A Learning Health Sciences Approach to Understanding Clinical Documentation in Pediatric Rehabilitation Settings

by

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Dedication

This dissertation is dedicated to my mother. You have challenged me every day since I was born to think critically, to believe in myself, and that no problem is too difficult to solve. I love you and thank you.

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Like all great expeditions, a dissertation is a long arduous process that requires a team effort. It is a journey that requires the support, counsel, and love of friends, families, and colleagues, and the constant self-monitoring and reflection to keep moving forward. I would not be the analytical creature I am today without the time, energy, love, and support from my mother, D.A.B.; thank you for being there every step of the way and teaching me to trust the process. R.J.E., thank you for your love and kindness and being my best friend, you were my catalyst throughout this process. J.M.K., thank you for inspiring me to pursue healthcare research and teaching me early in my childhood that when a task is once begun you leave it not until its done. C.R.K., my other equal, thank you for always understanding me. M.R.J.K., thank you for blazing the path, our academic journey together finally concludes. To G.A.P., C.P.F., C.A.T., A.H.V., A.G.K., and all the mentors and advisors along the way, thank you for supporting my ideas and shaping me into the researcher I am today. To J.S.T., I appreciate the help pulling data. To S.H.C., thank you for providing me with a context to do research. To the current and future HILS cohorts, I did my best to set the bar. To all DLHS faculty and staff, thank you for building the HILS program and taking a chance on me. To π, you are a great turtle and companion. No acknowledgements could be complete without reflecting on what drove me to this field of study. I gained my passion for this research out of my experience as a sick patient in my early childhood and as a practicing clinician. I strive to build a better healthcare system through embracing opportunities for knowledge, discovery, and improved continuity of care for all populations. Thank you.

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Abstract

The work presented in this dissertation provides an analysis of clinical documentation that challenges the concepts and thinking surrounding missingness of data from clinical settings and the factors that influence why data are missing. It also foregrounds the critical role of clinical documentation as infrastructure for creating learning health systems (LHS) for pediatric rehabilitation settings. Although completeness of discrete data is limited, the results presented do not reflect the quality of care or the extent of unstructured data that providers document in other locations of the electronic health record (EHR) interface. While some may view imputation and natural language processing as means to address missingness of clinical data, these practices carry biases in their interpretations and issues of validity in results. The factors that influence missingness of discrete clinical data are rooted not just in technical structures, but larger professional, system level and unobservable phenomena that shape provider practices of clinical documentation. This work has implications for how we view clinical documentation as critical infrastructure for LHS, future studies of data quality and health outcomes research, and EHR design and implementation.

The overall research questions for this dissertation are: 1) To what extent can data networks be leveraged to build classifiers of patient functional performance and physical disability? 2) How can discrete clinical data on gross motor function be used to draw conclusions about clinical documentation practices in the EHR for cerebral palsy? 3) Why does missingness of discrete data in the EHR occur? To address these questions, a three-pronged approach is used

to examine data completeness and the factors that influence missingness of discrete clinical data in an exemplar pediatric data learning network will be used. As a use-case, evaluation of EHR data completeness of gross motor function related data, populated by providers from 2015-2019 for children with cerebral palsy (CP), will be completed. Mixed methods research strategies will be used to achieve the dissertation objectives, including developing an expert-informed and standards-based phenotype model of gross motor function data as a task-based mechanism, conducting quantitative descriptive analyses of completeness of discrete data in the EHR, and performing qualitative thematic analyses to elicit and interpret the latent concepts that contribute to missingness of discrete data in the EHR. The clinical data for this dissertation are sourced from the Shriners Hospitals for Children (SHC) Health Outcomes Network (SHOnet), while qualitative data were collected through interviews and field observations of clinical providers across three care sites in the SHC system.

Chapter 1

Introduction

Doctors, nurses, and therapists (i.e., physical, occupational and speech) all work and communicate in an iterative and dynamic healthcare system, while interacting daily with each other, patients, and technology. These providers operate in an ever-expanding socio-technical system, where social and technical dimensions are interrelated, and experience the frequent implementation of new technologies and evidence-based practices for managing health and health-related conditions.[1] As these conditions increase in complexity, at both physiological and physical disability levels, their management becomes equally complex, difficult, and distributed across a consortium of diverse care providers. The electronic health record (EHR) is one infrastructural technology that supports the distributed management of disease via care coordination, real-time communication, and the absorption and application of data and information across healthcare workers in these systems.

