

Optimizing the Integration of Health Apps with the Electronic Health Record by
Quantifying Data Readiness and Interoperability

by

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Dissertation submitted in partial fulfillment of
the requirements for the degree of Doctor
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ABSTRACT

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Abstract

Health apps are emerging as useful tools with the potential to deliver powerful health interventions, conduct research, and improve patient involvement in their care. While the development of health apps is gaining momentum, the ability to integrate these apps with electronic health records (EHRs) is limited, decreasing their potential impact on patient outcomes. Data exchange standards can facilitate the exchange of data between apps and EHRs, but these standards are not yet complete and will require collaboration, work, and time to be finalized and adopted. Prioritization of data standards development areas (that address health system needs and app requirements) and tools to assess the readiness of current EHR data will speed the integration of health apps with EHR systems.

This dissertation 1) addresses priority areas for the development of data exchange standards, and 2) provides insights for health systems and app developers to assess for the readiness of apps to be implemented with a given EHR system in its current state.

The products of this dissertation provide a framework to assess EHR data readiness for apps, outline priority areas to be developed in the United States Core Data for Interoperability standards specifications, and explore the associations between quantifiable characteristics of health apps and implementation feasibility.

Dedication

For my parents- thank you for the support all along the way.

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1. Introduction

1.1 Background

Applications (shortened to “apps”) are being developed by health and medical innovators and researchers to facilitate the collection and use of various types of data to improve a number of health care activities, ranging from handoff reporting, to quality of life assessments, to sensor data for managing chronic illness (Esvant et al., 2016; Motulsky et al., 2017; Schuler et al., 2016). While there is no official definition of what an “app” is, several definitions have been proposed and share a common theme: apps are meant to be transferrable tools with an ability to be integrated with different hardware. Apps can be seen in both consumer markets (e.g. apps that are downloaded through an app store on a smart phone) and in industry (e.g. apps that are developed for and sold to different health systems). For this reason, apps are excellent candidates to share knowledge artifacts (e.g. clinical decision support [CDS] tools) and to collect and deliver data for clinical and research applications. While not a steadfast rule, apps are generally developed with the intent to be shared and hence accessed by several different user bases.

Health apps have been developed to support a variety of purposes such as research data collection (Do & Yamagata-Lynch, 2017; Google, 2020), intervention delivery (Brindal, Hendrie, Freyne, & Noakes, 2019; Ni et al., 2018), and real-time decision support (Bedoya et al., 2019; Martins et al., 2020), and hence present in a variety

of formats. Most commonly, health apps may present as an integrated app with an EHR, a web-based app, or a mobile app (or a combination of the three). This flexibility has contributed to the rapid growth of the number and type of health apps designed to be used in organizational (i.e. researcher, health system) and consumer (i.e. patient, individual, family member) settings. The ability for apps to be both stand-alone tools and have mobile components bolsters their use to collect, manage, and present health and clinical data to users in ways that traditional siloed EHR systems cannot.

Health apps are being developed at an unprecedented pace. The COVID-19 pandemic has accelerated the use and spending on health apps in the public space by almost 40% from 2019 to 2020 (Natanson, 2020). As consumers become more conscious of their health and demand more autonomy in decisions regarding their plan of care, a format for communicating their data with the health providers increases. This trend is not unique to patients, but to clinicians and health researchers as well. CDS, intervention delivery, data collection, and knowledge access can be augmented through the use of apps. The Office of the National Coordinator (ONC) included a requirement in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (21st Century Cures Act Final Rule) that ONC certified health IT must have standardized APIs for patient data, the intent of which is to give patients immediate access to and control of their data including for apps. Institutions that provide grants for health research are certainly aware of this benefit: In a review of

grant applications from 2014 to 2018, the National Institutes of Health (NIH) issued 1524 grants related to app development, with 397 that focused specifically on intervention delivery (Hansen & Scheier, 2019).

In healthcare, one of the more challenging aspects of data collection is accessing and collecting data that exists outside of the health system (Holden, McDougald Scott, Hoonakker, Hundt, & Carayon, 2015). For example, data that are collected and generated by patients in their day-to-day life, such as their symptoms, physiologic measurements, moods, and preferences, are not easily captured. However, the use of apps with patient-facing components has begun to address this issue, albeit with significant challenges related to privacy, connectivity, and data access (Neinstein, Thao, Savage, & Adler-Milstein, 2020). While challenges do exist, the great utility and promise of Health Apps to improve health outcomes has captured the attention from app developers in private industry and grant funding agencies alike, and their interest is growing. Given the potential health impact of apps, the level and momentum of app development, and the well-known challenges for designing apps that are safe, trustworthy, useful and usable, an understanding of how to facilitate the development and implementation of health apps integrated into EHRs and healthcare decision making is badly needed.

1.2 Challenges with App Integration

Despite the expanding development and potential impact of health apps, interoperability, or the ability for apps to connect data from different sources, is an essential and unrealized infrastructure requirement for scalable and ubiquitous adoption of apps that are integrated into health care planning, delivery, and decision making. For example, a patient with diabetes might want to share their blood sugar (laboratory result) data with their care team, so they collect this information through an app (potentially automatically uploaded through a Bluetooth enabled glucometer). If this data cannot be shared via the EHR, the patient would be limited to either printing and sending the information through email or waiting until their next appointment to physically show their providers the data displayed on their mobile app. These exchange limitations are due to several reasons, including to the use of different EHR vendors, underlying architecture of local EHR builds, and the inconsistent use of data standards. This inability to exchange data from apps severely limits their utility, but the development of data exchange standards is beginning to address the challenges of integrating apps with the EHR.

The Substitutable Medical Applications, Reusable Technologies (SMART) (Boston Children's Hospital Computational Health Informatics Program, 2019) platform in tandem with the Fast Healthcare Interoperability Resources (FHIR) (Health Level 7, 2017) standard have been a major step towards app integration and interoperability.

Health institutions that have enabled a SMART on FHIR platform can much more easily implement apps built using these standards, also enabling the sharing of such apps between developers. In fact, Boston Children’s Hospital hosts the SMART on FHIR app gallery (apps.smarthealthit.org/), a central location for developers to share their apps with both free and paid options. There are also a number of other repositories for such apps and tools, including Apple’s toolkit (apple.com/healthcare/health-records/), vendor specific solutions (such as through Cerner and the Epic App Orchard), 1uphealth (1up.health/health-apps/gallery) and others. It is worth noting that other platforms exist that can facilitate apps outside of the FHIR standard, such as enterprise solutions such as Xealth (xealth.com). However, such solutions are limited to health systems that are able and willing to pay the costs associated with these solutions. The development and use of open access standards for apps will allow for smaller health systems and regional hospitals to easily integrate and adopt apps developed outside their organization and thereby enable their patients and providers to benefit from the utility of apps.

1.3 Beyond Data and Interoperability Challenges

Interoperability is not the only challenge with app implementation. As with any health information technology (HIT), the deployment of a new tool requires attention to both technical and sociotechnical challenges. The combination of these challenges necessitates several approaches to learn how to best facilitate the integration of health apps with the EHR, various workflows, and patient day-to-day life. This is supported by

a number of frameworks, including the Data to Knowledge (D2K) -Knowledge to Performance (K2P) - Performance to Data (P2D) learning cycle (University of Michigan Medical School, 2021), and other emerging implementation science frameworks (Allotey, Reidpath, Ghalib, Pagnoni, & Skelly, 2008; Glasgow, Eckstein, & Elzarrad, 2013; Peters, Adam, Alonge, Agyepong, & Tran, 2014) which provides a scaffold for evaluation and bringing about change. Beyond the informatics perspective, other criteria to evaluate health apps include efficacy, functionality, user acceptance, and others. These factors are critical for the successful adoption and integration of apps into clinical practice but are beyond the scope of this dissertation. This dissertation will focus the data-related challenges to app-EHR system integration, as outlined in Section 1.6 (Aims).

1.4 Gaps to Address

To support the integration of apps into health care delivery and EHR systems, the most immediate problem to address is how to prioritize and advance the development of interoperability standards that can enable data exchange between apps and EHRs. Despite their potential, the SMART and FHIR standards do not present a complete nor seamless solution to the interoperability problem at this time. One standards approach that is gaining traction is the use of the United States Core Data for Interoperability (USCI, or US Core) (The Office of the National Coordinator for Health Information Technology, n.d.), which puts constraints on the FHIR standard to lessen the customization needed to implement an app from site to site (Health Level 7, 2019).

To gain adoption and enable interoperability, the US Core needs to expand its coverage for various FHIR resource specifications to include those that are most meaningful or useful to EHR systems and apps developers and users. At present, there is a knowledge gap on how to determine which FHIR resources have most potential impact and to use this information prioritize development of the US Core.

Looking at lists of apps that are developed and promoted for adoption, it is apparent that multiple competing pp-based solutions do and will continue exist to solve the same clinical problem, such as weight loss, for instance. Patients and providers selecting and using these apps will have different informational needs, health goals, and preferences, suggesting that multiple apps addressing similar needs will continue to exist. These apps may be promoted by providers or “clinical champions” who may request the healthcare institution adopt and integrate particular apps into their EHR systems or processes. At present, there is little formal guidance to help institutions select the optimal app choice from among a number of apps, or to evaluate the feasibility to integrate a particular app into their local EHR architecture. One approach to enable these types of app feasibility assessments is to quantify the “data readiness” of an organization and its local EHR system, which would inform health HIT administrators on strategy, budget, and timelines for app adoption. Further, the concept of a quantified data readiness assessment would also inform developers about data availability, format, and standardization so that they can design apps that are more easily implemented.

1.5 Theoretical Framework

Every health app is data-centric in the respect that they require data, or generate data, or both. The sources and types of data for apps can vary, depending on the clinical use case, and may require complete data from multiple sources, including data from EHRs, to function as intended. This dissertation explores the readiness of EHR data for use by health apps, and thus is heavily influenced by the principles and standards for data and system interoperability. The framework of this dissertation that underlies the development and execution of the work presented in the following chapters was developed by borrowing from two pivotal works. First, two concepts (technical standards and services [1], and individuals accessing and sharing health information within a health IT ecosystem [2]) were taken from the Office of the National Coordinator's (ONC) "Ten Year Vision to Achieve Interoperable Health IT Infrastructure" (The Office of the National Coordinator for Health Information Technology, 2014). The second work, the D2K-K2P-P2D learning cycle (University of Michigan Medical School, 2021), presents the infrastructure for a learning health system (LHS) feedback loop, and we have adopted this infrastructure paradigm in this dissertation research to represent how feedback loop can be used to inform technical standards. The "Framework for Informing Data Readiness and Interoperability" was developed (Figure 1) from the concepts taken from the ONC and LHS works.

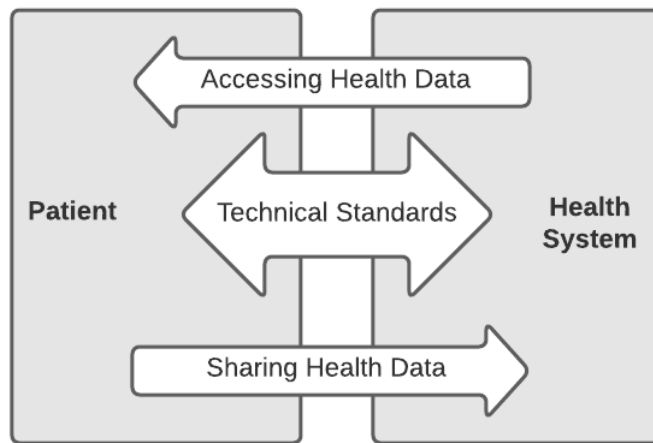


Figure 1: A Framework for Informing Data Readiness and Interoperability

1.6 Aims

The purpose of this dissertation is to describe and explore data-focused approaches to assist in the assessment and prioritization of health apps that could be integrated with the EHR. This will be addressed through five aims in the following chapters:

1. Aim 1 (Chapter 1): Identify current gaps in current app integration strategies in the broader context of patient care.
2. Aim 2 (Chapter 2): Define “data readiness” as a concept in healthcare informatics that can be used to facilitate the characterization and assessment of data requirements for health apps.

3. Aim 3 (Chapter 3): Conduct a data-requirement analysis of existing apps and identify priority areas for development in the US Core Data for Interoperability and the FHIR standard specifications.

4. Aim 4 (Chapter 4): Explore the relationships between different data readiness components -for a sample of existing health apps and discuss how these concepts can be used to empower health system leaders to assess the feasibility of integrating any app with their EHR system.

5. Aim 5 (Chapter 5): Synthesize the findings of the above research and discuss future directions and implications for research.

2. A Conceptual Framework of Data Readiness: The Contextual Intersection of Quality, Availability, Interoperability, and Provenance

2.1 Background and Significance

The term data readiness has been growing in popularity in health technology and informatics circles, from its use in blogs of companies such as IBM (Jain et al., 2019), to being offered as a service by various companies and agencies (General Services Administration, 2020; Tableau, n.d.). Yet, its meaning varies widely depending upon its use and application. A critical examination and conceptual exploration of the meaning of this term is necessary if ‘data readiness’ is to be used to guide future research and practice. For example, in lay language, this term may convey the notion that “data” is in a state that is considered to be “ready” to use in a particular application. However, it is likely that there are many facets and interpretations that must be considered and assimilated to provide a common conceptual framework for discussion and use in health sciences. If left without critical examination, we may find ourselves using the term data readiness in conflicting circumstances that may undermine its use for describing informatics research and applications.

