Informatics Methods to

Support Patient-Driven Granular Medical Record Sharing

by

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ABSTRACT

The traditional model of assessing and treating behavioral health (BH) and physical health (PH) in silos is inadequate for supporting whole-person health and wellness. The integration of BH and PH may result in better care quality, patient-provider experiences, outcomes, and reduced costs. Cross-organizational health data sharing between BH and PH providers is critical to patients with BH conditions (BHCs).

In the last few decades, many initiatives -including health information exchange organizations- have facilitated cross-organizational health data sharing. The current challenge is affording meaningful consent and ensuring patient privacy, two of the core requirements for advancing the adoption and use of health information technology (HIT) in the US.

The Office of the National Coordinator for HIT (ONC) recommends that patients should be given granular control beyond the “share all” or “share none” approach widely used currently in consent practices. But there is no consensus on the variables relevant to promote granularity in data sharing to honor privacy satisfaction for patients. As a result, existing granular data sharing (GDS) studies use ad-hoc and non-standardized approaches to implement or investigate patient data sharing preferences.

Novel informatics methods were proposed and piloted to support patient-driven GDS and to validate the suitability and applicability of such methods in clinical environments. The hypotheses were: H1) the variables recommended by the ONC are relevant to support GDS; H2) there is diversity in medical record sharing preferences of individuals with BHCs; and H3) the most frequently used sensitive data taxonomy captures sensitive data sharing preferences of patients with BHCs.

Findings validated the study hypotheses by proposing an innovative standards-based GDS framework, validating the framework with the design and pilot testing of a clinical decision support system with 209 patients with BHCs, validating with patients the adequacy of the most frequently used sensitive data taxonomy, and systematically exploring data privacy views and data sharing perceptions of patients with BHCs.

This research built the foundations for a new generation of future data segmentation methods and tools that advances the vision of the ONC of creating standards-based, interoperable models to share sensitive health information in compliance with patients' data privacy preferences.

DEDICATION

This dissertation is dedicated to,

My Peace Corps Volunteer Teacher,

Thank you for showing me unconditional love and for supporting me throughout these years. Your faith in me and your constant encouragement are what brought me here today. Thank you for inspiring me to chase my dreams, Rebekah Schulz!

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Standing here today, I stand on your shoulders. You both have sacrificed a lot for me to reach this far. Thank you for everything. Mama and papa, I love you!

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LIST OF ABBREVIATIONS

Abbreviation	Description
42 CFR Part 2	Title 42 of the Code of Federal Regulations Part 2: Confidentiality of Substance Use Disorder Patient Records
AHRQ	Agency for Healthcare Research and Quality
AMI	Any Mental Illness
BH	Behavioral Health
BHC	Behavioral Health Conditions
BHP	Behavioral Healthcare Providers
CDC	Centers for Disease Control and Prevention
EHR	Electronic Health Record
GDS	Granular Data Sharing
GLMM	Generalized Linear Mixed Model
GMI	General Mental Illness
HIE	Health Information Exchange
HIPAA	Health Information Portability and Accountability Act
HIV	Human Immunodeficiency Virus
IRB	Institutional Review Board
MDC	My Data Choices
NCVHS	National Committee on Vital and Health Statistics
NIMH	National Institute of Mental Health

Abbreviation	Description
ONC	Office of the National Coordinator of Health Information Technology
PCHR	Personally Controlled Health Records
PCP	Primary Care Providers
PEMAT-P	Patient Education Materials Assessment Tool for Printable Materials
PH	Physical Health
PHI	Personal 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
VA	Veteran Administration

CHAPTER 1

INTRODUCTION

1. 1 Background

Electronic health record (EHR) has created a wide range of opportunities to collect, store, and share data on a larger scale than possible with paper records. EHRs enable the utilization of health information exchange (HIE) to facilitate machine-to-machine information exchange across multiple health facilities and organizations to provide tailored information to clinicians when needed. This exchange of information allows the integration and coordination of two inextricably linked components of health that have traditionally been disconnected, physical health (PH)– the state of an individual's physical body and how well it operates (*Physical Wellness Toolkit*, 2017) and behavioral health (BH)– the mental/emotional well-being and/or actions that affect wellness (Hedden et al., 2015). The integration of care enables the provision of better care via a team-based approach to caring for the total person (*NIMH » Integrating Mental Health*, n.d.). Caring for the whole person is critical to those receiving both BH and PH treatment who often see multiple providers and require coordinated care amongst a variety of providers and organizations (*Integrated Health*, n.d.). Individuals with behavioral health conditions (BHCs), for example, often receive treatments at multiple BH and PH care organizations and could benefit from cross-organizational health data sharing between various providers (California Health Care Foundation, 2008; *HealthIT.Gov.*, n.d.; *SAMHSA-HRSA Center for Integrated Health Solutions.*, n.d.). However, patients with BHCs are often at a higher risk of stigma and discrimination (Ricciardi, 2010; Saks et al., 2018). There is a need to improve cross-organizational

health data sharing for patients, especially those with BHCs, to motivate them in participating in cross-organizational health data sharing practices.

BHCs include substance use disorders, serious psychological distress, suicide, and mental disorders (*National Framework for Quality Improvement in Behavioral Health Care. Substance Abuse and Mental Health Services Administration*, n.d.). Mental disorder is classified as any mental illness (AMI) or serious mental illness (SMI). AMI, also known as general mental illness (GMI), is a mental, behavioral, or emotional disorder that ranges from no impairment to mild, moderate, and even severe impairment (*NIMH » Mental Illness*, n.d.). SMI is a mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities (*NIMH » Mental Illness*, n.d.). Percent of adults aged 18 or older in the United States suffering from GMI increased from 17.7 (39.8 million people) in 2008 to 20.6 (51.5 million people) in 2019, while SMI increases from 3.7% (8.3 million people) to 5.2% (13.1 million people) respectively (*NIMH » Mental Illness*, n.d.). Among patients with GMI have a 40% higher risk of developing cardiovascular and metabolic diseases than the general population and about 70% also have at least one additional medical condition, such as type 2 diabetes or hypertension (*HealthIT.Gov.*, n.d.; *NIMH » Mental Illness*, n.d.). SMI patients, on average, have higher rates of emergency room, primary care and specialty care visits (*HealthIT.Gov.*, n.d.; *SAMHSA-HRSA Center for Integrated Health Solutions.*, n.d.).

Consent decisions related to sharing health data is vital in cross-organizational health data sharing between providers; for patients with BHCs, however, their decisions can be influenced by perceived social stigma, fears related to discrimination and

insurance or legal concerns (California Health Care Foundation, 2008; Grando et al., 2017; Hiestand et al., 2017; Soni et al., 2018). There is a need to improve the current consent process for this growing population whose data sharing decisions are impacted by many factors.

Affording meaningful consent and ensuring patient privacy have become an issue of paramount concern to patients in this new era. Health information privacy is an individual's right to control the acquisition, uses, or disclosures of their identifiable health data (Barrows & Clayton, 1996). Protecting patient privacy and securing their health information was a core requirement for the adoption and use of EHR in the United States. The Office of the National Coordinator for Health Information Technology (ONC) urges healthcare facilities to know that "EHR represents a unique and valuable human being: it is not just a collection of data that you are guarding – it's a life" (*Guide to Privacy and Security of Health Information. Office of National Coordinator for Health IT.*, n.d.). The security and privacy of digital patient information is, therefore, quite vital.

Federal and state laws and policies have been established to regulate health information sharing to encourage patients to seek treatment, satisfy patient privacy rights, and to allow them to exercise information autonomy. 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 US Department of Health and Human Services, 2014). The Confidentiality of Alcohol and Drug Abuse Patient Records, 42 Code of Federal Regulations 2 (42 CFR Part 2) guarantees confidentiality for individuals seeking substance use disorder treatment from federally assisted programs (42 CFR Part 2, n.d.). While these laws encourage treatment-

seeking behaviors, satisfying patient privacy needs requires understanding individual patients' perceptions and preferences regarding the sharing of their medical information. BHCs, for instance, are tied to many stigmas that may affect patients' perceptions and preferences for sharing of their medical information (Dinos et al., 2004). There is a need for a solution that offers patients a greater degree of control over the sharing of their digital information.

To increase patient satisfaction and activate patient engagement, two key components that are recognized to improve care quality (Carman et al., 2013; Chase, 2012; Kohn & Corrigan, 1999; McGinnis et al., 2011; *National EHealth Collaborative Shares Results Of 2012 Stakeholder Survey*, n.d.; Sajid & Baig, 2007; Wilkins, 2012), the ONC recommended in 2010 that patients should be given more control over the sharing of their personal health information (PHI). According to the ONC, "patients should have a greater degree of choice to determine, at a granular level, which PHI should be shared with whom, and for what purpose" (*Health IT Policy Committee*, n.d.). Granular data sharing (GDS) refers to "a detailed choice an individual makes to share specific types of health data…[enabling] the capture and exchange of patients' preferences to advance coordination of care in multiple settings for treatment, payment, healthcare operations, and research" (Office of the National Coordinator for Health Information Technology, 2020). Patient-directed selection and sharing of their granular digital information such as diagnoses, laboratory results, medications, etc. could lessen privacy concerns and promote higher patient satisfaction. Implementing GDS requires the identification of relevant variables such as sensitive data types, purposes of use, and data recipients. Regarding sensitive data types, there is a need to identify categorizations of data that are

generally considered sensitive and education of individuals on these categorizations. Identification of relevant GDS variables and patient education on these is key to the development and deployment of clinical decision support systems that inform patient choices and comply with their preferences.

There has been a movement toward GDS research in the last decade. Multiple studies have acknowledged the need for more comprehensive sensitive data categorizations and assessment of individual perceptions on the control of health data sharing to satisfy patient privacy needs (Bell et al., 2014; Bell et al., 2014a; Caine & Hanania, 2013; Grando et al., 2017; *SAMHSA-HRSA Center for Integrated Health Solutions.*, n.d.; Whiddett et al., 2006). Currently, however, there is no universal agreement on types of data generally considered sensitive. As a result, data sensitivity 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 may influence preferences or willingness to share sensitive data that could significantly impact one's care and treatment.

The National Committee on Vital and Health Statistics (NCVHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) have each created sensitive data categorizations (taxonomies) to capture patients' data sharing needs (National Committee on Vital and Health Statistics, n.d.; SAMHSA, n.d.). The NCVHS taxonomy has been used to implement and evaluate an online consent tool for the purpose of sharing medical records for research (Bell et al., 2014; Kim et al., 2017) and care (Caine et al., 2015; Caine & Hanania, 2013; Schwartz et al., 2015; Tierney et al., 2015).

The SAMHSA taxonomy has been implemented in Consent2Share, a consent engine developed by SAMHSA and the Veteran Administration (VA) to support GDS (Grando et al., 2020; Saks et al., 2018; Soni et al., 2018, 2020, 2021). Soni et al. (2020, 2021) asked patients to sort their own medical records using the SAMHSA categories and found that 42% of patients (N=25) thought that the SAMHSA terminology was unclear. For instance, they suggested substituting the category "Drug Abuse" for "Drug Use" (Soni et al., 2020, 2021). NCVHS categories appear less ambiguous and are frequently used to assess GDS (Bell et al., 2014; Caine et al., 2015; Caine & Hanania, 2013; Kim et al., 2017; Schwartz et al., 2015; Tierney et al., 2015). However, neither NCVHS nor SAMHSA taxonomies has been validated with key stakeholders, including patients, guardians, and health providers, to inform strategic agencies, such SAMHSA and ONC, about the adequacy of these taxonomies to capture patients' privacy needs.

Studies on GDS approaches have been limited (Bell et al., 2014; Caine et al., 2015; Dhopeshwarkar et al., 2012; Grando et al., 2017; Schwartz et al., 2015; Teixeira et al., 2011; Whiddett et al., 2006). Few studies have attempted to understand individual privacy perceptions and preferences for sharing medical information (Caine & Hanania, 2013; Grande et al., 2015; Grando et al., 2017; Kim et al., 2017; King et al., 2012; Soni et al., 2019; Weitzman et al., 2012). Although GDS aims to protect sensitive data from unauthorized disclosures, there are very few studies focusing on patient groups with stigma concerns, such as those with BHCs (Grando et al., 2017, 2020; Ivanova et al., n.d., 2020; Soni et al., 2021). There is a need to assess the granular data sharing views of patients with BHCs to provide actionable insights into the data privacy and

confidentiality needs of individuals whose data is subject to highly protective laws, such as the 42 CFR Part 2.

Additionally, there has been little emphasis on validating the electronic consent tools or processes to support GDS (Caine & Hanania, 2013; Grando & Schwab, 2013; Kim et al., 2017; Meslin et al., 2013; Schwartz et al., 2015). There is no consensus among data privacy researchers and agencies on variables that should be included in consent engines to honor the patient GDS desires (Soni et al., 2020). Studies assessing individuals' GDS preferences have used a variety of variables such as data recipient and data type (Bell et al., 2014; Caine et al., 2015; Caine & Hanania, 2013; Grando et al., 2017; Weitzman et al., 2012), data type, data recipient, and data use purpose (Grande et al., 2015; Kim et al., 2017; Soni et al., 2019a, 2019b), data type, data recipient and data sharing duration (e.g., one year) (Schwartz et al., 2015; Tierney et al., 2015), data recipient and participant's characteristics (e.g. age) (Teixeira et al., 2011), and data type and participant's characteristics (King et al., 2012). As a result, it is not possible to directly compare study outcomes, hindering the ability to fully understand the current status of GDS. To advance the GDS vision of ONC, there is a need to identify relevant variables and replace the non-standardized data sharing processes with formal methods, thereby advancing the availability and applicability of standards-based GDS (Grando et al., 2020; Grando & Schwab, 2013; Grando et al., 2017; Saks et al., 2018). This is essential for granular information sharing research, healthcare delivery, and the development of consent-based data sharing technology.

The overall goal of this study is to address the ad-hoc approaches that currently exist in GDS research. Specifically, this study aims to address these key **knowledge**

gaps: 1) lack of consensus on the health data variables relevant to honor patient GDS desires; 2) need for patient validation of existing sensitive data taxonomies used to support GDS and categorize sensitive medical records; and 3) sparse research on GDS of patients with BHCs. Our **hypotheses** are: H1) the ONC variables (information, recipient, and purpose of use) are relevant to participants' sharing preferences as demonstrated by statistically significant differences in data sharing choices; H2) there is diversity in medical record sharing preferences of individuals with BHCs; and H3) the NCVHS taxonomy captures sensitive data sharing needs of patients with BHCs.

A literature review on state-of-the-art methods and frameworks available to assess GDS perceptions of individuals and their willingness to share medical records revealed ad-hoc approaches used to support patient-driven GDS. These ad-hoc approaches hinder EHRs interoperability and discoverability in GDS research. To address this knowledge gap, we propose a standard based **GDS framework** based on the ONC variables, and we validate the framework using a **clinical decision support system, My Data Choices (MDC),** with individuals with BHCs to: 1) identify data sharing priority variables, 2) validate the adequacy of the most frequently used sensitive data categorizations, and 3) systematically explore GDS views of patients with BHCs.

A three-step approach was used to design the MDC clinical decision support tool. First, the MDC interface was designed using the concept of scenarios to model the GDS patient experience at an integrated care facility within a healthcare network. In the three scenarios created, the data source (patients' choices grantors) was behavioral healthcare providers (BHP) within the integrated care. The **NCVHS sensitive data taxonomy** was selected to model sensitive data types (domestic violence, genetic information, mental

health information, reproductive health, substance abuse) and support medical record sharing granular choices. Three recipients (patients' choices grantees) were selected to capture health data sharing preferences of patients within and outside of the healthcare network: 1) primary care providers (PCPs) within participants' facility, 2) PCPs outside the participants' facility, and 3) BHP outside of participants' facility. Two data use purposes (treatment and research) were chosen.

Second, patient education content was designed to explain the NCVHS sensitive data types using systematic approaches based on key concepts from national pedagogical guidelines and Information Systems research. The incorporation of patient EHR data into each data category to provide realistic data sharing scenarios that patient could connect to and the involvement of clinicians and patients in the design and evaluation led to the production of high-quality health information communication contents. The content was embedded into the MDC clinical decision support system via info buttons to help patients understand their NCVHS data type choices.

Finally, the MDC tool was pilot tested with patients in a prospective study. A sample of 209 English and Spanish speaking patients with BHCs and guardians were recruited for the study. Eligible participants used the MDC tool to indicate their sharing preferences in the scenario based GDS intervention. A semi-structured survey was used to collect participants' perceptions of the NCVHS taxonomy.

1.2 Research Aims

Aim 1: Review literature on perceptions on data sensitivity and sharing

Conduct a systematic literature review of methodological approaches to implement GDS and assess individuals' perceptions on data sensitivity, privacy, and willingness to share their EHRs. Identify knowledge gaps to guide research aims.

Aim 2: Design and implement patient education content to support informed data sharing

Propose an approach that combines key concepts from national pedagogical guidelines and Information Systems research to systematically design and evaluate patient education content for each of the sensitive data categories in the NCVHS taxonomy. Incorporate medical record data elements (e.g., labs, medications, procedures, etc.) from de-identified EHR extracts data into the educational content.

Aim 3: Propose and validate a GDS framework with patients with behavioral health conditions

Use the knowledge gaps identified during the systematic literature review (Aim 1), to propose a GDS framework based on variables from the ONC and validate the framework with a clinical decision support system (MDC). Embed the education content developed in Aim 2 in the MDC tool to support informed data sharing choice. Recruit patients with BHCs and their guardians to use the MDC tool to express GDS choices. Solicit views on the adequacy of the NCVHS taxonomy to capture their data privacy needs.

1.3 Research Outcomes

We proposed a **GDS framework** based on the ONC variables (data source, data recipient, data type, and data use purpose). The framework was validated with the design and pilot testing of the **MDC clinical decision support system**. When patients used MDC to make data sharing choices, the ONC variables had significant effect on their

preferences, validating hypothesis H1. Insights from this research help to replace the 'ad-hoc' approaches currently existing in GDS research with formal methods to advance patient-controlled GDS.

Ours was the largest (n=209) study to assess GDS preferences of vulnerable populations. Evaluation of sharing preferences revealed that all participants desired granular control over the sharing of their health data, validating hypothesis H2.

Our study was the first one to validate the **NCVHS taxonomy** with patients. Patients indicated the suitability of the taxonomy to capture their data sharing preferences, validating hypothesis H3.

1.4 Outline of Thesis

The Introduction is an overview of the scope of the research, aims and research plan. In Chapter 2, a summary of a literature review on methods assessing patients' data privacy and data sensitivity perceptions is presented. Chapter 3 describes a method for the development of education content and validates it with the design and evaluation of the five sensitive data categories in the NCVHS taxonomy. Chapter 4 presents the proposed framework, design and deployment of the MDC decision support system to valid the proposed framework, validation of the NCVH taxonomy and the recruitment of patients with BHCs. Conclusions, limitations, and impact are provided in Chapter 5.

CHAPTER 2

SYSTEMATIC LITERATURE REVIEW TO CHARACTERIZE GRANULAR DATA SHARING STUDIES

2.1 Introduction

We conducted a systematic literature review to understand the state-of-the-art methods and frameworks available to implement GDS and assess data sharing and/or data sensitivity perceptions. This chapter summarizes methods and frameworks available to support GDS and evaluate willingness to share health data and sensitivity perceptions. This research corresponds to Aim 1 of the thesis.

In collaboration with domain experts and a librarian, relevant keywords and databases were identified. We searched PubMed, Scopus, Elsevier, BioMed Central and IEEE Xplore for journal and conference articles published between 2009 and 2019 with a focus on design, assessment or evaluation of willingness to share and/or data sensitivity perceptions of patients, legal guardians or surrogates of the patients, healthy individuals and health providers. In addition, a snowball search using both backward and forward methods (Wohlin, 2014) was used to find additional relevant articles. Of the 1,065 articles retrieved, five met all inclusion criteria. Additionally, seven publications were found from the snowball search, three from backward approach and four from forward method. Overall, 12 articles meeting all inclusion criteria were included in the review.

Most studies (N=7) used qualitative methods (such as interviews, surveys, focus groups, etc.) to evaluate individuals-driven GDS. Two studies used card sorting tasks, two implemented a demonstration exercise to solicit patients' sharing preferences and to

examine how healthcare providers react to such preferences during care encounters, and one study implemented electronic consent tool that honored granular medical sharing preferences of patients for research. In terms of evaluation, most of the studies focused on individuals' sharing preferences for care (N=6), followed by research (N=4), and then both care and research (N=2).

First, the review revealed that patients want control over the sharing of their medical records. Of the 12 studies, eight publications reported the desire of individuals to exercise control over the sharing of their digital health records including who could access what information in their EHR (Bell et al., 2014; Caine et al., 2015), restricting access to some information from some providers (Caine & Hanania, 2013; Grando et al., 2017), and the willingness to share if given granular choices (Bell et al., 2014). Additionally, participants' willingness to share data decreases for some data recipients such as for-profit research organization (Soni et al., 2019a, 2019b), the number of health record items restricted was higher for for-profit institution recipients (Kim et al., 2017), and participants were more willing to share with clinicians involved in their care than non-clinical staff (Teixeira et al., 2011). It was also reported that patients with and without sensitive records preferred less sharing of sensitive versus less-sensitive information and no patients wanted to share all records with all potential recipients (Caine & Hanania, 2013).

Second, we discovered that there is no consensus on what variables are relevant to support GDS. Variables used included a combination of data recipients and data type to assess participants' sharing preferences and/or perceptions (Bell et al., 2014; Caine et al.,

2015; Caine & Hanania, 2013; Grando et al., 2017; Weitzman et al., 2012), data type, data recipients and data use purpose (Grande et al., 2015; Kim et al., 2017; Soni et al., 2019a, 2019b), data type, data recipients and duration of data restriction (Schwartz et al., 2015; Tierney et al., 2015), data recipients and participants' characteristics (Teixeira et al., 2011), and data type and participants' characteristics (King et al., 2012).

Third, the review showed that there are two taxonomies available to capture granular medical record sharing choices: NCVHS and SAMHSA taxonomies. No studies in our review used the SAMHSA taxonomy. While seven of the publications used the NCVHS taxonomy (Bell et al., 2014; Caine et al., 2015; Caine & Hanania, 2013; Grando et al., 2017; Kim et al., 2017; Schwartz et al., 2015; Tierney et al., 2015), no studies have validated the NCVHS taxonomy with patients or any other stakeholders. Additionally, no patient education materials exist for the NCVHS sensitive data categorizations to support informed data sharing decision-making.

Finally, our systematic literature review revealed limited research on data sharing for members of vulnerable populations, defined as the economically disadvantaged, racial and ethnic minorities, the uninsured, low-income children, the elderly, the homeless, those with human immunodeficiency virus (HIV), and those with other chronic health conditions such as heart disease, cancer, diabetes, and severe mental illness (*A Portrait of the Chronically Ill in America*, n.d.). While our study showed that vulnerable populations may require ancillary considerations and augmented protections in data privacy research (*WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*, n.d.), only five of the 12 studies focused on vulnerable patient groups

such as individuals living with HIV (Kim et al., 2017; Teixeira et al., 2011), patients with BHCs (Grando et al., 2017; Soni et al., 2019a, 2019b), and people with cancer (Grande et al., 2015).

In summary, while patients want control over the sharing of their medical records, there is no consensus on what variables are relevant to honor that wish. Current sensitive data taxonomies proposed to capture patients' medical record sharing choices have not been validated with patients. Finally, there is a dearth of studies focused on vulnerable patient groups—such as patients with BHCs —even though GDS is purported to protect sensitive health data.

Preliminary results of the systematic review have been published in the Journal of Biomedical Informatics-X (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

The research team applied expert advice to develop the inclusion and exclusion criteria that guided the systematic literature review. Preliminary narrative searches were conducted to identify keywords and candidate search terms. 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 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, using both backward and forward methods, 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 1). Disagreements between the two reviewers were resolved by consensus. Final outcomes were revised by a third reviewer.

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	-

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, 956 were excluded when checking inclusion and exclusion criteria during title and abstract screening. Table 2 outlines the primary objectives of the excluded articles. Of the remaining 109 publications, 104 articles appeared in the multiple databases and were removed. Upon de-duplication, five publications meeting all inclusion criteria were included in the full text review. We also identified seven additional articles through snowball search, three from backward approach and four from forward method. The snowballing process was iterated until no more relevant articles were found in the author citations. Overall, 12 articles were included in the final review. Figure 1 depicts the literature search strategy and process.

Table 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

Table 2. Continue

Objectives of Excluded Articles	# of Articles
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 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**

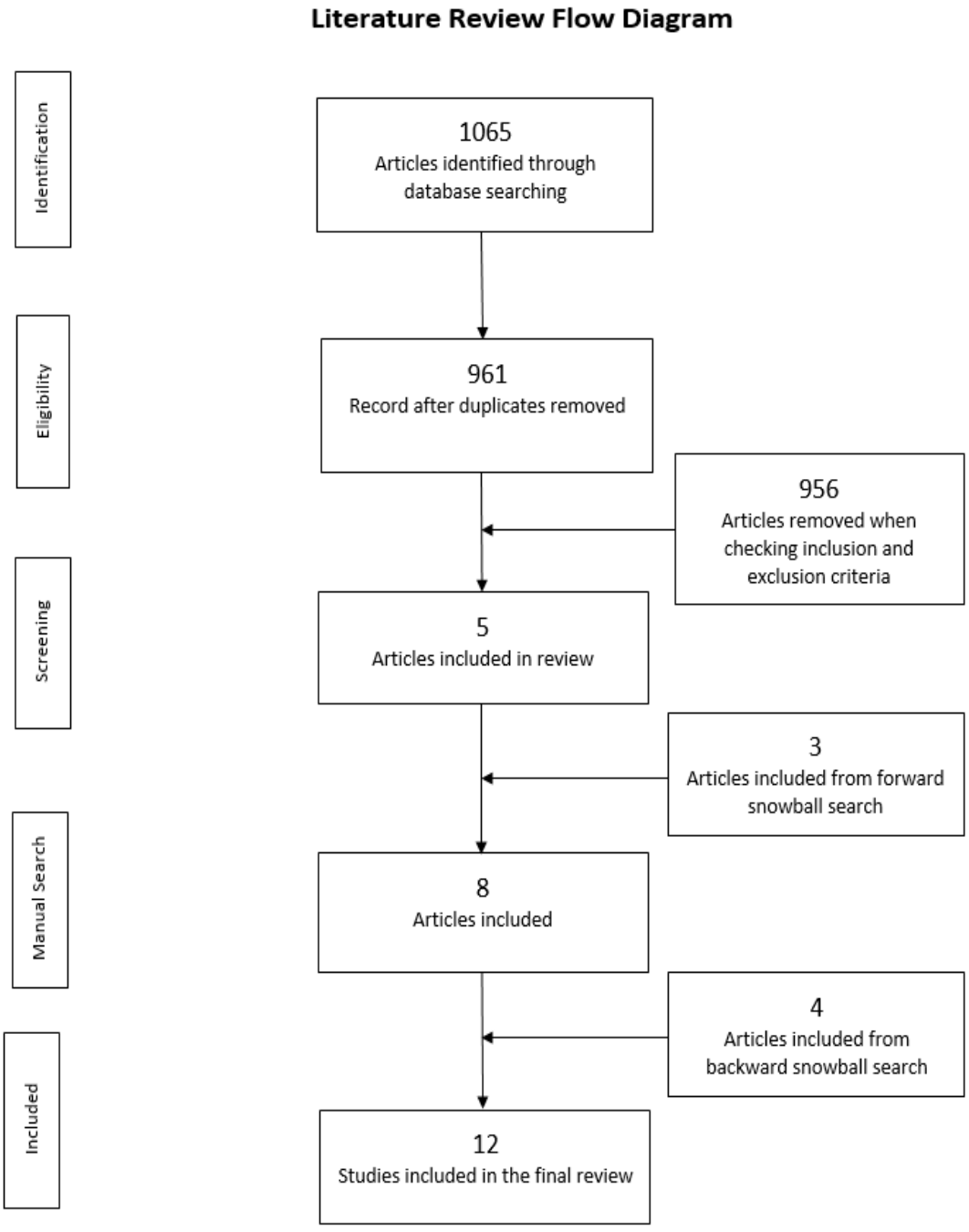

Figure 1. Literature Search Strategy and Process

2.4 Main Findings

This section summarizes the main findings of the 12 studies included in the review as outline in Table 3.

Various qualitative and quantitative methods were employed in understanding individuals' perspectives of sensitive data sharing. Five studies (Caine et al., 2015; Caine & Hanania, 2013; Schwartz et al., 2015; Teixeira et al., 2011; Tierney et al., 2015) provided insight into perceptions of health data sensitivity as well as preferences for sharing the data for care. Four studies (Grande et al., 2015; King et al., 2012; Weitzman et al., 2012) focused on evaluating sensitive perceptions and/or preferences towards sharing health data for both research and treatment. Three studies (Grande et al., 2015; King et al., 2012; Weitzman et al., 2012) provided insight into sensitivity perceptions as well as preferences for sharing health data for research.

Participants wanted control over the sharing of their medical records. Eight publications reported desire of individuals over the sharing of their digital health records. Four studies reported individuals desire to control who could access what information in their EHR (Bell et al., 2014; Caine et al., 2015), to restrict access to some information from some providers (Caine & Hanania, 2013; Grando et al., 2017), and willingness to share if given granular choices (Bell et al., 2014). Three studies reported that participants' willingness to share data decreases for some data recipients (Soni et al., 2019a, 2019b), the number of health record items restricted was higher for some recipients (Kim et al., 2017), and participants were more willing to share with clinicians involved in their care than non-clinical staff (Teixeira et al., 2011). Patients with and without sensitive records preferred less sharing of sensitive versus less-sensitive information and no patients wanted to share all records with all potential recipients (Caine & Hanania, 2013).

In terms of variables to capture individuals' GDS preferences and/or perceptions, five studies used a combination of data recipients and data type (Bell et al., 2014; Caine et al., 2015; Caine & Hanania, 2013; Grando et al., 2017; Weitzman et al., 2012), three used data type, data recipients, and data use purpose (Grande et al., 2015; Kim et al., 2017; Soni et al., 2019a, 2019b), two used data type, recipients, and duration of data restriction (Schwartz et al., 2015; Tierney et al., 2015), one used data recipient and participants' characteristics (Teixeira et al., 2011), and another used data type and participants' characteristics (King et al., 2012).

The NCVHS and SAMHSA taxonomies created to capture medical record sharing choices, have not been evaluated with patients. The NCVHS taxonomy has been used to assess patients' preferences on GDS for research (Bell et al., 2014; Kim et al., 2017) and care (Caine et al., 2015; Caine & Hanania, 2013; Schwartz et al., 2015; Tierney et al., 2015). The SAMHSA taxonomy has been implemented in Consent2Share, a consent engine developed to support GDS (Grando, 2020; Saks et al., 2018; Soni et al., 2018, 2020, 2021). None of the 12 studies used the SAMHSA taxonomy in assessing data sharing perceptions and/or preferences. Seven studies used the NCVHS taxonomy (Bell et al., 2014; Caine et al., 2015; Caine & Hanania, 2013; Grando et al., 2017; Kim et al., 2017; Schwartz et al., 2015; Tierney et al., 2015). However, the NCVHS taxonomy has never been assessed with patients.