Researchers, information technology experts, informaticians and EHR vendors (i.e. Epic, Cerner, Meditech, etc.) continue to innovate EHRs and other health technologies to leverage patient health data and support clinical care delivery. A subsequent technological advancement is the design of infrastructural tools for extracting and storing EHR data elements across (heterogeneous) information systems from different healthcare systems and integrated clinical data research networks (CDRN). These CDRN networks can provide cost-effective infrastructures compared to double-entry of research-specific data collected at the point-of-care

by clinical providers, often reduced to the concept of "collect once and use many times", or improved economy of scale.[2] Example CDRNs (e.g., Patient Centered Outcomes Research Network, PEDSnet, Shriners Health Outcomes Network, Improve Care Now, etc.) maintain a data architecture that is capable of supporting the development of real-world evidence from routinely collected patient health data (i.e. real-world data) and could potentially improve measurement of healthcare system performance and patient health outcomes.

Healthcare organizations participating in CDRNs may leverage the data from these networks to identify strengths and deficiencies in clinical care delivery, improve and support performance of clinical practices, and measure patient health outcomes.[3,4] This is an optimal long-term goal, to continuously analyze real-world data, but its achievement cannot reasonably occur without scientifically evaluating both the documentation of these data and the data themselves, or what Friedman et al. (2017) identifies as the process of "performance to data".[5] The preferred route to examine documentation is through evaluating data completeness, or the proportion of data elements that are actually recorded in the EHR without reference to actual values.[6,7] This often results in handling missing data to ensure the sample of record for analysis is most complete[8], but a complete record is not necessarily attainable, especially in healthcare systems research. The missingness, or the proportion of data not recorded in the EHR without reference to actual values, that is the inverse of completeness, is actually a product of the healthcare system and many other external generative mechanisms that researchers need to examine to optimize data resources as infrastructure for healthcare system learning. Although real-world data appear necessary to measure healthcare system performance, a gap exists on two fronts: 1) in understanding the documentation practices and other sociotechnical and professional factors that influence the missingness of real-world data from patient-provider encounters, and 2)

in how to measure the management of health conditions when conditions are multidimensional, complex, impact physical functioning, and not easily quantifiable by surveying the medical record.

The following dissertation presents an analysis of clinical documentation from a pediatric-specific CDRN that challenges the concepts and thinking surrounding missingness of data in the EHR and the factors that influence whether or not data are documented. The dissertation foregrounds the critical role of clinical documentation as infrastructure for creating learning health systems (LHS) for pediatric rehabilitation settings and how discrete clinical data in the EHR can be used to create potentially computable classifiers of physical functional performance. The dissertation includes an analysis of discrete data only; however, the processes and practices providers use to document these data are subject to biases which impacts how these data are interpreted for research. While the results demonstrate the extensive missingness of clinical data, the iterative process of the dissertation points to a need for further research to understand why missingness of discrete data in the EHR occurs. Thus, the analysis of missing data requires an understanding of the technical structures and the larger educational, professional, system level and unobservable phenomena that shape provider practices of clinical documentation. The work presented in this dissertation has implications for the role of clinical documentation as critical infrastructure for LHS and associated activities such as research and data quality assessment, implementation science, health outcomes research, and EHR design.

This dissertation is organized around three primary research questions. These questions are mapped to a use-case that incorporates a CDRN and a complex multidimensional disorder in the context of pediatrics and physical medicine and rehabilitation. The three questions include:

1) To what extent can data networks (CDRNs) be leveraged to build classifiers of patient functional performance and physical disability?

2) How can discrete clinical data on gross motor function be used to draw conclusions about clinical documentation practices in the EHR for cerebral palsy?
3) Why does missingness of discrete data in the EHR occur?

This dissertation is organized into eight chapters. Chapter 2 is a literature review of the breadth of knowledge and research necessary to address the dissertation questions. Chapter 2 covers foundational topics of clinical documentation, the role of the EHR, the concepts of infrastructure and implementation science for LHS, and background on the data resource and disease for the use-case analysis in this dissertation. Chapter 3 reviews the dissertation research proposal which focuses on three Specific Aims and the methods used to design and conduct the dissertation research.