The act of analyzing terminology in informatics is not new; the exploration of “data quality” by Weiskopf and Weng (2013) showed that a standard definition of a concept is important when attempting to operationalize measurement, having real-world implications for research and quality improvement. Their work revealed five

dimensions of data quality, with each dimension representing unique concepts in the literature, many of which had overlapping and conflicting uses prior to this work. Their analysis demonstrated the confusion and possible misinterpretation of results (and ultimately consequent risk of misinformed patient care and interventions), that can result from an assumed but not explicit definition of a concept. The clear definition and expansion of the concept of data quality has since laid a critical foundation for the informatics community to advance methods and tools that can impact data quality.

Similarly, data readiness is frequently used in reference to specific clinical health information technology (HIT) tools but is often vague and left to individual interpretation. To our knowledge, data readiness has not been formally defined nor operationalized in healthcare informatics, nor in any other field. A definition of data readiness could be applied to informatics applications, such as through the implementation of clinical practice guidelines as clinical decision support (CDS) (R. L. Richesson et al., 2020), to provide a shared understanding of how to assess data for its ability to be used in pragmatic applications. Data readiness as a conceptual framework could help to guide the development of interoperable health solutions, synergistic technology development collaborations across different medical centers, and reuse of informatics solutions (such as apps and CDS tools) that could be integrated into heterogeneous electronic health record (EHR) systems and data repositories. This will provide a foundation for metrics that can be used by organizations to prioritize

applications most suited to their data and systems and can further guide researchers and implementers to ensure that planned applications fit the data they intend to use.

Using the extant literature, our objective is to provide a conceptual definition and framework for the term data readiness that can be used to guide research and development related to data-based applications in health care. To achieve this goal, we will a) identify related and surrogate constructs associated with or determinants of data readiness, and b) integrate these constructs into a parsimonious conceptual framework to define data readiness.

2.2 Methods

To define data readiness, we conducted a review of the informatics-related literature for published manuscripts that use the term “data readiness”. We searched the databases of PubMed, the National Institutes of Health (NIH) RePORTER, Scopus, the Cochrane Library, the American Medical Informatics Association (AMIA) Knowledge Center, and the Duke University Library for all available business and information sciences databases. The initial search strategy included exact phrase matching for “data readiness”, “readiness of data”, and “readiness of the data”. When applicable, “all fields” were selected for search results. No date restrictions were imposed; all results were included through July 2020.

Once the initial articles were retrieved, we confirmed that each article contained one of the search terms of data readiness. If one of the terms was found in the title,

abstract, or body of the article, the article was included in the full review. Often, articles were picked up by the database searches due to a citation containing one of the search phrases. If this was the case, this cited article was assessed for term matching and whether it was already identified in the initial search (i.e., a duplicate). In addition, while conducting this search, we sought synonyms for data readiness within the manuscripts, and included the term matching strategy within our selected databases. Once the articles were identified and confirmed for phrase matching, two authors (BD and RR) conducted independent full-text reviews of each article to confirm if the term data readiness (and its associated phrases and synonyms) was used in a way that contributed to a conceptual definition. For example, we looked for the inclusion of definitions, frameworks, or figures explaining data readiness as a whole or in part, using the concept in a clearly defined use case, or operationalizing the concept for measurement. This iterative search process is outlined in Figure 2.

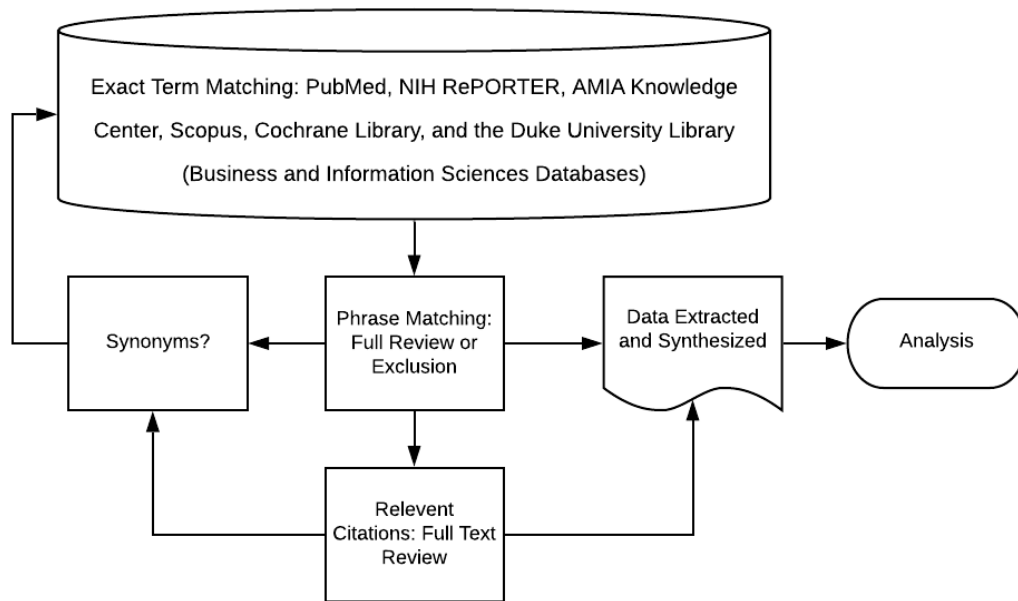


Figure 2: Literature Search and Article Screening Strategy to Define the Concept of Data Readiness

With the final corpus of literature identified, we summarized information from each article that informed a definition of data readiness in a summary table. With inspiration from Rogers' Evolutionary Method of Concept Analysis (Rogers & Knafl, 2000), the extracted information was synthesized to both identify relevant constructs within data readiness and to propose a conceptual framework for data readiness to be used in future informatics literature and research. This process included reviewing and summarizing the information provided by each article, identifying key constructs, assimilating the constructs into categories, and identifying the final dimensions of data readiness.

2.3 Results

The initial search produced 256 publications, after removing duplicates. Of note, only one grant was found through the NIH RePORTER. 149 articles did not have any mentions of data readiness and were excluded from the final reviews (often from 'data' and ready' being adjacent to each other but being separated by a comma or period). Four were excluded due to the full text not being available in English. 65 articles only had mentions of data readiness in the references; 57 were duplicates already included in the search, but eight were not previously identified and were all selected for full review. Two potential synonyms were identified in the initial search: e-readiness and database readiness. E-readiness was not considered as a synonym as it already has a formal definition and does not pertain to health data, but rather information technology infrastructure (Hung, Chang, Lin, & Hsiao, 2014). Four articles referring to 'database readiness' were found, two of which met inclusion for exact term matching. However, neither yielded input to the definition of data readiness.

In all, 46 articles were included in the full text review. Of the 46 articles, 20 met inclusion to define the concept of data readiness. Cohen's Kappa between the raters was 0.68, or strong agreement (McHugh, 2012). Discrepancies were resolved through consensus between the raters. Figure 3 outlines the search results.

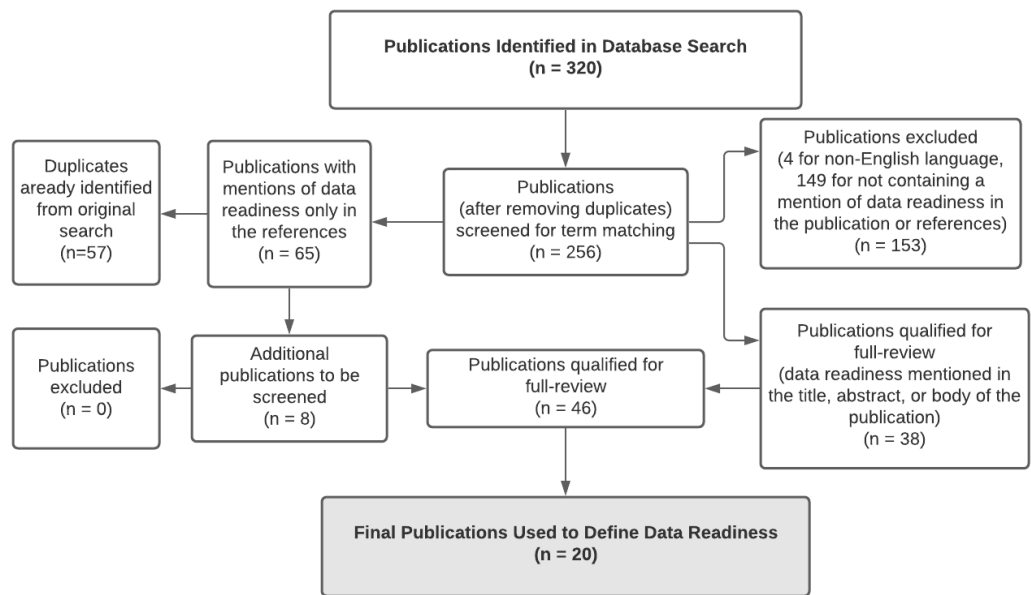


Figure 3: Results of Literature Search for Publications to Define Data Readiness

The 20 publications were then reviewed and discussed to extract relevant constructs and contextual information to define data readiness. Following review by the authors, four distinct and salient constructs were identified: data quality, data availability, interoperability, and data provenance. Many publications articulated the importance of considering data readiness within the context of what the data is to be used for. Table 1 lists the included manuscripts, highlighting key information to define data readiness and potential data readiness constructs.

Table 1: Summary of the Literature’s Contributions to Define Data Readiness

Author (Year) & Title	Publication Type	Objective	Key Contributions to Define Data Readiness	Construct Defined
Austin, C. (2019) A Path to Big Data Readiness	Opinion	To describe practical solutions to common problems experienced when integrating diverse datasets from disparate sources.	Characterizes readiness as the “intensity of data use” and whether it is collected. Also highlights the FAIR principles(Wilkinson et al., 2016) for data management and data ownership.	Data Availability; Data Provenance; Interoperability
Campbell, S. et al (2020) Research Data Network Ontologies for Precision Cancer Medicine Supporting I2b2 and OMOP	Panel Abstract	To explore the use of ONC ontologies and reference termonologies to support research activities.	Furtheres the importance of data standards to achieve interoperability.	Interoperability
Carr, H. et al. (2014) Defining Dimensions of Research Readiness: a Conceptual Model for	Literature Review	To create a conceptual model of “research readiness” to be used to help identify key requirements	Readiness includes an assessment of how data is held (i.e. how it is distributed and centralized) and understanding its underlying quality.	Data Quality; Interoperability

Primary Care Research Networks		for participation in research.		
Cheriath, K. (2018) Data Governance 2.0	Opinion	To provide an outline for using <i>data governance 2.0</i> , a solution to issues in data legacy infrastructure and data stewardship in business applications.	Data readiness is described as part of data management; conflicts somewhat with the other sources and delineates readiness from quality.	Data Provenance
Chirkova, R., Doyle, J., & Reutter, J. (2018) The Data Readiness Problem for Relational Databases	Case Report	To present and demonstrate a framework to address a “data readiness problem” (returning an accurate boolean query) in a database.	Defines readiness as the inclusion of data to fit the parameters of the intended query.	Data Quality
de Lusignan, S. et al. (2011) Key Concepts to Assess the Readiness of Data for International Research: Data	Literature Review	To define the key concepts which inform whether a system for collecting, aggregating and processing	Covers many dimensions of data readiness; as noted in the title, includes data quality and provenance principles. Also describes data models and	Data Quality; Data Provenance; Interoperability

Quality, Lineage and Provenance, Extraction and Processing Errors, Traceability, and Curation		routine clinical data for research is fit for purpose.	semantics in the body of the paper.	
Digital Curation Centre (n.d.) 5 Steps to Research Data Readiness – A Guide for IT Managers	Brochure/ Opinion	To describe the five steps to research data readiness.	Describes readiness as the availability of data and addresses the importance of having data standards and an adequate data infrastructure.	Data Availability; Interoperability
Ellaway, R., Topps, D., & Pusic, M. (2019) Data, Big and Small: Emerging Challenges to Medical Education Scholarship	Opinion	To provide an agenda to change data collection processes for use in medical education and scholarship.	Explores human-centered processes of data; quality and stewardship is essential to readiness.	Data Quality; Data Provenance
Gibbs, L. et al. (2017) IDS Governance: Setting Up for Ethical and Effective Use	Expert Panel Report	Panel report to describe an action plan to support integrated data systems for use in driving social policy.	Describes data readiness as: relevance and sufficiency, quality, collection frequency, granularity, history, privacy, and documentation (quality).	Data Quality; Data Availability; Data Provenance