Only five studies focused on vulnerable patient populations. Two studies focused on adults living with HIV, one assessing attitudes of persons with HIV towards their medical records storage and sharing (Teixeira et al., 2011), while the other compared data

sharing preferences of individuals living with HIV to those without HIV (Kim et al., 2017). The other two studies evaluated sharing preferences and perceptions of patients with BHCs toward research and care (Grando et al., 2017; Soni et al., 2019a, 2019b). The final study focused on understanding differences in willingness to share and sensitivity of health information of individuals with and without history of cancer (Grande et al., 2015).

Table 3. Summary of the 12 Selected Papers in Terms of Population, Objectives, Methods Used, and Key Findings

Author(s) & Year	**Population**	**Objective(s)**	**Method(s)**	**Findings**
(Teixeira et al., 2011)	Adults 21 years or older living with HIV	Assess attitudes towards PHI storage and sharing	Survey	The majority (84%) of individuals were willing to share their 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.
(Weitzman et al., 2012)	Adult 18 years or older 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.
(King et al., 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.

Table 3. Continued.

Author(s) & Year	Population	Objective(s)	Method(s)	Findings
(Caine & Hanania, 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.
(Bell et al., 2014)	Adults 18 years or older	Survey healthy volunteers to understand their choices about how the information in their health record should be shared for researchers and their choices about how the information should be shared for research	Survey and demonstration	Respondents felt comfortable participants in research if they were given choices about which portions of their medical data would be share, and with whom. Participants indicated a strong preference towards controlling access to specific data (83%), and a large proportion (68%) indicated concern about the possibility of their data being used by for-profit entities.
(Tierney et al., 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.
(Caine et al., 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.
(Schwartz et al., 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 PHI 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.

Table 3. Continued.

Author(s) & Year	Population	Objective(s)	Method(s)	Findings
(Grande et al., 2015)	Adults 18 years or older 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)
(Grando et al, 2017)	Adults 21 years and older with a mental health diagnosis	Explored patient preferences regarding what health information should be shared for care and whether these preferences vary based on data sensitivity and/or data recipients	Survey	The majority of participants (70%) wanted to share all information, sensitive and non-sensitive, though they would prefer to have control over the type of providers accessing the data. Participants did not have the same sharing desires for all providers and there was not one recipient with whom all patients wanted to share all of the information in their EHR.
(Kim et al., 2017)	Adults 18 years or older with and without the history of HIV	Developed a web-based informed consent tool and piloted it in four outpatient clinics of an academic medical center.	E-consent evaluation and survey	There was more willingness to share demographics and body measurements and least willingness to share family history and financial data. Willingness to share was greater among participants from a HIV clinic than those from internal medicine clinics. Less data was shared with for-profit researchers. Participants indicated that having granular choices for data sharing was appropriate, and that they liked being informed about who was using their data for what purposes, as well as about outcomes of the research.
(Soni et al., 2019)	English and Spanish-speaking adults 21 years or older, with a mental health diagnosis	Survey participants on their perceptions regarding data sensitivity, willingness to share health data for care and research, and related motivations.	Survey	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.

2.5 Summary of Methodologies Employed To Assess Sensitivity Perceptions and/or Sharing Preferences

This section describes GDS factors\variables used in the 12 studies to assess individuals' sharing preferences and/or perceptions as outlined in Table 4.

Table 4. Summary of Findings on Methods Used To Assess Perceptions and Sharing Preferences

Author(s) & Year	**Use Granular Data Sharing Variables**			**Evaluate significant of variables**	**Use National Sensitive Data Taxonomy**		**Assess Taxonomy**	**Involve people with BHCs**
	Type	**Recipient**	**Purpose of use**		**SAMHSA**	**NCV HS**		
(Teixeira et al., 2011)		✓						
(Weitzman et al., 2012)	✓	✓						
(King et al., 2012)	✓							
(Caine & Hanania, 2013)	✓	✓				✓		
(Bell et al., 2014)	✓	✓				✓		
(Tierney et al., 2015)	✓	✓				✓		
(Caine et al., 2015)	✓	✓				✓		
(Schwartz et al., 2015)	✓	✓				✓		
(Grande et al., 2015)	✓	✓	✓					
(Grando et al., 2017)	✓	✓				✓		✓
(Kim et al., 2017)	✓	✓	✓			✓		
(Soni et al., 2019)	✓	✓	✓					✓

2.5.1 Sensitivity Perceptions and Sharing Preferences Based on Data Type and Data Recipients

This section summarizes the five studies that utilized data type and data recipients as factors to assess sensitivity perceptions and/or sharing preferences of individuals.

As a part of a larger study, Weitzman et al. (2012) conducted a semi-structured web-based survey to capture attitudes and practices related to sharing health information of patients and parents/guardians using their personally controlled health records (PCHR) system. The authors evaluated participants' willingness to share data types including *contagious illness, violence, sexually transmitted diseases, tobacco, alcohol, other substances, genetic disorders, mental illness, family information and financial information* with the following data recipients: *out-of-hospital health care provider and the state/local public health department.* The odds of reticence to share PCHR information were estimated using chi square tests. Of the 261 participants, 63.3% reported willingness 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 financial information, family histories, mental health, alcohol, substance use, genetic, and sexual transmitted diseases information.

In a survey evaluating current consent process from the perspective of patients and providers, Grando et al. (2017) asked patients about their willingness to share their health records with data recipients classified as health providers (*PCPs, BHPS, specialty*

care providers, pharmacists, and nurses) or researchers (*non-profit research, university research, paid research, for profit research, government research, and research involving the participant's condition*). Participants were also given a list of data types classified into four categories (medication list, laboratory results, medical diagnoses, and medical history) and further subdivided into sensitive *(included domestic violence, genetic information, mental health information, reproductive health, and substance abuse, which are part of the NCVHS sensitive data categories) or non-sensitive (information outside of the NCVHS sensitive data categories)*. Participants could answer questions by selecting between one or multiple answers. Authors analyzed frequencies and percentages of 50 participants' responses as well as relationship among responses. Although most participants wanted to share with PCPs (84%) and with BHPs (78%), they desired greater levels of granularity to restrict access to some information by specialty care providers (50%), nurses (36%), pharmacists (34%), or all types of providers (6%). For research, 64% of the participants would share their medical information if it might help them get better treatments for their personal conditions. More than half of the participants (58%) expressed that the current broad consent process generally reflects their needs.

Caine and Hanania, (2013) 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. Two card sorting tasks were designed to understand patient preferences for sharing medical records with potential data recipients (*for example, providers, researchers, family members, etc.*). Authors assessed preferences of sharing

highly sensitive data (*NCVHS sensitive data categories*) and other data types (*contact information and demographics, information relevant to current condition, medications, recent test results, and past medical history (unrelated)*). The study did not capture sensitivity perceptions of participants. Descriptive statistics were used to analyze sharing preferences and ANOVA was used to examine differences in sharing patterns. Of the 30 participants, none reported that they would prefer to share all records with all potential recipients. Sharing preferences varied by type of information (0.001) and recipient (0.01). Patients with and without sensitive records were more likely to share less-sensitive information with recipients (mean=54.5%) than highly-sensitive items (mean=28.8%) and they were willing to share significantly (0.01) more information with some recipients (e.g., PCPs) than with others (e.g., non-treating physicians). Overall sharing preferences varied significantly (p=0.016) by participant. Participants with highly-sensitive health information indicated sharing a smaller percentage of their health information (mean=34.8%) than participants without highly-sensitive information (mean=48.6%).

In another study, Caine et al. (2015) reported on the outcomes of 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 content and desire for granular control over this data. Qualitative analysis was conducted to find themes. About half of the 30 participants had little to no idea what might be contained in their EHR, all participants (100%) reported that they would like access to the information in their EHR. All participants (100%) wanted to be able to control who could access what information in their EHR and wanted to be notified when their data were accessed. Participants described three distinct

methods for how they would like to manage access control of their EHR: 1) the majority (93%) wanted to grant permission, 2) 30% mentioned a desire to block or restrict certain information, and 3) 20% described a desire for temporal control where they could restrict information based on the time period during which data were collected. A majority of participants (83%) spontaneously mentioned that access to EHR data about them should be done only on a "need to know" basis.

Finally, Bell et al. (2014) assessed data sharing preferences of 70 healthy individuals. In a survey coupled with a graphic user interface, participants indicated their choices about how information in their EHR should be shared for research. Participants were given options on data types they wished to share (*demographics, test and lab results, and diagnostic information, which included the NCVHS sensitive data categories and non-sensitive information*), with data recipients of type researcher (*affiliated institutions, affiliated institutions but involving members from outside, no restriction on type of institution, commercial, mixed or non-commercial institution, and unfunded research*). Authors analyzed frequencies and percentages of participants' responses as well as association among outcome of interest using chi square test. When given choices about which aspects of their data they wished to share, 77% of the participants were significantly more willing to have their health data shared for research, 13% were less willing and 10% selected "other." Sixty-nine percent indicated that it is important to know whether their data are being shared with for-profit or non-profit institutions, 89% desire to know who is accessing their information, another 89% would feel comfortable sharing their information if they know who is accessing the information, and 49% desire to control the sharing of their biosamples such as tissue, blood, and urine.

2.5.2 Sensitivity Perceptions and Sharing Preferences Based on Data Type, Recipients, and Data Use Purpose

This section summarizes the three studies that utilized data type, data recipients, and data use purpose as factors to assess sensitivity perceptions and/or sharing preferences of individuals.

In a comparative study, Grande et al. (2015) administered an online survey with embedded conjoint experiments to understand the differences in willingness to share health information and sensitivity of health information of 2945 individuals with and without history of cancer. Using scenario-based conjoint experiments, the authors compared data recipients (*university hospitals, public health departments, and drug companies*), data use purpose (*research, quality improvement, marketing)* and data sensitivity level *(lower = medical history, and higher = medical history plus results of a personal genetic test that predicts your chance of getting cancer*). Participants were randomly assigned six out of 18 scenarios and were asked to rate their willingness to share PHI on a 1–10 scale (1=low, 10=high). Authors measured the relative importance of user, purpose of use, and level of sensitivity and compare sharing preferences based on participants' diagnosis. Participants with a diagnosis of cancer (6.3%) and those without a diagnosis 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).

Soni et al. (2019) evaluated English and Spanish-speaking patients with BHCs about their willingness to share health data and sensitivity perceptions. In a survey, the authors asked 86 participants about their willingness to share based on data types (*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*) and data recipient (*behavioral health provider at the clinic, emergency care providers, other providers at the clinic, behavioral health provider outside the clinic, and other provider outside the clinic*) for two data use purposes (*benefit their own care, and care for others*). Participants could answer questions by selecting between one or multiple answers. Data sensitivity and willingness to share were analyzed using univariate statistics (frequencies, means, percentage, etc.) and differences in sharing preferences were examined using the chi-square test. A direct correspondence between perceived sensitivity of information and willingness to share with all or some providers was revealed. For instance, while participants considered genetic data the eighth most sensitive type of information, they ranked it as the third most shareable. Although most participants (64.15%) wanted to restrict access to information from some or all health care providers, when prescribing a new medication, most participants (78%) indicated that providers should have access to all their information and 70% reported that their emergency providers should have access to all their information during a life-threatening situation. A main motivation for sharing data with providers among participants was improving the patient's own care (77.8%). Majority of participants (83.3%) indicated that they would be upset if their providers shared their health data without their consent and that they might react by leaving such providers

(65.6%). Most participants (78.9%) desired control over how they want to share data with different research organizations, and they were generally willing to share with researchers when their own care (91.1%) or care for others (78.9%) could be improved.

Kim et al. (2017) developed a web-based tiered informed consent tool that honors granular patient preferences for use of EHR data in research. The tool was piloted in four outpatient clinics. A list of *37 data types,* including the *NCVHS sensitive data taxonomy*, was provided. Data recipients included *for-profit researchers only*, *nonprofit researchers only, and researchers from the affiliated institutions (the academic medical center and Veterans Affairs only)* and the data use purpose was *research.* Participants logged into the web tool and indicated their data sharing preferences. During the study, participants could change their sharing preferences through the platform. Descriptive statistics, Fisher's exact test, Wilcoxon rank sum test were used to examine differences in sharing between clinics, and by data recipients and data types. The difference in the means between the two clinics was significant (p=0.002). The majority of the participants (43 of 126, 34%) were willing to share every data item with every type of researcher, while minority (5 of 126, 4%) were unwilling to share their data with any type of researchers. Indeed, withdrawal of "sensitive" information was not more frequent than "nonsensitive" information. Willingness to share was greater among participants from a HIV clinic (35 of 84, 42%) than those from internal medicine clinics (8 of 42, 19%). The number of items declined was higher for for-profit institution recipients.

2.5.3 Sensitivity Perceptions and Sharing Preferences Based on Data Type, Recipients, and Duration of Data Restriction

This section summarizes the two studies that utilized data type, data recipients, and duration of data restriction as factors to assess sensitivity perceptions and/or sharing preferences of individuals.

Schwartz et al. (2015) studied primary care patients' willingness to share EHR data. Participants were allowed to restrict EHR access to various providers via a web-based tool. Patients were asked to restrict access based on data recipient (*doctors, nurses, and "other staff"),* data type (*no information, all information, and NCVHS sensitive data categories*) and *how long they wish to restrict the data*. Descriptive statistics were used for analysis. Of the 105 patients, 60 (57%) did not restrict access to EHR for any providers. Thirty-four patients (32.3%) blocked access to all PHI 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.

In a study concurrent with Schwartz et al. (2015), Tierney et al. (2015) asked providers their opinions about patients controlling access to their EHR data. 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 have been redacted, they could "break the glass" to view the redacted data during that EHR use session. Descriptive statistics along with other methods including comparing logs of "breaking glass" were used. During the 6-month prospective study, 92 study patients (88 %) returned 261 times, during which providers

viewed their EHRs 126 times (48 %). Providers "broke the glass" 102 times, 92 times for patients not in the study and ten times for six returning study patients, all of whom had restricted EHR access. Providers "broke the glass" for six (14 %) of 43 returning study patients with redacted data vs. zero among 49 study patients without redactions (p=0.01). Although 54 % of providers agreed that patients should have control over who sees their EHR information, 58 % believed restricting EHR access could harm provider–patient relationships and 71 % felt quality of care would suffer.

2.5.4 Sensitivity Perceptions and Sharing Preferences Based on Data Recipients, and Participants' Characteristics

This section summarizes the one study that utilized data recipients and participants' characteristics as factors to assess sensitivity perceptions and/or sharing preferences of individuals.

Teixeira et al. (2011) conducted a survey study to understand attitudes of persons with HIV towards their PHI storage and sharing. On a scale from strongly agree to strongly disagree, the authors asked participants their willingness to share with the following data recipients (*PCPs, other clinicians at their clinic, and non-clinical staff*). The authors also evaluated participants' trust in their HIV care team, satisfaction with provider communications, HIV-associated stigma, age, race, Hispanic ethnicity, education, and internet use. Authors examined differences by participants' characteristics and willingness to share as well as the association between participants' willingness to share and other independent variables such as stigma, age, race, etc. The majority (84%) of the 93 individuals was willing to share their PHI with clinicians involved in their care.

Fewer individuals (39%) were willing to share with non-clinical staff. Willingness to share PHI was positively associated with trust and respect of clinicians.

2.5.5 Sensitivity Perceptions and Sharing Preferences Bases on Data Type and Participants' Characteristics

This section summarizes the one study that utilized data type and participants' characteristics as factors to assess sensitivity perceptions and/or sharing preferences of individuals.

King and colleagues (2012) focused on discovering Australian adults' (18 years or older) attitudes towards privacy for research via focus groups and a social survey. The focus groups asked 23 participants about their views on privacy of health information and a social survey asked 700 individuals about privacy concerns towards a list of data types 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 collected participants' characteristics. The authors examined the presence of an association between participants' characteristics and privacy concerns. The study did not focus on participant's willingness to share information for care and treatment purposes. Results of the focus group discussions showed a wide range of views on EHR systems ranging from unambiguous approval to complete rejection of their necessity. Participants were also concerned about losing the ability to have some say in what happens with their health information in EHR systems. Majority of the participants rated medical research very highly and indicated willingness to share sensitive health information for medical

research provided that they could not be identified. Results of the national survey revealed both great support for medical research (98%), and concern about privacy of health information (66%). 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 patients' name with sensitive data (such as sexually transmitted diseases) in a situation not related to medical treatment.

2.6 Studies on Vulnerable Populations

This section describes the five studies in the review that focused on vulnerable populations, as outlined in Table 5.

Of the 12 studies retrieved, only five focused on vulnerable populations: two focused on understanding data sharing preferences and/or perceptions of individuals living with HIV, two on patients with behavioral health conditions, and one on individuals with cancer. Vulnerable populations may require ancillary considerations and augmented protections in data privacy research (*WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*, n.d.). For instance, individuals living with HIV are protected by HIPAA, state laws, and "common law," (*Privacy, Confidentiality and Disclosure*, n.d.), patients with BHCs are the subject of highly protective laws, such as the 42 CFR Part 2 and different state laws (42 CFR Part 2, n.d.), and patients with cancer are protected by different policies and regulations implemented by states and cancer registry to keep cancer data confidential and prevent improper disclosures (*Confidentiality | SEER Training*, n.d.).

In terms of sample size, none of the five studies used a sufficient sample size (N>188). Large sample size is important not only to yield statistically significant results, but to ensure that the likelihood of an inaccurate extrapolation due to outlier is minimized (Fay, 2013). While Grande et al. (2015) administered an online survey with embedded conjoint experiments to 2945 participants to understand their willingness to share and sensitivity of health information, only 6.3% (187) had a history of cancer. Similarly, while the majority (67%) of participants in Kim et al. (2017) were individuals living with HIV, this sample size (N=84) was still low due to the low overall sample size of the study (N=129) (2017b). For individuals with BHC, the highest sample size analyzed to understand data sharing preferences and/or perceptions has been 86 individuals (Soni et al., 2019).

Survey has been the most popular method to understand data sharing preferences and perceptions of participants. Teixeira et al. (2011) conducted survey in private offices using audio computer-assisted self-interviewing technology, Grande et al. (2015) conducted internet-based surveys, Grando et al. (2017) carried out a tablet-based survey completed in a private office, and Soni et al. (2019) conducted electronic and paper-based survey. Only Kim et al. (2017) implemented a tool to honor GDS preferences and allowed participants to make data sharing choices, review and modify choices when needed.

Regarding data analysis, only Soni et al. (2019) administered a test to assess participants' comprehension of the study and excluded those with a lower score on the test. Although Grande et al. (2015) did not assess participants' comprehension of the

study, they excluded speeders – defined as participants with half the median completion time (< 5 minutes). The remaining three studies did not assess study comprehension of participants nor did they use any exclusion criteria during data analysis (Grando et al., 2017; Kim et al., 2017; Teixeira et al., 2011).

Other limitations discovered from the five studies included short duration and English-only research instruments. With the exception of Teixeira et al. (2011), which has a duration of approximately 50 minutes, the majority of the studies have a very short duration, indicating that participants may not have had enough time to make data sharing decisions (Grande et al., 2015; Grando et al., 2017; Kim et al., 2017). For instance, the median time in Grande et al. (2015) was 10 minutes, the average time in Grando et al. (2017) was 15 minutes, and the mean time in Kim et al. (2017) was 3.6 minutes. Duration was not reported in Soni et al. (2019). Regarding languages, only two studies (Soni et al., 2019; Teixeira et al., 2011) provided participants the option to complete the study in either Spanish or English. The rest of the studies were conducted only with English speakers. (Grande et al., 2015; Grando et al., 2017; Kim et al., 2017)

Table 5. Summary of the 5 Studies That Focused on Vulnerable Patient Groups

Author(s) & Year	**Population**	**Vulnerable Population (% total population)**	**Language**	**Data Collection Method**	**Tool used to solicit sharing choices**	**Study comprehension assessment**
(Teixeira et al., 2011)	Adults living with HIV	93 (100%)	English & Spanish	Survey using audio computer-assisted self-interviewing technology	N/A	N/A
(Grande et al., 2015)	Adults with and without history of cancer	187 (6.3%)	English	Internet-based surveys	N/A	Lower than median completion time

Table 5. Continue

Author(s) & Year	Population	Vulnerable Population (% total population)	Language	Data Collection Method	Tool used to solicit sharing choices	Study comprehension assessment
(Grando et al., 2017)	Adults with a mental health diagnosis	50 (100%)	English	Tablet-based survey	N/A	N/A
(Kim et al., 2017)	Adults with and without the history of HIV	84 (67%)	English	Web-based password protected tool	iCONCUR	N/A
(Soni et al., 2019)	Adults with a mental health diagnosis	86 (100%)	English & Spanish	Electronic or paper-based survey	N/A	University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) test.

2.7 Conclusion

Driven by a need to identify and employ standard approaches to understand data sharing preferences and perceptions, this Chapter reviews the current state of the art on such methodologies. Key findings identify a need to 1) introduce and formalize research approaches to assess individuals' GDS preferences accurately and effectively, 2) evaluate the NCVHS taxonomy with patients, and 3) provide insights on GDS of patients with BHCs, a vulnerable population often excluded from data privacy research.

In support of the goals of this research, this literature review informed the development of patient education content for each of the sensitive data categories in the NCVHS taxonomy (Chapter 3), the design of a clinical decision support system to implement GDS using key variables and the evaluation of these variables and the NCVHS taxonomy with patients with BHCs (Chapter 4). Next chapters aim to address the knowledge gaps identified through the completed systematic literature review.

CHAPTER 3

SYSTEMATIC APPROACHES TO DESIGN PATIENT EDUCATION MATERIALS ON SENSITIVE MEDICAL RECORD DATA

3.1 Introduction

The systematic literature review summarized in Chapter 2 revealed that patients desire granular control over the sharing of their digital health information (e.g., "I want to share all my medical records, except those related to a past history of mental health diagnosis and treatment') (Soni et al., 2020). Honoring such desires require identification, understanding and communication of sensitive data categories.

There is no agreed upon or validated sensitive data categorization or taxonomy. The two sensitive data categorizations most often represented in data sharing research are those promoted by HHS's National Committee on Vital and Health Statistics (NCVHS) and Substance Abuse and Mental Health Services (SAMHSA) (*Home*, n.d.; *SAMHSA*, n.d.).

The SAMHSA taxonomy has been adopted by Consent2Share, a consent engine developed to support GDS (Grando, 2020; Saks et al., 2018; Soni et al., 2018, 2020, 2021). Soni et al. asked patients to sort their own medical records using the SAMHSA categories and found that (42%, n=25) patients had challenges applying the SAMHSA terminology to their records. For example, they suggested substituting "Drug Abuse" for "Drug Use," merging categories like Communicable Diseases and Sexual Health, and providing a broader categories like Family History/Genetic Data (Soni et al., 2020, 2021).

The NCVHS taxonomy has been used to implement and evaluate an online consent tool to share medical records for research (Soni et al., 2020, 2021) and to assess

patients' preferences on GDS for care (Caine et al., 2015; Caine & Hanania, 2013; Schwartz et al., 2015; Tierney et al., 2015).

Patient education materials have been identified as a cornerstone in improving health literacy, the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (National Academies of Sciences, Engineering, and Medicine, 2018). Patient education materials have been associated with enhanced patient knowledge, confidence, and recall of information (Griffin et al., 2003; Haga et al., 2013; Pierce, 2010; Shoemaker et al., 2014; Strachan et al., 2012; Williams et al., 2018).

However, there is a dearth of lay education materials to support sensitive data sharing. Educational content could help patients make more informed data sharing decisions. There are many sources of online educational materials that explain generally accepted sensitive data categories, but limitations are noted, including 1) higher than recommended literacy level, 2) nonadherence to recommended development guidelines, 3) limited patient and provider engagement, 4) lack of Spanish translation, among others.

Development of quality patient education materials requires the use of standardized tools and processes to ensure understandability. Understandability has been linked to care improvement and overall patient participation (Pierce, 2010). The Agency for Healthcare Research and Quality (AHRQ) has developed gold standard tools for evaluating the understandability and actionability (Shoemaker et al., 2014), while validated tools are available to assess readability and grade level (McLaughlin, 1969; Thomas et al., 1975), quality and reliability (Charnock et al., 1999), cultural suitability (Demir et al., 2008), and complexity of graphs and charts used for patient education

(Mosenthal & Kirsch, 1998). Despite the availability of these tools, many current patient educational materials lack comprehensibility and content quality (Guan et al., 2018; Prabhu et al., 2016; Smith et al., 2014; Weiss, 2007).

Quality education material development also require patient engagement, a cornerstone of quality of care (Bradshaw, 2008; Coulter, 2005; Darzi, 2009; Baker, 2001; *Ontario Health Quality Council*, n.d.; Say & Thomson, 2003). The Centers for Disease Control and Prevention (CDC) recommends eight steps for developing health communication materials that are evidence-based and user friendly (*Simply Put: A Guide for Creating Easy-to-Understand Materials*, n.d.): six of those steps involve engaging the intended audience in the development and evaluation of the materials (*Simply Put: A Guide for Creating Easy-to-Understand Materials*, n.d.).

3.2 Objective

To address the gaps in lay educational materials for granular sharing consent, we designed an approach for the development of effective educational materials with a focus on sensitive medical data categories. We used key concepts from national pedagogical guidelines and Information Systems (IS) research. We applied these methods to the design of low literacy educational content to explain the most common sensitive data types, i.e., Domestic violence, Genetic information, Mental health, Sexual and Reproductive Health, and Substance use information, to English and Spanish-speaking patients.

3.3 Methods

3.3.1 Overview

Our 6 phase methodology used CDC's eight steps (*Simply Put: A Guide for Creating Easy-to-Understand Materials*, n.d.) for developing evidence-based and user friendly health communication materials as a foundation. We added two steps (steps 4 and 5 in phase 2), to include the reuse of available educational materials. We adopted three of the seven steps (steps 6 to 8 in phase 3) that Nickerson et al. proposed for identifying subcategories within a taxonomy (Nickerson et al., 2013), provided examples within those subcategories, and determined whether the classification is sufficient for participants' understanding. We also added five new steps (steps 9 to 13 in phases 4 and 5) to the CDC guidelines to guide the selection and use of standardized evaluation instruments to assess the quality of educational materials.

The proposed methods guide the process of reusing available educational materials or developing new educational materials on sensitive data categories to meet the needs of the intended audience. The approach consists of six phases as described in Table 6.

Table 6. Step-by-Step Approach for Developing Effective Patient Educational Materials

Phase	**Description**	**Steps**	**Source**
1	Identification of Research Problem, User Needs, and Education Contents	1) Define/research the key health problem 2) Determine the needs of the audience 3) Determine key concepts and messages	CDC guideline
2	Identification and Assessment of Available Educational Materials to Explain the Sensitive Data Taxonomies	4) Identify available educational materials 5) Assess the suitability of the materials	New

Table 6. Continue

Phase	Description	Steps	Source
3	Development of New Educational Materials or Modification of Existing Materials to Meet the Needs of the Intended Audience	Draft educational materials on sensitive data categories by: 6) Identify categories within the taxonomy 7) Classify common data items into each category within the taxonomy 8) Determine the end of classification	CDC guideline + Nickerson et al. Method
4	Selection of Relevant Questionnaires for Evaluating Educational Materials with the Intended Audience	Choose evaluation methods: 9) Select standardized instruments 10) Examine possible questions from the instruments 11) Determine relevant questions for pre and post testing of the materials	CDC guideline + New
5	Evaluation of the Educational Materials with Key Stakeholders	Test educational materials: 12) Recruit sample of key stakeholders for pre and post testing of the materials 13) Use mixed methods to collect feedback from stakeholders	CDC guideline + New
6	Revision of the Educational Materials Based on Feedback from Key Stakeholders	14) Analyze stakeholders' feedback 15) Revise based on feedback 16) Publish and distribute final product 17) Evaluate users' satisfaction and understanding of the materials	CDC guideline

3.3.2 Phase 1: Identification of Research Problem, User Needs, and Education Contents

This phase focuses on the first three step from the CDC guideline for developing effective health communication materials. The steps include defining the research problem, determining the needs of the intended audience, and determining the key concepts and messages that needs to be communicated to the intended audiences.

3.3.3 Phase 2: Identification and Assessment of Available Education Materials To Explain the Sensitive Data Taxonomies

This phase focuses on searching for existing educational materials and assessing the suitability of these materials for reuse. Steps in this phase include identifying available educational materials from the literature and assessing the suitability of these materials based on users' needs and the research problem. Standard criteria to assess the suitability of educational materials include Reading Ease (Flesch, 1948), Grade Reading Level (Thomas et al., 1975), quality metrics for concept development (Charnock et al., 1999; Demir et al., 2008; Shoemaker et al., 2014), and involvement of intended audience in the creation and/or evaluation of the education contents (*Simply Put: A Guide for Creating Easy-to-Understand Materials*, n.d.). Additionally, the use of common examples in education content is known to result in easier understanding and relatability of the materials to the intended audience (Dorcely et al., 2015). Table 7 summarizes the criteria for assessing the suitability of educational materials.

Table 7. Criteria for Assessing the Suitability of Existing Educational Materials

Assessment	**Criteria**
Readability	Reading ease score is 60 or above (Flesch, 1948).
Grade level	Grade reading level is sixth grade or lower (Thomas et al., 1975).
Quality metrics	Reliability, culturally suitability, and understandability are utilized (Charnock et al., 1999; Demir et al., 2008; Shoemaker et al., 2014).
Patient engagement in the design or evaluation	Yes or no (*Simply Put: A Guide for Creating Easy-to-Understand Materials*, n.d.)
Use of frequently occurring types of health information (For example, depression, is a common type of Mental Health diagnosis)	Yes or no (Dorcely et al., 2015).

3.3.4 Phase 3: Development or Modification of Existing Education Materials

The fourth step in the CDC guideline for creating easy-to-understand educational materials is drafting the materials (*Simply Put: A Guide for Creating Easy-to-Understand Materials*, n.d.). We combined this CDC step with the three steps from Nickerson et al. method to create educational materials on sensitive data categories that have uniform structure and content (Nickerson et al., 2013). Steps in this phase include identifying categories or subsets within the taxonomy for which the education content is being developed, classifying common data items into each subset within the taxonomy (using patient medical records items or clinical concepts from terminologies to provide examples that are relatable to patients), and determining whether the classification is sufficient for patients' understanding of the materials (classification ends when the materials is determined to be concise, robust, comprehensive, extendible, and explanatory). Figure 2 summarizes the steps required for developing new educational materials or modifying existing materials that meet the needs of the intended audience.