Cerebral Palsy (CP) serves as the use-case disorder for this dissertation and is discussed in Chapter 2. CP is a group of heterogeneous conditions resulting in varying degrees of impaired motor function that impact mobility, movement, and performance of activities of daily living. Sparse literature exists on measuring the clinical management of physical disability and functional performance resulting from more complex and multidimensional disorders like CP. Health conditions are more easily identifiable and measurable using current data structures on physiological function. These may include endocrine, metabolic, and cardiovascular function, such as measuring clinical management of chronic kidney disease, hypothyroidism, diabetes, etc. These types of conditions comprise clinical indicators that were established through scientific study to determine normal ranges of values. Aside from the markers of physiological function and the development of computable definitions for and of conditions above related to their presence or absence, more research is needed to understand markers of physical function in complex multidimensional disorders that cause physical disability and impair participation.

Many CP-associated complications are managed by orthopedic surgery and physical medicine and rehabilitation clinicians. Standardized measures and approaches exist to classify severity of impaired motor function for mobility, movement, and performance of self-care tasks related to CP; however, these are inconsistently performed and documented by clinicians or collected as patient-reported outcomes in the EHR. These data are critical to measure the clinical management and health outcomes of a disorder like CP and offer an opportunity to develop computable representations of physical disability and motor function.

The data resource for this use-case is the Shriners Hospitals for Children (SHC) Health Outcomes Network (SHOnet). Most CDRNs are not oriented around the measurement of orthopedic and rehabilitation-related data elements of physical function, commonly collected as observation data elements.[9] Rather, many networks leverage laboratory values, admissions information, medication data, and administrative health data such as International Classification of Disease (ICD) 9/10 codes and Current Procedural Terminology (CPT) codes to develop computable knowledge to classify the presence or absence of diagnoses, study readmissions, or surround pharmacotherapy interventions. SHOnet is the exception. SHOnet stores real-world data extracted from EHRs at 21 SHCs in North America. SHOnet is the most advanced real-world data resource for supporting pediatric orthopedic and rehabilitation research and clinical practice. SHOnet leverages EHR data for system-wide research studies to learn from real-world healthcare data, with the goal of transforming clinical practice and improving the health outcomes of SHC patients. CP is one of the largest populations managed by SHC. SHOnet supports many system-wide opportunities to generate meaningful knowledge and inform clinical practice for CP. Therefore, SHC and SHOnet provide a unique case selection to study how and what real-world data are documented in routine care, the extent that these data inform the

computable classification of motor function for children with CP, and a use-case to evaluate new concepts surrounding missingness.

The first research paper of this dissertation is Chapter 4 and it focuses the development of a phenotype model of gross motor function that comprises discrete data elements mapped to a common reference terminology for observational research in pediatrics. Chapter 5 leverages this phenotype model as a task-based mechanism for a descriptive analysis to study data completeness and missingness. Chapter 6 then presents a qualitative study to explore why missingness of discrete data occurs in the EHR. Each Specific Aim in Chapter 3 corresponds to Chapters 4-6 of the dissertation, and each chapter is written as a free-standing manuscript comprising an introduction, methods, results, and discussion section. Although separate manuscripts, each progressively builds on the other and culminates in the discussion and conclusion in Chapters 7 and 8 that expound on how the papers address the research questions, the implications of this work, and role of future research studies.

Chapter 2

Literature Review

This literature review provides the background necessary to address the research questions outlined in the Introduction. This chapter is divided into six sections. Section 1 is a review of the literature on clinical documentation and the role of EHRs in clinical care delivery. Section 2 introduces the concept of LHS and discusses the existing models and theories surrounding LHS that support learning health sciences approaches. Section 3 provides an overview of definitions of infrastructure and details the types of data infrastructures that support LHS. Section 4 is an introduction to computable phenotypes and their role as an infrastructural solution in pediatric rehabilitation LHS research initiatives to optimize real-world data to generate meaningful knowledge. Section 5 reviews cerebral palsy, complications from hip dysplasia, and the role of classifying gross motor function to support pediatric care delivery processes for cerebral palsy. Lastly, Section 6 focuses on the role of implementation science methods for LHS and how the use of frameworks can guide learning health sciences for understanding clinical documentation.