<p>Ivers, A., Byrne, J., & Byrne, P. (2014)</p> <p>Analysis of SME Data Readiness: A Simulation Perspective</p>	<p>Literature Review</p>	<p>To investigate the data profile of manufacturing small and medium enterprises with specific emphasis on understanding the data readiness for discrete event simulation modeling.</p>	<p>Data readiness is described in terms of different data quality dimensions.</p>	<p>Data Quality</p>
<p>Jennings, E. et al. (2018)</p> <p>An Instrument to Identify Computerised Primary Care Research Networks, Genetic and Disease Registries Prepared to Conduct Linked Research: TRANSFoRm International Research Readiness (TIRRE) Survey</p>	<p>Cross Sectional Study</p>	<p>To conduct a survey to assess for the ability of European databases to exchange data.</p>	<p>Data readiness is described as the ability to extract and synthesize data from different sources.</p>	<p>Interoperability</p>
<p>Klievink, B. et al. (2017)</p>	<p>Exploratory Qualitative</p>	<p>To assess a framework for</p>	<p>Data readiness is contextual to the</p>	<p>Data Availability</p>

Big Data in the Public Sector: Uncertainties and Readiness	Study	evaluating public organizations' big data readiness.	organization. Stresses the availability of data for use in organizational goals.	
Lawrence, N. (2017) Data Readiness Levels	Opinion	To propose the use of data readiness levels to facilitate project management.	Data readiness includes three levels of assessment: ability to be exchanged, level of missing data, and the ability to show knowledge representation.	Interoperability; Data Quality
Lu, Y. et al. (2014) Data Readiness Level For Unstructured Data With a Focus on Unindexed Text Data	Cross Sectional Study	To define the concept of "data readiness levels".	Metrics of quality are important to assess readiness. Data readiness is also dependent on the objective.	Data Quality
Nanotechnology Signature Initiative (2013) Nanotechnology Knowledge Infrastructure (NKI): Enabling National Leadership in Sustainable Design	Opinion	To discuss and define data readiness levels.	The quality of the data is key to assess its maturity, which in turn is a major factor in data readiness.	Data Quality

*Richesson, R. (2016) Quantifying System and Data Readiness for Automated Clinical Decision Support	Research Grant	To quantify the alignment of CDS data with EHR structures relating to data quality and provider preferences.	Data readiness explains the ability for data to be used in clinical practice guideline-based CDS; availability and quality are essential to successful guideline translation into CDS.	Data quality; Data Availability
The World Bank (2015) Readiness Assessment Tool	Executive Summary	To give instruction on conducting Open Data Readiness Assessments and associated guidance for leadership.	The assessment tool largely judges the availability of data for public health use.	Data Availability
United Nations Office for Disaster Risk Reduction (2017) Sendai Framework Data Readiness Review 2017 – Global Summary Report	Executive Summary	To report the findings of the Sendai Framework Data Readiness Review, and discuss each component.	To achieve data readiness, it must be available for use.	Data Availability
Vorhees Group, LLC (2007) Institutional Data Readiness	Institutional Data Readiness Assessment Tool	A tool to assess institutional data readiness;	Describes data readiness as a product of human interaction with data; stresses importance	Data Provenance

Assessment Tool		three part assessment with five level Likert-scale	of management.	
Wen, Y. and Hwang, Y. (2019) The Associativity Evaluation Between Open Data and Country Characteristics	Cross Sectional Study	To assess the levels of open government data among various countries.	Data readiness is described as an intersection between availability and quality; focuses on interoperability principles.	Data Availability; Data Quality; Interoperability

*This contribution is the only grant summary found in the NIH RePORTER; all other contributions were publications found through database searches

2.3.1 Data Quality

In the data readiness literature review, data quality presented in two significant ways; as an antecedent to data readiness, and as a prospective benchmark. When data quality presents as an antecedent, the concept of “readiness” refers to the adequate quality of data to facilitate the task at hand. For instance, several publications (Carr et al., 2014; Chirkova, Doyle, & Reutter, 2018; de Lusignan et al., 2011; Gibbs et al., 2017; Lu, Fang, & Zhan, 2014; Wen & Hwang, 2019) state that in order to use data, it must pass an initial test of data quality, otherwise it should not be used to make informed decisions. On the other hand, some literature referred to data quality as a prospective goal of readiness, such as how the Nanotechnology Signature Initiative (National Nanotechnology Initiative, 2013) posits the need to continually assess quality as a

measure to predict its longevity. We noted that different approaches to assess for data quality were recommended based on the specific use-case.

2.3.2 Data Availability

The term data availability was noted in the literature both through explicit use of the term and via contextual explanation. While this term may appear closely related to data quality, availability of the data for use in a particular application, is distinct and refers to the accessibility (or existence) of the data, as compared to how well it suits the application. This is confirmed by the finding that some publications used availability either separately or in addition to quality (Austin, 2019; Digital Curation Centre, n.d.; Gibbs et al., 2017; Klievink, Romijn, Cunningham, & de Bruijn, 2017; Richesson, 2016; The World Bank Group, 2015; United Nations Office for Disaster Risk Reduction, 2017; Wen & Hwang, 2019). Data availability is often used in reference to larger scale and public health applications. In these cases, there is a call for certain data to become available to aid in an international health collaboration (The World Bank Group, 2015; United Nations Office for Disaster Risk Reduction, 2017; Wen & Hwang, 2019).

2.3.3 Interoperability

Interoperability is widely accepted as the ability of multiple systems to exchange and meaningfully use data (Health Information Management Systems Society, 2019). In the data readiness literature, interoperability seems to be a focus of national and international infrastructure (de Lusignan et al., 2011; The World Bank Group, 2015; Wen

& Hwang, 2019), as well as research networks (Campbell, Campbell, Reich, & Belenkaya, 2020; Carr et al., 2014; Jennings et al., 2018). In addition, a significant body of literature noted interoperability as a fundamental construct to assess for the viability of HIT applications (Austin, 2019; Digital Curation Centre, n.d.; Lawrence, 2017).

Interoperability is often used as an umbrella term for data exchange; in the literature we explored, it appears that the most frequent use of interoperability (if clearly defined), is the use of data standards. We did not note any article referencing specific measurements for interoperability.

2.3.4 Data Provenance

Data provenance refers to the ability to follow a piece of data's lineage; from where it first appeared, to how it has been manipulated, to where it rests at the current moment (Wang, Crawl, Purawat, Nguyen, & Altintas, 2015). This often accompanies questions regarding data ownership, management, and responsibility for keeping it up to date. The literature, like with interoperability, does not give specific measures to assess for provenance. Rather, provenance is stated to be an integrated feature of data readiness as manifested by governance structures (Austin, 2019; Cheriath, 2018; Ellaway et al., 2019). However, we noted that provenance also relates to quality and interoperability, as having strong governance contributes to quality assurance and the prioritization of collecting essential data across multiple sites (de Lusignan et al., 2011; Digital Curation Centre, n.d.; Gibbs et al., 2017).

2.3.5 Conceptual Framework of Data Readiness

In Figure 4, we propose a guiding conceptual framework for data readiness, highlighting the interactions of the four essential constructs. As a whole, provenance, interoperability, availability, and quality all contribute to the feasibility of using data for any given healthcare application. Provenance is depicted first, as this is an overarching concept that has impact on the other three constructs. Without provenance, long-term interoperability and availability are uncertain, and data quality cannot be assured if the data are not able to be followed over time. Interoperability follows (defined as the ability of multiple systems to exchange data), as without interoperability (in cases where data exchange or multiple sources of data are needed), the data become less available. The data would need to either be recollected (which in turn hampers feasibility (R. L. Richesson et al., 2020)), or would simply not be available, impacting feasibility. Availability precedes data quality, as without available data, quality cannot be assessed. This then leads to feasibility, which shows a feedback loop between data readiness in feasibility. This is to represent the continual need to assess these constructs over time, as a change in any one construct may affect feasibility.

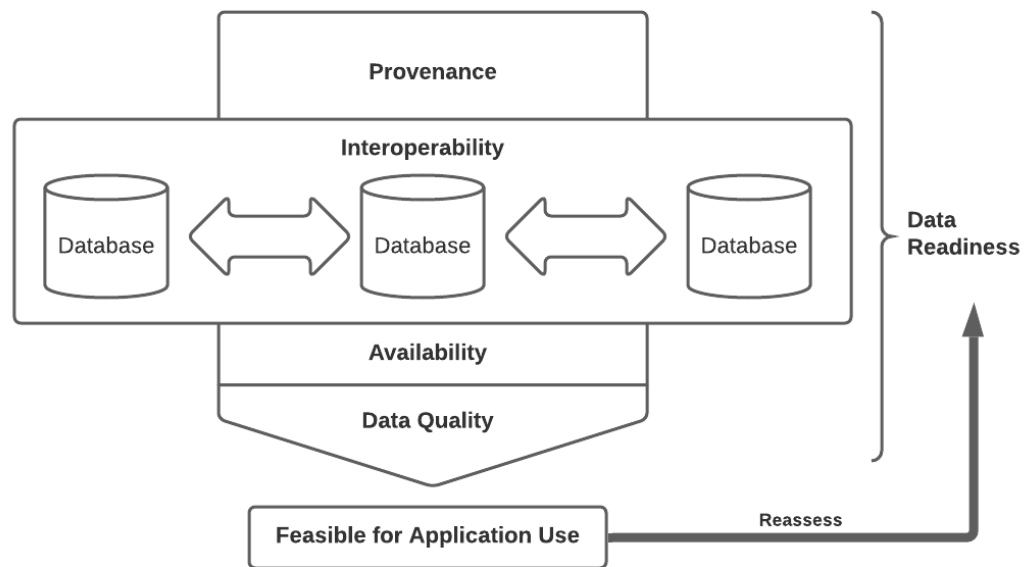


Figure 4: Data Readiness Conceptual Framework for Data-Driven HIT Feasibility

2.4 Discussion

Our concept analysis found that data readiness can be expressed as a hierarchical conceptual framework involving four constructs: data quality, data availability, interoperability and data provenance. While our resulting framework represents all four constructs within the concept of data readiness, depending upon the application, we believe that not all necessarily need to be considered. Data readiness is a context-dependent operationalization of these different constructs. As noted from the body of literature identified in our search, each example focuses on different aspects of data readiness to fit its research question or goal. When using data readiness to inform

research and HIT feasibility, all aspects should be considered and addressed when possible or relevant. With this caveat, we propose the definition of data readiness as the application-specific intersection of data quality, data availability, interoperability, and data provenance.

Data quality is a heavily studied area and is well recognized as a critical factor in the success of research and any data-based intervention (Gass et al., 2017; Mulissa et al., 2020; Weiskopf, Bakken, Hripcsak, & Weng, 2017). It is also apparent that this is an important factor in data readiness, as 11 of the 20 publications reviewed determined data quality to be essential to assess. While this is the case, how data quality is to be assessed cannot be immediately explained by data readiness. Rather, to assess data readiness, it is necessary that data quality be examined depending on the data requirements of the application. While it is not possible to make specific recommendations for measuring data quality from our definition of data readiness, our review of the literature has revealed that both measuring data quality as a prerequisite and as an ongoing measure is important to consider when implementing HIT. Data quality, while the most frequently cited construct, also has been noted to be dependent on data availability (see Figure 4). Therefore, prior to assessment of data quality, data availability should be confirmed first.

Data availability appears to bridge data quality and interoperability together; if the data is not interoperable it cannot be accessed and used effectively, while if data

quality is not adequate the data cannot be used for specific applications. In reference to data readiness, the data must be available to use, or it is indeed not “ready” for health applications. Data availability appears relatively straight forward to assess, as data is either accessible or not. However, as with data quality, time may be a factor in feasibility. To assess availability, we recommend both longitudinal and short-term approaches. For longitudinal assessment, if there are uncertainties of whether data will be available for the lifespan it is needed, the readiness of the data for HIT use is in question. As for short-term assessments, timeliness of data availability is also important to consider; some applications may require real-time data that may not be available at the time it is needed. In addition, even if the data is available, the format of the data must be considered, as it is possible that there is not a sufficient granularity to serve the needs of certain applications.

In an era where concepts such as the learning health system, research networks, and international data repositories are becoming a reality, interoperability (the ability for one system to meaningfully use data from another system) (Health Information Management Systems Society, 2019) has become a topic of great importance in healthcare. It is not surprising that this construct is a key factor in data readiness, as the most current healthcare tools and applications demand interoperable systems. Implementing the most up-to-date healthcare practices and conducting cutting-edge research require access to many different sources of data, but there are many factors that

make up the construct of interoperability. In the data readiness literature, the use of standards to facilitate data exchange is key to the construct of interoperability. However, this becomes complicated when considering issues of syntactic and semantic interoperability; standards alone do not predict interoperability.

Assessing interoperability is a unique challenge. One reason for this challenge is likely due to the dynamic nature of standard specifications (e.g., the Fast Healthcare Interoperability Resources standard (FHIR) (Health Level 7, 2019a)) led by groups such as HL7 where national and international focus is driving the development of common data representation. Because of rapid change, it is difficult to develop metrics, especially when considering the lifespan of a HIT tool. However, one strategy might be to examine the proportion of required data elements that are covered by locally supported data standards and are supported by relevant implementers. Such an assessment would need to be re-evaluated at periodic intervals but would at least provide some insight into the feasibility of achieving interoperability.