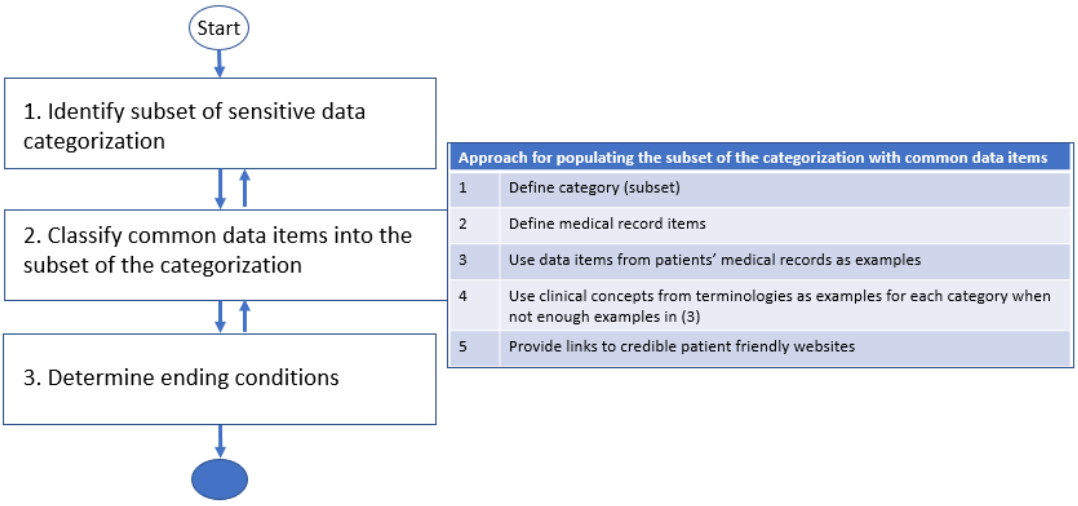

Figure 2. Steps for Developing Effective Education Contents To Explain Sensitive Data Taxonomies

3.3.5 Phase 4: Selection of Relevant Questionnaires for Evaluating Educational Materials

The fifth step in the CDC guidelines is pre-testing the materials with the intended audience (*Simply Put: A Guide for Creating Easy-to-Understand Materials*, n.d.). This phase focuses on selecting relevant questionnaires for pre and post evaluations of the materials using standardized instruments. Specific steps in this phase include selecting standardized instruments, examining lists of questions from those instruments to choose relevant ones (duplicate questions and questions that do not meet the purpose of the educational materials are excluded), and determining relevant questions for pre and post evaluation of the materials (determining whether different sets of questions are needed for pre and post evaluation).

3.3.6 Phase 5: Evaluation of the Educational Materials With Key Stakeholders

After selecting relevant questions for pre and post evaluation of the materials, the next step is recruiting key stakeholders for the pre and post evaluations of the educational materials. This step falls within the fifth step in the CDC guidelines (*Simply Put: A Guide for Creating Easy-to-Understand Materials*, n.d.). Involvement of patients and providers in the design of education contents is critical to developing effective materials. The used of mixed methods for participants' evaluation ensure that comments on the overall structure and content of the materials are fully captured.

3.3.7 Phase 6: Revision of the Educational Materials Based on Feedback From Key Stakeholders

This step is concerned with evaluating users' satisfaction and understanding of the materials, aligned closely with the last three steps in the CDC guidelines (*Simply Put: A*

Guide for Creating Easy-to-Understand Materials, n.d.). This step focuses on analyzing feedback from the intended audience and revising the education contents prior to distribution. This step consists of publishing and distributing the final educational materials to the intended audience in a suitable format (printed, web-based, etc.).

3.4 Results

In the following sections, we validated the proposed methods with the design and implementation of effective education contents for the five sensitive data categories from the NCVHS taxonomy.

3.4.1 Phase 1: Identification of Research Problem, User Needs, and Education Contents

Table 8 summarizes the steps required for the completion of this phase.

Table 8. Steps for Research Problem Definition, Users' Needs Identification, and Education Contents Selection

Steps for research problem definition, identification of users' needs, and education contents	
Research problem	Lack of lay educational materials to explain the NCVHS taxonomy to patients.
Intended audience needs	Patients may benefit from education contents on the NCVHS taxonomy when making data sharing decisions.
Key concepts and messages	Need for low literacy educational materials to explain the NCVHS taxonomy to English and Spanish-speaking patients.

3.4.2 Phase 2: Identification and Assessment of Available Education Materials To Explain the Sensitive Data Taxonomies

We conducted a literature search for educational materials explaining the five NCVHS sensitive data categories. The search yielded eleven documents (three for domestic violence, two for genetic information, two for mental health, two for sexual and reproductive health, and two for substance use information) that met our criteria for use

(Table 7). These materials were retrieved from a variety of creditable sources such as SAMHSA, WHO, National Institute of Mental Health and the Mayo Clinic.

Patient engagement in the design and evaluation process was not reported in any of the materials. Additionally, no material reported using standardized instruments to guide the design and evaluation process. Spanish translations were available for 45% (n=5) and only 36% (n=4) of the materials used frequently occurring or common health data items as examples to explain a particular sensitive data category (Table 9). In terms of reading level and reading ease, on average, materials retrieved had higher than recommended values: 15.4 and 22.47 for domestic violence, 14.3 and 23.30 for genetic information, 10.2 and 46.75 for mental health, 9.15 and 42.65 for sexual and reproductive health, and 9.45 and 54.5 for substance use information (Table 9).

Table 9. Assessment of Materials Retrieved in the Literature Search To Explain the NCVHS Data Types to Patients

Data categoriza-tion	**Material retrieved**	**Reading ease**	**Reading level**	**Patient engagement reported?**	**Quality metrics reported ?**	***Common health data items used?**	**Spanish translation available?**
Domestic violence	(*National Conference of State Legislatures*, n.d.)	19.5	15.8			✓	
	(Huecker et al., 2021)	22.8	14.8				
	(*National Domestic Violence Hotline*, n.d.)	25.1	15.6				✓

* Common health data items are frequently occurring data items in patients' medical records. For example, depression, is a common type of Mental Health diagnosis.

Table 9. Continue

Data categoriza-tion	Material retrieved	Reading ease	Reading level	Patient engagement reported?	Quality metrics reported?	*Common health data items used?	Spanish translation available?
Genetic information	(*Fact Sheet: Genetic Information Nondiscriminati on Act | U.S. Equal Employment Opportunity Commission*, n.d.)	5.8	19.6			✓	✓
	(*Understanding the Genetic Information Nondiscriminati on Act of 2008*, n.d.)	40.8	9.0				
Mental health	(*National Institute of Mental Health*, n.d.)	27.5	13.5				✓
	(*MedlinePlus*, n.d.)	66	6.9			✓	✓
Sexual and reproductiv e health	(*Overview of Reproductive Health*, n.d.)	35.1	10				
	(*National Coalition for Sexual Health*, n.d.)	50.2	8.3				
Substance use	(*Mayo Clinic - substance use disorder (Symptoms and Causes)*, n.d.)	52.3	20.5			✓	✓
	(*Quick Facts: Substance Use Disorders*, n.d.)	56.7	8.4				

* Common health data items are frequently occurring data items in patients' medical records. For example, depression, is a common type of Mental Health diagnosis.

3.4.3 Phase 3: Development of New Educational Materials or Modification of Existing Materials To Meet the Needs of the Intended Audience

When existing educational materials did not meet the needs of our intended audience, we developed new educational materials to explain each of the five sensitive data categories that constitute the NCHVS taxonomy. Using available patients' EHR obtained from a previous study (Soni, Grando, Aliste, Murcko, Todd, Mukundan, Saks,

Horrow, Sharp, Dye, et al., 2019a), the following subcategories were selected within the NCVHS sensitive data taxonomy: 1) Diagnosis, 2) Medication, 3) Labs, and 4) Procedures or services. Table 10 summarizes the five-step approach used to classify medical record items and clinical concepts from terminologies into the NCVHS sensitive data taxonomy. Table 11 displays the results of the classification of medical record items into the NCHV sensitive data taxonomy. Overall, 108 common data items were used across the five sensitive data categories as examples of data items.

Table 10. Overview of the-Approach Used To Classify Medical Record Items and Clinical Concepts From Terminologies Into the NCVHS Sensitive Data Taxonomy

Step		**Description**
1	Define category	Definition of sensitive data category: 1) Domestic violence 2) Genetic information 3) Mental health 3) Sexual and reproductive health 5) Substance use information
2	Define medical record items	Definition of medical record items for each sensitive data category
3	Use data items from patients' medical records as examples	Frequently occurring or common medical record items categorized by: 1) Diagnosis 2) Medication 3) Labs 4) Procedures or services
4	Use clinical concepts from terminologies as examples for each category when not enough examples in (3)	Clinical concepts from terminologies to supplement item-poor categories: 1) Diagnosis 2) Medication 3) Labs 4) Procedures or services
5	Provide links to credible patient friendly websites	Links to author-curated materials

Table 11. Classification of Frequently Occurring or Common Data Items Extracted From Patient's EHRs and Clinical Terminologies and Used As Examples in the Educational Materials

Data categorization	**Data source**	**Diagnosis n (%)**	**Medication n (%)**	**Lab n (%)**	**Procedures/ Services n (%)**	**Total n (%)**
Domestic violence	Patients' EHR	1 (17%)	1 (100%)	0 (0%)	2 (33%)	4 (22%)
	Clinical concept	5 (83%)	0 (0%)	5 (100%)	4 (67%)	14 (78%)
Genetic information	Patients' EHR	2 (40%)	1 (20%)	1 (17%)	1 (20%)	5 (24%)
	Clinical concept	3 (60%)	4 (80%)	5 (83%)	4 (80%)	16 (76%)
Mental health	Patients' EHR	6 (75)	4 (80%)	3 (50%	3 (75%)	16 (70%)
	Clinical concept	2 (25%)	2 (20%)	3 (50%)	1 (25%)	7 (30%)
Sexual and reproductive health	Patients' EHR	5 (83%)	3 (60%)	5 (83%)	3 (50%)	16 (70%)
	Clinical concept	1 (17%)	2 (40%)	1 (17%)	3 (50%)	7 (30%)
Substance use	Patients' EHR	4 (67%)	2 (33%)	3 (50%)	2 (40%)	11 (48%)
	Clinical concept	2 (33%)	4 (67%)	3 (50%)	3 (60%)	12 (52%)

3.4.4 Phase 4: Selection of Relevant Questionnaires for Evaluating Educational Materials With the Intended Audience

The three instruments (Table 12) that collectively guided the design of questions for pre and post evaluation of educational materials were:

1) DISCERN, to appraise (judge) written information on treatment choices (tools) (Charnock et al., 1999). It consists of 16 questions in three parts to evaluate the reliability, and quality of a written material.
2) Evaluation of Suitability of Written Materials forms, to evaluate the suitability of a written materials (Demir et al., 2008). It is composed of 27 questions in six parts to evaluate the content, literacy, learning and motivation, and cultural suitability of a written material.
3) Patient Education Materials Assessment Tool for Printable Materials (PEMAT-P), to assess the understandability (the ability of the materials being understood) and actionability (the ability of person to act on the information provided) in the materials (*Agency for Healthcare Research and Quality (AHRQ)*, n.d.). It is composed of 26 questions in seven parts.

Table 12. Source of Questions Used for Pre and Post Evaluation of Educational Materials

Instrument	**Total questions**	**Questions for pre (internal) evaluation**	**Question for post (external) evaluation**
DISCERN	16 questions in three parts: 1) Reliability 2) Information quality 3) Overall quality of the materials	5 questions selected: Reliability	None
Evaluation of Suitability of Written Materials Form	27 questions in six parts: 1) Content 2) Literacy 3) Pictures and graphs 4) Plan and type 5) Learning and motivation 6) Cultural suitability	2 questions selected: Cultural suitability	2 questions selected: Cultural suitability

Table 12. Continue

Instrument	Total questions	Questions for pre (internal) evaluation	Question for post (external) evaluation
PEMAT-P	26 questions in seven parts: 1) Content 2) Word choice & style 3) Use of numbers 4) Organization 5) Layout and design 6) Use of visual aids 7) Actionability	19 questions selected: 1) Content 2) Word choice & style 3) Use of numbers 4) Organization 5) Layout and design 6) Use of visual aids 7) Actionability	8 questions selected: 1) Word choice & style 2) Organization 3) Use of visual aids

Questions for pre and post evaluation of the educational materials on the NCVHS sensitivity categories were drawn from three standardized instruments (Table 12). For uniformity, the five-point Likert-type scale was changed to two-point Likert-type scale (1=agree, 0=disagree) to ensure that all instruments are rated on the same scale. Additionally, specific questions were selected from the three instruments for pre-evaluation (26 questions + a free response question, see APPENDIX A) and post evaluation (10 questions + a free response question, see APPENDIX A). The rationale for selecting specific questions from the three instruments included duplicates and/or non-applicability of the questions to our evaluation. Overall, selected questions were used to evaluate the reliability and quality, cultural suitability, and understandability of the educational materials.

3.4.5 Phase 5: Evaluation of the Educational Materials With Key Stakeholders

An interdisciplinary research team including experts in biomedical informatics, behavioral health, medicine, law, and ethics were involved in the development and evaluation of the patient educational materials. Drafts of the materials for each of the five NCVHS sensitive data categories were first reviewed by six members of the research team and one healthcare provider using the 26 questions developed. Each reviewer

evaluated all five sensitive data categories. For the multiple-choice questions, a cumulative score was computed for each data category as a percentage. A score >75% was deemed to represent high quality on a given materials. The materials with low score (≤75%) were revised and iteratively evaluated until a higher score (>75%) was received. Comments on the overall structure and content of each material, provided through the free response question, were used to address limitations related to these areas.

After that, the materials for each of the five sensitive data categories were translated to Spanish using the back-translation approach by two bilingual researchers. The same approach was used to translate the ten multiple-choice questions and the one free response question to Spanish. Disagreement during translation was addressed by consensus. The site leaders reviewed the final draft of the educational materials for appropriateness and compliance prior to sharing with patients.

The Arizona State University Institutional Review Board (IRB) approved the recruitment of adult (18 years old or older) English and Spanish-speaking patients diagnosed with general mental illness (GMI) and/or serious mental illness (SMI) from two integrated health clinics providing physical and behavioral health care to evaluate the materials (APPENDIX E). The final educational materials were shared with patients as a web-based survey in their respective language. The web-based program ensured that each educational material was evaluated by at least two different participants and no participants evaluated one educational material twice (APPENDIX B).

Twenty-six adult patients from two integrated health clinics consented to evaluate the educational materials. Of those, two individuals (8%) opened the survey but did not complete the evaluation. The survey completion rate was 92%.

3.4.6 Phase 6: Revision of the Educational Materials Based on Feedback From Key Stakeholders

Participants' responses to the online questions were analyzed based on scores on the multiple-choice questions using Excel and feedback provided in the free response questions. A cumulative score expressed as a percentage was computed for the multiple-choice questions and a deductive approach of qualitative content analysis was used for the free response question.

For the free responses, 11 of the 24 participants provided comments. A majority of the comments were general statements about the overall content of the materials while others were specific to a particular sensitive data category. In the general comments, only one participant suggested edits to the background of the educational material template by stating, *"my only edit would be, change the color for My data choice."*

Most of the general comments were positive statements about the relatability of the materials to the target audience and their simplicity of content and reading easiness. Regarding relatability of the materials to our audience, one participant stated that *"the information in this material is what most people can relate to."* For simplicity, a rater commented, *"I found that the material was well simplified and easy to understand. Was short and direct, allowing for a clear understanding of the topic."* Another stated, *"I think that this particular education material was well simplified. Knowing that the topic can be a bit difficult to fully understand, I think that it was condensed in a good manner and provided common examples that allowed for a good understanding of what data may be collected."* Finally, one participant mentioned that *"This education material did a*

good job of summarizing and simplifying terminology as well as defining what the disorder is."

Scores from patients' evaluation were used to make changes and create the final version of the educational material (see Figure 3 for an example). The final educational materials were embedded in a consent technology to support participants when making decisions regarding the sharing of their medical records. Participants' evaluation regarding their satisfaction and understanding of the materials after distributing was positive.

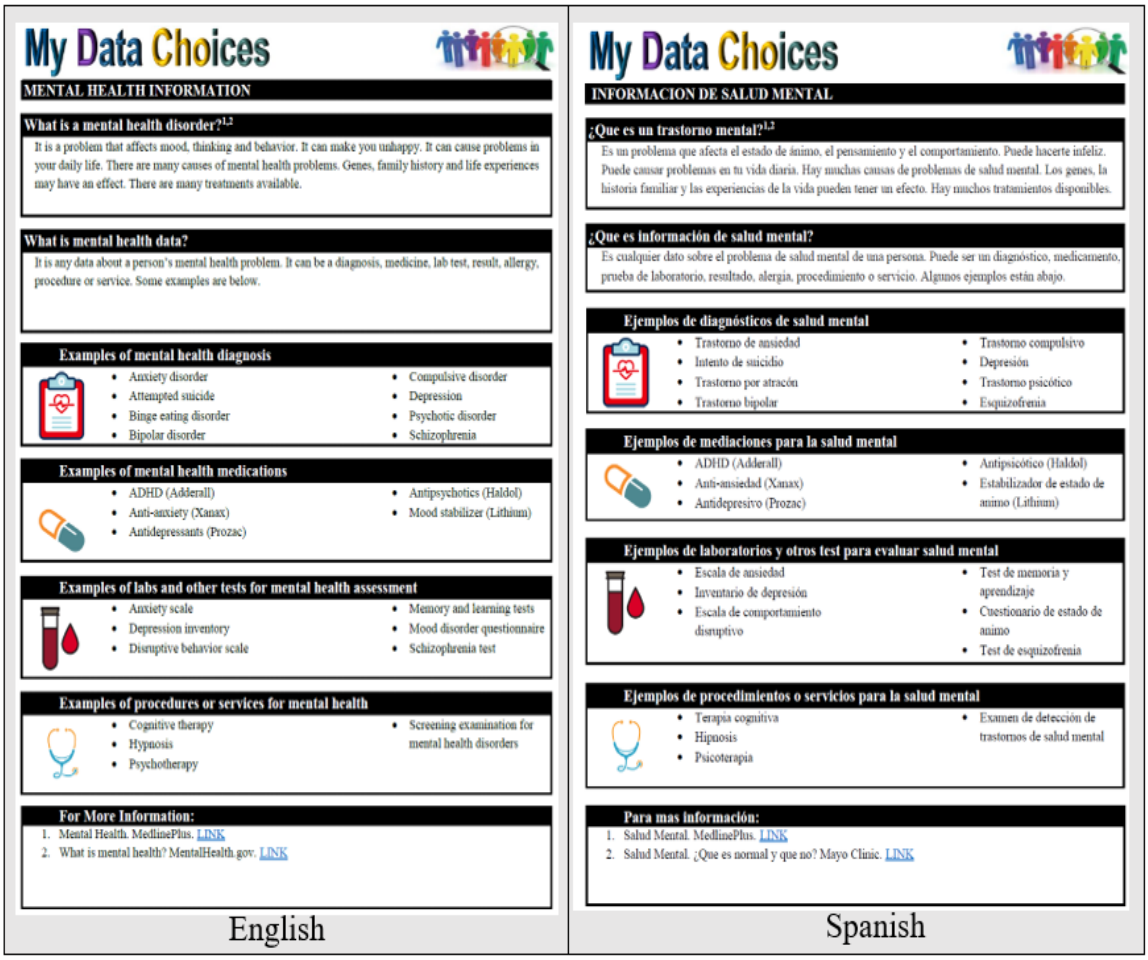

Figure 3. Resulting material in English and Spanish for the Mental Health category

3.5 Discussion

Research on understanding and building processes and technologies that honor patients' GDS desires is rapidly growing, as is the need to educate patients on sensitive health data categorizations within their EHR. Effective patient education materials could increase health literacy and promote understanding of sensitive data categorizations. Enhanced patient knowledge, confidence, and information recall could improve informed decision making regarding the sharing of sensitive medical records. However, existing education content to explain types of sensitive medical information have several common limitations that hinder the accessibility and comprehension of the materials by the intended audiences.

We proposed a systematic approach to guide the process of reusing available educational materials or developing new materials on sensitive data categories to meet the needs of the intended audience. The framework supported the design of educational materials with uniform structure and content, and the creation of subcategories within a data taxonomy to enhance participant understanding. We validated the framework by systematically developing educational materials to explain subcategories within the five most frequently used sensitive data categories (domestic violence, genetic information, mental health, sexual and reproductive health, and substance use information). The sixth-grade level materials were developed in English and Spanish and were reliable, understandable, easy to read, and culturally suitable for both English and Spanish-speaking patients.

We adopted the methodology of Nickerson et al. to incorporate medical records that provide patients with realistic examples of sensitive data items (Nickerson et al.,

2013). The involvement of clinicians and patients in the design and evaluation phases led to the production of high-quality health information communication materials. Approaches used in this study may be applicable to the design of educational materials to support a wide-range of consent-based GDS processes, such as those built around the SAMHSA sensitive data categories (*SAMHSA*, n.d.). This study may serve as a roadmap for others interested in developing patient-centered educational materials that are evidence-based and user-friendly. Adhering to the proposed framework permits efficient development and testing of content that meets the literacy standards of the target audience (Griffin et al., 2003).

This study has several limitations. When applying the framework to develop our educational materials, we did not collect the demographics of participants involved in the evaluation of the materials. While the evaluation was shared with only adult patients from the two integrated care facilities, collecting participants' demographic would have allowed us to look at participants' perspectives based on different demographic variables such as gender, education levels, race, ethnicity, etc. Also, while each of the educational material was evaluated by at least two different individuals, our overall sample size is small. Although multiple instruments were used to assess reading grade level, reading ease, quality, reliability, understandability, readability, and cultural suitability, these tools do not evaluate the accuracy or comprehensiveness of the content in the materials. Additionally, these tools do not consider limitations related to polysyllabic words when evaluating education contents.

Finally, our study was modified from in-person to online due to the COVID-19 pandemic. While our study completion rate was high, there is a possibility of

nonresponse bias due to the online delivery method used. Participants who did not have internet access, phone or computer may have declined to participate. Conducting the evaluation in person would have also allowed us to explore different aspects that cannot be captured with an online survey such as participants' interactions with the materials, questions asked during the evaluation, among others.

The creation of educational materials for the NCVHS taxonomy provided the opportunity to validate the proposed method and demonstrate its effectiveness in guiding the systematic design and evaluation of educational materials that are evidence-based and user-friendly. Future work will further explore the generalizability and scalability of the proposed approach in the context of patient GDS.

3.6 Conclusion

Driven by the desire to educate patients on data sharing options, we proposed methods to design and implement effective educational content on sensitive medical records categorizations (taxonomies), drawing on key concepts from national pedagogical guidelines and Information Systems research.

Using the NCVHS sensitive data categorization as a case study, we systematically applied the proposed framework to the development and evaluation of sixth-grade reading level materials on the most commonly used sensitive data categories (Domestic violence, Genetic information, Mental health, Sexual and reproductive health information, Substance use information).

The framework created in this study may be applicable to the systematic design and evaluation of a wide range of educational materials that promote patient understanding and are patient-centered and evidence-based.

In the next chapter, the education content will be embedded in MDC – a clinical decision support system that offers scenario-based GDS choices to patients and their guardians. These materials will help to inform participants on the NCVHS taxonomy when making data sharing decisions. As part of the MDC study, patients' opinions will be solicited on the applicability of NCVHS taxonomy to meet their data privacy needs.

CHAPTER 4

MY DATA CHOICES: PILOT EVALUATION OF PATIENT-CONTROLLED MEDICAL RECORD SHARING TECHNOLOGY

4.1 Introduction

The systematic literature review presented in Chapter 2 revealed the desire of individuals to control the sharing of their health records, the lack of consensus on variables that should be included in consent engines to honor that desire, and limited research focusing on preferences in vulnerable populations (Soni et al., 2020). Regarding data sharing variables, while two sensitive data categorizations or taxonomies have been proposed to capture granular medical record sharing choices of patients the NCVHS and the SAMHSA (National Committee on Vital and Health Statistics, n.d.; SAMHSA, n.d.), and the NCVHS taxonomy has emerged as the most frequently used sensitive data categorizations in GDS research, these variables have been used inconsistently to understand participants' privacy views and health data sharing intentions. As a result, no agreement exists on which variables should be included in consent engines. Previous studies have used: (1) data recipient and data type (Bell et al., 2014; Caine et al., 2015; Caine & Hanania, 2013; Grando et al., 2017; Weitzman et al., 2012), (2) data type, data recipient and data use purpose (Grande et al., 2015; Kim et al., 2017; Soni et al., 2019), (3) data type, data recipient and data sharing duration (e.g., one year) (Schwartz et al., 2015; Tierney et al., 2015), (4) data recipient and participant's characteristics (e.g. age) (Teixeira et al., 2011), and (5) data type and participant's characteristics (King et al., 2012).

Additionally, there are very few studies on the data sharing preferences of vulnerable patient groups (Knickman et al., 2002; Grande et al., 2015; Grando et al., 2017; Kim et al., 2017; Soni et al., 2019; Teixeira et al., 2011) e.g. those with BHC, defined as conditions that impact the mental, emotional well-being and/or actions that affect wellness (*Behavioral Health vs Mental Health*, n.d.; Ivanova et al., 2020) —even while GDS is purported to protect sensitive data (Grando et al., *2020*; Grando et al., 2017; Ivanova et al., 2020; Karway et al., 2021; Soni et al., 2021). Providers and researchers are also concerned that patients may unknowingly choose to withhold information needed for their care (Campos-Castillo & Anthony, 2015; Wright et al., 2010), despite evidence to the contrary (Knaak et al., 2017; Schwartz et al., 2015; Soni et al., 2021).

There is a need to validate existing data type taxonomies with key stakeholders, including vulnerable and non-vulnerable patients, guardians, and health providers to inform regulatory agencies about the adequacy of the taxonomy to capture patients' privacy preferences. Also there is a need to replace the diverse and mostly 'ad-hoc' data sharing approaches with formal methods to advance the availability and applicability of standards-based GDS (Grando & Schwab, 2013; Grando et al., 2017; Grando et al., 2020; Saks et al., 2018). Assessing existing data type taxonomies, however, necessitates that patient making choices are educated on the data type taxonomies and replacing the diverse data sharing approaches with formal methods requires understanding which variables are relevant to be included in consent engines.

In this Chapter, we propose a standard based **GDS framework** based on the ONC variables and we apply the framework to the MDC – an electronic informed clinical decision support system that offers scenario-based GDS choices to patients and their guardians. We embed the sixth-grade reading level health information developed in Chapter 3 as infobuttons in the MDC tool to explain the NCVHS sensitive data taxonomy in English and Spanish. We recruit patients with BHCs to understand their desires when making data sharing decisions, and their opinions on the applicability of NCVHS taxonomy to their data privacy preferences. We validate the framework to assess the impact of data source, data recipient, sensitive data type, and data use purpose to establish formal methods to replace address the diverse and mostly 'ad-hoc' data sharing approaches.

In summary, we propose a standard based **GDS framework** based on the ONC variables, and we validate the framework using the **MDC clinical decision support system.** Individuals with BHCs use the MDC tool to indicate 1) how data recipient, sensitive data type, and data use purpose impact their GDS choices, 2) data sharing choices, and 3) perceptions on using the NCVHS taxonomy for sharing health data. **Our hypotheses** are **1) the ONC variables are relevant and impact participants' sharing preferences; 2) patients with BHCs desire granular control over the sharing of their medical records, and 3) the NCVHS taxonomy captures sensitive data sharing needs of patients with BHCs.**

Two-hundred Spanish and English-speaking patients with BHC (included serious mental illness) from two integrated care facilities used MDC. Data were analyzed using

mixed methodology. To the best of our knowledge, this is the largest study on granular data privacy involving a vulnerable population. All participants desired granular control over the sharing of their health data, with sensitive data type, data recipient, and data use purpose having significant impact (Ps<.001) on willingness to share. Participants were significantly more willing to share sensitive data for treatment than for research (P<.001) and to share with providers within integrated facilities than with outside providers (P<.005). Majority of the participants (83%) indicated that the NCVHS sensitive data taxonomy satisfied their data-sharing privacy needs. By systematically exploring the data privacy views of individuals with BHCs using the MDC tool, we validated the proposed framework, sufficiency of the NCVHS sensitive data taxonomy, and established data source, sensitive data type, data recipient, and purpose of use as relevant data sharing variables.

4.2 Materials and Methods

4.2.1 My Data Choices Conceptualization and Design

MDC is an electronic informed consent tool that offers scenario-based GDS choices and provides education to inform participants' decision-making. Building upon the proposed framework based on the ONC variables (data source, data recipient, and data use purpose) and employing the NCVHS sensitive data taxonomy to capture data type, MDC was designed to model the GDS patient experience at an integrated care facility within a healthcare network using the concept of scenarios. In the three scenarios created, the data source (patients' choices grantors) was BH) within the integrated care. The **NCVHS sensitive data taxonomy** was selected to model sensitive data types

(domestic violence, genetic information, mental health information, reproductive health, substance abuse). Previously developed educational content (Chapter 3) on each of the sensitive data types supported by the NCVHS taxonomy was made available to patients to support medical record sharing granular choices. Three recipients (patients' choices grantees) were selected to capture health data sharing preferences of patients within and outside of the healthcare network: 1) primary care providers (PCPs) within participants' facility, 2) PCPs outside the participants' facility, and 3) BHP outside of participants' facility. Two data use purposes (treatment and research) were chosen.

An interdisciplinary research team including experts in biomedical informatics, behavioral health, medicine, law, and ethics guided the development of the MDC tool and its content. The team met regularly over 9 months (August 2019 – April 2020) to reach consensus on the content and logic of the tool. This final version of the MDC tool was presented to the research advisory board that included 12 experts from various disciplines including law, health policy, technology, ethics, patient privacy, patient advocacy, health information exchange, healthcare consulting, and statistics. Feedback from this meeting in the form of meeting minutes was used to make final revisions to the tool (Figure 4).

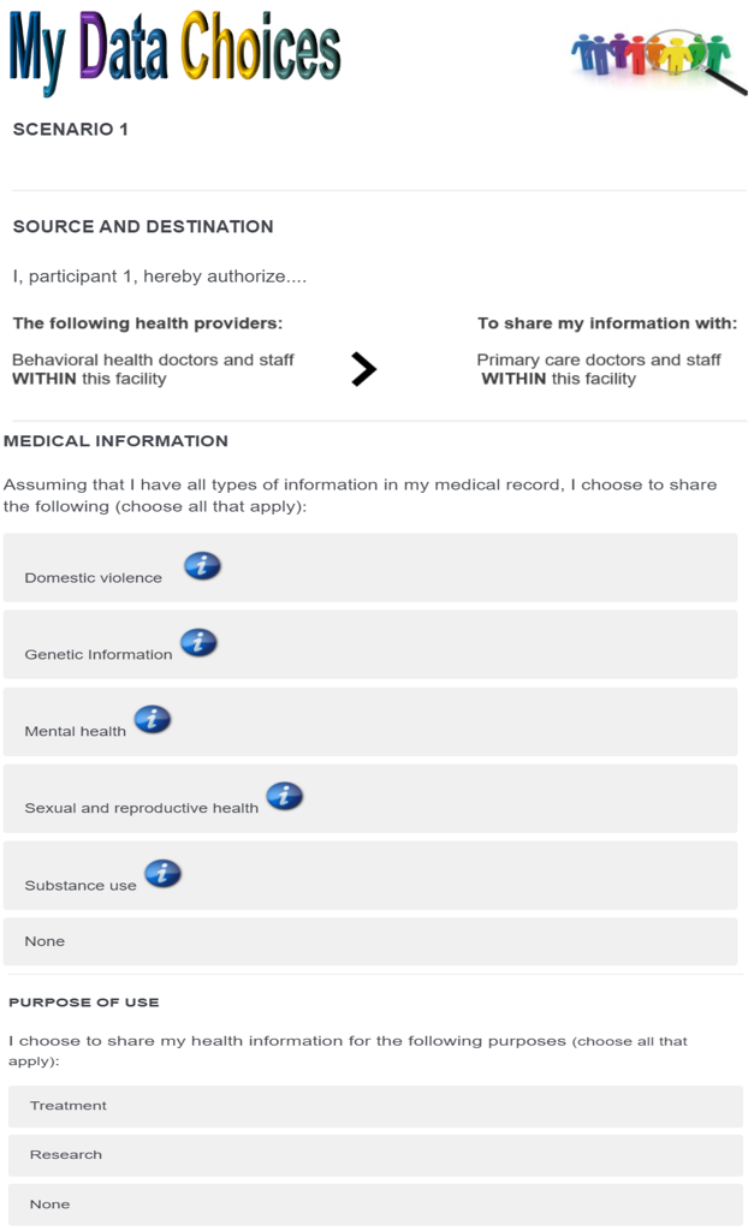

Figure 4. Screenshot of the My Data Choices Tool for Selecting Data Categories for Sharing With Provider Type and Data Use Purpose Based on the Framework. Info Buttons Connect Users With Educational Material

4.2.2 Study Design

The final MDC tool (Figure 4) was integrated as one of the four components of this study as outlined in Table 13.