SECTION 1. Clinical Documentation and the Electronic Health Record

Clinical Documentation

Clinical documentation is the process of creating clinical notes that record the observations, impressions, plans and other activities surrounding patient-clinician encounters in a healthcare system.[10] Clinical notes are generated to achieve numerous goals: recordkeeping and prompting; communication between collaborating clinicians to support continuity of clinical

care; to justify reimbursement by third-party payers for service provided; a record to be used in the court of law; and to support clinical research and quality-improvement efforts.[10-12] Notes also serve as a clinician's extended mind to orient them and their colleagues to previous patient encounters.[13,14] Furthermore, documentation is important because it captures and supports clinician knowledge, application and performance of guidelines and evidence-based care.[11] Computerized documentation is a process whereby the clinicians interact routinely with a computer interface (EHR) to describe a patient encounter. Computerized documentation systems (EHRs) ultimately provide an instantaneous mode of transporting abstract data and knowledge between clinicians and across units and settings in a healthcare system.[13,14]

Documentation can be considered heteropraxial and heteroglossial, two concepts defined by Star (1999).[15] Heteropraxial refers to "different practices according to region, local constraints and beliefs (p. 385)", while heteroglossial refers to "inscribing different voices in a seemingly monotonous form (p.385)".[15] Clinicians often have discretion regarding how, when and what they document: whether narrative/dictation, structured or unstructured entry; during, directly after an encounter, or after all patient encounters in a day. *What* is documented is based on department, organization, state and federal policy, however this often relates to reimbursement and other financial incentives: documentation of quality measures, CPT codes, ICD-9/10 codes, and requirements by the Centers for Medicare and Medicaid Services (CMS). The variability in how and what clinicians document in a large-scale system may influence the quality and representativeness of data used for research purposes.

Research and learning in healthcare systems using real-world data stored in CDRNs or directly queried from EHRs presents major concerns related to data quality and veracity of findings because these data are rarely collected systematically or with a clear collection

procedure. While CDRNs hold much promise in measurement and translatability of a clinical practice in a healthcare system and patient outcomes, at a granular level, variability exists in documentation of data in the EHR as part of routine care delivery.[6,11,16-18] Studies using CDRNs for research identified heterogeneity and variation in documentation practices across different systems as key barriers to accurately measure clinical performance.[3,18,19] These clinical documentation practices are known to vary by healthcare systems, regional geography, and due to the design and implementation of EHRs**.**[3,18,19]

A paradigm shift is occurring in clinical documentation. In 1991, van der Lei stated, "data should be used for the purpose for which they were collected," and warned of the reuse of clinical data for research.[20,21] This idea has been recycled over the past three decades. However, since Østerlund's work, documentation practices are now mostly confined to the EHR where data are collected in structured and unstructured fields. The purpose of clinical documentation is evolving to collect data which support the development of computable knowledge and representations of patients, outcomes, care quality and gaps in clinical performance. The concept of continuous learning healthcare, the evolution of EHRs and the development of new clinical interventions, thus points to the necessary realignment in clinician beliefs, values, and perceptions about the meaning of documentation.

Electronic Health Records

Although the EHR is the primary mode of clinical documentation in most U.S. healthcare settings and a core infrastructural component for continuous learning, myriad problems occurred during and following EHR implementation. Barriers to successful implementation and sustainability included initial adoption and operating/maintenance costs, misaligned incentives, lack of trained technical support staff, the loss of work productivity and workflow issues due to

training of clinical staff, and absence of interoperability.[22-24] Efforts to address many of these issues took effect over the past decade, and included studies on how to effectively implement EHRs into health systems with extensive training, piloting and stepped deployment within complex health organizations.[22,23]

EHRs do maintain favorability because of improved accessibility to patient information, documentation quality and efficiency,[25] however, EHRs continue to receive mixed reactions from the healthcare professional community.[24] Several reviews of EHR implementation found clinicians report issues of inadequate support for communication and coordination between providers and the cognitive burden associated with a number of factors from task-switching, clicking and documentation time to workflow disruption, reduced clinical discretion and documentation workarounds resulting in inaccurate data.[18,25-27] In a review by Nguyen et al. (2014), authors concluded that EHR implementation lacks a socio-technical frame of reference for understanding the interactions between clinicians, technology and patients, and that further research is needed to understand the connection to quality of care.[24]

EHRs are predominately designed for clinical operations and not research, resulting in variability of how, where, when and what data clinicians document after patient encounters.[28] The non-research design may impact the completeness of EHR data extracted, and complicate the interpretation of results by studies analyzing EHR data.[29] The extent that clinical documentation practices can be evaluated and their influence on researching clinical performance and patient outcomes using CDRNs requires further study.