In comparison to the other three constructs, data provenance asserts a human-centric factor of data readiness. The literature suggests that without strong data governance, the long-term success of a HIT is at risk. This is plausible, especially when long-term and research funded HIT solutions are considered. One example may be a data repository of patient data collected for research; it is crucial that “ownership” of the repository be clear, and audit of the data (both collection and changes) be traceable. If the

data in the repository are recorded in dissimilar formats, the integrity of the data is in question. Although data provenance is important for data readiness, it is not necessarily a requirement for any of the other three constructs. Rather, it is important to consider overall, especially with long-term projects. While this may be true, interoperability can facilitate provenance. For example, use of FHIR can support data provenance through clear definition of data mapping and clinical models (Health Level 7, 2019c). However, similar to the other three constructs, provenance is application dependent. An individual querying data from a local EHR for a cross-sectional study would be less concerned about provenance than a team developing a global repository.

To summarize, the concept of data readiness is relevant to informatics applications – either explicitly or implicitly. All data-driven HIT applications use data, and hence require access to the data to operate, and require an assessment of readiness to determine the feasibility and plan work for implementation and integration of the tool. To assess data readiness, one must consider all four constructs identified in our definition. Depending on the context of the data's use, assessments for each construct should be customized as needed. As we found in the literature we reviewed, the constructs of data quality, data availability, interoperability, and provenance are not siloed; rather, it appears that complex interactions and sequential analysis are needed to fully assess the concept of data readiness. Our proposed framework for data readiness

may guide future research and assessments related to data-driven applications in healthcare.

2.5 Limitations

This work represents a synthesis of literature that encompasses specific references to the term “data readiness”; although we sought to identify synonyms, none were found in this review. Therefore, this work is influenced solely by studies that used the data readiness term verbatim. Studies using different terms to convey data readiness would have been missed. Our interpretation of the resulting publications, although rigorous, is a subjective process, so we must accept the possibility of misinterpretation. Further, as data readiness is highly dependent on the particular application of the data, our findings should not be used to suggest specific assessments for data readiness in the real world, but we do believe that our conceptual framework provides a foundation that may be used to guide specific assessments and study designs.

2.6 Conclusion

We propose that data readiness can be defined as the application-specific intersection of four constructs: data quality, data availability, interoperability, and data provenance. This work provides a foundation to expand upon and apply to real-world applications that require health data. In future work, this definition of data readiness should be validated, with alterations being suggested as applicable. Importantly, each construct of data readiness should be evaluated with different applications, so that

specific metrics for each component may be developed and disseminated to aid in future research.

3. Informing Interoperability Standards by Dissecting Health Apps to Identify FHIR Resources and Attributes

3.1 Background and Significance

The creation of apps for the purposes of improving health and healthcare has been growing at an exponential rate (Wallace, Clark, & White, 2012). Many companies, researchers, and healthcare institutions expend vast amounts of capital and time into the development of mobile apps to improve a number of metrics, including hospital throughput, symptom management, chronic disease outcomes, patient experience, and others (Al Ayubi et al., 2016). Even with the development of new apps, their use is often stifled by the complexities that exist in using health data. These domains include but are not limited to the following: non-consistent adoption of standardized medical terminologies (Hammond, 2005), the complex mapping of standards between vocabularies (Zhu et al., 2006), the lack of interoperability (the ability for two different systems to exchange data) between programs (H. Zhang, Zhang, Wang, Yang, & Zhao, 2017), security and privacy considerations (Zhou, Bao, Watzlaf, & Parmanto, 2019), data quality (Weiskopf et al., 2017), and end-user acceptance (Zaidi et al., 2020). These considerations often hinder the intended use of an app, often by technical limitations and effort. The seemingly simple requirement of an EHR-based tool to require additional data impacts feasibility (Rachel L. Richesson et al., 2020).

Data exchange standards, such as the Fast Healthcare Interoperability Resources (FHIR) (Health Level 7, 2017), have emerged as a solution to how we may share

information between healthcare facilities. FHIR defined “resources”, or structures for data with a number of “attributes” that define data structure and format. In addition, the Substitutable Medical Applications, Reusable Technologies (SMART) has emerged as a standards platform to support interoperable health app development. Thus, SMART on FHIR has emerged as a leading, government supported standard for health app development.

While SMART on FHIR is gaining momentum and shows great promise for interoperability, there are still gaps that need to be addressed. While FHIR can virtually accommodate any type of data, the specifications for how data should be modeled are not clearly defined in many cases leading to extra challenges including increased greatly increased effort in implementation. The United State Core for Data for Interoperability (USCDI) (The Office of the National Coordinator for Health Information Technology, n.d.), or US Core, is a current US standard for a core set of data elements that all EHRs should be able to capture and exchange. These data elements are at their most granular level, reducing possibilities for ambiguity which results in clear and concise requirements for data formatting. The US Core attempts to further standardize FHIR by defining minimum conformance requirements for FHIR resources, minimizing some areas variability and allowing for more seamless data exchange. This is done by defining mandatory data elements, extensions (reusable definitions for a number of data elements) and terminology requirements. The FHIR standard is not yet complete, and

the subsequent coverage of each FHIR resource by the US Core is only partially fulfilled. To maximize benefits and promote health app interoperability, efforts must be focused to develop and modify priority US Core profiles.

The purpose of this study was to report the usage of FHIR resources and attributes across a representative sample of SMART on FHIR health apps in order to inform priority development areas for US Core profiles. By informing priority areas for development for the US Core, important data elements will become more interoperable ensuring their meaningful use to clinicians and patient alike.

3.2 Methods

3.2.1 Design

This descriptive exploratory study informed priority areas for development of the US Core by quantifying the use of FHIR resources and attributes. This was done through identification and extraction of data requirements from a sample of SMART on FHIR enabled apps. First, a sample of SMART on FHIR apps was selected. Second, the FHIR resources and attributes of the apps were identified when readily available or were revealed through the extraction of data elements from the apps. Third, resource and attribute frequencies were reported to reveal patterns that may inform future US Core development. Fourth, we report any extensions used. This study was approved by the local Institutional Review Board. All data and suggestions are based on the FHIR specification v4.0.1.

3.2.2 App Selection

This sample of apps was derived from two sources: The SMART on FHIR app gallery (apps.smarthealthit.org/) and the American Medical Informatics Association (AMIA) FHIR app competition. This was done to 1) ensure a high degree of quality of each app, 2) include a number of apps with different purposes and clinical focus areas, and 3) include apps that implementable with multiple EHR vendors.

The SMART on FHIR app gallery is hosted by the Boston Children's Hospital Computational Health Informatics Program (CHIP). The SMART on FHIR standards-based application programming interface (API) has been supported by the United States government, and has been adopted by companies such as Apple (apple.com/healthcare/health-records/), Microsoft (azure.microsoft.com/en-us/services/azure-api-for-fhir/), and Amazon (aws.amazon.com/blogs/opensource/using-open-source-fhir-apis-with-fhir-works-on-aws/). As of March 2021, the SMART on FHIR gallery hosts 90 apps from different organizations with varying access option (open access vs. paid) and EHR vendor optimization.

The AMIA FHIR app competition is a yearly competition that invites developers on SMART on FHIR apps to showcase their latest developments. A peer-review process is conducted to allow for only the highest-quality submissions to be involved in the competition. Three cash prizes are awarded for the top three apps as judged by an expert panel. Entries are received from both national and international developers. For

this study, we acquired app data and developer contacts for the 2018, 2019, and 2020 AMIA FHIR app competition participants.

3.2.3 FHIR Resource and Attribute Identification

FHIR resources and subsequent attributes were identified for each app included in the study. This was done using a variety of methods depending on the availability of the data. The following methods were used in order:

1. App authors were contacted directly to acquire information regarding FHIR resource and attribute use in the app
2. If the authors did not respond, open-source coding was used to identify resources and attributes
3. If open-source coding was not available, app demos and/or statements of FHIR resource use were used to acquire data elements and were processed to map to resources

In the third step, we adapted an approach developed by Shiffman, Michel, Essaihi, and Thornquist (2004) with clarifications from Tso et al. (2016) to process the data requirements. Once the data requirements were fully prepared, we mapped them to the appropriate FHIR resource. These steps were used iteratively and are defined in Table 2.

Table 2: Methodology to process data requirements of apps for mapping to FHIR resources

Process	Definition
---------	------------

Atomization	The process of extracting and refining single concepts from narrative text or data entry fields (i.e. demographics, vitals, labs)
Deabstraction	The process of adjusting the level of generality at which a concept or data element is described to permit operationalization (i.e. demographics to age)
Disambiguation	The process of establishing a single semantic interpretation for an app data requirement (i.e. age to birthdate)
Mapping	The process of associating the disambiguated data requirement to the appropriate FHIR resource (i.e. birthdate to the Patient Resource).

Once the data requirements were processed, they were then mapped to the most appropriate FHIR resources. We did not include apps in the attribute analysis if we were not able to acquire data directly from the authors or from the open-source code, as this would result in speculation and not be useful in informing the development of US Core profiles. We also did not include apps if they did not include a demo (past step three) due to an inability to assess app data requirements.

3.2.4 Analysis

To inform interoperability standards development, we first summarized our findings by reporting frequency of overall FHIR resource use among all apps. For resources that do not have associated US Core profiles, we reported the most frequent use of FHIR resources that may be priority areas for development. For the apps in which we were able to acquire the resource attributes, we reported the proportion of apps that used each attribute, organizing by “must support” elements within the US Core and

elements that are only addressed in the base FHIR resource. Data was collected and analyzed using Excel (Microsoft Corporation, Redmond, Washington).

3.3 Results

3.3.1 App Sample

90 apps were available in the SMART on FHIR gallery, and 27 apps were submitted to the AMIA FHIR app competition between 2018 and 2019. Following our three-step method to identify FHIR resources and attributes, 51 apps were included for FHIR resource analysis, and 18 were included in the FHIR resource attribute and US Core analysis.

3.3.2 FHIR Resource Summary

In the 51 apps included in the FHIR resource summary, 39 different FHIR resources were used. Each app used between 1 and 12 resources per app, with a median of 4 resources per app. Use of each resource varied greatly, with a range of 1 to 41 uses across all of the 51 apps, with a median of 2 uses across all apps. Frequency of resource use is summarized in Table 3.

Table 3: Use of FHIR resource across all apps

Resource	Count (number of apps that use the resource)	Frequency (percent of apps that use the resource)
Patient*	41	80.4%
Observation**	39	76.5%
Condition*	22	43.1%
Medication*	17	33.3%
AllergyIntolerance*	15	29.4%

Procedure*	12	23.5%
DiagnosticReport* (ResultsSection)	10	19.6%
MedicationStatement	8	15.7%
FamilyMemberHistory	7	13.7%
Questionnaire	5	9.8%
QuestionnaireResponse	5	9.8%
CarePlan*	5	9.8%
MedicationRequest*	4	7.8%
Immunization*	4	7.8%
Practitioner*	3	5.9%
Encounter*	3	5.9%
Organization*	3	5.9%
Composition	2	3.9%
RelatedPerson	2	3.9%
Communication	2	3.9%
Device	2	3.9%
Goal*	2	3.9%
Invoice	1	2.0%
ValueSet	1	2.0%
Claim	1	2.0%
ServiceRequest	1	2.0%
MedicationAdministration	1	2.0%
Slot	1	2.0%
TerminologyCapabilities	1	2.0%
CommunicationRequest	1	2.0%
CapabilityStatement	1	2.0%
CoderSystem	1	2.0%
ConceptMap	1	2.0%
NamingSystem	1	2.0%
StructureDefinition	1	2.0%
ValueSet	1	2.0%
BundleResources	1	2.0%
Appointment	1	2.0%
CareTeam	1	2.0%

*Resources are those included in the US Core

**Some observations are included as US Core Profiles

For the observation resource, we summarize the use of various data elements used under the resource in Table 4. In our sample of 51 apps, 31 used the observation resource.

Table 4: Summary of Observation resource use among apps

Observation	Count
Vitals**	20
Lab Result*	17
Weight	6
Smoking Status*	6
Height	5
Pediatric Weight*	3
Pediatric Height*	2
Gestational Age	2
Years Smoking	2
Symptoms	2
Blood Type	1
Labs of Relatives	1
Packs/day (Smoking)	1
Alcohol Use	1
Steps (Pedometer)	1

*Observations that have associated US Core Profiles

**US Core utilizes the base FHIR resource

3.3.3 FHIR Attribute and US Core Summary

Of the 51 apps included in the FHIR resource summary, 18 met inclusion for US Core summary. Among the 18 apps, 8 used resources that have an associated US Core profile (excluding the Observation resource, which is summarized in Table 4), and the Medication resource, which was used as an attribute through the MedicationStatement resource which does not have an associated US Core Profile). These resources are displayed separating attributes that must be present in the US core, optional attributes in

US Core (when applicable), and attributes that are only included in the base resource.

Table 5 presents an abbreviated table with all resources, omitting values of zero.

Appendix A contains the full table.