Table 13. The Four Components of the Study and Their Objectives

Components of the study				
Component		**Descriptions**	**Aim**	**Outcome**
1	Study consent and UBACC test	Administered the UBACC test after obtaining participants' consent.	To assess consent comprehension and decision-making capacity using the UBACC test.	Responses below the established UBACC test threshold were removed for analysis.(Jeste et al., 2007)
2	Demographic survey	Administered questionnaires that focused on participants' demographics and their care histories within the facility.	To obtain participants' demographics including their care histories within the facility.	Responses used to determine the impact of participants' demographics on sharing preferences.
3	Pilot testing of the MDC tool	Allowed participants to select data categories for sharing with provider type and the purpose for sharing the data.	To elicit participants' willingness to share digital health data (Table 1)	Responses used in multivariate analysis to understand participants' sharing preferences based on these variables.
	Access to education material	Allowed participants to refer to the education materials to inform data sharing-decision making.	To track participants' access to educational material.	Responses used to determine the impact of education material on sharing preferences.
4	Study experience survey	Administered questionnaires that focused on participants' experience using the MDC tool, and their views regarding the choices offered by the tool.	To assess participant's experience with the MDC tool in a multiple choice and free response format.	Responses used to analyze user feedback on the MDC tool including participants' perceptions of the NCVHS sensitive data taxonomy.

4.2.3 Study Recruitment

The Arizona State University IRB approved the recruitment of adult (18 years or older) patients diagnosed with GMI and/or SMI from two integrated health facilities providing physical and behavioral health care. One facility (GMI facility) predominantly works with patients with GMI, while the other facility (SMI facility) with individuals with SMI. Together, these facilities care for more than 34,000 patients with BHC and represent the care of a third of the Maricopa County patients with SMIs and over a quarter of those with GMI. Participants could choose to take the study in English or Spanish.

Recruitment was performed using electronic flyers via facility email lists (APPENDIX C). Participants could choose to complete the study (APPENDIX D) using

the web-based MDC tool or with researcher by phone. During the study, participants were informed that their responses would have no effect on the sharing of their actual health records.

4.2.4 Data Analysis

Table 14 provides an overview of the data sharing scenarios, methods, and outcomes. Descriptive analysis was conducted using responses to the three MDC data sharing scenarios to calculate participants' willingness to share none, some, and all health data across scenarios, between SMI and GMI facilities, care vs research, and inside vs outside providers. Next, bivariate analyses was conducted to examine associations between demographic factors and willingness to share. The responses (1=share and 0=not share) for five types of information under each of the three data sharing scenarios were analyzed in a generalized linear mixed model (GLMM) framework using mixed effects logistic regression models. The responses for the different information types were fit under the three different scenarios and treated as repeated measurements nested within participants.

To evaluate associations between demographic factors and overall willingness to share, a separate model was fit for each demographic factor (e.g., age, race, etc.), with that factor as the only model covariate. For some variables, demographic categories with extreme small cell sizes were combined. American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, and participants identifying as multiracial were combined into one group, yielding a three-category race variable (White/Caucasian, Black/African American, and Other); in the education category, Master and Doctorate

degrees were combined; and in the age groups category, 56 to 75 years and 76 years and above were combined. In the case of gender, the sole participant who identified as "other" in the gender category was excluded from the analysis. Differences between Spanish speakers and English speakers were not examined due to the small number of Spanish-speaking participants (N = 5) who scored above 14 on the UBACC test.

To evaluate the overall impact (i.e., main effect) of each of the three factors (data type, data recipient, and data use purpose), the fit of a model including that factor plus patient background characteristics (e.g., age) as covariates (Model 2) was compared to that of a baseline model including only patient characteristics (Model 1) via a likelihood ratio test (LRT) with α=.05 as the criterion for statistical significance. To evaluate potential differential impacts of data type and data use purpose across different data recipients, main effect models were extended to include interaction terms (either data type x data recipient or data use purpose x data recipient), and each of these (Model 3) was compared to the relevant main effects model (Model 2) via a LRT. All GLMMs included a random effect for participant-level intercepts and were estimated using the lme4 package in R.

Table 14. Overview of the Data Sharing Scenarios Supported by the MDC Tool and the Mixed Methodology Used for Data Analysis

DATA SHARING SCENARIOS				
Scenario	**Data source**	**Data recipient**	**Data type**	**Data use purpose**
1	Current BHP	PCP within same facility	(1) domestic violence, (2) genetic information, (3) mental health, (4) sexual and reproductive health, (5) substance use, (6) none	(1) treatment, (2) research (3) none
2		PCP outside the facility		
3		BHP outside the facility		
DATA ANALYSIS METHODS				
Data Source		**Methods**	**Software**	**Outcomes**
UBACC test		Descriptive statistics	Excel	Study comprehension score
Demographic survey		Descriptive statistics and bivariate analysis using GLMMs	Excel and R	Sharing preferences by demographics
willingness to share survey		Multivariate analysis using GLMMs and adjusting for demographics	R	Sharing preferences based on data types, data recipients and data use purpose
education material access		Descriptive statistics	Excel	Number of times material was accessed
Study experience survey		Descriptive statistics	Excel	User feedback
		Thematic analysis	MAXQDA	Themes

4.3 Results

4.3.1 Demographics

Of the 524 participants who expressed interest, 218 initiated and 209 completed the study, yielding a completion rate of 96%. All participant responses (100% of 209) were collected via phone. The average UBACC score was 19.145 out of 20. Nine scored below the threshold on the UBACC test and were removed from further analysis. For the remaining 200 participants (Table 15), the average age was 43 years (SD = 13), the mean age at the GMI facility was 43 years (SD = 14) and 45 years for the SMI facility (SD = 13). Most were Caucasian (81%), female (76%), and some had a college degree (39%). Majority (60%) of participants had a diagnosis of GMI. Twenty-five (13%) received both behavioral and primary care at the GMI facility and 40 (20%) at the SMI facility.

Table 15. Demographics of Participants Completing the Study (N=200). Percentage May Not Total 100 Due to Rounding

Demographics	**GMI facility (n=120)**	**SMI facility (n = 80)**	**Total (n=200)**
	n (%)	**n (%)**	**n (%)**
Gender			
Female	95 (79%)	57 (71%)	152 (76%)
Male	24 (20%)	23 (29%)	47 (24%)
Other	1 (1%)	0 (0%)	1 (1%)
Age group			
18 – 35	41 (34%)	22 (28%)	63 (32%)
36 – 55	58 (48%)	38 (48%)	96 (48%)
56 – 75	20 (17%)	20 (25%)	40 (20%)
76 and older	1 (1%)	0 (0%)	1 (1%)
Race			
American Indian or Alaska Native	2 (2%)	1 (1%)	3 (2%)
Asian	2 (2%)	0 (0%)	2 (1%)
Black or African American	15 (13%)	2 (3%)	17 (9%)
Native Hawaiian or other Pacific Islander	2 (2%)	0 (0%)	2 (1%)
White	92 (77%)	70 (88%)	162 (81%)
More than one race	7 (6%)	7 (9%)	14 (7%)
Ethnicity			
Hispanic or Latino	25 (21%)	13 (16%)	38 (19%)
Non-Hispanic or Latino	95 (79%)	67 (84%)	162 (81%)
Annual income			
< $5,000	33 (28%)	25 (31%)	58 (29%)
$5,000 – $9,999	8 (7%)	11 (14%)	19 (10%)
$10,000 – $14,999	26 (22%)	11 (14%)	37 (19%)
$15,000– $19,999	9 (8%)	5 (6%)	14 (7%)
$20,000 – $24,999	6 (5%)	10 (13%)	16 (8%)
≥ $25,000	38 (32%)	18 (23%)	56 (28%)
Education level			
< High school graduate	6 (5%)	7 (9%)	13 (7%)
High school graduate (or equivalence)	13 (11%)	20 (25%)	33 (17%)
Some college (1-4 years, no degree)	48 (40%)	30 (38%)	78 (39%)
Associate degree	22 (18%)	12 (15%)	34 (17%)
Bachelor degree	20 (17%)	6 (8%)	26 (13%)
Master degree	9 (8%)	5 (6%)	14 (7%)
Doctoral degree	2 (2%)	0 (0%)	2 (1%)

Table 15. Continue

Demographics	**GMI facility (n=120)**	**SMI facility (n = 80)**	**Total (n=200)**
	n (%)	n (%)	n (%)
Length of care history			
< 1 year	24 (20%)	9 (11%)	33 (17%)
1 – 2 years	39 (33%)	12 (15%)	51 (26%)
3 – 4 years	18 (15%)	18 (23%)	36 (18%)
5- 6 years	12 (10%)	12 (15%)	24 (12%)
7 – 8 years	6 (5%)	8 (10%)	14 (7%)
9 – 10 years	8 (7%)	5 (6%)	13 (7%)
> 10 years	13 (11%)	16 (20%)	29 (15%)
Language			
Spanish	3 (3%)	2 (3%)	5 (3%)
English	117 (98%)	78 (98%)	195 (98%)
Care history			
Receive BHP and PCP	25 (21%)	40 (50%)	65 (33%)
Receive BHP only	95 (79%)	40 (50%)	135 (68%)
Participant type			
Patients	113 (94%)	76 (95%)	189 (95%)
Guardians	7 (6%)	4 (5%)	6%)

4.3.2 Data Sharing Preferences

No participant indicated willingness to share all their health data with all data recipients, and no participant chose to restrict access to all their data. All participants wanted to restrict access to some health data. On average, patients with GMI were more willing (69%) to share than those with SMI (66%) (P=.001) (Figure 6a). There was also variability in willingness to share across the scenarios. On average, there was more willingness to share for care (treatment) than for research (P<.001) (Figure 6b). Although patients with GMI and SMI were more willing to share for care (95% for GMI and 93% for SMI), those with SMI were more willing to share for research (80%) than those with GMI (75%) (Figure 6c). Participants were, on average, more willing (87%) to share with

providers inside their facility than providers outside their facilities (83% for outside PCP and 82% for outside BHP, P<.005) (Figure 6d).

Figure 5. Mean Willingness of Participants With SMI and GMI To Share the NCVHS Sensitive Data Types Based on: (a) Data Recipient, (b) Data Use Purpose and Data Recipient, (c) Data Use Purpose, and (d) Data Recipient

Results of the bivariate logistic regression analysis did not show a significant association between demographic factors and willingness to share (all Ps>.09). Table 16 shows percentage of sharing none, some, and all health data across the three scenarios.

Table 16. Overall Willingness To Share None, Some, and All Health Data Across Scenarios. Percentages May Not Total 100 Due to Rounding

Variables	**Inside PCP**			**Outside PCP**			**Outside BHP**		
	None	Some	All	None	Some	All	None	Some	All
Gender									
Female	2%	26%	72%	4%	25%	71%	6%	28%	66%
Male	2%	34%	64%	6%	34%	60%	9%	30%	62%
Age groups									
18 - 35 years	2%	27%	71%	3%	29%	68%	6%	32%	62%
36 - 55 years	2%	31%	67%	5%	27%	68%	5%	28%	67%
56 years and older	2%	22%	76%	5%	24%	71%	10%	22%	68%
Race									
Black or African American	0%	59%	41%	12%	41%	47%	0%	53%	47%
White	2%	23%	75%	4%	25%	71%	8%	25%	67%
Other	5%	38%	57%	0%	33%	67%	0%	29%	71%
Ethnicity									
Hispanic or Latino	3%	18%	79%	8%	26%	66%	8%	31%	61%
Non-Hispanic or Latino	2%	30%	68%	4%	27%	69%	6%	27%	67%
Annual income									
< $5,000	0%	21%	79%	3%	23%	74%	5%	26%	69%
$5,000 – $9,999	5%	47%	47%	0%	32%	68%	11%	37%	53%
$10,000 – $14,999	0%	30%	70%	5%	30%	65%	5%	30%	65%
$15,000– $19,999	0%	21%	79%	14%	21%	64%	21%	21%	57%
$20,000 – $24,999	6%	25%	69%	0%	38%	63%	0%	25%	75%
≥ $25,000	4%	30%	66%	5%	27%	68%	5%	29%	66%
Education level									
< High school	8%	15%	77%	23%	23%	54%	23%	8%	69%
High school graduate (or equivalence)	6%	15%	79%	3%	18%	79%	3%	27%	70%
Some college (1-4 years, no degree)	1%	37%	62%	4%	29%	67%	5%	32%	63%
Associate	0%	18%	82%	3%	29%	68%	9%	26%	65%
Bachelor degree	0%	31%	69%	0%	27%	73%	4%	27%	69%
≥ Master degree	0%	37%	63%	6%	31%	63%	6%	31%	63%

Table 16. Continue

Variables	Inside PCP			Outside PCP			Outside BHP		
	None	Some	All	None	Some	All	None	Some	All
Length of care history									
< 1 year	0%	24%	76%	6%	27%	67%	0%	36%	64%
1 – 2 years	2%	39%	59%	0%	33%	67%	4%	35%	61%
3 – 4 years	3%	22%	75%	8%	25%	67%	6%	25%	69%
5 – 6 years	4%	42%	54%	0%	38%	63%	4%	29%	67%
7 – 8 years	0%	14%	86%	7%	14%	79%	14%	21%	64%
9 – 10 years	0%	15%	85%	15%	8%	77%	31%	8%	62%
> 10 years	3%	21%	76%	3%	24%	72%	7%	21%	72%
Diagnosis									
GMI	1%	28%	71%	3%	24%	73%	6%	29%	65%
SMI	4%	27%	69%	6%	31%	63%	8%	26%	66%
Care history									
Receive BHP and PCP	2%	27%	71%	8%	32%	60%	6%	28%	66%
Receive BHP only	2%	28%	70%	3%	24%	73%	7%	28%	65%

4.3.3 Impact of Data Type, Data Recipients, and Data Use Purpose on Granular Data Sharing

When considering participants' willingness to share based on data sharing scenarios, significant main effects of data type, data recipient, data use purpose, and the interaction between data type and data recipient (all Ps<.001) on willingness to share PHI (0=share none vs. 1=share some or all) were found. The interaction between data use purpose and data recipient was not significant (P=.317).

Table 17 shows the results of pairwise comparisons of likelihood of sharing across the three data recipients, the five NCVHS sensitive data categories, and the two purposes of use in a pairwise fashion using model-estimated probabilities derived from the GLMMs. Participants were significantly more willing to share their health data with the PCP within their facility than with PCP outside their facility (P=.003) and with BHP outside their facility (P<.001). There was significantly more willingness to share domestic violence than genetic information (P=.002) and mental health (P=.025). Also, there was significantly more willingness to share genetic than sexual and reproductive

health information (P<.001) and substance use (P<.001). The analysis also showed significantly more willingness to share mental health information than sexual and reproductive health (P<.001) and substance use information (P=.002). Finally, participants were significantly more willing to share their health data for treatment than for research (P<.001).

Table 17. Pairwise Comparison of Willingness To Share Based on Data Types, Data Recipients, and Data Use Purpose

Pairwise comparison	**P value**	**Description**
Data recipients		
PCP within same facility vs PCP outside the facility	.003	More willingness to share with PCP within same facility than PCP outside the facility
PCP within same facility vs BHP outside the facility	<.001	More willingness to share with PCP within same facility than BHP outside the facility
PCP outside the facility vs BHP outside the facility	.355	No difference in sharing between PCP outside the facility and BHP outside the facility
Data types		
Domestic violence vs genetic information	.002	More willingness to share domestic violence than genetic information
Domestic violence vs mental health	.025	More willingness to share domestic violence than mental health
Data types		
Domestic violence vs sexual and reproductive health	.371	More willingness to share domestic violence than sexual and reproductive health
Domestic violence vs substance use	.947	More willingness to share domestic violence than substance use
Genetic information vs mental health	.945	More willingness to share genetic information than mental health
Genetic information vs sexual and reproductive health	<.001	More willingness to share genetic information than sexual and reproductive health
Genetic information vs substance use	<.001	More willingness to share genetic information than substance use
Mental health vs sexual and reproductive health	<.001	More willingness to share mental health than sexual and reproductive health
Mental health vs substance use	.002	More willingness to share mental health than substance use
Sexual and reproductive health vs substance use	.824	More willingness to share sexual and reproductive health than substance use
Data use purpose		
Treatment vs research	<.001	More willingness to share for treatment than research

4.3.4 Perceptions on the NCVHS Taxonomy and Granular Information Control

Majority of participants (83%, N=200) indicated that the NCVHS taxonomy captured their data privacy needs (Figure 6a). Over half (55%) reported that being able to specify data type, data recipient and data use purpose made them more willing to share their medical data (Figure 6b). Most respondents (87%) indicated that knowing how data is being used (either for care or research) made them feel more comfortable sharing their data (Figure 6c). Most (82%) of the participants wanted to be notified each time someone used their medical data (either for care or research) (Figure 6d).

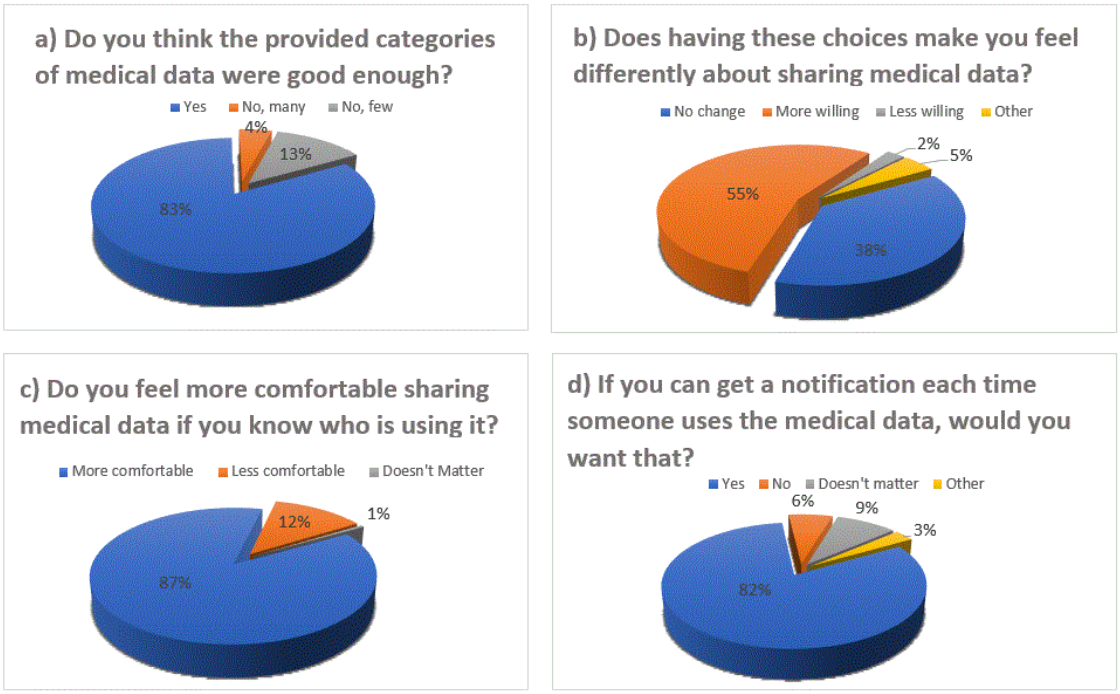

Figure 6. Results of user experience survey

4.3.5 Access to Patient Educational Materials

Fifty-five participants (28%, N= 200) accessed the education materials across the three scenarios 86 times. Across the three scenarios, on average, participants who accessed the education material were more willing to share (86%) overall than

participants who did not (69%). Sharing all health data was selected fewer times for those who had accessed material (58%) than for those who did not (74%). A majority of those who accessed the education materials were more likely to restrict some health data (40%) than those that did not access the materials (24%). On average, there was no difference in participant perspectives about the adequacy of the NCVHS taxonomy to capture data sharing needs between participants who accessed the educational materials and those who did not. More (33%, N= 80) patients with SMI accessed the materials than those with GMI (24%, N=120).

Across the five NCVHS data types, educational material for genetic information was accessed the most (36 times) followed by sexual and reproductive health information (26 times), substance use (15 times) and domestic violence (7 times). Mental health was accessed the least (2 times).

4.3.6 Qualitative Analysis of Comments and User Experience Survey Feedback

Of the 200 participants, 91 (46%) responded with free-text feedback. Application of content analysis definitions yielded 173 codes of positive (131 codes), mixed (33 codes), and concerned (9 codes) feedback. Mixed feedback encompassed four key themes: 1) comments regarding notification system, 2) changes to categories, 3) additional options in sharing, and 4) more details needed for decision-making (Figure 7).

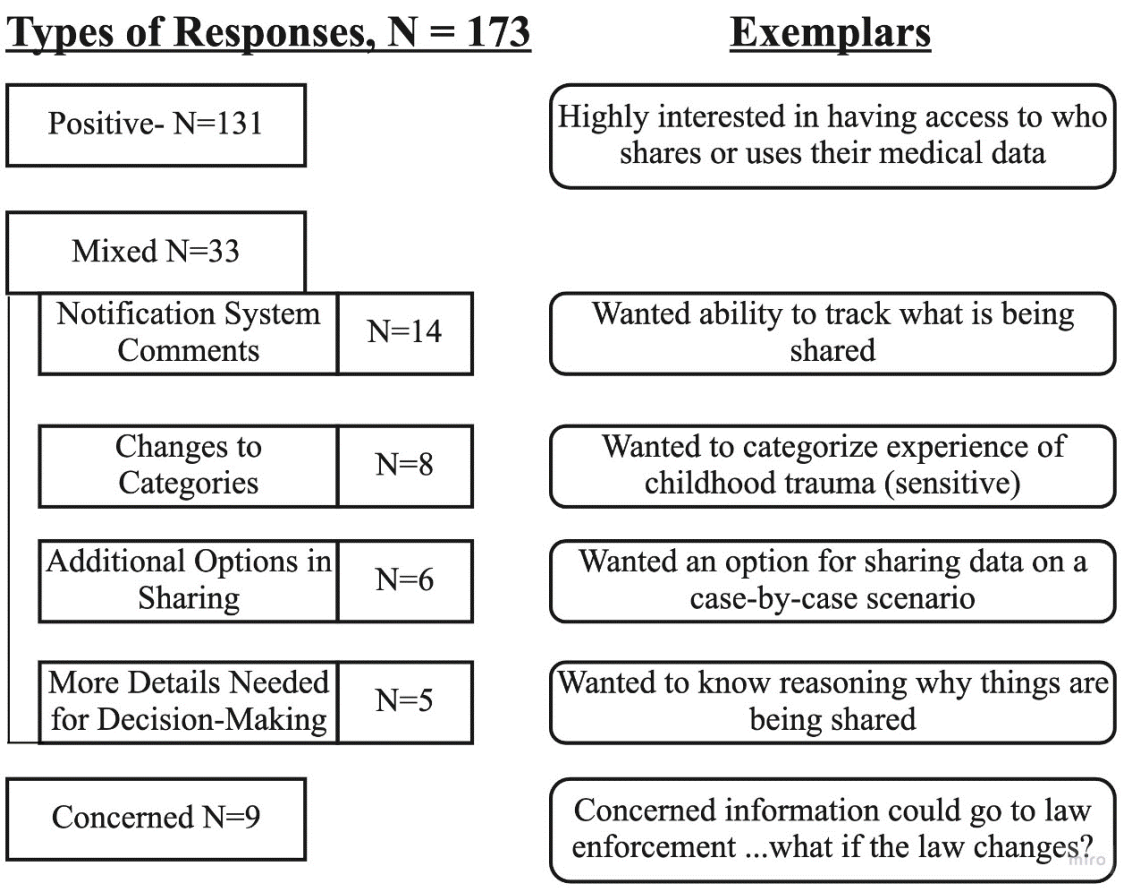

Figure 7. Content Analysis Results of 173 Comments Provided by 91 Participants With Example Commentary

4.4 Discussion

The implementation and pilot testing of the MDC web-based electronic informed consent tool brings us closer to the ONC and NCVHS GDS visions. Several key messages emerged from the analysis as detailed below.

While data type, data recipient and data use purpose have been examined in previous data sharing studies(Bell et al., 2014; Caine et al., 2015; Caine & Hanania, 2013; Grande et al., 2015; Grando et al., 2017; Kim et al., 2017; King et al., 2012; Schwartz et al., 2015; Soni et al., 2019; Teixeira et al., 2011; Tierney et al., 2015;

Weitzman et al., 2012) to support patient-controlled data sharing, this study was the first to demonstrate that these variables have significant impact on patients' willingness to share health data. Additional studies are needed to see if these findings can be reproduced in different patient populations and to understand the impact that other relevant variables such as duration of data access (one year), opt-in vs opt-out policy, etc. have on willingness to share.

Patients with BHCs wanted granular control over the sharing of their health data. No participant indicated sharing all their data with all data recipients. Majority reported that having granular choices would make them more willing to share their medical data. Most participants wanted to know how their data was to be used (for care or research) and reported that such control made them feel more comfortable sharing. These findings are consistent with previous studies also focused on patients with BHCs (Grando et al., 2017; Soni et al., 2020; Soni et al., 2019). Similar results on granular control have been reported in studies focusing on healthy individuals (Bell et al., 2014) and participants of a state HIE (Caine et al., 2015; Caine & Hanania, 2013). However, the desire for granular control as revealed in this study contrasts with previous studies that showed less willingness to restrict access (Schwartz et al., 2015) and fewer concerns about the risk of sharing (Mello et al., 2018).

Patients with GMI were more willing to share their health data for care than those with SMI. While previous studies have focused on understanding granular data sharing preferences of these two groups (Soni et al., 2018; Soni et al., 2019; Soni et al., 2020; Soni et al., 2021), this is the first study to compare difference in sharing preferences

between the two populations. We assume that the reluctancy of individuals with SMI to share their sensitive medical records could be due to the way SMI is represented in the media. While it is reported that people with SMI are more than 10 times likely to be a victim of violent crimes, they are often represented in the media as "violent population," "dangerous group," and "unpredictable individuals" (*Mental Health Myths and Facts | MentalHealth.Gov*, n.d.). The result about less willingness of individuals with SMI to share their sensitive health records is consistent with previous studies that found inverse correspondence between perceived sensitivity of information and willingness to share (Caine et al., 2015; Caine & Hanania, 2013; King et al., 2012). In contrast, a direct correlation between perceived sensitivity of information and willingness to share has been found (Soni et al., 2019).

Sharing for research was greater among SMI patients. This finding is consistent with previous studies (Grande et al., 2015; Kim et al., 2017; Mello et al., 2018). It has been found that patients from an HIV clinic were more willing to share their information for research than those from an internal medicine clinic (Kim et al., 2017). Similar results were reported in patients with cancer (Grande et al., 2015). Perhaps patients with particular diagnoses that are generally considered sensitive information are eager to share their information for research to benefit society (Grande et al., 2015; Grando, et al., 2017; Kim et al., 2017; King et al., 2012; Soni et al., 2019).

Willingness to share with providers inside the health care facility was higher than with providers outside the facility. This seems to support the integrated care models that care for the individual as a whole. This differentiation in sharing preferences based on

data recipients (data users) is consistent with previous studies (Teixeira et al., 2011; Weitzman et al., 2012).

While previous studies have raised concern that distrust in research among certain majority groups may extend to data sharing (*Kaufman*, n.d.; *Sanderson*, n.d.; *Storr*, n.d.; RISK, 2015), our study did not find significant differences by race, consistent with (Mello et al., 2018). Other demographic factors (age, gender, education level, income, gender, ethnicity, length of care history, and diagnosis) also were not significantly related to overall willingness to share. This contrasts with (King et al., 2012) that reported age, level of education, place of birth and employment status as factors strongly associated with privacy concerns.

Results of the free-text feedback showed participants were satisfied with the MDC tool, with most participants highly interested in using a tool that offered granular options for executing data sharing decisions. This result showed the potential of data sharing technologies such as the one developed by SAMHSA (i.e., Consent2Share) to support automatic granular data segmentation.

Our study had limitations. We did not assess participants' health status. Although health status was not a significant predictor of attitudes to share (Mello et al., 2018), a less healthy group may have different views regarding data sensitivity and their willingness to share may have been different. Despite our greater effort to recruit representative sample of English and Spanish speakers, we were able to recruit only a modest number of Spanish-speaking participants. While 40% of our population were individuals with SMI, it is possible that findings would not be true representative of the

overall SMI population due to the sample size. Also, participants who are willing to take part in a study about data sharing choices may be more willing to share their medical record than those who did not consent to participate.

Additionally, the sample size for guardians of individuals with SMI was small, hindering our ability to analyze and make statistical inferences about their willingness to share the health records of the patients they represent. Our study mode was modified from in-person to online or via phone due to the COVID-19 pandemic. While our study completion rate was very high, there is a possibility of nonresponse bias due to the use of digital devices and network. Participants who did not have access to phone may have declined to participate. On the other hand, we were able to adjust to the participants' working schedules – weekends included- and study participation did not require transportation to the health care facility. Moreover, the physical absence of a recruiter may have given participants more autonomy when making data sharing decisions.

Another limitation was that this study like previous studies on GDS (Bell et al., 2014; Kim et al., 2017), was hypothetical. Participants' willingness to share their actual health data may be different from hypothetical willingness. Previous studies on genomic data have shown that factual willingness was actually greater than hypothetical willingness (Johnsson et al., 2010; Oliver et al., 2012). Additionally, the COVID-19 pandemic could have increased participants' willingness to share data (Molldrem et al., 2021; Dye et al., 2016; Pearce et al., 2020; Littler et al., 2017; Chretien et al., 2016; Moorthy et al., 2020; Fegan & Cheah, 2021; Gardner et al., 2021; Galvin et al., 2021; Cosgriff et al., 2020; Paul et al., 2020; Curioso et al., 2020; Foraker et al., 2021; Aguiar

et al., 2020; Gewin et al., 2020; Amit et al., 2021; Petkova et al., 2020; Laato et al., 2020; Pratt et al., 2021; Anane-Sarpong et al., 2018; Barnes et al., 2019; Merson et al., 2016; Morten et al., 2020; Langat et al., 2011; Modjarrad et al., 2016; Briamacombe et al., 2020; Cai et al., 2020; He et al., 2020; Pisani et al., 2018; Gorina et al., 2020; Rahimi et al., 2020; Yozwiak et al., 2015; Abramowitz et al.,2018; Norton et al., 2019; Whitty et al., 2015).