The evolving documentation systems (paper-based tools to EHRs) and the growth in scientific discovery in clinical fields are influencing how and what people document, but it is also changing the purpose of documentation. Prior to the EHR boom in 2009, Østerlund (2004)

sought to understand how clinicians use documents to share their knowledge within and between clinical settings.[13] Østerlund studied the documentation practices central to managing the care of patients with asthma across healthcare settings.[13] Clinical documentation practices included recordings made on notecards, templated forms, online systems and whiteboards. Østerlund described how providers use clinical documentation as maps and itineraries to organize their daily work practices and considered documentation as primarily practice-centered records to coordinate care, rather than patient-centered records.[13] Fast-forward to the present day, and clinical documentation has changed from simply a means of coordinating and managing care to also measuring, evaluating, and improving care and outcomes.

In-depth scientific inquiry into clinical documentation practices is required to understand how data are produced and determine the extent that documentation systems can be optimized for continuous learning capability. While Rosenbloom et al. discuss the tension between expressivity and structured documentation, and the benefits of allowing clinicians to choose their documentation method based on factors such as workflow and note content requirements, the extent that expressive/narrative text and structured data entry should and can be balanced requires further study.[10,12] SHOnet offers a unique opportunity to address these problems. The following dissertation will, therefore, focus on the extent that use of EHRs and relevant contextual factors at SHC sites affect clinical workflow and documentation practices. By studying this socio-technical relationship, we can better understand the cognitive, social, and technological constraints and tensions related to clinical documentation routines and types of EHR data elements documented. Specifically, a focus on how and what providers document in clinical practice is necessary. These contextual processes and individual and collective actions that influence clinical documentation practices may also reveal important factors that affect

implementation of technological innovation, new evidence and standardized processes, and the necessity of de-implementing the antiquated in socio-technical healthcare systems.

SECTION 2. Overview of Learning Health Systems and Models

Learning Health Systems

The progression of technology has resulted in new policy approaches and innovations to improve the patient care experience and flow of people and information within the US healthcare system. Since the advent of the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the American Recovery and Reinvestment Act (ARRA) in 2009, the Federal government invested approximately $35 billion in electronic health record (EHR) software adoption and installation for hospitals and healthcare practitioners across the US.[30] This was meant to improve the process of collecting patient health data and streamline reimbursement procedures, while incentivizing healthcare systems to adopt and use EHRs through meaningful use criteria.[23,31-33]

Rather than report patient encounters on paper, clinician roles are facilitated by frequent computer use to complete daily tasks and enter comprehensive patient data into EHRs.[34] These systems enable the collection of an array of clinical information, outcome measures and quality performance measures, and provide the opportunity to build a longitudinal patient medical record. As such, the routine collection of these data gives healthcare organizations and clinical practices a unique opportunity to address critical system-level problems.[35] These problems may be related to compliance and effectiveness of clinical practice guidelines, evaluation of practice patterns, implementation of new practices and standards.[36,37]

Several barriers impacted the adoption and installation of EHRs. These included initial adoption and operating/maintenance costs, misaligned incentives, lack of trained technical

support staff, the loss of work productivity and workflow issues due to training of clinical staff, and absence of interoperability.[22,23] Efforts to address many of these barriers took effect over the succeeding years of HITECH, with a primary emphasis on how to effectively implement EHRs into health systems with extensive training, piloting and stepped deployment within complex health organizations.[22,23] Developing standards criteria for interoperability in the US has gained prominence as well, through the combination of grassroots campaigns, adoption of information sharing processes by healthcare stakeholders and the passage of the 21st Century Cures Act of 2016.[38]

Technology and policy approaches will continue to evolve in the US healthcare system to support innovations in service delivery and payment reform and reduce waste; however, there is an emerging need for a continuously learning and improving health system to address critical population health issues.[39,40] The concept of a continuously learning and improving health system is referred to as a Learning Health System (LHS), and its path dependence is closely aligned with EHRs, HITECH and healthcare quality improvement collaboratives.[41] As infrastructure is built across social and technical features and healthcare systems are adopting LHS initiatives for transformation, it is necessary to develop standards and frameworks for LHS practice and to study how large-scale healthcare systems make this transformation.