Table 5: Resource Attribute Use Summary

Attribute	Count	Percent of Apps
Patient Resource (14 apps)		
Must be Present in US Core Profile		
Identifier	4	28.6%
Name	7	50.0%
Gender	9	64.3%
Telecom	1	7.1%
BirthDate	11	78.6%
Address	2	14.3%
Race*	3	21.4%
Ethnicity*	2	14.3%
In Base Resource Only (not included in US Core)		
Deceased	2	14.3%
Condition Resource (9 apps)		
Must be Present in US Core Profile		
Category	1	11.1%
Code	9	100%
Subject**	1	11.1%
Optional in US Core		
clinicalStatus	3	33.3%
In Base Resource Only (not included in US Core)		
Identifier	1	11.1%
Severity	1	11.1%
BodySite	2	22.2%
Onset	7	77.8%
Abatement	2	22.2%
Stage	1	11.1%
Evidence	1	11.1%
Note	1	11.1%
Procedure Resource (3 apps)		
Must be Present in US Core Profile		

Status***	3	100%
Code	3	100%
Subject**	1	33.3%
Performed	1	33.3%
In Base Resource Only (not included in US Core)		
Subject**	1	33.3%
Performer	1	33.3%
ReasonCode	1	33.3%
ReasonReference**	1	33.3%
BodySite	1	33.3%
Outcome	1	33.3%
UsedReference**	1	33.3%
Encounter Resource (3 apps)		
Must be Present in US Core Profile		
Identifier	2	66.7%
Status	3	100%
Class	2	66.7%
Type	1	33.3%
Subject**	1	33.3%
Participant	1	33.3%
Period	2	66.7%
ReasonCode	2	66.7%
Hospitalization	1	33.3%
Location	2	66.7%
In Base Resource Only (not included in US Core)		
ServiceProvider**	1	33.3%
DiagnosticReport Resource - Report and Note Exchange (3 apps)		
Must be Present in US Core Profile		
Status***	3	100%
Category	1	33.3%
Code***	3	100%
Subject**	2	66.7%
Effective	1	33.3%
Issued	2	66.7%
In Base Resource Only (not included in US Core)		
Identifier	2	66.7%
Result**	2	66.7%
Conclusion	1	33.3%
ConclusionCode	1	33.3%

PresentedForm	2	66.7%
AllergyIntolerance Resource (3 apps)		
Must be Present in US Core Profile		
Code	3	100%
Reaction	2	66.7%
In Base Resource Only (not included in US Core)		
Identifier	1	33.3%
Onset	1	33.3%
MedicationRequest (2 apps)		
Must be Present in US Core Profile		
Intent***	1	50.0%
Medication***	2	100%
AuthoredOn****	1	50.0%
Requester***	1	50.0%
DosageInstruction	1	50.0%
In Base Resource Only (not included in US Core)		
Identifier	2	100%
ReasonCode	1	50.0%
DispenseRequest	1	50.0%
Practitioner Resource (1 app)		
Must be Present in US Core Profile		
Identifier****	1	100%

*US Core Specific Extensions

**Attributes that point to other resources

*** Must always be provided when the resource is used

**** Required in US Core, but not in base resource

3.3.4 Extension Use

Four apps used extensions. Two used extensions for genotyping, and two used extensions for birth time. This sample is not large enough to making recommendations but is important to consider in future research.

3.4 Discussion

3.4.1 FHIR Resources

This study sought to inform FHIR resource and US Core profile development by assessing resource and attribute use among a sample of SMART on FHIR apps.

Examining which FHIR resources have an associated US Core profile can give insight into which resources should be prioritized for profile development. Aside from observations (Section 3.4.2), 24 resources were used that do not have associated US Core profiles. Four of these resources were used five times or more, including MedicationStatement, FamilyMemberHistory, Questionnaire, and QuestionnaireResponse. Other medication resources are available, and it is likely that MedicationStatement will have a profile in the near future. FamilyMemberHistory was second most frequently used of the 24 resources and would be extremely useful to have a US Core profile, as most EHRs have family history as an essential part of a patient profile. Such data could also be leveraged with genetic counseling, which is becoming a central focus in precision health (Ramos, 2020). The two questionnaire resources (which are often paired together) is somewhat of a surprising finding. Questionnaires are obviously important sources of data as they often contain patient-centered data and can represent unique data not readily available across most EHRs. Creating a US Core profile (or verifying their use as is) would be extremely helpful for researchers to

distribute multi-site questionnaires, clinicians to gain insights into patient-centric data, and for patients to report their own data through an app.

3.4.2 Observation Resource Use

Observations are a unique resource, as they allow for the representation of any data that is not otherwise captured in the other resources. In addition, each “observation” may be covered by a separate US Core profile; this is the case for smoking history and lab results, for example. Of note, adult height and weight were frequent observations that do not yet have a US Core profile. Again, this is a frequent set of data that is used for BMI, as well as medication dosing. This would be extremely helpful to have as an interoperable data element. While infant length (height), weight, and BMI have US core profiles, two apps required gestational age as a data element through the observation resource. This element is an important element for maternal health that could be modeled with a US Core profile. Interestingly, years smoking (pack years) was used by two apps. While there is a US Core profile for smoking status, pack years is not included in this profile. It is recommended that this data element be added to the smoking status profile.

3.4.3 Attributes

By examining attributes, specific recommendations to existing core profiles can be made. Eight resources were able to be examined from the 18 apps that met inclusion. To make recommendations for modifications to a US Core profile, over 50% of the apps

were required to use an attribute that is not used in a US Core profile. With this metric, the practitioner, medicationrequest, allergyintolerance, encounter, and patient resources did not have any attributes that could be strongly recommended as additions to their associated US Core profiles. However, the attributes that did not make this cut off could possibly be included as optional attributes.

Of note, the diagnosticreport and condition resources had a few attributes that were included in most of the apps that were analyzed. For the diagnosticreport, identifier, result, and presented form were used in two out of the three apps. While 'result' is in the labresult profile, it is missing as an element in the US Core profile. The addition of this attribute in the diagnosticreport could be useful, although this might be contradictory to some tests. For this reason, more US Core profiles could be developed based on specific tests, or this could be included as an *optional* element. Identifier may also be helpful as an optional element, although standardization of test identifiers is not yet a reality, so this element may not be as useful. Lastly, presentedform was found in to be a frequently used attribute. The addition of the actual test image would be useful in many situations. This could include a visual of an electrocardiogram, or an image from another diagnostic test. With the addition of files in the DICOM standard, this would be extremely effective in creating an interoperable health record and would allow many new opportunities for patients to share study results with several institutions.

For the condition resource, the most significant result was found to be the use of the onset attribute. This attribute describes the start or addition of a condition (problem, diagnosis). The problem list within the EHR is notorious for being out of date and is often not useful for providers (Holmes, Brown, Hilaire, & Wright, 2012). With the addition of this element in the US Core profile, this may begin to help this problem. At a minimum, it would allow for some degree of data provenance between health systems. An interoperable problem list could also be available as knowledge artifact that is owned by the end user, that could be accessed by health systems with FHIR enabled EHRs, manipulated as needed, and resent to the patient. Regardless, this would be a strong addition to the list of US Core profiles.

3.4.4 Limitations

This study has four notable limitations. First, the sample is relatively small, especially for the US Core analysis. These results could be compounded every year with addition of new apps to the SMART on FHIR app gallery, and through future AMIA FHIR app competitions. Through conducting this study, we have made recommendations to AMIA to collect this data from applicants to the FHIR app competition. We will use this data in the future. Second, only SMART on FHIR apps were considered for the sample. While this addressed our research questions, it does not fully inform standard development based on the needs of app developers that do not rely on the standard. Third, FHIR resources may be over or underrepresented due to the

assumptions of the manual extraction process when open source code was not available. Fourth, different versions of FHIR are currently in use. We based this research on V4 and mapped to resources and attributes when possible, but this study may not be as helpful to implementers using previous versions of FHIR.

3.5 Conclusion

Through this study, we were able to make specific recommendations to guide the future development of FHIR resources and US Core profiles. While the results of this study are useful to make recommendations at this time, future work should continually be done to assess the state resource and US Core use across apps. Repetition of this work will ensure a continual needs assessment of the app developing community and will inform standard development to support the interoperability of important data elements.

4. Assessing Health App Implementation Feasibility by Exploring Data Availability and Health System Attributes

4.1 Background and Significance

Health apps have been shown to improve patient outcomes in several domains, including mental health (R. Zhang et al., 2019), diabetes (Desveaux et al., 2018), weight loss (Zaidan & Roehrer, 2016), hypertension (Xu & Long, 2020), and medication adherence (Wittig-Wells et al., 2020). For this reason, the creation of health apps has been on the rise, with health organizations, such as disease advocacy groups and organizations such as the NIH funding their development. One promising feature of apps is their potential to involve patients more closely in their health planning and monitoring by facilitating the access and transmission of their data with their healthcare team. However, there are several challenges to this seamless exchange of health and healthcare data. Depending on what data are available and if health systems have deployed certain data standards (among several other considerations), the feasibility of implementing an app varies. In addition, the number of apps available to solve any given clinical problem are increasing. Healthcare organizations may be met with suggestions for app adoption from clinical champions, vendors, and researchers. For a health system, it may be a daunting task to triage app implementation decisions when there are multiple options to choose from, with a variety of stakeholders giving specific recommendations. While there are multiple studies evaluating the usability and efficacy

of apps, there are few that guide the decision-making process of health systems when attempting to assess a health app's implementation feasibility.

Standards such as Substitutable Medical Applications, Reusable Technologies (SMART) on Fast Healthcare Interoperability Resources (FHIR) (Boston Children's Hospital Computational Health Informatics Program, 2019) are facilitating the implementation of apps in health systems, but not all apps are built upon these standards. There are also several factors outside of standards that influence implementation feasibility, including but not limited to data quality, workflow alignment, cost, user acceptance, usability, change management, and clinical need. In the literature, there is a paucity of studies that provide guidance for how to quantify the readiness of an app for implementation based on data availability. This is especially true when the data required by the app includes patient-facing components which probably are not readily available in most electronic health records (EHRs). While data availability can only partially assess for implementation feasibility, it is a pillar of data readiness that provides a foundation for additional assessments.

In a recent study of quantifying system readiness for implementing clinical practice guidelines (CPGs), the need to collect additional data to was shown to decrease implementation feasibility (R. L. Richesson et al., 2020). While implementing apps is not exactly synonymous to implementing CPGs, parallels may be drawn between the way we assess their feasibility for implementation. Like CPGs, apps have a predefined

number of data elements that must be available for them to work as intended. In the case of the 2020 study (R. L. Richesson et al., 2020) where implementation feasibility was impacted by the number of data elements that were readily available, it would be reasonable to hypothesize that this same principle could be applied to health apps.

The goal of this study was to explore the association of participant (representatives of health systems) characteristics and their evaluations of health apps regarding data availability with overall app implementation feasibility to inform future processes of app implementation. This was done by asking implementation experts at large academic medical centers to evaluate the availability of data requirements from two apps with patient-facing components. Expert ratings of implementation feasibility of the two apps were examined in relation to participant characteristics and their evaluations of health apps, giving insight into components that may be important when considering app implementation. These findings will help to inform future research and may be used to influence the formulation of metrics to assess health app implementation feasibility.

4.2 Methods

4.2.1 Design

This project was an exploratory descriptive, correlative study for which we selected two health apps that were developed outside of the SMART on FHIR standard and included patient-facing components. Participants were representatives of health

organizations, with one representative recruited per organization. Participants were required to have current experience with EHR development at their organization and have self-reported knowledge of what data elements are available within their EHR. For this exploratory study, participants were presented with an electronic survey to collect participants' characteristics and participant evaluation of the apps. The outcome of interest accessed as part of the online survey was the overall feasibility implementation rating for each health app.

4.2.2 App Selection

We selected two health apps that were developed outside of the SMART on FHIR standard and included patient-facing components. This was done for several reasons:

1. Apps developed using the SMART on FHIR standard would likely be viewed as highly implementable by most healthcare organizations, presumably built upon data that is easily accessible. These apps therefore might not have enough variability in data requirements to analyze, which would take away from the data availability focus.
2. Apps developed around the SMART on FHIR standard would be self-limited to the structure of the standard. In contrast, apps developed more "organically" would not be limited to how the app is created and are more likely to include all relevant data to address a clinical problem.

3. A major benefit of using apps is the ability to acquire data directly from the patient- for this reason and the fact that patient-facing apps may require data collection that is not typical for an EHR to already collect (or receive from patients), selected apps were required to have a patient-facing component.

Aside from these considerations, we purposively sampled apps that were developed by researchers using NIH funding. This ensured the apps were already tested for clinical efficacy and were peer reviewed for potential health impact, utility, and scientific integrity. To guarantee that we had full access to the app's data requirements, the research team contacted peers for their permission to use their app as an example in the survey.

Ultimately, we selected two apps to include in the survey. This included PCplanner (Cox et al., 2018) and QuestExplore (Vaughn, Summers-Goeckerman, Shaw, & Shah, 2019). PCplanner was developed for clinicians and Intensive Care Unit (ICU) patients and their family members to enhance the delivery of needs-targeted palliative care. First, the EHR is screened for ICU patients meeting specific triggers for palliative care consultation. Once identified, families are able to report unmet palliative care needs, which in turn alerts clinicians to these needs. QuestExplore is a mobile application built for pediatric patients with chronic illnesses, especially illnesses in which patients are required to stay in the hospital for more than one week. The main

purpose of the app is to track self-reported symptoms over time, both in terms of intensity and the level of distress of each symptom.