This is the first study to solicit patient opinion on the applicability of NCVHS taxonomy to their data privacy needs. The majority of our respondents indicated that the NCVHS taxonomy was sufficient for capturing their wishes. As future work, we are evaluating the NCVHS taxonomy with healthcare providers. Results will compare the perceptions of patients and providers on using the NCVHS taxonomy.

4.5 Conclusions

To address the lack of consensus on variables relevant to honor patient GDS desires, we pilot tested with patients a medical record sharing clinical decision support system and evaluated the impact of the ONC variables on participants' willingness to share their digital health records. Our evaluation showed that data source, data recipient, data type, and data use purpose are highly relevant variables to support granular medical record sharing of patients with BHC. Our study showed that patients think that the NCVHS data taxonomy is adequate to capture their sensitive data privacy needs. Finally, there was diversity in EHR sensitive and sharing preference of patients with BHC showing that patients desire granular control over the sharing of their sensitive medical records.

CHAPTER 5

CONCLUSION

The traditional model of assessing and treating patients with BH and PH conditions in silos has created obstacles to successful care coordination (Reed et al., 2016). The coordination of BH and PH results in best outcomes and provides the most effective approach for supporting whole-person health and wellness. During the past two decades, many initiatives including HIE organizations have sought to tackle these obstacles by creating infrastructure to facilitate cross-organizational health data sharing (Huffman et al., 2014; *Integrated Health*, n.d.; Peek, n.d.; *Welcome to the AHRQ Academy | The Academy*, n.d.; Guide, 2015; McGough et al., 2016). The current challenge, however, is affording meaningful consent and ensuring patient privacy, the cornerstones for advancing the adoption and use of health information technology in the US (*Guide to Privacy and Security of Health Information. Office of National Coordinator for Health IT.*, n.d.).

The ONC recommends that patients should be given granular control beyond the "share all" or "share none" approach that is widely used currently in consent practices (*Health IT Policy Committee*, n.d.). But there is no consensus on the variables relevant to honor patients' GDS preferences. As a result, existing GDS studies used ad-hoc approaches to implement or assess GDS preferences of patients. Implementing consent technologies to give patients meaningful choices over the sharing of their medical records requires the identification of relevant data sharing variables, categorizations of EHR data that are generally considered sensitive, education of individuals on data sharing preferences, and development of decision support systems to support patient-driven GDS.

The overall goal of this study is to address the ad-hoc approaches that currently exist in GDS research which hinder EHRs sharing and interoperability. Specifically, this study aims to address the following **knowledge gaps:** 1) lack of consensus on the variables relevant to honor patient granular sharing desires; 2) sparse research on GDS of patients with BHCs; and 3) need for patient validation of existing sensitive data taxonomies used to support GDS and categorize sensitive medical records.

The **hypotheses** of this work were that H1) the ONC variables (information, recipient, and purpose of use) are relevant to offer granular information sharing preferences as demonstrated by statistically significant differences in data sharing choices; H2) there is diversity in medical record sharing preferences of individuals with BHCs; and H3) the NCVHS taxonomy captures sensitive data sharing preferences of patients with BHCs.

5.1 Main Findings

The primary aim of this thesis has been to propose and pilot novel informatics methods to support patient-driven GDS and to validate the suitability and usefulness of such methods in clinical environments. To that end, we proposed an innovative standards-based GDS framework based on the ONC variables, designed and pilot tested a clinical decision support system to validate the framework, validated the adequacy of the NCVH sensitive data taxonomy with patients, and systematically explored health data privacy views and data sharing perceptions of patients with BHCs.

First, we demonstrated that data source, data recipient, data type, and data use purpose have a significant impact on granular medical record sharing of patients with BHCs, thereby validating hypothesis H1. The findings help to replace existing ad-hoc

data sharing processes, provide insights into GDS research and create a roadmap for other researchers and professionals working on consent tools to design and apply standards-based approaches to support patient-driven GDS.

Secondly, we showed that patients with BHCs desired granular control over the sharing of their health data, validating hypothesis H2. Ours was the largest (N=209) study of "people with lived expertise" to assess privacy preferences and perceptions on willingness to share medical records. We supported participants in data sharing decision-making by incorporating low literacy education materials to explain their sharing options and assessed their comprehension of the study to ensure that results reflected only those that are qualified to make consent-related decisions. Participants were satisfied with the granular options offered by MDC for executing data sharing decisions. The findings provide significant insights on ways to meaningfully engaged vulnerable patient groups, such as those with HIV, and assess individuals' GDS preferences accurately and effectively. We demonstrated that despite the many challenges related to engaging vulnerable population in research, including quality scrutiny, assiduous attention, among others (Shivayogi, 2013),we meaningfully incorporated the voice of populations that have largely been absent from health data privacy discussion (Karway et al., 2021).

Finally, the validation of the NCVHS taxonomy showed the sufficiency of the taxonomy for capturing patients' sensitive data preferences, validating hypothesis H3. The methods used and the outcomes of this study will guide the evaluation of individuals' perspectives towards other sensitive data categories.

5.2 Generalizability of the Proposed Methodologies and Findings

This work focuses on a specific population of patients with BHCs, but our proposed approaches should be applicable to other populations involved in consent-based medical record decisions. Our approaches should also be applicable to other data sharing areas that were brought to light amidst the public health emergencies caused by the COVID 19 pandemic (Molldrem et al., 2021; Dye et al., 2016; Pearce et al., 2020; Littler et al., 2017; Chretien et al., 2016; Moorthy et al., 2020; Fegan & Cheah, 2021; Gardner et al., 2021; Galvin et al., 2021; Cosgriff et al., 2020; Paul et al., 2020; Curioso et al., 2020; Foraker et al., 2021; Aguiar et al., 2020; Gewin et al., 2020; Amit et al., 2021; Petkova et al., 2020; Laato et al., 2020; Pratt et al., 2021; Anane-Sarpong et al., 2018; Barnes et al., 2019; Merson et al., 2016; Morten et al., 2020; Langat et al., 2011; Modjarrad et al., 2016; Briamacombe et al., 2020; Cai et al., 2020; He et al., 2020; Pisani et al., 2018; Gorina et al., 2020; Rahimi et al., 2020; Yozwiak et al., 2015; Abramowitz et al.,2018; Norton et al., 2019; Whitty et al., 2015).

The proposed GDS framework and examples used for data source, data recipients, and purpose of data assumed that patients received care at integrated care facilities providing both behavioral and primary care. Future work will study the scalability and generalizability of the framework to other patient populations and clinical settings.

The methods used for the validation of the NCVHS taxonomy were based on illustrative scenarios and surveys and therefore applicable to the evaluation of other sensitive data taxonomies, such as the one proposed by SAMHSA (*SAMHSA*, n.d.).

5.3 Limitations

Our population included patients with BHCs from two out-patients integrated behavioral and physical health clinics in Phoenix, Arizona. Most of our population included White Non-Latino females with some college education and diagnosed with GMI. While our studies included a large number of participants, considering the homogeneity of patient population, the results may not be generalizable.

While the demographic questionnaires used in this study have been piloted with 31 English and Spanish-speaking participants (Aliste et al., 2019) and questions accessing participants' opinion on the applicability of the NCVHS taxonomy to their GDS preferences has also been piloted with 126 patients from HIV and Internal Medicine Clinics (Kim et al., 2017), they have not been validated. Validation of these questionnaires through test and re-test is another interesting avenue to explore granular data sharing choices of participants and how these choices changed over time.

Additionally, we did not explore the variations in motivations behind information sharing in detail to analyze patient motivations. Our findings, therefore, might not directly meet the desires and motivations of other patient populations or healthy individuals.

Also, we did not validate the generalizability and scalability of the GDS framework or the MDC clinical decision support tool. Specifically, we did not assess the application of the framework and the MDC tool to other populations and different clinical environments to compare in situ and ex situ performances to support patient-driven GDS.

5.4 Dissemination of Research Outcomes

The outcomes of this research have been published through journal and conference papers and posters. Below, publications details are provided.

The outcomes of the literature review discussed in Chapter 2 (Aim 1) were published in the Journal of Biomedical Informatics- X:

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 evaluation of education materials for medical record sharing discussed in chapter 3 (Aim 2) has been submitted and is under review for the *American Medical Informatics Association (AMIA) 2022 Annual Symposium*. Alongside, a full conference paper discussing the findings of the systematic approach used to design patient education materials on sensitive medical record sharing has been submitted and is under review for the same conference:

Karway, G., Murcko, A., Kalpas E., & Grando, A. Systematic approach to design patient education materials on sensitive medical record data.

A poster discussing the initial outcomes of the design of My Data Choices based on the proposed framework discussed in Chapter 4 (Aim 3) was presented at the American Medical Informatics Association (AMIA) 2017 Annual Symposium. The final outcomes were summarized in a paper, currently under review for the Health *Informatics Journal*:

Karway G., Ivanova J., Kaing T., Todd M., Chern D., Murcko, A., Syed K., Garcia M., Franczak M., Whitfield, M. J., & Grando, A. My Data Choices: pilot evaluation of patient-controlled medical record sharing technology.

5.5 Future Work

In this work, we introduced a new methodological framework to support patient-driven GDS. Specifically, we developed and pilot tested the interface of the MDC clinical decision support system (see Figure 8) to validate the proposed GDS framework (Greenes, 2011). We also validated the NCVHS taxonomy with patients to assess their perceptions on the adequacy of the taxonomy to capture their sensitive medical record sharing reference. We are conducting a study to assess how physicians categorize medical record data and perceive the adequacy of NCVHS taxonomy. Results would be compared to patients' perception on the same sensitive data categorizations. Insights would inform ONC and NCVHS recommendations and policies on sensitive data sharing and granular patient-driven consent process and technology development. Future work will focus on the development of the remaining clinical decisions modules of the MDC: 1) knowledge base and 2) decision rules (inference engine).

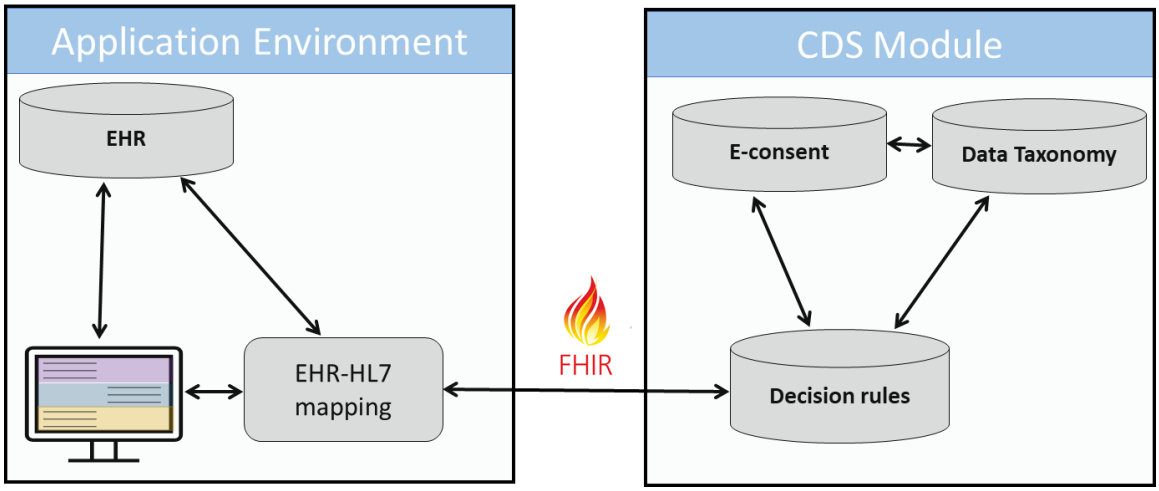

Figure 8: MDC Clinical Decision Support System Specification.

As part of the knowledge base, an option to consider for the development of the electronic consent (e-consent) module could be adopting the Fast Healthcare Interoperability Resources (FHIR) Consent resource (*Consent - FHIR v4.0.1*, n.d.; Lackerbauer et al., 2018). The consent FHIR resource allows to create specifications of the agreements by a healthcare consumer [grantor] or a personal representative to an authorized entity [grantee]. This enables the grantor to specify authorized or restricted actions relating to collecting, accessing, using, or disclosing (share) information.

Also, as part of the knowledge base, the NCVHS taxonomy will need to be extended with computer-interpretable specifications. An option could be the development of value sets (lists of codes from NLM-hosted standard clinical vocabularies) for each of the sensitive data categories in the taxonomy (Bodenreider et al., 2013; *Value Set Authority Center*, n.d.).

Finally, regarding the decision rules module, future work may extend the existing Consent2Share decision engine with more advanced non-binary rules beyond the

identification of information as “sensitive” or “not sensitive.”. Clinicians will be engaged in the process of understanding how contextual information in the patient’s EHR affects the sensitivity of medical information. Dysfunctional uterine bleeding, for example, may be categorized as “sexual and reproductive health information” if considered as a factor causing “reproductive health problem” for the patients. Dysfunctional uterine bleeding may also be categorized as “mental health information” when being caused by “trauma” as recorded in the patient encounter visits. By engaging physicians in the classification, a better approach would be used to determine the categorization of information such as the ones mentioned above that may potentially fall into more than one categorization based on the clinical contextual information.

In terms of the NCVHS taxonomy, future research could focus on adding other sensitive data categories reported in the literature, such as social-economic data, lifestyle-behavior data, tracking data, financial data, and authenticating data (Chua et al., 2021). Clinicians will need to be involved in the process of further refining and extending the NCVHS taxonomy.

Summarizing, this research builds the foundations for a new generation of future data segmentation methods and tools that advances the visions of the NCVHS, ONC, and SAMHSA initiatives of creating standard-based, interoperable models to share sensitive health information in compliance with patients’ data privacy preferences and applicable regulations.

REFERENCES

42 CFR Part 2—Confidentiality of Substance Use Disorder Patient Records. (n.d.). LII / Legal Information Institute. Retrieved September 8, 2021, from https://www.law.cornell.edu/cfr/text/42/part-2

Agency for Healthcare Research and Quality (AHRQ). (n.d.). Retrieved October 26, 2021, from https://www.ahrq.gov/

Abramowitz, S., Giles-Vernick, T., Webb, J., Tappan, J., Uretsky, E., Varanda-Ferreira, J., ... & Sall, A. (2018). Data sharing in Public Health Emergencies: Anthropological and historical perspectives on data sharing during the 2014-2016 Ebola epidemic and the 2016 Yellow Fever epidemic. *Final report to the Wellcome-DfID joint initiative on epidemic preparedness*

Aguiar, E. R., Navas, J., & Pacheco, L. G. (2020). The COVID-19 diagnostic technology landscape: efficient data sharing drives diagnostic development. *Frontiers in Public Health*, *8*, 309

Aliste, M. P., Grando, A., Murcko, A., 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. *MEDINFO 2019: Health and Wellbeing e-Networks for All*, 1891–1892. https://doi.org/10.3233/SHTI190699

Amit, A. M. L., Pepito, V. C. F., Gutierrez, B., & Rawson, T. (2021). Data Sharing in Southeast Asia During the First Wave of the COVID-19 Pandemic. *Frontiers in public health*, *9*

Anane-Sarpong, E., Wangmo, T., Ward, C. L., Sankoh, O., Tanner, M., & Elger, B. S. (2018). "You cannot collect data using your own resources and put It on open access": Perspectives from Africa about public health data-sharing. *Developing world bioethics*, *18*(4), 394-405

Baker, A. (2001). *Crossing the quality chasm: a new health system for the 21st century* (Vol. 323, No. 7322, p. 1192). *British Medical Journal Publishing Group*

Barnes, K. I., Canario, J. A., Vernekar, S. S., Goudar, S. S., Espinal, R., Merson, L., & Cheah, P. Y. (2019). Equitable data sharing: challenges and suggestions for ways forward. *Wellcome Open Research*, *4*(172), 172

Barrows, R. C., & Clayton, P. D. (1996). Privacy, confidentiality, and electronic medical records. *Journal of the American Medical Informatics Association: JAMIA*, 3(2), 139–148

Behavioral Health vs Mental Health: What's the Difference? (n.d.). Alvernia Online. Retrieved July 7, 2021, from https://online.alvernia.edu/program-resources/behavioral-health-vs-mental-health/

Bell, E. A., Ohno-Machado, L., & Grando, M. A. (2014). Sharing my health data: A survey of data sharing preferences of healthy individuals. *AMIA Annual Symposium Proceedings. AMIA Symposium*, 2014, 1699–1708

Bell, E., Grando, M. A., & Ohno-Machado, L. (2014a). *A Pilot Evaluation of Patient Data Sharing Preferences*

Bodenreider, O., Nguyen, D., Chiang, P., Chuang, P., Madden, M., Winnenburg, R., McClure, R., Emrick, S., & D'Souza, I. (2013). The NLM value set authority center. Studies in Health Technology and Informatics, 192, 1224

Bradshaw, P. L. (2008). Service user involvement in the NHS in England: Genuine user participation or a dogma-driven folly? *Journal of Nursing Management*, 16(6), 673–681. https://doi.org/10.1111/j.1365-2834.2008.00910.x

Brimacombe, K. R., Zhao, T., Eastman, R. T., Hu, X., Wang, K., Backus, M., ... & Shen, M. (2020). An OpenData portal to share COVID-19 drug repurposing data in real time. *BioRxiv*

Cai, Q., Mi, Y., Chu, Z., Zheng, Y., Chen, F., & Liu, Y. (2020). Demand analysis and management suggestion: sharing epidemiological data among medical institutions in megacities for epidemic prevention and control. *Journal of Shanghai Jiaotong University (Science)*, *25*(2), 137-139

Caine, K., & Hanania, R. (2013). Patients want granular privacy control over health information in electronic medical records. *Journal of the American Medical Informatics Association: JAMIA*, 20(1), 7–15. https://doi.org/10.1136/amiajnl-2012-001023

Caine, K., Kohn, S., Lawrence, C., Hanania, R., Meslin, E. M., & Tierney, W. M. (2015). Designing a Patient-Centered User Interface for Access Decisions about EHR Data: Implications from Patient Interviews. *Journal of General Internal Medicine: J. Gen. Intern. Med.*, 30(Suppl 1), 7–16. https://doi.org/10.1007/s11606-014-3049-9

California Health Care Foundation. (2008, March). *A Delicate Balance: Behavioral Health, Patient Privacy, and the Need to Know*. https://www.chcf.org/publication/a-delicate-balance-behavioral-health-patient-privacy-and-the-need-to-know/

Campos-Castillo, C., & Anthony, D. L. (2015). The double-edged sword of electronic health records: Implications for patient disclosure. *Journal of the American Medical Informatics Association: JAMIA*, 22(e1), e130–e140. https://doi.org/10.1136/amiajnl-2014-002804

Carman, K. L., Dardess, P., Maurer, M., Sofaer, S., Adams, K., Bechtel, C., & Sweeney, J. (2013). Patient and family engagement: A framework for understanding the elements and developing interventions and policies. *Health Affairs*, 32(2), 223–231

Charnock, D., Shepperd, S., Needham, G., & Gann, R. (1999). DISCERN: An instrument for judging the quality of written consumer health information on treatment choices. *Journal of Epidemiology and Community Health.,* 53(2), 105–111. https://doi.org/10.1136/jech.53.2.105

Chase, D. (2012). Patient engagement is the blockbuster drug of the century. *Forbes. Com*

Chretien, J. P., Rivers, C. M., & Johansson, M. A. (2016). Make data sharing routine to prepare for public health emergencies. *PLoS medicine*, *13*(8), e1002109

Chua, H. N., Ooi, J. S., & Herbland, A. (2021). The effects of different personal data categories on information privacy concern and disclosure. *Computers & Security*, 110, 102453

Confidentiality | SEER Training. (n.d.). Retrieved September 16, 2021, from https://training.seer.cancer.gov/registration/data/confidentiality.html

Consent—FHIR v4.0.1. (n.d.). Retrieved March 20, 2022, from https://www.hl7.org/fhir/consent.html

Cosgriff, C. V., Ebner, D. K., & Celi, L. A. (2020). Data sharing in the era of COVID-19. *The Lancet Digital Health*, *2*(5), e224

Coulter, A. (2005). What do patients and the public want from primary care? *BMJ (Clinical Research Ed.)*, 331(7526), 1199–1201. https://doi.org/10.1136/bmj.331.7526.1199

Curioso, W. H., & Carrasco-Escobar, G. (2020). Collaboration in times of COVID-19: the urgent need for open-data sharing in Latin America. *BMJ Health & Care Informatics*, *27*(1), e100159

Darzi, A. (2009). High quality care for all: our journey so far. *London: TSO*

Demir, F., Ozsaker, E., & Ilce, A. O. (2008). The quality and suitability of written educational materials for patients*. *Journal of Clinical Nursing*, 17(2), 259–265. https://doi.org/10.1111/j.1365-2702.2007.02044.x

Dhopeshwarkar, R. V., Kern, L. M., O'Donnell, H. C., Edwards, A. M., & Kaushal, R. (2012). Health Care Consumers' Preferences Around Health Information Exchange. *Annals of Family Medicine.*, 10(5), 428–434. https://doi.org/10.1370/afm.1396

Dinos, S., Stevens, S., Serfaty, M., Weich, S., & King, M. (2004). Stigma: The feelings and experiences of 46 people with mental illness. Qualitative study. T*he British Journal of Psychiatry: The Journal of Mental Science*, 184, 176–181. https://doi.org/10.1192/bjp.184.2.176

Dorcely, B., Agarwal, N., & Raghuwanshi, M. (2015). Quality assessment of diabetes online patient education materials from academic institutions. *Health Education Journal*, 74(5), 568–577. https://doi.org/10.1177/0017896914552203

Dye, C., Bartolomeos, K., Moorthy, V., & Kieny, M. P. (2016). Data sharing in public health emergencies: a call to researchers. *Bulletin of the World Health Organization*, *94*(3), 158-158

Fay, D. S. (2013). A biologist's guide to statistical thinking and analysis. *WormBook: the online review of C. elegans biology*, 1–54. Retrieved September 16, 2021, https://doi.org/10.1895/wormbook.1.159.1

Fegan, G., & Cheah, P. Y. (2021). Solutions to COVID-19 data sharing. *The Lancet Digital Health*, *3*(1), e6

Flesch, R. (1948). A new readability yardstick. *Journal of Applied Psychology*, 32(3), 221

Foraker, R. E., Lai, A. M., Kannampallil, T. G., Woeltje, K. F., Trolard, A. M., & Payne, P. R. (2021). Transmission dynamics: data sharing in the COVID-19 era. *Learning Health Systems*, *5*(1), e10235

Galvin, C. J., Fernandez-Luque, L., & Li, Y. C. J. (2021). Accelerating the global response against the exponentially growing COVID-19 outbreak through decent data sharing. *Diagnostic Microbiology and Infectious Disease*, *101*(2), 115070

Gardner, L., Ratcliff, J., Dong, E., & Katz, A. (2021). A need for open public data standards and sharing in light of COVID-19. *The Lancet Infectious Diseases*, *21*(4), e80

Gewin, V. (2020). Six tips for data sharing in the age of the coronavirus. *Nature (Lond.)*

Gorina, Y., Redd, J. T., Hersey, S., Jambai, A., Meyer, P., Kamara, A. S., ... & Kamara, M. A. (2020). Ensuring ethical data access: the Sierra Leone Ebola Database (SLED) model. *Annals of epidemiology*, *46*, 1-4

Grande, D., Asch, D. A., Wan, F., Bradbury, A. R., Jagsi, R., & Mitra, N. (2015). Are Patients With Cancer Less Willing to Share Their Health Information? Privacy, Sensitivity, and Social Purpose. *Journal of Oncology Practice*, 11(5), 378–383. https://doi.org/10.1200/JOP.2015.004820

Grando, 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 professional perspectives on health data sharing: Mixed methods study. *Health Informatics Journal*, 26(3), 2067–2082. https://doi.org/10.1177/1460458219893848

Grando, A., Murcko, A., Mahankali, S., Saks, M., Zent, M., Chern, D., Dye, C., Sharp, R., Young, L., Davis, P., Hiestand, M., & Hassanzadeh, N. (2017). A Study to Elicit Behavioral Health Patients' and Providers' Opinions on Health Records Consent. *The Journal of Law, Medicine & Ethics : A Journal of the American Society of Law, Medicine & Ethics*, 45(2), 238–259. https://doi.org/10.1177/1073110517720653

Grando, A., & Schwab, R. (2013). Building and evaluating an ontology-based tool for reasoning about consent permission. *AMIA Annual Symposium Proceedings. AMIA Symposium*, 2013, 514–523

Greenes, R. A. (2011). Clinical decision support: The road ahead. *Elsevier*

Griffin, J., McKenna, K., & Tooth, L. (2003). Written health education materials: Making them more effective. *Australian Occupational Therapy Journal*, 50(3), 170–177. https://doi.org/10.1046/j.1440-1630.2003.00381.x

Guan, Y., Maloney, K. A., Roter, D. L., & Pollin, T. I. (2018). Evaluation of the Informational Content, Readability and Comprehensibility of Online Health Information on Monogenic Diabetes. *Journal of Genetic Counseling*, 27(3), 608–615. https://doi.org/10.1007/s10897-017-0155-y

Guide, A. (2015). Integrating behavioral health into primary care. *Institute for Clinical and Economic Review*, 2. Retrieved May 24, 2021, from https://icer.org/wp-content/uploads/2020/10/New-England-Action-Guide-FINAL-FOR-POSTING.pdf

Guide to Privacy and Security of Health Information. Office of National Coordinator for Health IT. (n.d.). Retrieved May 10, 2021, from

https://www.healthit.gov/sites/default/files/pdf/privacy/onc_privacy_and_security_v1_022112.pdf

Haga, S. B., Barry, W. T., Mills, R., Ginsburg, G. S., Svetkey, L., Sullivan, J., & Willard, H. F. (2013). Public Knowledge of and Attitudes Toward Genetics and Genetic Testing. Genetic Testing and Molecular Biomarkers, 17(4), 327–335. https://doi.org/10.1089/gtmb.2012.0350

He, Y., Yu, H., Ong, E., Wang, Y., Liu, Y., Huffman, A., ... & Smith, B. (2020). CIDO, a community-based ontology for coronavirus disease knowledge and data integration, sharing, and analysis. *Scientific data*, *7*(1), 1-5.