The concept of an LHS first appeared in the National Academy of Medicine (NAM) workshop summary titled, "The Learning Healthcare System," in 2007. Workshop attendees supported the concept of a LHS capable of generating and applying the best evidence for collaborative decision-making for enhancing the patient-provider relationship; that improves the delivery and quality of care; that improves health; and reduces healthcare costs.[41] These objectives align with the Institute for Healthcare Improvement's triple aims that drive quality

improvement efforts nationwide: 1) improving patient care quality and satisfaction, 2) improving the health of populations, and 3) reducing the per capita healthcare cost.[5,31,39,42,43]

Along with the NAM convening workshops, the Agency for Healthcare Research and Quality (AHRQ) has supported the concept of a LHS since 2015, and assists healthcare delivery organizations and researchers in transforming in to LHSs through means of training and competency development, grant funding, and initiatives at any scale.[44] Such initiatives include the Patient Centered Outcomes Research (PCOR) Clinical Decision Support (CDS), which comprises four key areas of 1) establishing funding opportunities to translate evidence-based research findings into CDS tools, 2) developing an online learning network for researchers, clinicians, professional societies, and others to discuss transforming PCOR findings into clinical decision support, 3) designing a CDS repository of CDS strategies and technologies, and lastly, 4) an evaluation piece to evaluate the overall initiative.[44] The Comparative Health Systems Performance (CHSP) initiative is another AHRQ funded LHS-based project. CHSP is a five-year project which aims to understand how healthcare systems promote the use of evidence-based practices in clinical care.[44] Three centers of excellence (Dartmouth College, RAND Corporation, and the National Bureau of Economic Research) and one coordinating center (Mathematica Policy Research) were established to promote this work.[44] These are just a few of the national efforts to understand the scope of the US healthcare system and develop the infrastructure for LHSs; however, others are designing LHS conceptual models to help guide the research and practice within healthcare systems and academic health centers.

Models for Learning Health Systems

One of the most consistent findings in health services research is the gap between best practices and actual clinical care; [45] a LHS perspective can bridge this gap. Central to the concept

of LHSs is the iterative relationship between research and practice, and the emphasis on improving the transformation of data to new knowledge to clinical practice.[5,46] Two predominant process models exist in the literature to highlight the features and process of a LHS. Friedman et al. developed the Virtuous Cycle of Learning for LHSs.[5]

In a LHS, digital forms of healthcare data are purported to traverse iterative cycles of knowledge generation and curation, tailored feedback, implementation and evaluation, support transformative health system change[47], conduct outcomes research, measure clinical performance, define gaps in care delivery, etc. The Virtuous Cycle for Learning Health Systems (LHS Cycle) is a useful process model that conceptualizes the iterative relationship, types of activities, and necessary components of a LHS: convening a learning community; a cycle of data, knowledge and performance; and supportive infrastructure composed of people, process, policy and technology (**Figure 2.1**).[5] The model closely aligns with the type of components that described by Nadeem et al., most notably related to convening a expert panel and emphasis on the cycle of data; however, the distinguishing feature is the inclusion of the infrastructure to support the learning endeavors.[48] It also shares similarities with the Knowledge to Action Framework (**Figure 2.2**); an implementation-focused process model that depicts the continuum required for translating evidence into clinical practice through knowledge generation, use, monitoring and evaluation.[49]