4.2.3 Survey Development

We developed an electronic survey in REDcap (Vanderbilt University, Nashville, TN) to allow participants to assess the availability of data in their EHR required by PCplanner and QuestExplore. To prepare the apps for analysis, we conducted the following steps:

1. Identified both read and write data elements from each app, contacting the developers for clarification as needed
2. Listed each element by app (one app per page), each with a four-level, single choice response: readily available with minimal processing; available but requires significant data processing; unavailable but could be collected, not possible or feasible to collect
3. Inserted a question regarding general feasibility of implementing the app in regards to data availability, ranging from 1 (much easier/feasible to integrate with the EHR than other tools that have been implemented in the past year) to 5 (much more difficult to integrate with the EHR than other tools)
4. Inserted a question regarding the level of effort needed to provide data for elements that were not readily available, ranging from 1 (no extra effort) to 5 (a prohibitive level of effort)

5. Queried participants for years of experience with their EHR, years of experience with CDS/app implementation, the number of SMART on FHIR apps at their organization, and their organization's expertise in implementing SMART on FHIR apps from 1 (no expertise) to 5 (is a leading organization in implementing SMART on FHIR)

Following each question, an optional text box was available for the participants to elaborate on any response. We also included one question regarding the difficulty of collecting data elements through a patient portal, but this was ultimately excluded from this study as it did not directly address data availability. Participants were able to skip questions if they were unable to find information regarding a particular data element. The only required questions were the two final structured questions using a Likert scale to estimate feasibility of implementation of the app. The complete survey can be found in Appendix B. We acquired approval from the Institutional Review Board overseeing the study.

4.2.4 Survey Piloting

We piloted the survey with two informaticists who were current graduate students in a biomedical informatics master's program to achieve face validity. Pilot testers completed the survey, and gave detailed feedback regarding the content, clarity, and usefulness of the survey to meet the research goals. Once initial feedback was given, the survey was revised and returned to the testers to confirm the changes addressed their concerns.

4.2.5 Survey Participant Selection

Our goal was to recruit 10 participants, with only one participant recruited per healthcare organization. As noted earlier, participants were required to have current experience with EHR development at their organization and have self-reported knowledge of what data elements are available within their EHR. Participants were excluded if they were not currently employed in a position at their organization where they were actively involved in EHR development. Participants were recruited as part of a convenience sample, initially all professional contacts of the authors. Additional participants were recruited by snowball sampling, with one contact recruiting several other respondents. Recruited participants were asked to complete the electronic survey that had been developed and platformed on in REDcap.

4.2.6 Key Study Variables

The key study variables are defined in Table 6.

Table 6: Key Measures

Construct	Definition	Coding
Participant Characteristics		
Years of Experience with Current EHR	Number of years the participant has been working with their current EHR vendor.	Number of years
Years of Experience with Implementing Apps and CDS	Years of experience the participant has with implementing apps and CDS tools in their career, not specific to current EHR.	Number of years
Organizational	Rating (1-5) the participant assigned to	1. No expertise/not able to

Expertise with Implementing SMART on FHIR Apps	their organization regarding the overall expertise the organization has with implementing SMART on FHIR apps.	<p>use SMART on FHIR</p> <ol style="list-style-type: none"> 2. Some ability/can only implement SMART on FHIR with significant effort 3. Has the ability to implement SMART on FHIR apps with moderate effort 4. Able to implement SMART on FHIR apps with minimal effort 5. Is a leading organization in implementing SMART on FHIR
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Participant Evaluation of Apps

Level of Effort to Provide Data	The overall level of effort the participant assigned to providing all of the data required by the app in totality.	<ol style="list-style-type: none"> 1. No extra effort 2. --- 3. No more effort than other similar projects OR a moderate/reasonable level of effort 4. --- 5. A prohibitive level of effort
Proportion of Data Readily Available	The number of data elements the participant noted to be readily available out of the number of data element required by the app.	$\frac{\text{Number of data elements readily available}}{\text{Number of data elements required by the app}}$

Outcome

Overall feasibility Rating	The feasibility rating the participant assigned to the app regarding its overall ability to be implemented at their organization.	<ol style="list-style-type: none"> 1. Much easier/feasible to integrate with the EHR than other tools/apps we have implemented in the past year OR extremely feasible to integrate with the EHR 2. --- 3. Similar in feasibility to other tools/apps OR feasible to
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integrate with the EHR with a reasonable amount of effort

4. ---

5. Much more difficult to integrate with the EHR than other tools/apps OR not reasonably feasible to integrate with the EHR

4.2.7 Statistical Analysis Plan

Descriptive statistics were used to describe both participant characteristics, participant evaluation of apps, and overall feasibility of implementing the app. The median and 25th, 75th percentiles along with minimum and maximum scores were used to describe the continuous survey measures due to the small sample size and non-normality of the data distributions. When significance testing was performed, non-directional statistical tests were performed with the significance level set at 0.05 per test. A non-parametric approach was taken due to the small sample size. Effect sizes were calculated to address clinical significance. Of note, the focus of this small exploratory study was to estimate effect sizes rather than conduct significance testing. Data were analyzed using SAS version 9.4 (SAS Institute, Cary, NC).

Spearman rank-order correlations were used to examine the linear association of the participant characteristics and participant evaluation of app information with overall feasibility of implementing the app (outcome). Participant explanatory variables were: (1) level of effort needed to provide data elements that were not readily available; (2)

proportion of data elements that were marked as “readily available”; (3) participant assessment of organizational expertise with implementing SMART on FHIR apps; and (4) participant years of experience implementing apps and CDS. Scatterplots were created to illustrate and further understand the each of these bivariate relationships. The Spearman coefficient (r_s) was used as an indicator of the effect size for each correlation. The standard Spearman r_s criteria of 0.10, 0.30, and 0.50 were used to denote small, medium, and large effects. Spearman r_s^2 values were calculated to detail the proportion of variability of general feasibility of implementing the app explained by each of the participant explanatory variables.

4.3 Results

4.3.1 Participant Characteristics and Evaluations of Apps

We recruited seven participants, one representative from seven healthcare organizations. Table 7 summarizes the characteristics of these six participants. Participants had varying experience with their current EHRs, with experience ranging from 6 to 12 years (median=7 years). Implementation experience with apps and CDS ranged from 3 to 25 years (median=20 years). Only 4 of the 7 participants provided data for the number of SMART on FHIR apps currently in production at participant’s organizations, and the responses ranged from 3 apps to 12 apps (median=6.5 apps). Participants rated their organizational expertise with implementing SMART on FHIR apps from 1 (unable to implement SMART on FHIR apps) to 5 (a leading organization in

implementing SMART on FHIR apps). The median rating for this later measure was 3, with a range of 2 to 5.

Table 7: Participant Characteristics- Descriptive Statistics

Characteristic	N	Median	25th, 75th Percentile	Minimum, Maximum
Years of Experience with their Current EHR	7	7.0	7.0, 9.0	6.0, 12.0
Years of Experience with Implementing Apps and CDS	7	20	10.0, 20.0	3.0, 25.0
Number of Smart on FHIR Apps Currently in Production at Participant's Organization	4	6.5	3.0, 11.0	3.0, 12.0
Assessment of Organizational Expertise with Implementing SMART on FHIR Apps	7	3	2.0, 3.0	2.0, 5.0

Table 8 provides description statistics for participants' evaluation of the apps measures and the overall feasibility outcome for the two apps. The scores for level of effort to provide data ranged from 2 to 5 for PCplanner (median=4.0) and ranged from 3 to 5 for QuestExplore (median=4.0). The percent of data readily available ranged from 36% to 86% for PCplanner (median=50%) and from 14% to 71% for QuestExplore (median=29%). Finally, The overall feasibility rating ranged from 3 to 5 for both PCplanner (median=3.0) and QuestExplore (median=4.0).

Table 8: Participant Evaluations of Apps and Feasibility Outcome- Descriptive Statistics

Application	Measure	N	Median	25th, 75th Percentile	Minimum, Maximum
PCplanner					
	Level of Effort to Provide Data	7	4.0	3.0, 4.0	2.0, 5.0

Proportion of Data Readily Available	7	0.50	0.42, 0.86	0.36, 0.86
Overall Feasibility Rating	7	3.0	3.0, 4.0	3.0, 5.0
QuestExplore				
Level of Effort to Provide Data	6	3.0	3.0, 4.0	3.0, 5.0
Proportion of Data Readily Available	6	0.29	0.14, 0.43	0.14, 0.71
Overall Feasibility Rating	7	4.0	3.0, 5.0	3.0, 5.0

Level of effort to provide data: possible range=1 to 5; with higher scores represent greater effort; Overall feasibility rating: possible range=1 to 5; with lower scores represent greater feasibility.

4.3.2 Participant Evaluation of App and Participant Characteristics: Relationship to Overall Feasibility

Table 9 provides the Spearman correlation coefficients describing the linear relation of the measures of participant evaluation of app and participant characteristics with the overall feasibility rating (outcome). No statistically significant correlations were detected (all $p > 0.16$), which is not surprising given the small sample size and lack of statistical power. Several medium to large effect sizes, however, were observed despite the lack of statistical significance. A medium effect was defined as a r_s value of ± 0.30 to 0.49 , while a large effect was indicated by a r_s of ± 0.50 or greater.

For the PCplanner app, medium effects were indicated for the positive relationships for level of effort to provide data ($r_s = +0.33$) and years of experience with implementing apps and CDS ($r_s = +0.42$) with overall feasibility ratings. These correlation coefficients indicate that implementation feasibility difficulty increases (higher scores) as

(a) the level of effort to provide data becomes more prohibitive (higher scores) and (b) participant experience with implementing apps and CDS increases (higher scores). A medium negative correlation was noted between proportion of data readily available ($r_s = -0.30$) and overall implementation feasibility, indicating that feasibility difficulty decreases and the proportion of data that are readily available increases.

For the QuestExplore app, we noted a large effect of the negative correlation ($r_s = -0.65$) between organizational expertise with SMART on FHIR apps and overall feasibility rating. This correlation coefficient indicates that overall implementation feasibility increases (lower scores) as the organizational expertise with SMART on FHIR apps increases (higher scores). A medium effect was noted between the negative correlation of organization expertise with SMART on FHIR apps ($r_s = -0.33$) and overall feasibility, indicating that the overall feasibility increases with less years of experience with implementing apps.

Table 9: Participant Evaluation and Characteristics Relationship to Overall Feasibility Rating

Explanatory Variable	Overall Feasibility Rating: Spearman Coefficient (r_s)	
	PCplanner	QuestExplore
Participant Evaluation		
Level of Effort to Provide Data	0.31	0.39
Proportion of Data Readily Available	-0.30	-0.02
Participant Characteristics		

Years of Experience with Implementing Apps and CDS	0.31	-0.33
Organizational Expertise with Implementing SMART on FHIR Apps	0.13	-0.63

All p-values > 0.16; Bold = medium ($r_s = \pm 0.30$ to 0.49) or large effect sizes ($r_s = \pm 0.50$ to 1.00); Overall feasibility rating: lower scores represent greater implementation feasibility and higher score indicated less implementation feasibility (feasibility difficulty).

Figure 5 provides scatterplots of the above relationships in this small sample.

Interestingly, these plots indicate possible non-linear relationships between some participant measures and overall feasibility ratings for which future research with a larger sample should take into account in the statistical analytic models. For example, years of experience with implementing apps and CDS and QuestExplore overall feasibility rating appear to have a quadratic (inverted U) relationship. This non-linear relationship shows that implementation feasibility difficulty increases (progressively higher scores) as the year of experience with implementing apps and CDS increase up to 15 years, then feasibility increases (progressively lower scores) as the years of experiences increase beyond 15 years. For PCplanner, it appears that level of effort and proportion of data readily available may have a quadratic (U-shaped) relationship with overall feasibility as well. A larger sample size is needed to better evaluate linear or non-linear relationships.