Health IT policy committee. (n.d.). Retrieved May 10, 2021, from https://www.healthit.gov/sites/default/files/hitpc-transmittal-letter-priv-sectigerteam-020211.pdf

HealthIT.gov. (n.d.). Retrieved May 25, 2021, from https://www.healthit.gov/resource/current-state-sharing-behavioral-health-information-health-information-exchanges

Hedden, S. L., Kennet, J., Lipari, R., Medley, G., Tice, P., Copello, E. A. P., & Kroutil, L. A. (2015). Key Substance Use and Mental Health Indicators in the United States: Results from the 2015 National Survey on Drug Use and Health. 74

Hiestand, M., Grando, M. A., Murcko, A., Soni, H., Varkey, J., Bs, C., Horrow, Saks, M., Sharp, R., Whitfield, M., Callesen, M., Dye, C., & Chern, D. (2017). Behavioral Health Provider Perspectives on Health Data Sharing

US Department of Health and Human Services. (2014). Hipaa privacy rule and sharing information related to mental health. *Office for Civil Rights. https://www. hhs. gov/sites/default/files/hipaa-privacy-rule-and-sharing-info-related-to-mental-health. pdf*

Home. (n.d.). National Committee on Vital and Health Statistics. Retrieved July 7, 2021, from https://ncvhs.hhs.gov/

Huffman, J. C., Niazi, S. K., Rundell, J. R., Sharpe, M., & Katon, W. J. (2014). Essential Articles on Collaborative Care Models for the Treatment of Psychiatric Disorders in Medical Settings: *A Publication by the Academy of Psychosomatic Medicine Research and Evidence-Based Practice Committee. Psychosomatics*, 55(2), 109–122. https://doi.org/10.1016/j.psym.2013.09.002

Integrated Health. (n.d.). National Council. Retrieved May 24, 2021, from https://www.thenationalcouncil.org/integrated-health-coe/

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*, 26(3), 2011–2029. https://doi.org/10.1177/1460458219893845

Ivanova, J., Tang, T., Idouraine, N., Murcko, A., Grando, A., Whitfield, M. J., Dye, C., & Chern, D. (n.d.). Behavioral Health Professionals' Perceptions on Patient-Controlled Granular Information Sharing: Focus Groups. *Journal of Medical Internet Research: JMIR Preprints*. Retrieved May 13, 2021, from https://preprints.jmir.org/preprint/18792

Johnsson, L., Helgesson, G., Rafnar, T., Halldorsdottir, I., Chia, K.-S., Eriksson, S., & Hansson, M. G. (2010). Hypothetical and factual willingness to participate in biobank research. *European Journal of Human Genetics*, 18(11), 1261–1264. https://doi.org/10.1038/ejhg.2010.106

Karway, G., Ivanova, J., Bhowmik, A., Murcko, A., Saks, M., McCarty, D., Campbell, A., & Grando, M. A. (2021). Recommendations to Inform Substance Use Disorder Data Sharing Research: Scoping Review and Thematic Analysis. *Journal of Addiction Medicine*

Kaufman, DJ., Murphy-Bollinger J., Scott J., Hudson KL (2009). Public opinion about the importance of privacy in biobank research. *Am J Hum Genet*. 2009 Nov 13;85(5):643-54.41

Kim, H., Bell, E., Kim, J., Sitapati, A., Ramsdell, J., Farcas, C., Friedman, D., Feupe, S. F., & Ohno-Machado, L. (2017). iCONCUR: Informed consent for clinical data and bio-sample use for research. *Journal of the American Medical Informatics Association: JAMIA*, 24(2), 380–387. https://doi.org/10.1093/jamia/ocw115

King, T., Brankovic, L., & Gillard, P. (2012). Perspectives of Australian adults about protecting the privacy of their health information in statistical databases. *International Journal of Medical Informatics*, 81(4), 279–289. https://doi.org/10.1016/j.ijmedinf.2012.01.005

Knaak, S., Mantler, E., & Szeto, A. (2017). Mental illness-related stigma in healthcare. *Healthcare Management Forum*, 30(2), 111–116. https://doi.org/10.1177/0840470416679413

Knickman, J., Bethell, C., Fiorillo, J., & Lansky, D. (2002). A portrait of the chronically ill in America, 2001. Retrieved September 27, 2021, from https://folio.iupui.edu/bitstream/handle/10244/775/ChronicIllnessChartbook2001.pdf?sequence=1

Kohn, L. T., & Corrigan, J. M. (1999). donaldson, MS, eds. To err is human: Building a safer health system. *Committee on Quality of Health Care in America. Institute of Medicine*

Laato, S., Islam, A. N., Islam, M. N., & Whelan, E. (2020). What drives unverified information sharing and cyberchondria during the COVID-19 pandemic?. *European journal of information systems*, *29*(3), 288-305

Lackerbauer, A. M., Lin, A. C., Krauss, O., Hearn, J., & Helm, E. (2018). A Model for Implementing an Interoperable Electronic Consent Form for Medical Treatment Using HL7 FHIR. *European Journal of Biomedical Informatics*, 0(0). https://doi.org/10.24105/ejbi.2018.14.3.6

Langat, P., Pisartchik, D., Silva, D., Bernard, C., Olsen, K., Smith, M., ... & Upshur, R. (2011). Is there a duty to share? Ethics of sharing research data in the context of public health emergencies. *Public Health Ethics*, 4-11

Littler, K., Boon, W. M., Carson, G., Depoortere, E., Mathewson, S., Mietchen, D., ... & Segovia, C. (2017). Progress in promoting data sharing in public health emergencies. *Bulletin of the World Health Organization*, *95*(4), 243

McGinnis, J. M., Saunders, R. S., & Olsen, L. (2011). Patients charting the course: Citizen engagement and the learning health system: workshop summary

McGough, P. M., Bauer, A. M., Collins, L., & Dugdale, D. C. (2016). Integrating Behavioral Health into Primary Care. *Population Health Management*, 19(2), 81–87. https://doi.org/10.1089/pop.2015.0039

McLaughlin, G. H. (1969). SMOG grading: A new readability formula. *Journal of Reading*, 12(8), 639–646

Mello, M. M., Lieou, V., & Goodman, S. N. (2018). Clinical Trial Participants' Views of the Risks and Benefits of Data Sharing. *New England Journal of Medicine*, 378(23), 2202–2211. https://doi.org/10.1056/NEJMsa1713258

Mental Health Myths and Facts | MentalHealth.gov. (n.d.). Retrieved April 18, 2022, from https://www.mentalhealth.gov/basics/mental-health-myths-facts

Merson, L., Gaye, O., & Guerin, P. J. (2016). Avoiding data dumpsters—toward equitable and useful data sharing. *New England Journal of Medicine*, *374*(25), 2414-2415

Meslin, E. M., Alpert, S. A., Carroll, A. E., Odell, J. D., Tierney, W. M., & Schwartz, P. H. (2013). Giving patients granular control of personal health information: Using

an ethics “Points to Consider” to inform informatics system designers. *International journal of medical informatics*, *82*(12), 1136-1143

Modjarrad, K., Moorthy, V. S., Millett, P., Gsell, P. S., Roth, C., & Kieny, M. P. (2016). Developing global norms for sharing data and results during public health emergencies. *PLoS Medicine*, *13*(1), e1001935

Molldrem, S., Hussain, M. I., & McClelland, A. (2021). Alternatives to sharing COVID-19 data with law enforcement: Recommendations for stakeholders. *Health Policy*, *125*(2), 135-140

Moorthy, V., Henao Restrepo, A. M., Preziosi, M., & Swaminathan, S. Data sharing for novel coronavirus (COVID-19) Bull World Health Organ. 2020 Mar 01; 98 (3): 150. doi: 10.2471/BLT. 20.251561

Morten, C. J., Kapczynski, A., Krumholz, H. M., & Ross, J. S. (2020). To help develop the safest, most effective Coronavirus tests, treatments, and vaccine, ensure public access to clinical research data. *Health Aff*

Mosenthal, P. B., & Kirsch, I. S. (1998). A New Measure for Assessing Document Complexity: The PMOSE/IKIRSCH Document Readability Formula. *Journal of Adolescent & Adult Literacy*, 41(8), 638–657

National Academies of Sciences, Engineering, and Medicine. (2018). *Understanding Disparities in Access to Genomic Medicine: Proceedings of a Workshop*. The National Academies Press. https://doi.org/10.17226/25277

National Committee on Vital and Health Statistics. (n.d.). Home. National Committee on Vital and Health Statistics. Advising the Secretary of Health and Human Services on Health Data, Privacy, and National Health Information Policy. Retrieved May 19, 2021, from https://ncvhs.hhs.gov/

National Committee on Vital and Health Statistics. Recommendations Regarding Sensitive Health Information. (2010). https://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/101110lt.pdf

National eHealth Collaborative Shares Results Of 2012 Stakeholder Survey. (n.d.). Retrieved March 20, 2022, from https://www.healthitoutcomes.com/doc/national-ehealth-collaborative-shares-results-0001

National Framework for Quality Improvement in Behavioral Health Care. Substance Abuse and Mental Health Services Administration. (n.d.). Retrieved May 10, 2021, from https://www.nasmhpd.org/sites/default/files/SAMHSA%20Quality%20Improvement%20Initiative.pdf

Nickerson, R. C., Varshney, U., & Muntermann, J. (2013). A method for taxonomy development and its application in information systems. *European Journal of Information Systems*, 22(3), 336–359

NIMH » Integrating Mental Health. (n.d.). Retrieved May 11, 2021, from https://www.nimh.nih.gov/news/media/2019/integrating-mental-health-into-pediatric-primary-care

NIMH » Mental Illness. (n.d.). Retrieved September 14, 2021, from https://www.nimh.nih.gov/health/statistics/mental-illness

Norton, A. (2019). Data sharing in Public Health Emergencies to maximise health benefits-the role for the GloPID-R funders

Office of the National Coordinator for Health Information Technology. (2020). Privacy and Security Framework for Patient-Centered Outcomes Research. Enabling Granular Choice for Health Care Delivery and Research Consent. 26

Oliver, J. M., Slashinski, M. J., Wang, T., Kelly, P. A., Hilsenbeck, S. G., & McGuire, A. L. (2012). Balancing the Risks and Benefits of Genomic Data Sharing: Genome Research Participants' Perspectives. *Public Health Genomics*, 15(2), 106–114. https://doi.org/10.1159/000334718

Ontario Health Quality Council. (n.d.). Retrieved November 10, 2021, from https://www.hqontario.ca/portals/0/Documents/pr/qmonitor-full-report-2009-en.pdf

Paul, S., & Chatterjee, M. K. (2020). Data sharing solutions for biobanks for the COVID-19 pandemic. *Biopreservation and Biobanking*, *18*(6), 581-586

Pearce, N., Vandenbroucke, J. P., VanderWeele, T. J., & Greenland, S. (2020). Accurate statistics on COVID-19 are essential for policy guidance and decisions. *American journal of public health*, *110*(7), 949-951

Peek CJ, National Integration Academy Council. Lexicon for Behavioral Health and Primary Care Integration: Concepts and Definitions Developed by Expert Consensus. Agency for Healthcare Research and Quality. Retrieved May 24, 2021, from https://integrationacademy.ahrq.gov/sites/default/files/2020-06/Lexicon.pdf

Petkova, E., Antman, E. M., & Troxel, A. B. (2020). Pooling data from individual clinical trials in the COVID-19 era. *Jama*, *324*(6), 543-545

Physical Wellness Toolkit. (2017, June 21). National Institutes of Health (NIH). https://www.nih.gov/health-information/physical-wellness-toolkit

Pierce, L. L. (2010). How to choose and develop written educational materials. Rehabilitation Nursing: *The Official Journal of the Association of Rehabilitation Nurses*, 35(3), 99–105. https://doi.org/10.1002/j.2048-7940.2010.tb00284.x

Pisani, E., Ghataure, A., & Merson, L. (2018). Data sharing in public health emergencies: A study of current policies, practices and infrastructure supporting the sharing of data to prevent and respond to epidemic and pandemic threats.

Prabhu, A. V., Hansberry, D. R., Agarwal, N., Clump, D. A., & Heron, D. E. (2016). Radiation Oncology and Online Patient Education Materials: Deviating From NIH and AMA Recommendations. *International Journal of Radiation Oncology, Biology, Physics*, 96(3), 521–528. https://doi.org/10.1016/j.ijrobp.2016.06.2449

Pratt, B., & Bull, S. (2021). Equitable data sharing in epidemics and pandemics. *BMC medical ethics*, *22*(1), 1-14

Privacy, Confidentiality and Disclosure. (n.d.). Lambda Legal. Retrieved September 16, 2021, from https://www.lambdalegal.org/know-your-rights/article/hiv-privacy-and-confidentiality

Rahimi, F., & Abadi, A. T. B. (2020). Transparency and information sharing could help abate the COVID-19 pandemic. *Infection Control & Hospital Epidemiology*, *41*(11), 1366-1367

Reed, S. J., Shore, K. K., & Tice, J. A. (2016). Effectiveness and Value of Integrating Behavioral Health Into Primary Care. *JAMA Internal Medicine*, 176(5), 691–692. https://doi.org/10.1001/jamainternmed.2016.0804

Ricciardi, L. (2010). Protecting sensitive health information in the context of health information technology. *Consumer Partnership for eHealth*

RISK, M. (2015). Committee on Strategies for Responsible Sharing of Clinical Trial Data, Board on Health Sciences Policy, Institute of Medicine. Sharing clinical trial data: maximizing benefits, minimizing risk. *Washington, DC: National Academies Press*, 2015

Sajid, M. S., & Baig, M. K. (2007). Quality of health care: An absolute necessity for public satisfaction. *International Journal of Health Care Quality Assurance*

Saks, M. J., Grando, A., Murcko, A., & Millea, C. (2018). Granular patient control of personal health information: *Federal and state law considerations. Jurimetrics*, 58(4), 411

SAMHSA. (n.d.). SAMHSA - Substance Abuse and Mental Health Services Administration. SAMHSA - The Substance Abuse Mental Health Services Administration. Retrieved May 19, 2021, from https://www.samhsa.gov/node

SAMHSA-HRSA Center for Integrated Health Solutions. (n.d.). Retrieved May 10, 2021, from https://mentalhealthce.com/courses/contentPC/PC-Sharing-Behavioral-Health-Information.pdf

Sanderson SC, Brothers KB, Mercaldo ND, Clayton EW, Antommaria AHM, Aufox SA, et al (2017). Public attitudes toward consent and data sharing in biobank research: a large multi-site experimental survey in the US. *Am J Hum Genet.* 2017 Mar 2;100(3):414-27

Say, R. E., & Thomson, R. (2003). The importance of patient preferences in treatment decisions—Challenges for doctors. *BMJ (Clinical Research Ed.)*, 327(7414), 542–545. https://doi.org/10.1136/bmj.327.7414.542

Schwartz, P. H., Caine, K., Alpert, S. A., Meslin, E. M., Carroll, A. E., & Tierney, W. M. (2015). Patient preferences in controlling access to their electronic health records: A prospective cohort study in primary care. *Journal of General Internal Medicine*, 30 Suppl 1, S25-30. https://doi.org/10.1007/s11606-014-3054-z

Shivayogi, P. (2013). Vulnerable population and methods for their safeguard. *Perspectives in Clinical Research*, 4(1), 53–57. https://doi.org/10.4103/2229-3485.106389

Shoemaker, S. J., Wolf, M. S., & Brach, C. (2014). Development of the Patient Education Materials Assessment Tool (PEMAT): A new measure of understandability and actionability for print and audiovisual patient information. *Patient Education and Counseling*, 96(3), 395–403. https://doi.org/10.1016/j.pec.2014.05.027

Simply Put: A guide for creating easy-to-understand materials. (n.d.). Retrieved November 10, 2021, from https://www.cdc.gov/healthliteracy/pdf/simply_put.pdf

Smith, F., Carlsson, E., Kokkinakis, D., Forsberg, M., Kodeda, K., Sawatzky, R., Friberg, F., & Öhlén, J. (2014). Readability, suitability and comprehensibility in patient education materials for Swedish patients with colorectal cancer undergoing elective surgery: A mixed method design. *Patient Education and Counseling*, 94(2), 202–209. https://doi.org/10.1016/j.pec.2013.10.009

Soni, H., Grando, A., Aliste, M. P., Murcko, A., Todd, M., Mukundan, M., Saks, M., Horrow, C., Sharp, R., & Dye, C. (2019a). Perceptions and preferences about granular data sharing and privacy of behavioral health patients. *In MEDINFO* 2019: Health and Wellbeing e-Networks for All (pp. 1361–1365). IOS Press

Soni, H., Grando, A., Aliste, M. P., Murcko, A., Todd, M., Mukundan, M., Saks, M., Horrow, C., Sharp, R., & Dye, C. (2019b). Perceptions and Preferences About Granular Data Sharing and Privacy of Behavioral Health Patients. *Studies in Health Technology and Informatics*, 264, 1361–1365

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., Callesen, M., Dye, C., & Chern, D. (2018). Current State of Electronic Consent Processes in Behavioral Health: Outcomes from an Observational Study. *AMIA Annual Symposium Proceedings*, 2017, 1607–1616

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

Soni, H., Ivanova, J., Grando, A., Murcko, A., Chern, D., Dye, C., & Whitfield, M. J. (2021). A pilot comparison of medical records sensitivity perspectives of patients with behavioral health conditions and healthcare providers. *Health Informatics Journal*, 27(2), 14604582211009924. https://doi.org/10.1177/14604582211009925

Storr CL., Or F., Eaton WW., Lalongo N (2014). Genetic research participation in a young adult community sample. *J community genet*. 2014 Oct 1;5(4):363-75

Strachan, P. H., de Laat, S., Carroll, S. L., Schwartz, L., Vaandering, K., Toor, G. K., & Arthur, H. M. (2012). Readability and Content of Patient Education Material Related to Implantable Cardioverter Defibrillators. *The Journal of Cardiovascular Nursing*, 27(6), 495–504. https://doi.org/10.1097/JCN.0b013e31822ad3dd

Teixeira, P. A., Gordon, P., Camhi, E., & Bakken, S. (2011). HIV patients' willingness to share personal health information electronically. *Patient Education and Counseling*, 84(2), e9-12. https://doi.org/10.1016/j.pec.2010.07.013

Thomas, G., Hartley, R. D., & Kincaid, J. P. (1975). Test-Retest and Inter-Analyst Reliability of the Automated Readability Index, Flesch Reading Ease Score, and the Fog Count. *Journal of Reading Behavior*, 7(2), 149–154. https://doi.org/10.1080/10862967509547131

Tierney, W. M., Alpert, S. A., Byrket, A., Caine, K., Leventhal, J. C., Meslin, E. M., & Schwartz, P. H. (2015). Provider Responses to Patients Controlling Access to their Electronic Health Records: A Prospective Cohort Study in Primary Care.

Journal of General Internal Medicine, 30(Suppl 1), 31–37. https://doi.org/10.1007/s11606-014-3053-0

Value Set Authority Center. (n.d.). Retrieved March 20, 2022, from https://vsac.nlm.nih.gov/

Weiss, B. D. (2007). Health literacy and patient safety: Help patients understand. *Manual for clinicians*. American Medical Association Foundation

Weitzman, E. R., Kelemen, S., Kaci, L., & Mandl, K. D. (2012). Willingness to share personal health record data for care improvement and public health: A survey of experienced personal health record users. *BMC Medical Informatics and Decision Making*, 12(1), 39. https://doi.org/10.1186/1472-6947-12-39

Welcome to the AHRQ Academy | The Academy. (n.d.). Retrieved March 20, 2022, from https://integrationacademy.ahrq.gov/

Whiddett, R., Hunter, I., Engelbrecht, J., & Handy, J. (2006). Patients' attitudes towards sharing their health information. *International Journal of Medical Informatics*, 75(7), 530–541. https://doi.org/10.1016/j.ijmedinf.2005.08.009

Wilkins, S. (2012). Patient engagement is the holy grail of health care. *MedPage Today's KevinMD. Com*

Williams, J. R., Yeh, V. M., Bruce, M. A., Szetela, C., Ukoli, F., Wilkins, C. H., & Kripalani, S. (2018). Precision medicine: Familiarity, perceived health drivers, and genetic testing considerations across health literacy levels in a diverse sample. *Journal of Genetic Counseling*, 10.1007/s10897-018-0291-z. https://doi.org/10.1007/s10897-018-0291-z

Whitty, C. J., Mundel, T., Farrar, J., Heymann, D. L., Davies, S. C., & Walport, M. J. (2015). Providing incentives to share data early in health emergencies: the role of journal editors. *The Lancet*, *386*(10006), 1797-1798

WMA Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects. (n.d.). 7. Retrieved July 29, 2021, from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Wohlin, C. (2014). Guidelines for snowballing in systematic literature studies and a replication in software engineering. *Proceedings of the 18th International Conference on Evaluation and Assessment in Software Engineering* - EASE '14, 1–10. https://doi.org/10.1145/2601248.2601268

Wright, A., Soran, C., Jenter, C. A., Volk, L. A., Bates, D. W., & Simon, S. R. (2010). Physician attitudes toward health information exchange: Results of a statewide survey. *Journal of the American Medical Informatics Association : JAMIA*, 17(1), 66–70. https://doi.org/10.1197/jamia.M3241

Yozwiak, N. L., Schaffner, S. F., & Sabeti, P. C. (2015). Data sharing: Make outbreak research open access. *Nature, 518*(7540), 477-479

APPENDIX

A. SUPPLEMENTARY MATERIALS (AIM 2)

A.1 Questionnaire for Internal Evaluation of the Educational Materials

QUESTIONNAIRES FOR PATIENT EVALUATION

Instructions: Accessed from: https://www.ahrq.gov/ncepcr/tools/self-mgmt/pemat-p.html

1. Rate an item "Agree" when a characteristic occurs throughout the education material. Rate an item "disagree" when a characteristic does not occur throughout the material or if there is no clarity.
2. Do not use any knowledge you have about the subject before you read or view the patient education material. Base your ratings ONLY on what is in the material that you are rating.
3. Do not let your rating of one item influence your rating of other items. Be careful to rate each item separately and distinctly from how you rated other items.
4. If you are rating more than one material, focus only on the material that you are reviewing and do not try to compare it to the previous material that you looked at.

Item	Response Options	Rating
UNDERSTANDABILITY		
Content		
1. The material makes its purpose completely evident?	Disagree = 0 Agree = 1	
2. The material does not include information or content that distracts from its purpose?	Disagree = 0 Agree = 1	
Word Choice & Style		
3. The material uses common, everyday language	Disagree = 0 Agree = 1	
4. Medical terms are used only to familiarize audience with the terms. When used, medical terms are defined.	Disagree = 0 Agree = 1	
5. The material uses the active voice.	Disagree = 0 Agree = 1	
Use of Numbers		
6. Numbers appearing in the material are clear and easy to understand.	Disagree = 0 Agree = 1	
7. The material does not expect the user to perform calculations.	Disagree = 0 Agree = 1	
Organization		
8. The material breaks or "chunks" information into short sections.	Disagree = 0 Agree = 1	
9. The material's sections have informative headers.	Disagree = 0 Agree = 1	
10. The material presents information in a logical sequence.	Disagree = 0 Agree = 1	
11. The material provides a summary	Disagree = 0 Agree = 1	

Layout & Design		
12. The material uses visual cues (e.g., arrows, boxes, bullets, bold, larger font, highlighting) to draw attention to key points.	Disagree = 0 Agree = 1	
Use of Visual Aids		
13. The material uses visual aids whenever they could make content more easily understood (e.g., illustration of healthy portion size).	Disagree = 0 Agree = 1	
14. The material's visual aids reinforce rather than distract from the content.	Disagree = 0 Agree = 1	
15. The material's visual aids have clear titles or captions.	Disagree = 0 Agree = 1	
16. The material uses illustrations and photographs that are clear and uncluttered.	Disagree = 0 Agree = 1	
17. The material uses simple tables with short and clear row and column headings.	Disagree = 0 Agree = 1	
Cultural Suitability		
18. Do the language, logic and lifestyles show suitability to the society?	Disagree = 0 Agree = 1	
19. Are the cultural images positive, realistic and suitable?	Disagree = 0 Agree = 1	
Reliability		
20. Is it clear what sources of information were used to compile the publication (Other than the author or producer)?	Disagree = 0 Agree = 1	
21. Is it clear when the information used or reported in the publication was produced?	Disagree = 0 Agree = 1	
22. Is it balanced and unbiased?	Disagree = 0 Agree = 1	
23. Does it provide details of additional sources of support and information?	Disagree = 0 Agree = 1	
24. Does it refer to areas of uncertainty?	Disagree = 0 Agree = 1	
ACTIONADABILITY		
25. The material addresses the user directly when describing actions.	Disagree = 0 Agree = 1	
26. The material uses visual aids whenever they could make it easier to act on the instructions.	Disagree = 0 Agree = 1	

Do you have any comments or suggestions on this material?

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A.2 Questionnaire for External Evaluation of the Educational Materials

QUESTIONNAIRES FOR PATIENT EVALUATION

Instructions: Accessed from: https://www.ahrq.gov/ncepcr/tools/self-mgmt/pemat-p.html

1. Rate an item "Agree" when a characteristic occurs throughout the education material. Rate an item "disagree" when a characteristic does not occur throughout the material or if there is no clarity.
2. Do not use any knowledge you have about the subject before you read or view the patient education material. Base your ratings ONLY on what is in the material that you are rating.
3. Do not let your rating of one item influence your rating of other items. Be careful to rate each item separately and distinctly from how you rated other items.
4. If you are rating more than one material, focus only on the material that you are reviewing and do not try to compare it to the previous material that you looked at.

Item	Response Options	Rating
1. Does this material use common, everyday language?	Disagree = 0 Agree = 1	
2. Does this material define all medical terms used?	Disagree = 0 Agree = 1	
3. Does this material break information into short sections?	Disagree = 0 Agree = 1	
4. Does each section in this material have good heading?	Disagree = 0 Agree = 1	
5. Does information in this material flow well?	Disagree = 0 Agree = 1	
6. Does the material provide a summary?	Disagree = 0 Agree = 1	
7. Does graphics use in this material have a clear titles or captions?	Disagree = 0 Agree = 1	
8. Is the graphics use in this material distract you from understanding it?	Disagree = 0 Agree = 1	
9. Is the language use in this material suitability to you?	Disagree = 0 Agree = 1	
10. Are the images use in the material positive, realistic and suitable to you?	Disagree = 0 Agree = 1	

Do you have any comments or suggestions on this material?

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A.3 Educational Material on Domestic Violence Information for English Patients

My Data Choices

DOMESTIC ABUSE OR VIOLENCE INFORMATION

What is domestic violence?[1,2]

It is any violence or abuse used by a household member against another household member. It is also any violence used by a person to maintain power and control over another person. Domestic abuse can happen one time or many times.

What is domestic violence data?

It is any data about domestic violence or abuse of a person. It can be a diagnosis, an assessment, and a procedure or service. Some examples are below.

Examples of domestic violence diagnosis

- Bullying and intimidation
- Emotional abuse
- Neglect or abandonment
- Physical abuse
- Sexual abuse
- Perpetrator of abuse

Examples of medications related to domestic violence

- Pain medication for abuse injuries

Examples of labs and other tests for domestic violence assessment

- Danger assessment
- Domestic violence inventory
- Lethality screen
- Intimate justice scale
- Spousal assault risk assessment

Examples of procedures or services for domestic violence

- Behavioral therapy
- Cognitive therapy
- Counseling for victims
- Counseling for perpetrators
- Safety plans
- Support group for victims

For More Information:

1. Forms of abuse. National Network to End Domestic Violence. LINK
2. What is domestic violence? National Domestic Violence Hotline. LINK

A.4 Educational Material on Domestic Violence Information for Spanish Patients

My Data Choices

INFORMACION DE VIOLENCIA O ABUSO DOMESTICO

¿Que es violencia domestica?[1,2]

Es cualquier violencia o abuso utilizado por un miembro del hogar contra otro miembro del hogar. También es cualquier violencia utilizada por una persona para mantener el poder y el control sobre otra persona. El abuso doméstico puede suceder una o muchas veces.

¿Que es información de violencia domestica?

Es cualquier dato sobre violencia doméstica o abuso de una persona. Puede ser un diagnóstico, una evaluación y un procedimiento o servicio. Algunos ejemplos están abajo.

Ejemplos de diagnósticos de violencia domestica

- Bullying e intimidación
- Abuso emocional
- Descuido o abandono
- Abuso fisico
- Abuso sexual
- Perpetrador de abuso

Ejemplos de medicaciones relacionadas a la violencia domestica

- Medicamentos para el dolor por lesiones de abuso

Ejemplos de laboratorios y otros test de violencia domestica

- Evaluación de peligro
- Inventario de violencia domestica
- Evaluación de letalidad
- Escala de justicia intima
- Evaluación de riesgo de asalto conyugal

Ejemplos de procedimientos o servicios de violencia domestica

- Terapia conductual
- Terapia cognitiva
- Asesoramiento para victimas
- Asesoramiento para perpetradores
- Planes de seguridad
- Grupos de apoyo para victimas

Para mas información:

1. Tipos de abusos. Women Against Abuse. LINK
2. Violencia domestica. MedlinePlus. LINK

A. 5 Educational Material on Genetic Information for English Patients

My Data Choices

GENETIC INFORMATION

What are genes?[1]

Genes are the instructions inside your body. They control how you look. They control how your body works. A person has two copies of a gene, one from the mother and one from the father. Sometimes the genes from your parents can result in problems in the child. Genes can be handed down in the family.

What is genetic data?[2]

It is any data about your genetic test results. It can be the results of your family members' genetic tests. It can be your family history of diseases. It can be data about your participation in research that involves genetic testing, counseling or education. Some examples are below.

Examples of genetic diagnosis

- Autism
- Carrier of a genetic disease
- Cystic fibrosis
- Family history of genetic disease
- Sickle cell disease

Examples of medications for genetic conditions

- Enzyme replacement pill
- Familial hyperlipidemia pill
- Gaucher disease pill
- Hemophilia A pill (Advate)
- Sickle cell disease pill (Adakyeo)

Examples of labs and other tests for genetic conditions

- Amniocentesis
- Cytochrome P450 (CYP450)
- FMR1 DNA test
- Newborn genetic screening
- Rh factor blood test
- Whole genome sequencing

Examples of procedures or services for genetic conditions

- Genetic counseling
- Genetic testing
- Karyotyping
- Music therapy for autism
- Stem cell transplant

For More Information:

1. What are Genes. Kids Health. LINK
2. Understanding Genetic information. The genetic information nondiscrimination act of 2008. LINK

A. 6 Educational Material on Genetic Information for Spanish Patients

My Data Choices

INFORMACION GENETICA

¿Que son los genes?[1]

Los genes son las instrucciones dentro de su cuerpo. Ellos controlan cómo te ves. Controlan cómo funciona tu cuerpo. Una persona tiene dos copias de un gen, una de la madre y otra del padre. A veces, los genes de tus padres pueden causar problemas en el niño. Los genes se pueden transmitir en la familia.

¿Que es información genetica?[2]

Es cualquier dato sobre los resultados de su prueba genética. Pueden ser los resultados de las pruebas genéticas de los miembros de su familia. Puede ser su historia familiar de enfermedades. Pueden ser datos sobre su participación en investigaciones que involucren pruebas genéticas, asesoramiento o educación. Algunos ejemplos están abajo.

Ejemplos de diagnósticos genéticos

- Autismo
- Portador de una enfermedad genética
- Fibrosis quística
- Historia familiar de enfermedad genética
- Enfermedad de célula falciforme

Ejemplos de medicaciones para condiciones genéticas

- Píldora de reemplazo de enzimas
- Píldora de hiperlipidemia familiar
- Píldora de enfermedad de Gaucher
- Pastilla para la hemofilia A (Advate)
- Píldora de la enfermedad de células falciformes (Adakyeo)

Ejemplo de laboratorios y otros test para condiciones genéticas

- Amniocentesis
- Citocromo P450 (CYP450)
- Prueba de AND FMR1
- Examen genético de recién nacido
- Análisis de sangre con factor Rh
- Secuenciación del genoma completo

Ejemplos de procedimientos y servicios para condiciones genéticas

- Asesoramiento genético
- Evaluación genética
- Cariotipo
- Terapia musical para autismo
- Trasplante de células madre

Para mas información:

1. ¿Que es un gen? Kids Health. LINK
2. Ley de no discriminación por información genética. GINA. LINK

A.7 Educational Material on Mental Health Information for English Patients

My Data Choices

MENTAL HEALTH INFORMATION

What is a mental health disorder?[1,2]

It is a problem that affects mood, thinking and behavior. It can make you unhappy. It 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.

What is mental health data?

It is any data about a person's mental health problem. It can be a diagnosis, medicine, lab test, result, allergy, procedure or service. Some examples are below.

Examples of mental health diagnosis

- Anxiety disorder
- Attempted suicide
- Binge eating disorder
- Bipolar disorder
- Compulsive disorder
- Depression
- Psychotic disorder
- Schizophrenia

Examples of mental health medications

- ADHD (Adderall)
- Anti-anxiety (Xanax)
- Antidepressants (Prozac)
- Antipsychotics (Haldol)
- Mood stabilizer (Lithium)

Examples of labs and other tests for mental health assessment

- Anxiety scale
- Depression inventory
- Disruptive behavior scale
- Memory and learning tests
- Mood disorder questionnaire
- Schizophrenia test

Examples of procedures or services for mental health

- Cognitive therapy
- Hypnosis
- Psychotherapy
- Screening examination for mental health disorders

For More Information:

1. Mental Health. MedlinePlus. LINK
2. What is mental health? MentalHealth.gov. LINK

A.8 Educational Material on Mental Health Information for Spanish Patients

My Data Choices

INFORMACION DE SALUD MENTAL

¿Que es un trastorno mental?[1,2]

Es un problema que afecta el estado de ánimo, el pensamiento y el comportamiento. Puede hacerte infeliz. Puede causar problemas en tu vida diaria. Hay muchas causas de problemas de salud mental. Los genes, la historia familiar y las experiencias de la vida pueden tener un efecto. Hay muchos tratamientos disponibles.

¿Que es información de salud mental?

Es cualquier dato sobre el problema de salud mental de una persona. Puede ser un diagnóstico, medicamento, prueba de laboratorio, resultado, alergia, procedimiento o servicio. Algunos ejemplos están abajo.

Ejemplos de diagnósticos de salud mental

- Trastorno de ansiedad
- Intento de suicidio
- Trastorno por atracón
- Trastorno bipolar
- Trastorno compulsivo
- Depresión
- Trastorno psicótico
- Esquizofrenia

Ejemplos de mediaciones para la salud mental

- ADHD (Adderall)
- Anti-ansiedad (Xanax)
- Antidepresivo (Prozac)
- Antipsicótico (Haldol)
- Estabilizador de estado de animo (Lithium)

Ejemplos de laboratorios y otros test para evaluar salud mental

- Escala de ansiedad
- Inventario de depresión
- Escala de comportamiento disruptivo
- Test de memoria y aprendizaje
- Cuestionario de estado de animo
- Test de esquizofrenia

Ejemplos de procedimientos o servicios para la salud mental

- Terapia cognitiva
- Hipnosis
- Psicoterapia
- Examen de detección de trastornos de salud mental

Para mas información:

1. Salud Mental. MedlinePlus. LINK
2. Salud Mental. ¿Que es normal y que no? Mayo Clinic. LINK

A.9 Educational Material on Sexual and Reproductive Health Information for English Patients

My Data Choices

SEXUAL AND REPRODUCTIVE HEALTH INFORMATION

What is sexual and reproductive health?[1,2]

It is health relating to sex and reproduction (having children.) Good sexual and reproductive health means that people can have a satisfying and safe sex life. It means they can have sex. It means they can have children. It means they can decide if, when and how often they want to have children.

