;

The IRB approved the protocol from 2/12/2018 to 2/11/2019 inclusive. Three weeks before 2/11/2019 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 2/11/2019 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the “Documents” tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Hiral Soni
Hiral Soni
Sabrina Diaz
Anita Murcko
Maria Grando