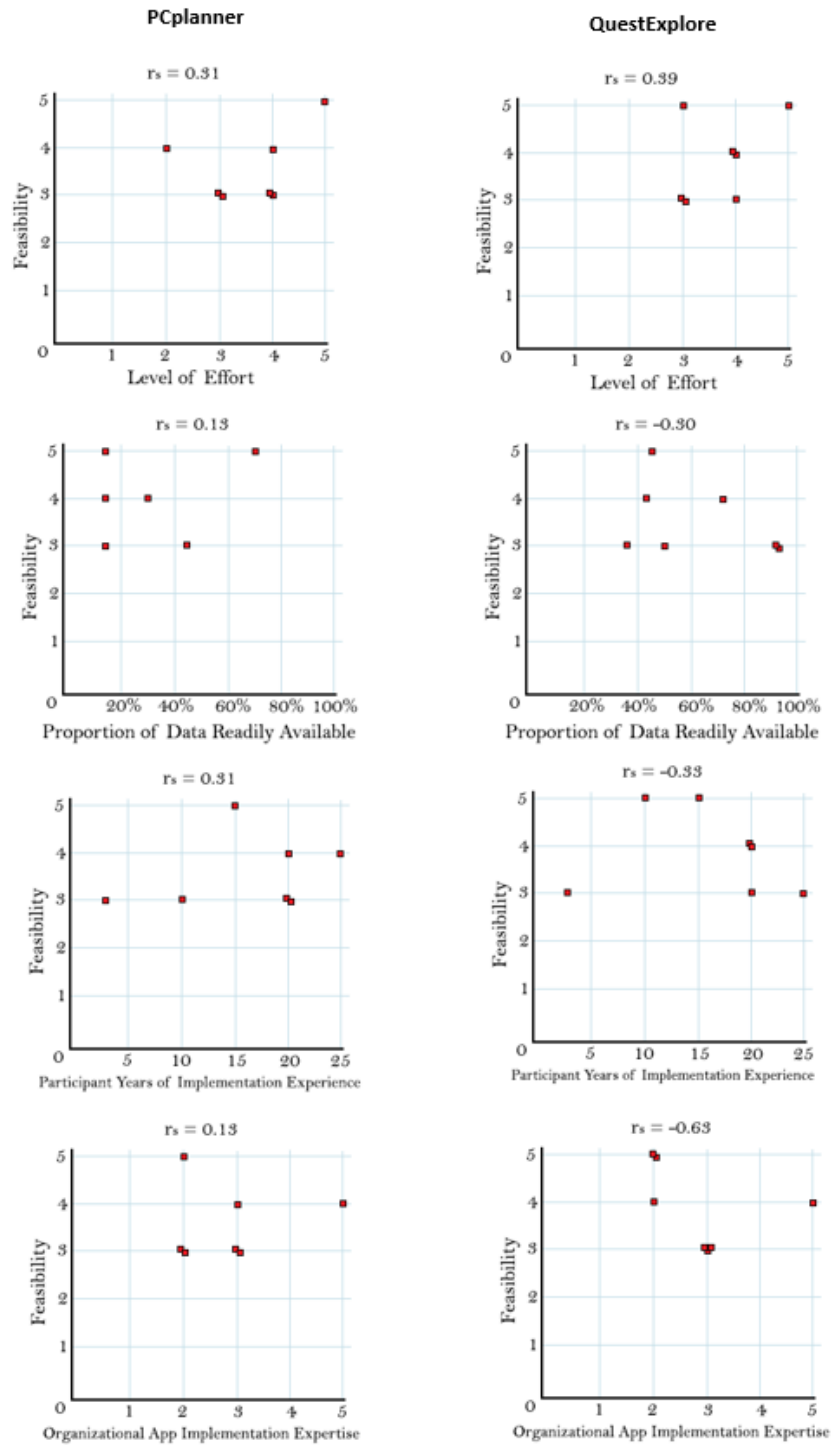


Figure 5: Scatterplots of Spearman Correlations by App

4.4 Discussion

This exploratory study has informed the relationship between data availability and app implementation feasibility by examining several health organization, implementer, and app characteristics with participant views of overall app feasibility. While no statistically significant correlations were detected, several medium and large effect sizes were noted between participant and app characteristics and overall app feasibility ratings.

First, the only consistent relationship with a similar direction and magnitude for both apps was between level of effort to provide data and overall feasibility. This is consistent with our expectations and may be suggestive patient facing components of the app (which would collect and use data not typically collected or stored in most EHRs in the current state) make their implementation more difficult. Further research is needed to confirm these findings and elaborate on specific strategies to overcome the limitations of integrating patient-generated data with the EHR.

A large effect size for the negative correlation between organizational expertise with implementing SMART on FHIR apps and overall feasibility was noted for the QuestExplore app, indicating that an increase in organizational expertise with SMART on FHIR increased the feasibility of implementing the app. This is logical, as organizations that area leaders in SMART on FHIR implementations would have greater

resources to implement apps in general. This was not reflected in the PCplanner app. Further research using more apps may reveal more consistent patterns.

Only small effects were noted between proportion of data readily available and overall feasibility for both apps. Unlike the literature around CPG as CDS implementation, the need to collect additional data does not seem to correlate strongly to feasibility. Instead, these results may suggest that the number of elements of an app may not play as important a role as it does in CPG-to-CDS implementation. Further research with a larger sample size would need to be done to confirm this.

Regarding years of experience with implementing apps and CDS and overall feasibility for PCplanner, it appears as though that an increase in implementation experience leads to a diminished view in implementation feasibility. This is interesting to consider, because this may indicate that more experienced implementers are more aware of the limitations of app-EHR integration. A limitation of this study is that we only examine data availability and do not examine other issues that are critical of the adoption and integration of health information technology and CDS, such as provider acceptance, organizational endorsement of the app, usability, or workflow issues. It would be interesting to explore the user and organizational facets of app implementation feasibility to see if this finding is constant throughout.

To summarize, our findings suggest an important consideration when implementing apps is the difficulty of providing additional data elements. Further work

is needed to give guidance on how to quantify this difficulty but could prove useful in an overall feasibility model to guide the selection and development of apps. Our Interestingly, a number of the scatterplots generated by this analysis appear to be quadratic in nature. This may be indicative that these relationships are not linear. Additional studies with larger sample sizes may reveal more complex relationships between app and organizational characteristics and implementation feasibility.

4.5 Limitations

This study has four significant limitations. First, the participant sample size and app sample size are small and severely limits our abilities to make confident conclusions from the data. A larger participant sample is needed to achieve at least 80% statistical power and obtain reliable estimate of effect sizes. Second, while this study purposefully only considers data availability, this only explains one of the many facets of app implementation feasibility. Third, participants and apps were selected as a convenience sample, limiting generalizability of the results. Fourth, this study does not separate read and write data requirements. Instead, it assesses for the capacity to store and provide each element, which is not nearly as complex in comparison to actual read and write functionality from an outside app.

4.6 Conclusion

Data availability is an important consideration when implementing health apps with EHRs but is only one area of assessment among many others. However, it does

appear that the level of effort to provide data elements impacts the feasibility of app implementation. In contrast to the literature regarding CPG translation to CDS, the number of elements of an app do not necessarily impact its feasibility to be implemented. More experienced app implementers may be wary of app implementation due to past experience, as noted in some of the responses. In summary, this work provides initial insights into using data availability as a component app implementation feasibility and lays a groundwork for future research.

5. Conclusion

5.1 Summary of Findings

Health apps are important tools to continually develop as they provide a common platform to conduct research, enable data exchange, deliver interventions, and empower patients to take control of their health (Baysari & Westbrook, 2015; Desveaux et al., 2018; Esvant et al., 2016; Loohuis et al., 2018). Unfortunately, many apps are less effective as they cannot be integrated with health systems and electronic health records (EHRs). Fortunately, standards and platforms exist to promote the implementation of apps in conjunction with health system infrastructure, such as the Fast Healthcare Interoperability Resources (FHIR) (Health Level 7, 2017) and Substitutable Medical Applications, Reusable Technologies (SMART) (Boston Children's Hospital Computational Health Informatics Program, 2019). While SMART on FHIR has enabled health app interoperability, challenges remain with health app implementation.

This dissertation has identified gaps in health app integration strategies, and has addressed these gaps by defining “data readiness” as a concept in healthcare informatics, identified priority areas of US Core development, and explored relationships between app data requirements availability in EHRs and implementation feasibility. In total, these products bring us closer to semantic interoperability, but much work still needs to be done.

5.2 Limitations

While this dissertation covers important questions related to app implementation by examining data readiness and interoperability, much work is still needed. First, this dissertation defined data readiness in a health informatics context, but application of its definition is needed for further refinement and framework development. Second, while specific recommendations for the US Core have been given, these recommendations are only useful at the current time. Re-evaluation is needed over time to continually inform the standards development. Third, while the evaluation of app data requirement availability showed some interesting correlations with implementation feasibility, this only explores one of the many components of feasibility. Further work is needed to explore other components of app implementation feasibility to develop a succinct model to quantify data readiness of health apps.

5.3 Future Directions

This dissertation provides a foundation for a lifetime of future research. Regarding the definition of the concept data readiness, it must be applied and continually refined to inform informatics theory, approaches to app implementation, and app developer planning. There must also be continual assessment of app requirements to inform FHIR resource development and priority areas for US Core profiles. This could be done by creating a national (or international) repository cataloging apps, and assessing for data requirements, FHIR resource use, and US Core

profile coverage. Finally, to develop a model to quantify data readiness for health apps, more studies should explore different components of readiness with implementation feasibility. Qualitative studies with implementation experts would also be helpful in identifying areas to include in a model or explore with in further work.

5.4 Conclusion

Exploring health app feasibility and quantifying data readiness is important for every clinician, nurses included. Using apps improves patient outcomes and empowers patients to be involved in their care. Apps can also improve clinical decisions making, reduce cognitive burden, and improve clinician experience with the EHR. Continuing this work and applying the results of this dissertation will contribute to the effort to bridge different data sources and improve healthcare overall.

Appendix A: Extended FHIR Attribute Table

Attribute	Count	Percent of Apps
Patient Resource (14 apps)		
Must be Present in US Core Profile		
Identifier	4	28.6%
Name	7	50.0%
Gender	9	64.3%
Telecom	1	7.1%
BirthDate	11	78.6%
Address	2	14.3%
Communication	0	0%
Race*	3	21.4%
Ethnicity*	2	14.3%
BirthSex*	0	0%
In Base Resource Only (not included in US Core)		
Active	0	0%
MaritalStatus	0	0%
MultipleBirth	0	0%
Photo	0	0%
Contact	0	0%
Deceased	2	14.3%
GeneralPractitioner	0	0%
ManagingOrganization	0	0%
Link	0	0%
Condition Resource (9 apps)		
Must be Present in US Core Profile		
VerificationStatus	0	0.0%
Category	1	11.1%
Code	9	100%
Subject**	1	11.1%
Optional in US Core		
clinicalStatus	3	33.3%
In Base Resource Only (not included in US Core)		
Identifier	1	11.1%
Severity	1	11.1%
BodySite	2	22.2%
Encounter**	0	0.0%

Onset	7	77.8%
Abatement	2	22.2%
RecordedDate	0	0.0%
Recorder**	0	0.0%
Asserter**	0	0.0%
Stage	1	11.1%
Evidence	1	11.1%
Note	1	11.1%
Procedure Resource (3 apps)		
Must be Present in US Core Profile		
Status***	3	100%
Code	3	100%
Subject**	1	33.3%
Performed	1	33.3%
In Base Resource Only (not included in US Core)		
Identifier	0	0.0%
InstantiatesCanonical**	0	0.0%
InstantiatesUri	0	0.0%
BasedOn**	0	0.0%
PartOf**	0	0.0%
StatusReason	0	0.0%
Category	0	0.0%
Subject**	1	33.3%
Encounter**	0	0.0%
Recorder**	0	0.0%
Asserter**	0	0.0%
Performer	1	33.3%
Location**	0	0.0%
ReasonCode	1	33.3%
ReasonReference**	1	33.3%
BodySite	1	33.3%
Outcome	1	33.3%
Report**	0	0.0%
Complication	0	0.0%
ComplicationDetail**	0	0.0%
FolllowUp	0	0.0%
Note	0	0.0%
FocalDevice	0	0.0%
UsedReference**	1	33.3%

UsedCode	0	0.0%
Encounter Resource (3 apps)		
Must be Present in US Core Profile		
Identifier	2	66.7%
Status	3	100%
Class	2	66.7%
Type	1	33.3%
Subject**	1	33.3%
Participant	1	33.3%
Period	2	66.7%
ReasonCode	2	66.7%
Hospitalization	1	33.3%
Location	2	66.7%
In Base Resource Only (not included in US Core)		
StatusHistory	0	0.0%
Class	0	0.0%
ClassHistory	0	0.0%
ServiceType	0	0.0%
Priority	0	0.0%
EpisodeofCare**	0	0.0%
BasedOn**	0	0.0%
Appointment**	0	0.0%
Length	0	0.0%
ReasonReference**	0	0.0%
Diagnosis	0	0.0%
Account**	0	0.0%
Hospitalization	0	0.0%
Location	0	0.0%
ServiceProvider**	1	33.3%
PartOf**	0	0.0%
DiagnosticReport Resource - Report and Note Exchange (3 apps)		
Must be Present in US Core Profile		
Status***	3	100%
Category	1	33.3%
Code***	3	100%
Subject**	2	66.7%
Encounter**	0	0.0%
Effective	1	33.3%
Issued	2	66.7%

Performer**	0	0.0%
PresentedForm	0	0.0%
In Base Resource Only (not included in US Core)		
Identifier	2	66.7%
BasedOn**	0	0.0%
ResultsInterpreter**	0	0.0%
Specimen**	0	0.0%
Result**	2	66.7%
ImagingStudy**	0	0.0%
Media	0	0.0%
Conclusion	1	33.3%
ConclusionCode	1	33.3%
PresentedForm	2	66.7%
AllergyIntolerance Resource (3 apps)		
Must be Present in US Core Profile		
ClinicalStatus	0	0.0%
VerificationStatus	0	0.0%
Code	3	100%
Patient**	0	0.0%
Reaction	2	66.7%
In Base Resource Only (not included in US Core)		
Identifier	1	33.3%
Type	0	0.0%
Category	0	0.0%
Criticality	0	0.0%
Encounter**	0	0.0%
Onset	1	33.3%
RecordedDate	0	0.0%
Recorder**	0	0.0%
Asserter**	0	0.0%
LastOccurence	0	0.0%
Note	0	0.0%
MedicationRequest (2 apps)		
Must be Present in US Core Profile		
Status***	0	0.0%
Intent***	1	50.0%
Reported	0	0.0%
Medication***	2	100%
Subject*** (**)	0	0.0%

Encounter	0	0.0%
AuthoredOn****	1	50.0%
Requester***	1	50.0%
DosageInstruction	1	50.0%
In Base Resource Only (not included in US Core)		
Identifier	2	100%
Category	0	0.0%
Priority	0	0.0%
DoNotPerform	0	0.0%
SupportingInformation**	0	0.0%
Performer**	0	0.0%
PerformerType	0	0.0%
Recorder**	0	0.0%
ReasonCode	1	50.0%
ReasonReference**	0	0.0%
instantiatesCanonical**	0	0.0%
InstantiatesUri	0	0.0%
BasedOn**	0	0.0%
GroupIdentifer	0	0.0%
CourseOfTherapyType	0	0.0%
Insurance**	0	0.0%
Note	0	0.0%
DispenseRequest	1	50.0%
Substitution	0	0.0%
PriorPrescription	0	0.0%
DetectedIssue	0	0.0%
EventHistory	0	0.0%
Practitioner Resource (1 app)		
Must be Present in US Core Profile		
Identifier****	1	100%
Name****	0	0.0%
In Base Resource Only (not included in US Core)		
Active	0	0.0%
Name	0	0.0%
Telecom	0	0.0%
Address	0	0.0%
Gender	0	0.0%
BirthDate	0	0.0%
Photo	0	0.0%

Qualification	0	0.0%
Communication	0	0.0%

Appendix B: Case Report Form for App Data Availability Survey

Intro Page

Thank you so much for participating in this survey. Our goal is to understand the "availability" of EHR data required by two patient-facing apps across health systems. Your participation will be extremely helpful in guiding future research on the development and deployment of patient-facing apps with EHRs.