What is sexual and reproductive health data?

It is any information about a person's sexuality and reproductive history. It includes data about high risk sexual behavior. It also includes data about HIV/AIDS status. Some examples are below.

Examples of sexual and reproductive health diagnosis

- Abnormal uterine bleeding
- Erectile dysfunction
- HIV positive
- Infertility
- Prostatitis
- Syphilis

Examples of medications for sexual and reproductive health

- Birth control pills (Alesse)
- Erection pills (Viagra, Cialis)
- HIV pills (Abacavir, Zerit)
- Testosterone injection
- Vaginal ring

Examples of labs and other tests for assessing sexual and reproductive health

- HPV test
- Erectile dysfunction test
- Ovulation test
- Pelvic ultrasound
- Pregnancy test (HCG)
- Prolactin blood test

Examples of procedures or services related to sexual and reproductive health

- Abortion counseling
- Fertility preservation
- HIV counseling
- In vitro fertilization cycle
- Sex education
- Tubal ligation

For More Information:

1. Sexual and reproductive health. United Nations Population Fund. LINK
2. Sexual health issues. World Health Organization. LINK

A.10 Educational Material on Sexual and Reproductive Health Information for Spanish Patients

My Data Choices

INFORMACION DE SALUD SEXUAL Y REPRODUCTIVA

¿Que es salud sexual y reproductiva?[1,2]

Es la salud relacionada con el sexo y la reproducción (tener hijos). Una buena salud sexual y reproductiva significa que las personas pueden tener una vida sexual satisfactoria y segura. Significa que pueden tener relaciones sexuales. Significa que pueden tener hijos. Significa que pueden decidir si, cuándo y con qué frecuencia quieren tener hijos.

¿Que es información sobre salud sexual y reproductiva?

Es cualquier información sobre la sexualidad y el historial reproductivo de una persona. Incluye datos sobre el comportamiento sexual de alto riesgo. También incluye datos sobre el estado del VIH / SIDA. Algunos ejemplos están abajo.

Ejemplos de diagnostico de salud sexual y reproductiva

- Sangrado uterino anormal
- Disfunción eréctil
- VIH positivo
- Infertilidad
- Prostatitis
- Sífilis

Ejemplos de medicaciones para salud sexual y reproductiva

- Pastillas anticonceptivas (Alesse)
- Píldoras para erección (Viagra, Cialis)
- Inyección de testosterona
- Anillo vaginal
- Píldoras VIH (Abacavir, Zerit)

Ejemplos de laboratorios y otros test para evaluar salud sexual y reproductiva

- Prueba de VPH
- Prueba de disfunción eréctil
- Prueba de ovulación
- Ultrasonido pélvico
- Prueba de embarazo (HCG)
- Análisis de sangre de prolactina

Ejemplos de procedimientos y servicios relacionados a salud sexual y reproductiva

- Asesoramiento sobre aborto
- Preservación de la fertilidad
- Asesoramiento para VIH
- Ciclo de fertilización in vitro
- Educación sexual
- Ligadura de trompas

Para mas información:

1. Salud sexual y reproductiva. Fondo de Población de las Naciones Unidas. LINK
2. Salud sexual y reproductiva. Médicos sin Fronteras. LINK

A.11 Educational Material on Substance Use Information for English Patients

My Data Choices

SUBSTANCE USE INFORMATION

What is a substance use disorder or SUD?[1,2]

It is a disease that affects a person's brain and behavior. It is caused by using legal or illegal drugs or medications. These are known as substances. The person keeps using the substance even though it causes problems in the person's home or work. Drug addiction and drug abuse are other terms.

What is substance use data?

It is any data about a person's drug addiction, drug abuse, and other substance abuse problems. Some examples are below.

Examples of substance use diagnosis

- Cocaine abuse
- Excessive alcohol use
- Intravenous (IV) drug user
- Nicotine dependence
- Opioid abuse
- Sedative abuse

Examples of medications related to substance use

- Acamprosate (Campral)
- Buprenorphine (Subutex)
- Disulfiram (Antabuse)
- Methadone (Methadose)
- Naltrexone (ReVia)
- Suboxone (Zubsolv)

Examples of labs and other tests for substance use assessment

- Blood alcohol test
- Breathalyzers test
- Hair and saliva test
- Newborn drug screen
- Sweat test (sweat patches)
- Urine drug screen

Examples of procedures or services for substance use

- Detoxification services
- Drug abuse surveillance
- Nicotine replacement
- Smoking cessation counseling
- Substance use counseling

For More Information:

1. Substance Use Disorder. MedlinePlus Trusted Health Information for You. U.S. National Library of Medicine. LINK
2. Medication and Counseling Treatment. SAMHSA LINK

A.12 Educational Material on Substance Use Information for Spanish Patients

My Data Choices

INFORMACION DE USO DE SUSTANCIA

¿Que es el trastorno de uso de sustancia?[1,2]

Es una enfermedad que afecta el cerebro y el comportamiento de una persona. Es causada por el uso de drogas o medicamentos legales o ilegales. Estos se conocen como sustancias. La persona sigue usando la sustancia a pesar de que causa problemas en el hogar o el trabajo de la persona. La adicción a las drogas y el abuso de drogas son otros términos.

¿Que es información de uso de sustancia?

Son datos sobre la adicción a las drogas, el abuso de drogas y otros problemas de abuso de sustancias de una persona. Algunos ejemplos están abajo.

Ejemplos de diagnósticos de uso de sustancia

- Abuso de cocaína
- Excesivo uso de alcohol
- Consumidor de drogas intravenosas (IV)
- Dependencia a la nicotina
- Abuso de opio
- Abuso de sedantes

Ejemplos de medicaciones relacionadas al uso de sustancia

- Acamprosate (Campral)
- Buprenorphine (Subutex)
- Disulfiram (Antabuse)
- Methadone (Methadose)
- Naltrexone (ReVia)
- Suboxone (Zubsolv)

Ejemplos de laboratorios y otras pruebas para el uso de sustancias

- Prueba sanguínea de alcohol
- Prueba de alcoholemia
- Prueba de cabello y saliva
- Examen de drogas para recién nacidos
- Prueba de sudor (parches de sudor)
- Examen de drogas en orina

Ejemplos de procedimientos o servicios para uso de sustancias

- Servicios de desintoxicación
- Vigilancia de abuso de drogas
- Reemplazo de nicotina
- Asesoramiento para dejar de fumar
- Consejería sobre el uso de sustancias

Para mas información:

1. ¿Que es el tratamiento para el abuso de sustancias? US Department of Health and Human Services. LINK
2. El abuso de drogas y la drogadicción. National Institute on Drug Abuse LINK

APPENDIX

B. WEB-BASED SURVEY FOR PATIENT EVALUATION OF THE EDUCATIONAL MATERIALS (AIM 2)

PATIENT EVALUATION QUESTIONNAIRES

INSTRUCTIONS

Rate an item "Agree" when a characteristic occurs throughout the education material.

Rate an item "disagree" when a characteristic does not occur throughout the material or if there is no clarity.

Do not use any knowledge you have about the subject before you read or view the education material. Base your ratings ONLY on what is in the material that you are rating.

Do not let your rating of one item influence your rating of other items. Be careful to rate each item separately and distinctly from how you rated other items.

1. What is the name of the education material that you are evaluating?

- ○ Domestic violence
- ○ Genetic information
- ○ Mental health
- ○ Sexual and reproductive health
- ○ Substance use information

2. Does this material use common, everyday language?

- ○ Agree
- ○ Disagree

3. Does this material define all medical terms used?

- ○ Agree
- ○ Disagree

4. Does this material break information into short sections?

- ○ Agree
- ○ Disagree

5. Does each section in this material have good heading?

- ○ Agree
- ○ Disagree

6. Does information in this material flow well?

- ○ Agree
- ○ Disagree

7. Does the material provide a summary?

- ○ Agree
- ○ Disagree

8. Does graphics use in this material have a clear titles or captions?

- ○ Agree
- ○ Disagree

9. Is the graphics use in this material distract you from understanding it?

- ○ Agree
- ○ Disagree

10. Is the language use in this material suitability to you?

- ○ Agree
- ○ Disagree

11. Are the images use in the material positive, realistic and suitable to you?

- ○ Agree
- ○ Disagree

12. Do you have any comments or suggestions on this material?

_____

_____

APPENDIX

C. SAMPLE EMAIL FOR RECRUITMENT (AIM 3)

Dear <*name of potential participant*>,

My name is <insert name> and I am a student at Arizona State University.

I am writing to invite you to participate in the My Data Choices study. The study is about data sharing choices. In this study, you will answer questions that will help us understand how people make decision about sharing their sensitive health information. You will complete the study with a recruiter through a phone call. At the end of the study, you will receive an electronic $30 Amazon gift card as a thank you.

To be eligible for this study you need to:

- Be a <patient, or guardian> at <name of the facility.
- Be 18 years old or older.
- Have access to phone to participate in the study.
- If possible (OPTIONAL), have access to tablet or computer with reliable internet to complete the electronic survey.
- Have an hour to complete the study.

If you meet the above requirements and you are interested to participate, I would like to schedule a phone call with you. **Please write me an email to <recruiter email> or call me at <recruiter phone number> indicating:**

- Time and day to conduct the 60 minutes study. I am availability Monday to Saturday from 7:00 am to 4:00 PM.
- Phone number that you would like me to use to call you.
- Whether you have a tablet or computer with reliable internet. Please note a tablet or computer is NOT REQUIRED for the study.

If you have any more questions about this process or if you need to contact me about participation, I may be reached at <recruiter phone number> or <recruiter email>.

Thank you very much.

Sincerely,

APPENDIX

D. MY DATA CHOICES QUESTIONNAIRES (AIM 3)

My Data Choices Study

Q3 **Welcome to the study!**

In this study, you will reply to questions that we will ask you about yourself or the patient you represent.

Then you will indicate what health data you would like to share, with whom and for what purposes.

Finally, we will ask you questions about your experience with this study.

Q10 What is your participant identifier (ID)?

_____

Q7 Please select the name of your facility.

- ○ Partners in Recovery
- ○ Jewish Family and Children's Services

Q19 Are you a patient in this facility?

- ○ Yes
- ○ No, but legally authorized to consent for the patient

Q11 **Arizona State University, College of Health Solutions Consent Form for Research**

PROTOCOL TITLE: Evaluation of an online consent tool to determine data sharing preferences.

PRINCIPAL INVESTIGATOR:
Maria Adela Grando, PhD
Assistant Professor, College of Health Solutions
Arizona State University

CO-INVESTIGATOR/STUDENT INVESTIGATOR:
Anita Murcko, MD
George Karway, MS
Hunter Dyer
Kazi Syed
Tina Kaing
Julia Ivanova

You are being asked to take part in a research study because you are a patient or guardian of a patient at ${Q7/ChoiceGroup/SelectedChoices}. This study is funded by the National Institute of Health (NIH). This form has important information about the reason for the study and what you will do. This form also indicates the way we would like to use information about you, if you choose to be in the study. Please read this form carefully and ask questions you may have before agreeing to participate. There will be about 135 participants recruited at ${Q7/ChoiceGroup/SelectedChoices}.

Purpose of this study: The purpose of this study is to conduct an evaluation of a new online consent tool. The tool is designed to help patients or guardians in selecting what health data they want to share with doctors. Patients or guardians can use the tool to select choices like which data can be shared, with whom, for what purposes, and how long the data should be shared. You are being asked to take part in this study because your answers will help researchers to understand patients and guardians' choices on sharing health data for care. The choices you make in this study will not affect your care. It will not affect the sharing of your real health data.

Procedure: Your participation in the study will last approximately 45 minutes and at most 60 minutes. If you agree to be in this study, you will interact with an Arizona State University student. You will be given an online survey. The questions we will ask you will help us to get information like your race and ethnicity, gender, length of time at the facility, income, and level of education. We will ask you few questions to assess your understanding of the study. We will also explain to you the use of the online consent tool. Next, you will be given the online tool to make your choices about which parts of your medical record can be shared with your doctors. You will use the tool to create data sharing consent choices. At the end of the study, you will be asked to take a small online

survey about your experience. We will use your name to access your length of stay at the facility. We will collect how many years you have been receiving care from the facility. After the study, you will receive a $30 electronic Amazon gift card (eGift card) as a thank you for your participation. All the collected data will be used for research purposes only and will be kept confidential and secure. The results we will publish will be anonymous.

Possible Risks or Discomforts: There is a risk of stress because you will be working with new technology. There is also risk of anxiety from being asked to answer questions not directly related to care delivery. There is a small risk of loss of confidentiality.

Possible Benefits: You or the patient that you represent may not directly benefit from this study. But, the methods and results of this study may help to understand the views of patients and guardians on data sharing. It will also help to better understand the current informed consent process.

Financial information: Participation in this study will involve no cost to you. You will receive a $30 as a thank you for your participation.

Rights as a Research Participant: If you choose to be in this study, you have the right to be treated with respect. Your decision whether you wish to continue or stop being in the study will be respected. You are free to stop being in the study at any time. If you choose not to be in this study, it will not result in any penalty or loss of any benefits you are entitled to. You may choose not to answer particular questions if you do not want to.

Privacy: Unless required by law, only the study investigator, members of the investigator's staff, the Arizona State University Institutional Review Board, and representatives from the Office for Human Research Protections (OHRP) have the authority to review your study records. They are required to maintain confidentiality regarding your identity. Results of this study may be used for teaching, research, publications, and presentations at professional meetings. You will not be re-contacted after the study is completed. The information you provided will be known only to the personnel involved in the study. After the survey is completed it will be stored in a secure server at the ASU Biomedical Informatics unit.

Questions: You may wish to discuss this with others before you agree to take part in this study. If you have any questions about the research now or during the study, please contact Adela Grando, PhD at agrando@asu.edu or at (480) 884-0220. If you have any questions regarding your rights as a research subject, you may contact the ASU IRB at (480) 965-6788.

Statement of Consent: I am 18 years old or older. I am willing to take part in the study. I understand that the researchers from Arizona State University are hoping to collect my views on data sharing choices for care. I understand that I will be answering questions

online. I understand that the study will take at most 60 minutes of my time. I understand that if I participate in this study as a patient, information about my race and ethnicity, gender, years at the facility, income, level of education and medical record number will be collected. I understand that I will not be re-contacted after the study is completed.

I understand that if I participate in this study as a guardian of a patient, information about race and ethnicity, gender, years at the facility, income, level of education of patient and medical record number will be collected. I understand that myself or the patient I represent will not be re-contacted after the study is completed. I have read the above information. I have received answers to any questions I had about the study. I voluntarily consent to take part in the study.

*

Q13 Print your full name.

_____

Q29 **Questions about the patient**

Please answer the below questions for the patient you represent.

Q68 What is the patient's name?

_____

*

Q20 What is the patient's age in years (estimate if you are not sure)?

_____

Q25 How long has the patient received care at ${Q7/ChoiceGroup/SelectedChoices}?

- Less than a year
- 1 to 2 years
- 3 to 4 years
- 5 to 6 years
- 7 to 8 years
- 9 to 10 years
- More than 10 years

Q39 Does the patient see a primary care doctor at ${Q7/ChoiceGroup/SelectedChoices}?

- Yes
- No

Q59 **Question about healthcare outside ${Q7/ChoiceGroup/SelectedChoices}**

Please answer the below question about whether or not the patient is receiving any care outside this facility.

Q60 What type of care does the patient receive from doctors outside ${Q7/ChoiceGroup/SelectedChoices}? (Please select all that apply)

- ☐ Behavioral health care
- ☐ Primary medical care
- ☐ Specialty medical or surgical care (for example cardiologist)
- ☐ ⊗None
- ☐ Other _____

End of Block: S-P-outside-care

Start of Block: Surrogate demog

Q42 **Questions about yourself (legal representative of a patient)**

Please answer the following questions about yourself.

Q69 What is your age in years?

_____

Q44 What is your gender?

- ○ Male
- ○ Female
- ○ Others _____

Q45 What is your ethnicity?

- ○ Hispanic or Latino
- ○ Non Hispanic or Latino

Q46 What is your race? (Select all that apply)

- [ ] American Indian or Alaska Native
- [ ] Asian
- [ ] Black or African American
- [ ] Native Hawaiian or Other Pacific Islander
- [ ] White

Q61 What is your personal annual income?

- ○ Less than $5,000
- ○ $5,000 to $9,999
- ○ $10,999 to $14,999
- ○ $15,000 to $19,999
- ○ $20,000 to $24,999
- ○ Greater than $25,000

Q62 What is your highest education level?

- ○ Attended high school, but did not graduate
- ○ High school graduate (or equivalence)
- ○ Some college (1-4 years, no degree)
- ○ Associate degree
- ○ Bachelor degree
- ○ Master degree
- ○ Doctorate degree

End of Block: Surrogate demog

Start of Block: Patient demog

Q50 **Questions about yourself**

Please answer the below questions about yourself. If you do not know the exact answer for a question, please provide an estimate.

*

Q23 What is your age in years?

_____

Q24 What is your gender?

- ○ Male
- ○ Female
- ○ Others _____

Q25 What is your ethnicity?

- ○ Hispanic or Latino
- ○ Non Hispanic or Latino

Q26 What is your race? (Select all that apply)

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White

Q27 What is your personal annual income?

- ○ Less than $5,000
- ○ $5,000 to $9,999
- ○ $10,999 to $14,999
- ○ $15,000 to $19,999
- ○ $20,000 to $24,999
- ○ Greater than $25,000

Q28 What is your highest education level?

- Attended high school, but did not graduate
- High school graduate (or equivalence)
- Some college (1-4 years, no degree)
- Associate degree
- Bachelor degree
- Master degree
- Doctorate degree

End of Block: Patient demog

Start of Block: P-Inside-care

Q52 **Questions about your care at this facility**

Please answer the below questions about your care at ${Q7/ChoiceGroup/SelectedChoices}.

Q53 How long have you been receiving care at ${Q7/ChoiceGroup/SelectedChoices}?

- Less than a year
- 1 to 2 years
- 3 to 4 years
- 5 to 6 years
- 7 to 8 years
- 9 to 10 years
- More than 10 years

Q54 Do you see a primary care doctor at ${Q7/ChoiceGroup/SelectedChoices}?

- ○ Yes
- ○ No

End of Block: P-Inside-care

Start of Block: P-Outside-care

Q56 **Question about healthcare outside ${Q7/ChoiceGroup/SelectedChoices}**

Please answer the below question about your care outside this facility.

---

*

Q55 What type of care do you receive from doctors outside ${Q7/ChoiceGroup/SelectedChoices}? (Please select all that apply)

- ☐ Behavioral health care
- ☐ Primary medical care
- ☐ Specialty medical or surgical care (for example cardiologist)
- ☐ ⊗None
- ☐ Other _____

End of Block: P-Outside-care

Start of Block: MDC Welcome page

Q63 **My Data Choices!**

ASU is creating an online tool, My Data Choices, to allow patients and surrogates of patients to choose what health data to share, with whom and for what purposes.

To help us design this tool, in this study you will be asked questions about your data sharing choices.

This is only a study and your choices will not affect how your health data gets shared.

End of Block: MDC Welcome page

Start of Block: Consent 1

Q65
SCENARIO 1

Q66
SOURCE AND DESTINATION
I, participant ${Q10/ChoiceTextEntryValue}, hereby authorize....

Q67 **MEDICAL INFORMATION**

Assuming that I have all types of information in my medical record, I choose to share the following (choose all that apply):

- ☐ Domestic violence
- ☐ Genetic Information
- ☐ Mental health
- ☐ Sexual and reproductive health
- ☐ Substance use
- ☐ ⊗None

Q68 **PURPOSE OF USE**

I choose to share my health information for the following purposes (choose all that apply):

- ☐ Treatment
- ☐ Research
- ☐ ⊗None

End of Block: Consent 1

Start of Block: Consent 2

Q70
SCENARIO 2

Q71
SOURCE AND DESTINATION

I, participant ${Q10/ChoiceTextEntryValue}, hereby authorize....

Q72 **MEDICAL INFORMATION**

Assuming that I have all types of information in my medical record, I choose to share the following (choose all that apply):

- ☐ Domestic violence
- ☐ Genetic Information
- ☐ Mental health
- ☐ Sexual and reproductive health
- ☐ Substance use
- ☐ ⊗None

Q73 **PURPOSE OF USE**

I choose to share my health information for the following purposes (choose all that apply):

- ☐ Treatment
- ☐ Research
- ☐ ⊗None

End of Block: Consent 2

Start of Block: Consent 3

Q97
SCENARIO 3

Q98
SOURCE AND DESTINATION
I, participant ${Q10/ChoiceTextEntryValue}, hereby authorize....

Q99 **MEDICAL INFORMATION**

Assuming that I have all types of information in my medical record, I choose to share the following (choose all that apply):

- ☐ Domestic violence
- ☐ Genetic Information
- ☐ Mental health
- ☐ Sexual and reproductive health
- ☐ Substance use
- ☐ ⊗None

Q100 **PURPOSE OF USE**

I choose to share my health information for the following purposes (choose all that apply):

- ☐ Treatment
- ☐ Research
- ☐ ⊗None

End of Block: Consent 3

Start of Block: Post Survey Welcome Page

Q83 **Post Study Survey!**

This survey will help us to learn about your experience with the consent tool. Please answer each question. Remember that there is no wrong or right answer. We are interested in your feeling about the tool.

End of Block: Post Survey Welcome Page

Start of Block: Post survey questions

Q85 **Opinion and Feedback**

Please provide your feedback on this study by answering the following questions.

Q87 How easy did you find the online My Data Choices tool to use when creating consents?

- ○ It was very easy, I did not have any trouble using it
- ○ I had some trouble using it but overall it was easy to use
- ○ It was very hard to use. The tool needs a lots of updates.
- ○ N/A (Participant did not directly complete the survey electronically)
- ○ Other.. _____

Q94
Do you think the provided categories of medical data are good enough?

- ○ Yes, the information categories in the tool are enough for decision making
- ○ No, it needed more categories
- ○ No, there were too many categories

Q89 Does having these choices make you feel differently about sharing medical data?

- ○ No change
- ○ It makes me more willing to share my medical data
- ○ It makes me less willing to share my medical data
- ○ Other _____

Q90 Do you feel more comfortable sharing medical data if you know who is using it?

- ○ Yes, I would feel more comfortable
- ○ No, I would feel less comfortable
- ○ It does not matter to me
- ○ Other _____

Q91 If you can get notification each time someone uses the medical data, would you want that?

- ○ Yes, I would want to know each time
- ○ No, I don't need to know
- ○ It does not matter to me
- ○ Other _____

Q95 Please provide any final comments you have about the study

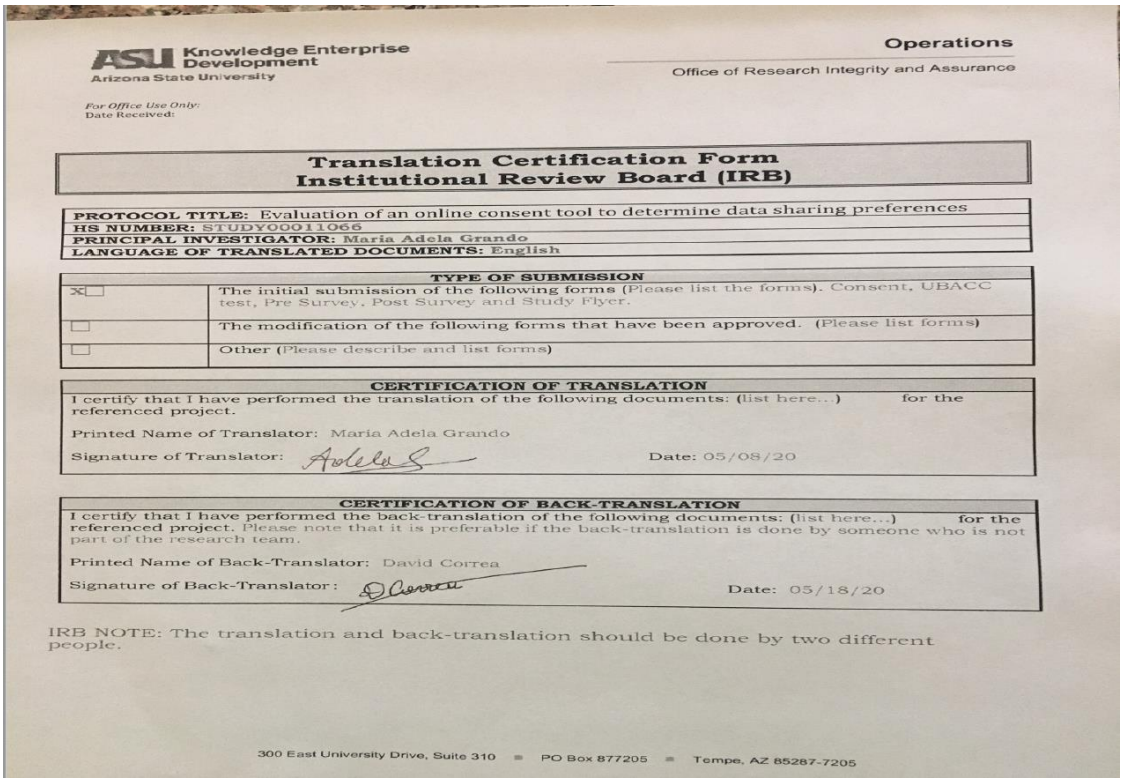
_____

End of Block: Post survey questions

APPENDIX

E. IRB DOCUMENTS

E.1 Translation Certificate Form



ASU Knowledge Enterprise Development
Arizona State University

Operations
Office of Research Integrity and Assurance

For Office Use Only:
Date Received:

Translation Certification Form
Institutional Review Board (IRB)

PROTOCOL TITLE: Evaluation of an online consent tool to determine data sharing preferences
HS NUMBER: STUDY0001066
PRINCIPAL INVESTIGATOR: Maria Adela Grando
LANGUAGE OF TRANSLATED DOCUMENTS: English

TYPE OF SUBMISSION

x☐	The initial submission of the following forms (Please list the forms). Consent, UBACC test, Pre Survey, Post Survey and Study Flyer.
☐	The modification of the following forms that have been approved. (Please list forms)
☐	Other (Please describe and list forms)

CERTIFICATION OF TRANSLATION

I certify that I have performed the translation of the following documents: (list here...) for the referenced project.

Printed Name of Translator: Maria Adela Grando

Signature of Translator: Adela S

Date: 05/08/20

CERTIFICATION OF BACK-TRANSLATION

I certify that I have performed the back-translation of the following documents: (list here...) for the referenced project. Please note that it is preferable if the back-translation is done by someone who is not part of the research team.

Printed Name of Back-Translator: David Correa

Signature of Back-Translator: D Correa

Date: 05/18/20

IRB NOTE: The translation and back-translation should be done by two different people.

300 East University Drive, Suite 310 ■ PO Box 877205 ■ Tempe, AZ 85287-7205

E.2 Consent Form for English Participants

Arizona State University,
College of Health Solutions
Consent Form for Research

PROTOCOL TITLE: Evaluation of an online consent tool to determine data sharing preferences.

PRINCIPAL INVESTIGATOR:

Maria Adela Grando, PhD
Assistant Professor, College of Health Solutions
Arizona State University

CO-INVESTIGATOR/STUDENT INVESTIGATOR:

Anita Murcko, MD
George Karway, MS
Hunter Dyer
Kazi Syed
Tina Kaing
Nisha Shankar
Julia Ivanova

You are being asked to take part in a research study because you are a patient or legal representative (surrogate) of a patient at <name of facility>. This study is funded by the National Institute of Health (NIH). This form has important information about the reason for the study and what you will do. This form also indicates the way we would like to use information about you, if you choose to be in the study. Please read this form carefully and ask questions you may have before agreeing to participate.

There will be about 135 participants recruited at <name of facility>.

Purpose of this study:

The purpose of this study is to conduct an evaluation of a new online consent tool. The tool is designed to help patients or surrogates in selecting what health data they want to share with doctors. Patients or surrogates can use the tool to select choices like which data can be shared, with whom, for what purposes, and how long the data should be shared. You are being asked to take part in this study because your answers will help researchers to understand patients and surrogates' choices on sharing health data for care. The choices you make in this study will not affect your care. It will not affect the sharing of your real health data.

ASU IRB IRB # STUDY00011066 | Approval Period 11/18/2019 – 10/14/2021

Procedure:
Your participation in the study will last approximately 45 minutes and at most 60 minutes. If you agree to be in this study, you will interact with an Arizona State University student. You will be asked questions. The questions we will ask you will help us to get information like your race and ethnicity, gender, length of time at the facility, income, and level of education. We will ask you few questions to assess your understanding of the study.

Next, you will be asked which parts of your medical record can be shared with your doctors. At the end of the study, you will be asked to answer few questions about your experience.

We will use your name to access your length of stay at the facility. We will collect how many years you have been receiving care from the facility.

After the study, you will receive a $30 Walmart gift card (electronic card if you have email or send by post with verbal reception confirmation) as a thank you for your participation.

All the collected data will be used for research purposes only and will be kept confidential and secure. The results we will publish will be anonymous.

Possible Risks or Discomforts:
There is risk of anxiety from being asked to answer questions not directly related to care delivery. There is a small risk of loss of confidentiality.

Possible Benefits
You or the patient that you represent may not directly benefit from this study. But, the methods and results of this study may help to understand the views of patients and surrogates on data sharing. It will also help to better understand the current informed consent process.

Financial information:
Participation in this study will involve no cost to you. You will receive a $30 as a thank you for your participation.

Rights as a Research Participant
If you choose to be in this study, you have the right to be treated with respect. Your decision whether you wish to continue or stop being in the study will be respected. You are free to stop being in the study at any time. If you choose not to be in this study, it will not result in any penalty or loss of any benefits you are entitled to. You may choose not to answer particular questions if you do not want to.

Privacy:

Unless required by law, only the study investigator, members of the investigator's staff, the Arizona State University Institutional Review Board, and representatives from the Office for Human Research Protections (OHRP) have the authority to review your study records. They are required to maintain confidentiality regarding your identity. Results of this study may be used for teaching, research, publications, and presentations at professional meetings.

You will not be re-contacted after the study is completed. The information you provided will be known only to the personnel involved in the study. After the survey is completed it will be stored in a secure server at the ASU Biomedical Informatics unit.

Questions:
You may wish to discuss this with others before you agree to take part in this study.
If you have any questions about the research now or during the study, please contact Adela Grando, PhD at agrando@asu.edu or at (480) 884-0220.
If you have any questions regarding your rights as a research subject, you may contact the ASU Institutional Review Board (IRB) at (480) 965-6788.

Statement of Consent: I am 18 years old or older. I am willing to take part in the study. I understand that the researchers from Arizona State University are hoping to collect my views on data sharing choices for care. I understand that I will be answering questions on the phone. I understand that the study will take at most 60 minutes of my time.

I understand that if I participate in this study as a patient, information about my race and ethnicity, gender, years at the facility, income, level of education and medical record number will be collected. I understand that I will not be re-contacted after the study is completed.

I understand that if I participate in this study as a surrogate of a patient, information about race and ethnicity, gender, years at the facility, income, level of education of patient and medical record number will be collected. I understand that myself or the patient I represent will not be re-contacted after the study is completed.

I have read the above information. I have received answers to any questions I had about the study. I voluntarily consent to take part in the study.

Date:

Printed Name:

This consent form will be kept by the researcher for at least three years beyond the end of the study.

E.3 Consent Form for Spanish Participants

Arizona State University,
College of Health Solutions,
Formulario de Consentimiento para Investigación

TITULO DEL PROTOCOLO: Evaluación de una herramienta online de consentimiento para determinar preferencias de compartimiento de datos.

INVESTIGADOR PRINCIPAL:

Maria Adela Grando, PhD,
Asistente de Profesor, College of Health Solutions
Arizona State University

INVESTIGADOR/ESTUDIANTE INVESTIGATOR:
Anita Murcko, MD
George Karway, MS
Hunter Dyer
Kazi Syed
Tina Kaing
Nisha Shankar
Julia Ivanova

Se le pide que tome parte en un estudio de investigación porque usted es un paciente o representante legal (guardián, tutor o protector de paciente) en este establecimiento. Este estudio esta financiado por el National Institute of Health (NIH). Este formulario tiene información importante sobre la razón del estudio y lo que usted hará. Este formulario también indica de que forma nos gustaría usar información sobre usted, si elige participar en el estudio. Por favor lea este formulario cuidadosamente y haga preguntas que pueda tener antes de aceptar participar.

Habrá alrededor de 135 participantes reclutados de <facility>.

Propósito del estudio:
El propósito de este estudio es conducir una evaluación de una nueva herramienta online de consentimiento. La herramienta esta diseñada para ayudar a pacientes o guardianes de pacientes en seleccionar que datos de salud desean compartir con doctores. Pacientes y guardianes de pacientes pueden usar esta herramienta para elegir que datos pueden ser compartidos, con quien y por que propósitos. Se le esta pidiendo tomar parte en este estudio porque sus respuestas ayudaran a investigadores a comprender las preferencias de pacientes y guardianes de pacientes de compartir datos de salud. Las elecciones que haga en este estudio no afectaran su cuidado. No afectara el intercambio de sus verdaderos datos médicos.

Procedimiento:
Su participación en el estudio durará aproximadamente 45 minutos y como máximo 60 minutos. Si acepta participar en este estudio, interactuará con un estudiante de la Arizona State University. Se le dará una encuesta online. Las preguntas que haremos nos ayudarán a obtener información como su raza y etnia, género, duración de tiempo en el establecimiento, ingresos y

nivel de educación. Le preguntaremos unas pocas preguntas para evaluar su comprensión del estudio. También te explicaremos el uso de la herramienta online de consentimiento.

A continuación, le preguntaremos que partes de su registro medico puede ser compartida con sus doctores. Al final del estudio se le preguntara que responsa algunas preguntas sobre su experiencia.

Usaremos su nombre para acceder a la duración de su estadía en el establecimiento. Recopilaremos información sobre cuántos años ha estado recibiendo atención en este establecimiento.

Después del estudio, recibirá una tarjeta de regalo de $ 30 de Walmart (electrónica si tiene email o sino enviada por correo con confirmación de recepción) como agradecimiento por su participación.

Todos los datos recopilados se utilizarán únicamente con fines de investigación y se mantendrán confidenciales y seguros. Los resultados que publicaremos serán anónimos.

Posibles riesgos e incomodidades:
Existe un riesgo de ansiedad de que se le pida que responda preguntas no directamente relacionadas al cuidado de su salud. Existe un pequeño riesgo de pérdida de confidencialidad.

Posibles Beneficios
Usted o el paciente que representa no pueden beneficiarse directamente de este estudio. Pero los métodos y resultados de este estudio pueden ayudar a comprender las opiniones de pacientes y guardianes de pacientes en el intercambio de datos. También ayudará a comprender mejor el proceso actual de consentimiento informado.

Información financiera:
La participación en este estudio no implicará ningún costo para usted. Recibirá una tarjeta de regalo electrónica de $30 como agradecimiento por su participación.

Derechos como participante de investigación:
Si elige participar en este estudio, tiene derecho a ser tratado con respeto. Su decisión de si desea continuar o dejar de participar en el estudio será respetada. Puede dejar de participar en el estudio en cualquier momento. Si elige no participar en este estudio, no resultará en ninguna multa o pérdida de ningún beneficio al que usted tenga derecho. Puede elegir no responder preguntas particulares si no quiere. Si no completa el estudio, no recibirá la tarjeta de regalo.

Privacidad:
A menos que lo exija la ley solo el investigador del estudio, los miembros del personal del investigador, la Junta de Revisión Institucional de la Arizona State University y representantes de la Oficina de Protección de la Investigación Humana (OHRP) tienen la autoridad para revisar sus registros de estudio. Están obligados a mantener confidencialidad con respecto a su identidad. Los resultados de este estudio pueden usarse para enseñanza, investigación, publicaciones y presentaciones en reuniones profesionales.

No será contactado nuevamente después de que se complete el estudio. La información que usted dio será conocida solo por el personal involucrado en el estudio. Después que el estudio sea completado, se almacenará en un servidor seguro en ASU Biomedical Informatics.

Preguntas:
Es posible que desee discutir esto con otros antes de aceptar participar en este estudio.
Si tiene alguna pregunta sobre la investigación ahora o durante el estudio, por favor contacte Adela Grando, PhD en agrando@asu.edu o (480) 884-0220.
Si tiene alguna pregunta sobre sus derechos como sujeto de investigación, puede comunicarse con la Junta de Revisión Institucional (IRB) de ASU al (480) 965-6788.

Declaración de consentimiento: tengo 18 años o más. Estoy dispuesto a participar en el estudio. Entiendo que los investigadores de la Arizona State University desean recopilar mis puntos de vista sobre las opciones de intercambio de datos para el cuidado medico. Entiendo que responderá preguntas online. Entiendo que el estudio tomará como máximo 60 minutos de mi tiempo.

Entiendo que si participo en este estudio como paciente, información sobre mi nombre, raza y etnia, género, años en el establecimiento, ingresos y nivel de educación se recopilara. Entiendo que no seré contactado después de que se complete el estudio.

Entiendo que si participo en este estudio como guardián de un paciente, información sobre mi raza y etnia, género, ingreso y nivel de educación del paciente se recopilará. El nombre del paciente será recopilado. Entiendo que yo mismo o el paciente que represento no seremos contactados después de se complete el estudio.

He leído la información anterior. He recibido respuestas a cualquier pregunta que he tenido sobre el estudio. Doy mi consentimiento voluntario para participar en el estudio.
El investigador conservará este formulario de consentimiento durante al menos tres años después del final del estudio.

Fecha
Su nombre (impreso)

Este formulario de consentimiento será archivado por el investigador por al menos tres anos después del final del estudio.

E.3 Recruitment Flyer for English Participants

A Research Study About Medical Data Sharing Preferences

Purpose of the study: Researchers at Arizona State University want to evaluate a new online consent tool and to know about preferences on sharing medical record from patients and surrogate (legal representative).

To participate in this research, you must:

- Be 18 years old or older
- Be a <facility> patient or surrogate of a patient
- Have a phone

College of Health Solutions
Arizona State University

Participation in this study is voluntary

Participation in this study involves:

- A time commitment of approximately 45 minutes
- Reply to questions related to medical record sharing
- A $30 Walmart gift card for participation

Benefits of Participation:
You may not directly benefit from taking part in this study. The results may help researchers in designing a better consent tool for patients.

To find out more about this study, please write an email to Kazi Syed at **mydatachoices2020@gmail.com** or call/send text to **480-300-1709**

ASU IRB IRB # STUDY00011066 | Approval Period 11/18/2019 – 10/14/2021

E.4 Recruitment Flyer for Spanish Participants

Estudio de Investigacion Sobre Preferencias de Compartimiento de Datos Medicos

Proposito del estudio: Investigadores de Arizona State University desean evaluar una herramienta online de consentimiento y conocer preferencias de compartimineto de datos medicos de pacientes y sustitutos de pacientes (tutor, guardian o protector).

Para participar en esta investigación, debe:

- Ser 18 anos de edad o mayor
- Ser paciente de <name of facility> o guardián de paciente
- Tener un teléfono

College of Health Solutions
Arizona State University

Participación en este estudio es voluntaria.

Participación en este estudio involucra:

- Un compromiso de tiempo de aproximadamente 45 minutos
- Contestar a preguntas relacionadas al compartimiento de registros médicos
- Una tarjeta Walmart de regalo de $30 por participación

Beneficios de Participación:
Quizás no te beneficies directamente de tomar parte en este estudio. Puede que los resultados ayuden a investigadores a diseñar una mayor herramienta de consentimiento para pacientes.

Para conocer mas sobre este estudio, escriba un email a Adela Grando agrando@asu.edu o llame al 8589974908

E.5 UCSD Brief Assessment of Capacity to Consent (UBACC) Test for English Participants

UCSD BRIEF ASSESSMENT OF CAPACITY TO CONSENT (UBACC)

Instructions:

After reviewing study details and the informed consent document, explain that you are going to ask a few brief questions about the study. Participants should be allowed to refer to the Informed Consent Form when answering these questions, but should be encouraged to respond in their own words. If a participant has trouble understanding one of the questions on the UBACC, rephrase the question. Rate the participant's responses on a scale of 0 – 2, with "0" being the lowest (little to no understanding of this aspect of the study) and "2" being the highest (clear understanding of this aspect of the study). A score of 15 or higher is needed for inclusion in the study.

	Score
1. What is the purpose of the study that was just described to you? Response: (2= The purpose of this study is to conduct an evaluation of a new online consent tool and to know about patients' and surrogate's (legal representative) preferences on sharing medical records.)	0 1 2
2. What makes you want to consider participating in this study? Response: (2= Help researchers understand the data sharing choices of patients and legal guardians, a $30 gift card)	0 1 2
3. Do you believe this study is primarily research or primarily treatment? Response: (2 =Research)	0 1 2
4. Do you want to be in this study if you do not want to participate? Response: (2= No)	0 1 2
5. If you withdraw from this study, will you still be able to receive regular treatment? Response: (2 =Yes)	0 1 2
6. If you participate in this study, what are some of the things that you will be asked to do? Response: (2= my name, medical record number, race and ethnicity, gender, and length of time at the facility will be collected from my medical record. I will complete HIPAA form to authorize the access to my medical records. I will complete a survey that will ask questions about my socioeconomic status. I will use the online consent tool to make my choices about which parts of my medical records I want to share with health providers. I will complete additional tasks depending on which group I am assigned to. I will complete a small survey about my experience using the tool.)	0 1 2
7. Please describe some of the risks or discomforts that people may experience if they participate in this study. (Please describe the 2 serious risks associated with the study)	0 1 2

Response: (2 = Anxiety, irritation or stress from being asked to answer survey questions. Loss of privacy for my data,.)	
8. Please describe some of the possible benefits of this study Response: (2 = Help researchers learn what health information you want to protect, may help others.)	0 1 2
9. Is it possible that being in this study will have any benefit to you? Response: (2 = No)	0 1 2
10. Who will pay for medical care if you are injured as a direct result of participating in this study? Response: (2 =None, there is no risk of getting injured)	0 1 2
TOTAL SCORE	

E.6 UCSD Brief Assessment of Capacity to Consent (UBACC) Test for Spanish Participants

UCSD BRIEF ASSESSMENT OF CAPACITY TO CONSENT (UBACC)

Instructions:

After reviewing study details and the informed consent document, explain that you are going to ask a few brief questions about the study. Participants should be allowed to refer to the Informed Consent Form when answering these questions, but should be encouraged to respond in their own words. If a participant has trouble understanding one of the questions on the UBACC, rephrase the question. Rate the participant's responses on a scale of 0 – 2, with "0" being the lowest (little to no understanding of this aspect of the study) and "2" being the highest (clear understanding of this aspect of the study). A score of 15 or higher is needed for inclusion in the study.

	Score
1. ¿Cual es el propósito del estudio que recién fue descripto? Respuesta: (2= El propósito del estudio es conducir una evaluación de una nueva herramienta online de consentimiento y saber las preferencias de compartimiento de registros médicos de pacientes y guardianes de pacientes.)	0 1 2
2. ¿Que le hace considerar participar en este estudio? Respuesta: (2= Ayudar a investigadores a comprender las elecciones de compartimiento de datos de pacientes y guardianes, una tarjeta electrónica de regalo de $30)	0 1 2
3. ¿Cree que este estudio es primariamente de investigación o primariamente de tratamiento? Respuesta: (2 =investigación)	0 1 2
4. ¿Desea estar en este estudio si no quiere participar? Respuesta: (2= No)	0 1 2
5. ¿Si se retira del este estudio, podrá aun recibir tratamiento regular? Respuesta: (2 =Si)	0 1 2
6. ¿Si participa en este estudio, cuales serán algunas de las cosas que se le pedirá hacer? Respuesta: (2= mi nombre, raza y etnicidad, genero y duración de tiempo en el establecimiento será obtenido de mi registro medico. Completare una	0 1

encuesta que me hará preguntas sobre mi estado socioeconómico. Usare la herramienta de consentimiento en línea para hacer elecciones sobre que partes de mis registros médicos quiero compartir con proveedores médicos. Completare una encuesta sobre mi experiencia usando la herramienta.)	2
7. Por favor describe algunos de los riesgos y molestias que la gente puede experimentar si participa en este estudio (Por favor describa los dos riesgos serios asociados a este estudio) Respuesta: (2 = Ansiedad, irritación o estrés de que se le pida responder preguntas. Perdida de privacidad de mis datos)	0 1 2
8. Por favor describe algunos de los posibles beneficios de este estudio Respuesta: (2 = Ayudar investigadores a aprender que información de salud desea proteger, quizás ayude a otros.)	0 1 2
9. ¿Es posible que estar en este estudio tendrá un beneficio para usted? Respuesta: (2 = No)	0 1 2
10. ¿Quien pagara por el cuidado medico si se lesiona como resultado directo de participar en este estudio? Respuesta: (2 =Nadie, no hay riesgo de lesionarse)	0 1 2
TOTAL SCORE	

E.7 Pre-Survey for English Participants

Pre Survey

1. **What is your Participant ID?**

_____

2. **Are you a patient in this facility?**
Mark only one oval.

- ◯ Yes
- ◯ No, but legally authorized to consent for the patient (CONFRIM CLIENT/CONSUMER)
- ◯ Other: _____

3. **How old are you?**
Mark only one oval.

- ◯ 20-24
- ◯ 25-29
- ◯ 30-34
- ◯ 35-39
- ◯ 40-44
- ◯ 45-49
- ◯ 50-54
- ◯ 55-59
- ◯ 60-64
- ◯ 65-69
- ◯ Greater than 69

4. **What is your gender?**
Mark only one oval.

- ◯ Female
- ◯ Male
- ◯ Other: _____

5. **What is your ethnicity?**
Mark only one oval.

- ◯ Hispanic or Latino
- ◯ Non Hispanic or Latino
- ◯ Other: _____

6. **What is your race ? (Select all that apply)**
Check all that apply.

- [ ] American Indian or Alaska Native
- [ ] Asian
- [ ] Black or African American
- [ ] Native Hawaiian or Other Pacific Islander
- [ ] White
- [ ] Other: _____

7. **How long have you been receiving care at this facility?**
Mark only one oval.

- ◯ Less than a year
- ◯ 1 to 2 years
- ◯ 3 to 4 years
- ◯ 5 to 6 years
- ◯ 7 to 8 years
- ◯ 9 to 10 years
- ◯ More than 10 years

8. **What is your personal annual income?**
Mark only one oval.

- ◯ Less than $5,000
- ◯ $5,000 to $9,999
- ◯ $10,000 to $14,999
- ◯ $15,000 to $19,999
- ◯ $20,000 to $24,999
- ◯ Greater than $25,000

9. **What is your highest education level?**
Mark only one oval.

- ◯ Attended high school, but did not graduate
- ◯ High school graduate (Or equivalent)
- ◯ Some college (1-4 years, no degree)
- ◯ College graduate
- ◯ Attended/completed graduate or professional school
- ◯ Other: _____

10. **If you see providers outside this facility, what type of care do you receive from them? Please select all that apply**

Check all that apply.

- [ ] Behavioral health care
- [ ] Primary medical care
- [ ] Specialty medical or surgical care
- [ ] Not applicable, I don't see providers outside this facility
- [ ] Other: _____

E.8 Pre-Survey for Spanish Participants

Pre Encuesta

1. ¿Cual es su identificador de participante?

   _____

2. ¿Es usted un paciente en este establecimiento?
[ ] Si
[ ] No, pero legalmente autorizado para consentir por el paciente
[ ] Otro _____

3. ¿Cuantos años tiene?
   [ ] 20-24
   [ ] 25-29
   [ ] 30-34
   [ ] 35-39
   [ ] 40-44
   [ ] 45-49
   [ ] 50-54
   [ ] 55-59
   [ ] 60-64
   [ ] 65-69
   [ ] Mas de 69

4. ¿Cual es su genero?
   [ ] Masculino
   [ ] Femenino
   [ ] Otro _____

5. ¿Cual es su etnicidad?
   [ ] Hispano o Latino
   [ ] No hispano o Latino

6. ¿Cual es su raza? (Seleccione todas las que correspondan)
   [ ] Indio Americano o Nativo de Alaska
   [ ] Asiático
   [ ] Negro o Afroamericano
   [ ] Hawaiano nativo u otro isleño del pacifico
   [ ] Blanco
   [ ] Otro _____

7. ¿Por cuanto tiempo ha recibido cuidados médicos en el establecimiento?
   [ ] Menos de un año

[ ] 1 a 2 años
[ ] 3 a 4 años
[ ] 5 a 6 años
[ ] 7 a 8 años
[ ] 9 a 10 años
[ ] Mas de 10 años

8. ¿Cual es su ingreso anual personal?
[ ] Menos de $5,000
[ ] $5,000 a $9,999
[ ] $10,999 a $14,999
[ ] $15,000 a $19,999
[ ] $20,000 a $24,900
[ ] Mayor de $25,000

9. ¿Cual es su nivel mas alto de educación?
[ ] Asistí a la escuela secundaria, pero no me gradué
[ ] Graduado de escuela secundaria (o equivalente)
[ ] Alguna educación superior (1-4 anos, no graduado)
[ ] Grado asociado
[ ] Atendí/complete grado universitario o profesional
[ ] Otro _____

10. Si ve a proveedores fuera de este establecimiento, ¿Qué tipo de atención recibe de ellos? Por favor seleccione todos los que aplica
[ ] Salud mental o conductual
[ ] Atención medica primaria
[ ] Especialidad medica o cuidado quirúrgico (por ejemplo, cardiólogo)
[ ] Ninguno
[ ] Otro _____

E.3 Post Survey for English Participants

Post Survey

1. **What is your participant ID?**

_____

2. **How easy did you find the online tool to use?**
Mark only one oval.

- ◯ It was very easy, I did not have any trouble using it
- ◯ I had some trouble using it but overall it was easy to use
- ◯ It was very hard to use. The tool needs alots of updates.
- ◯ Other: _____

3. **Do you think the categories of medical data in the online tool are good enough?**
Mark only one oval.

- ◯ Yes, the medical information in the tool are enough for decision making
- ◯ No, it needed more categories
- ◯ No, there were too many categories

4. **Does having these choices make you feel differently about sharing your medical data?**
Mark only one oval.

- ◯ No Change
- ◯ It makes me more willing to share my medical data
- ◯ It makes me less willing to share my medical data
- ◯ Other: _____

5. **Would you feel more comfortable sharing your medical data if you know who is using it?**
Mark only one oval.

- ◯ Yes, I would feel more comfortable
- ◯ No, I would feel less comfortable
- ◯ It does not matter to me
- ◯ Other: _____

6. **If you can get notification each time someone uses your medical data, would you want that?**
Mark only one oval.

- ◯ Yes, I would want to know each time
- ◯ No, I don't need to know
- ◯ It does not matter to me
- ◯ Other: _____

7. **Please provide any final comments you have about the study.**

_____

_____

_____

_____

_____

E.9 Post Survey for Spanish Participants

Post Encuesta

1. ¿Cual es su identificador de participante?

   _____

2. ¿Que tan fácil le resulto usar la herramienta online?
[ ] Muy fácil, no tuve ningún problema para usarla
[ ]Tuve algunos problemas usándola, pero en general fue fácil de usar
[ ]Fue muy difícil de usar. La herramienta necesita muchas actualizaciones
[ ] Otro _____

3. ¿Piensa que las categorías de datos médicos en la herramienta en línea son suficientemente buenas?
[ ]Si, las categorías de información de la herramienta so suficientes para tomar decisiones
[ ]No, necesitaba mas categorías
[ ]No, había demasiadas categorías

4. ¿Tener estas opciones le hace sentir diferente sobre compartir información medica?
[ ] Ningún cambio
[ ] Me hace sentir mas dispuesto a compartir mis datos médicos
[ ] Me hace sentir menos dispuesto a compartir mis datos médicos
[ ] Otro _____

5. ¿Se siente más cómodo compartiendo datos médicos si sabe quién los está usando?
[ ] Si, me sentiría mas cómodo
[ ] No, no me sentiría mas cómodo
[ ] No es importante para mi
[ ] Otro _____

6. Si puede recibir una notificación cada vez que alguien usa los datos médicos, ¿le gustaría?
[ ] Si, me gustaría saberlo cada vez
[ ] No, no necesito saberlo
[ ] No es importante para mi
[ ] Otro _____

7. Por favor provea comentarios finales que tenga sobre este estudio

   _____

E.10 Study Protocol

ASU Knowledge Enterprise Development
ARIZONA STATE UNIVERSITY

SOCIAL BEHAVIORAL INSTRUCTIONS AND TEMPLATE		
NUMBER	DATE	PAGE
HRP-503a		1of 3

Instructions and Notes:

- Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, mark as "NA".
- When you write a protocol, keep an electronic copy. You will need a copy if it is necessary to make changes.

1 Protocol Title

Evaluation of an online consent tool to determine data sharing preferences

2 Background and Objectives

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

- Describe the purpose of the study.
- Describe any relevant preliminary data or case studies.
  N/A
- Describe any past studies that are in conjunction to this study.
  N/A

The purpose of this study is to conduct an evaluation of a new online consent tool and to know about patients' and surrogate's (legal representative) preferences on sharing medical records. Responses and outcomes of this study will help to better understand the perspectives of patients and surrogates regarding their data sharing practices.

3 Data Use

Describe how the data will be used.

Thesis, Publication/journal article, conferences/presentations.

4 Inclusion and Exclusion Criteria

Describe the criteria that define who will be included or excluded in your final study sample. If you are conducting data analysis only describe what is included in the dataset you propose to use.
Indicate specifically whether you will target or exclude each of the following special populations:

- Minors (individuals who are under the age of 18) -No
- Adults who are unable to consent and have no surrogates- No
- Prisoners -No
- Undocumented individuals-No
- Non-English speakers -No

Inclusion Criteria: Patients who receive care at Partners in Recovery, or patients who receive care at Jewish Family and Children Services, or surrogates of patients who receive care at Partners in Recovery or at Jewish Family and Children Services; older than 18 years old, English or Spanish speakers and have a phone.

Exclusion Criteria: We will exclude patients and surrogates who do not satisfy the inclusion criteria.

5 Number of Participants

Indicate the total number of participants to be recruited and enrolled: 270

6 Recruitment Methods

- Describe who will be doing the recruitment of participants.
- Describe when, where, and how potential participants will be identified and recruited.
- Describe and attach materials that will be used to recruit participants (attach documents or recruitment script with the application).

We will use flyers in the facilities to invite interested patients and surrogates to participate. Interested participants will send their email addresses and phone number to recruiter along with their availabilities. We will set up a phone call with the potential participants based on their availabilities. During the phone call, recruiter will explain the study to potential participants. Recruiter will check inclusion/exclusion criteria and recruit the potential participants on the same day. Recruiter will send by email a copy of the electronic consent and wait for the participant to sign it. We will be notified when the consent is signed. Following consent (see attached Consent Form) recruiter will provide the participant a UBACC assessment (see attached UBACC assessment questionnaires) and administer a pre-survey (see attached survey questionnaires). Participants will make their choices about which parts of their medical record can be shared, with whom and for what purposes. After completing the study, the recruiter will administer a post-survey (see attached survey questionnaires) about participants experience using the tool.

Students from College of Health Solutions will be recruiting the patients for the study. The recruiter will be available during the study to answer any questions the subjects may have.

7 Procedures Involved

Describe all research procedures being performed, who will facilitate the procedures, and when they will be performed. Describe procedures including:

- The duration of time participants will spend in each research activity.
- The period or span of time for the collection of data, and any long term follow up.
- Surveys or questionnaires that will be administered (Attach all surveys, interview questions, scripts, data collection forms, and instructions for participants to the online application).
- Interventions and sessions (Attach supplemental materials to the online application).
- Lab procedures and tests and related instructions to participants.
  N/A
- Video or audio recordings of participants.
  N/A
- Previously collected data sets that that will be analyzed and identify the data source (Attach data use agreement(s) to the online application)
  N/A.

The recruiter will call each study participant individually, on date chosen by the participants. The purpose of the survey and the kinds of questions that will be asked will be explained to the participants. We will email a copy of the electronic consent to sign. After consent, the participant will complete a UBACC test, a pre-survey and then will use the answer questions related to data sharing choices. Participants will complete a post-survey about their experience.

The UBACC test will assess participants' comprehension of the study. The pre-survey will ask participants questions about their demographics and socioeconomic status such as their race and ethnicity, gender, length of time at the facility, income, and level of education. Participants will make data sharing decisions. Each participant will be issued a specific ID. The ID assigned to a participant will be used label the outcomes of the study.

Participants will indicate what data they wish to share (e.g. all medical records except mental health information), with whom (e.g. primary care providers at the facility) and for what purpose (e.g. research).

The post survey will collect information about participants experience with the study.

At the end of the study, we will use participants' name to ask the facilities information about length of stay in years. Example: the patient has been received care at the facility for 5 years. We will compare the length of stay as self-reported by participants (see pre-survey) and recorded in the EHR and we will assess if there are correlations between length of care at the facilities and willingness to share sensitive medical records with providers in the facility. A hypothesis is that longer the stay in the care facility, higher the willingness to share medical records with providers at the facility.

Any questions that the participants may have will be answered by the recruiter.

If the participant indicates not having email/internet, we will ask his/her home address to send the compensation by mail. We expect this to be a small group. So far, the participation of Spanish speaking patients has been minimal due to their lack of internet/email.

8 Compensation or Credit

- Describe the amount and timing of any compensation or credit to participants.
- Identify the source of the funds to compensate participants
- Justify that the amount given to participants is reasonable.

If participants are receiving course credit for participating in research, alternative assignments need to be put in place to avoid coercion.

In appreciation for their participation, the participants will be given a Walmart gift card of $30. If the participant indicates having an email, it will be sent electronically as a e-gift card. If, instead, the participant has no email/internet, it will be send by mail with a verbal confirmation of reception. The participants will be asked to spend at most 60 minutes of their time. Hence, they will be given the amount to compensate for that time. The gift cards are funded by the National Institute of Mental Health.

9 Risk to Participants

List the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research. Consider physical, psychological, social, legal, and economic risks.

There is a risk of loss of confidentiality, from participating in this study. For those who choose to have the compensation be sent by mail, the loss of confidentiality is higher. But we provide the (preferred) option of sending the compensation by email, which collects no data about participant's address.

There is risk of anxiety or stress from being asked to complete questions not directly related to care delivery.

If the participants wish to discontinue with the questions they will be allowed to do so. This will not result in any loss of benefits or penalty.

10 Potential Benefits to Participants

Realistically describe the potential benefits that individual participants may experience from taking part in the research. Indicate if there is no direct benefit. Do **not** include benefits to society or others.

There is no direct benefit to the patients.

11 Privacy and Confidentiality

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on with whom they interact or to whom they provide personal information.

Describe the following measures to ensure the confidentiality of data:

- Who will have access to the data?
- Where and how data will be stored (e.g. ASU secure server, ASU cloud storage, filing cabinets, etc.)?
- If applicable, how will audio or video recordings will be managed and secured. Add the duration of time these recordings will be kept.
  N/A
- If applicable, how will the consent, assent, and/or parental permission forms be secured. These forms should separate from the rest of the study data. Add the duration of time these forms will be kept.
  N/A
- If applicable, describe how data will be linked or tracked (e.g. masterlist, contact list, reproducible participant ID, randomized ID, etc.).

If your study has previously collected data sets, describe who will be responsible for data security and monitoring.

N/A

There will be a master list to link data collected during the study. To minimize the risks of loss of confidentiality only the research team will have access to the master list. All the collected data will be used for research purposes only. During the study, all data will be securely saved (encrypted files) in a password-protected computer in a locked room at ASU Biomedical Informatics facilities. Only the researchers in the study will have access to those files. After the study, the master list will be fully de-identified and the research team will not be able to re-identify the study participants. If the address of the participant was collected to send the compensation by mail, that information will be deleted after receiving the confirmation of mail reception from postal company.

12 Consent Process

Describe the process and procedures process you will use to obtain consent. Include a description of:

- Who will be responsible for consenting participants?
- Where will the consent process take place?
- How will consent be obtained?
- If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent. Translated consent forms should be submitted after the English is approved.
  N/A

The consent process will take place by phone on the day and time chosen by the participant. ASU students will be responsible for it. A copy of the electronic consent will be sent by email. The recruiter will ask the participant to sign it. We will be notified when the consent is signed.

13 Training

Provide the date(s) the members of the research team have completed the CITI training for human participants. This training must be taken within the last 4 year.

10/18/2017 – Dr Adela Grando
10/28/2019 – Dr. Anita Murcko
08/25/2017 – George Karway
08/25/2019 - Hunter Dyer
08/22/2020 – Kazi Syed
08/25/2019 – Tina Kaing
03/01/2023 – Nisha Shankar
2/11/2019 - Julia Ivanova

E.11 IRB Approval

ASU Knowledge Enterprise Development

APPROVAL: MODIFICATION

Maria Grando
CHS: Biomedical Informatics (BMI)
480/884-0259
Adela.Grando@asu.edu

Dear Maria Grando:

On 2/14/2020 the ASU IRB reviewed the following protocol:

Type of Review:	Modification / Update
Title:	Evaluation of an online consent tool to determine patient and surrogate data sharing preferences
Investigator:	Maria Grando
IRB ID:	STUDY00011066
Funding:	Name: HHS: National Institutes of Health (NIH), Grant Office ID: FP00021233, Funding Source ID: R01DA051634
Grant Title:	None
Grant ID:	None
Documents Reviewed:	• Consent Form, Category: Consent Form; • Flyer, Category: Recruitment Materials; • Grando_Final_GrantApplication.pdf, Category: Sponsor Attachment; • Post Survey, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Pre Survey, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); • Protocol, Category: IRB Protocol; • UBACC Test, Category: Screening forms;

The IRB approved the modification.

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: George Karway
George Karway
Maria Grando
Anita Murcko