Your participation is voluntary. Your responses will be used only for the purposes of this study. You may contact Brian Douthit (brian.douthit@duke.edu; 814-404-1000) at any time should you have questions or wish to retract your submission.

If you agree to participate, please continue to the next page.

Purpose and Instructions

Your goal is to provide ratings regarding the availability of different data elements from your local EHR. These responses are your opinion and specific to your experiences and local EHR; i.e. you do not need to provide evidence to support your answers. For each of the two apps (one per page), you will be presented with the following:

- A description of the app at the top of the page
- A list of data elements required to be available in your EHR (You will be asked to indicate whether you believe this data is readily available in your EHR, or if not, what effort would be needed to collect that data element)
- A text box after each element to discuss any additional information or nuances that you feel would help us understand your local EHRs data
- General questions regarding the feasibility of implementing the changes in data collection within your EHR that are required by the app

If you are unsure about the status of a data element at your institution, please skip that response.

Would you like to see an example?

Yes No

(Example Question): Number of days patient has been in the ICU

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

For the above question, you would pick one of the four responses. In this case, most institutions would be able to pull patient location data. However, the first choice might not be suitable because there might be more than "minimal" processing required. By processing, we mean that the data would need to be somehow transformed to be usable. For instance, while location data may be present, each unit might not be automatically "tagged" as an ICU. Therefore, additional transformation of the unit location data would need to take place to be usable. Whether or not this is "significant" processing is up to you; but if your institution has multiple sites and upwards of 40 different ICU units across these sites, you might imagine this would become a substantial task. Please utilize the provided text boxes to give us a better sense of the challenges you face with your local EHR.

Another consideration is if data is available only as free text at your institution. If it is, assume you must transform the data into a structured format. Again, how much effort that takes is situational a dependent on your judgement.

Remember:

- Skip questions if you are unsure
- Only consider the availability of each data element in context to your local EHR
- Data must be available in a structured format (not free text, clinical notes, etc.); If it is not, answer the questions assuming you must transform the data into a structured format for it to be "available" (It would also be helpful to note these cases in the free-text response boxes below each question)
- DO NOT take human factors, workflow, or data quality into consideration
- For this survey, it does not matter WHERE in the EHR the data comes from (i.e. duplicate elements between flowsheets, flowsheet vs monitor feed)

Click Submit to continue.

PCplanner

App Name: PCplanner (Palliative Care Planner)

Narrative Description: PCplanner was developed for clinicians and ICU patients and their family members to enhance the delivery of needs-targeted palliative care. First, the EHR is screened for ICU patients meeting specific triggers for palliative care consultation. Once identified, families are able to report unmet palliative care needs, which in turn alerts clinicians to these needs.

Assume your healthcare institution is interested implementing the app. The app developers have provided you with an implementation guide with the required data elements and functionalities listed below. Your job is to first assess if the data are available in your EHR. If the data are not readily available, indicate the level of difficulty it would be to collect it. Feel free to use the optional text boxes to further explain your choice.

Data Elements

Number of days patient has been in the ICU

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

Patient Age

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

Encounter Diagnosis; including previous inpatient and outpatient encounters

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

Use of ANY continuous intravenous vasopressor during admission

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

**Mechanical ventilation delivered via either an endotracheal tube or tracheotomy for
≥24 hours**

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

Admitted from Skilled Nursing Facility (SNF) or Long-Term Acute Care (LTAC) facility

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

≥2 hospital admissions (includes Emergency Department visits) AND/OR ≥1 ICU admission in the past 90 days

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

≥2 activities of daily living (ADL) limitations i.e. able to dress one's self (Duke's is found in a nursing intake survey)

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

Use of continuous veno-venous hemodiafiltration (CVVHD) for ≥1 hour

- Readily available with minimal processing
- Available but requires significant data processing

Unavailable but could be collected

Not possible or feasible to collect

Explain: _____

Laboratory Values: PaO₂, SpO₂, FiO₂, Total Bilirubin, Creatinine

Readily available with minimal processing

Available but requires significant data processing

Unavailable but could be collected

Not possible or feasible to collect

Explain: _____

Vital Signs: Mean Arterial Pressure (MAP)

Readily available with minimal processing

Available but requires significant data processing

Unavailable but could be collected

Not possible or feasible to collect

Explain: _____

Glasgow Coma Scale Score

Readily available with minimal processing

Available but requires significant data processing

Unavailable but could be collected

Not possible or feasible to collect

Explain: _____

Urine Output

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

Please feel free to make any comments or thoughts thus far regarding the above data elements

Nest Score

Needs of social nature, existential concerns, symptoms, and therapeutic interaction (NEST) score (custom item from -10 to +10)

Family member reports a score -10 to +10 (-10 being needs not met at all, 0 being neither met nor not met, +10 being need completely met)

11 Item scale with a total score (Communication, Social, Symptoms, Spiritual, Psychological, Value, Information, Cultural, Decision, Trust, Finances)

Note: This is a custom scale developed for this app and is most likely not already available in your EHR

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Rate the level of difficulty to collect the NEST score through your patient portal:

- Not at all difficult
- Somewhat difficult
- Moderately difficult
- Very difficult
- Extremely difficult
- Impossible/Not Available

Feel free to make any comments or provide thoughts below regarding your patient portal. Are there other ways you could collect some of this data outside of the EHR or portal?

App Functionality

Ability to send a message to a provider based on the NEST score (above) and have custom messages based on total score (through EHR messaging or other means)

- Not at all difficult
- Somewhat difficult
- Moderately difficult
- Very difficult
- Extremely difficult
- Impossible/Not Available

Make any comments regarding the above messaging functionality

Feasibility Questions (REQUIRED)

Choose an answer between 1 and 5

How do you view the general feasibility of implementing this app (from the perspective of data availability)?

- 1 Much easier/feasible to integrate with the EHR than other tools/apps we have implemented in the past year OR extremely feasible to integrate with the EHR
- 2 -----
- 3 Similar in feasibility to other tools/apps OR feasible to integrate with the EHR with a reasonable amount of effort
- 4 -----
- 5 Much more difficult to integrate with the EHR than other tools/apps OR not reasonably feasible to integrate with the EHR

What level of effort is needed to provide data for elements that are not readily available?

- 1 No extra effort
- 2 -----
- 3 No more effort than other similar projects OR a moderate/reasonable level of effort
- 4 -----
- 5 A prohibitive level of effort

Any comments regarding your responses for the above two questions?

QuestExplore

App Name: QuestExplore

Narrative Description: Quest Explore is a mobile application built for pediatric patients with chronic illnesses, especially illnesses in which patients are required to stay in the hospital for more than one week. The main purpose of the app is to track symptoms over time, both in terms of intensity and the level of distress of each symptom.

Data Elements

Pain Scale:

Pain Level

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

Pain Location

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

Level of Distress Regarding Pain (1-10)

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected
- Not possible or feasible to collect

Explain: _____

Feel free to make any other comments regarding the pain scales

Other Scales

The following scales are not based on standardized instruments. To save time, we have condensed these scales into two questions to be rated as a "cumulative" assessment of the scales in general. Below these questions, we provide a text box-- Please explain if any of these scales are markedly different from the others/general assessment.

Note: While it is unlikely you will choose the first two option (readily available or available with significant data processing), we leave these options available in the chance that they are.

The scales are as follows, for both level/intensity (1-10) and level of distress (1-10):

Tired, Nausea, Vomiting, Fever, Dizziness, Cold Symptoms, Rash, Headache, Sore Throat, Mouth Pain, Difficulty Breathing, Constipation, Diarrhea, Trouble Peeing, Bleeding

Intensity (1-10)

- Readily available with minimal processing
- Available but requires significant data processing
- Unavailable but could be collected

Not possible or feasible to collect

Explain: _____

Level of Distress Related to Symptom (1-10)

Readily available with minimal processing

Available but requires significant data processing

Unavailable but could be collected

Not possible or feasible to collect

Explain: _____

**Are there any exceptions in the scales above that don't fit the cumulative assessment?
Feel free to make any other comments as well.**

Interventions

The app assesses whether or not the child completed the following interventions:

Took Medicine, applied skin cream, practiced mindfulness, and completed physical exam

These responses are either "yes" or "no". Again, it is unlikely you will choose either of the first two responses.

Rate the ability of your EHR to collect these responses in general. Like the previous question, note any exceptions if applicable below.

Readily available with minimal processing

Available but requires significant data processing

Unavailable but could be collected

Not possible or feasible to collect

**Are there any exceptions in the scales above that don't fit the cumulative assessment?
Feel free to make any other comments as well.**

Mood Scale

The app assesses the child's mood in the following ways from 1 to 10:

Happy, Angry, Tired, Sad, Worried

**Rate the ability of your EHR to collect these responses in general. Like the previous questions,
note any exceptions if applicable below.**

Readily available with minimal processing

Available but requires significant data processing

Unavailable but could be collected

Not possible or feasible to collect

**Are there any exceptions in the scales above that don't fit the cumulative assessment?
Feel free to make any other comments as well.**

Data Collection

**Rate the level of difficulty to collect all the above data elements through the Patient
Portal**

- Not at all difficult
- Somewhat difficult
- Moderately difficult
- Very difficult
- Extremely difficult
- Impossible/Not Available

Make any comments regarding your patient portal. Are there other methods available at your institution to collect this data besides a patient portal?

Feasibility Questions (REQUIRED)

Choose an answer between 1 and 5

How do you view the general feasibility of implementing this app (from the perspective of data availability)?

- 1 Much easier/feasible to integrate with the EHR than other tools/apps we have implemented in the past year OR extremely feasible to integrate with the EHR
- 2 -----
- 3 Similar in feasibility to other tools/apps OR feasible to integrate with the EHR with a reasonable amount of effort
- 4 -----
- 5 Much more difficult to integrate with the EHR than other tools/apps OR not reasonably feasible to integrate with the EHR

What level of effort is needed to provide data for elements that are not readily available?

- 1 No extra effort
- 2 -----
- 3 No more effort than other similar projects OR a moderate/reasonable level of effort
- 4 -----
- 5 A prohibitive level of effort

Any comments regarding your responses for the above two questions?

Answer the following questions. Please skip any questions you do not feel comfortable answering.

Institution (for survey verification purposes only):

EHR Vendor

How many years of experience do you have with your current EHR?

How many years of experience do you have with implementing EHR-integrated clinical tools/apps/decision support?

How would you rate your institution's overall expertise in implementing SMART on FHIR apps?

About how many SMART on FHIR apps does your institution have in production?

Please enter any final thoughts or comments if applicable. Thank you again for completing this survey.

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Biography

Brian James Douthit graduated from The Pennsylvania State University in 2012 with a Bachelor of Science degree in Nursing. In 2016, he successfully passed his certification exam to become a board-certified informatics nurse through the American Nurses Credentialing Center. In 2017, he graduated from Duke University with a Master of Science in Nursing degree in nursing informatics. Later that same year, Douthit enrolled in the PhD program in the School of Nursing at Duke University. Upon enrollment, he was selected as a Robert Wood Johnson Future of Nursing Scholar. During his doctoral work at Duke, he published 11 peer-reviewed papers (six of which were first author), presented at a panel as part of the Annual Patient-Centered Clinical Decision Support Conference (PCCDS) sponsored by the Agency For Healthcare Research and Quality (AHRQ), presented a peer-reviewed podium abstract, wrote a book chapter, and was included on two peer-reviewed posters. In addition, he served most of his two-year term as student editor for *Applied Clinical Informatics* during his studies. Douthit also served as a peer-reviewer for several journals and conferences, and participated as a member in several professional societies, including Health Level 7 (HL7), the American Medical Informatics Association (AMIA), the American Nursing Informatics Association (ANIA), and the Healthcare Information and Management Systems Society (HIMSS).