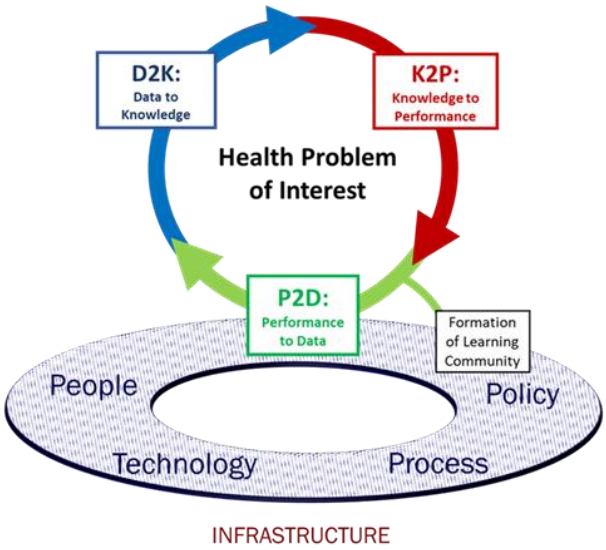
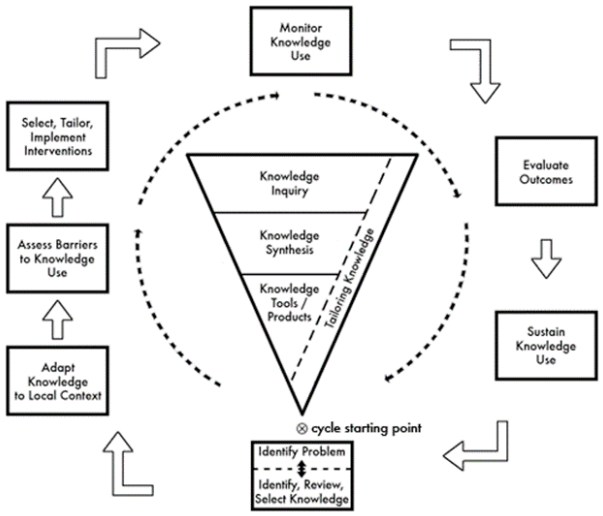


Figure 2.1. Friedman's Virtuous Cycle for Learning Health Systems.

Figure 2.2. Knowledge to Action Framework.



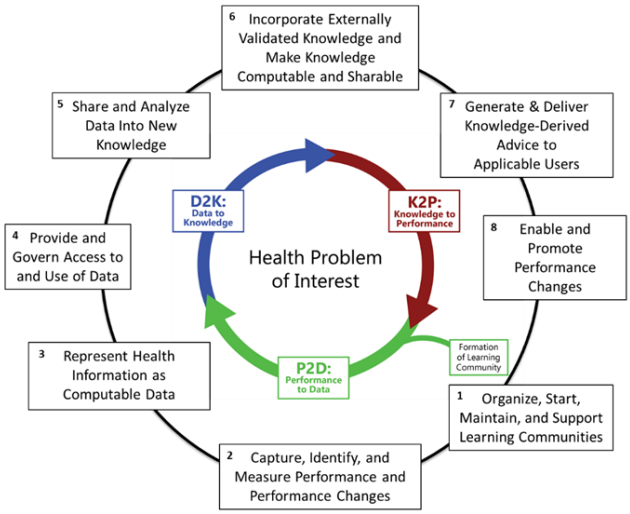


Figure 2.3. The eight infrastructure services for Friedman's Learning Health Systems Cycle.

Friedman et al. also unpack five key attributes of a fully functional LHS: 1) availability of secure, large-scale, routinely-collected patient data; 2) best-practice knowledge derived from these data capable of being computable for translating into clinical practice; 3) multiple simultaneous and continuous learning and health improvement cycles; 4) presence of infrastructures to support learning cycles; 5) identification of stakeholders and experts for establishing learning communities surrounding health-related issues.[5] Recent work by Friedman and colleagues has furthered this model to include LHS infrastructure services along the cycle (**Figure 2.3**).

The LHS Cycle also draws from the Plan, Do, Study, Act (PDSA) Cycle commonly employed for conducting quality improvement work. The PDSA Cycle is a four step cyclic learning approach that resembles the scientific experimental method but is applied to quality improvement (**Figure 2.4**).[50,51] The cycle begins at the "plan" stage which means that a change is needed to improve a process, practice or outcome. The "do" stage equates to testing the change by implementation, whereas the "study" stage serves as the evaluation of the change. The last

stage is the 'act' stage, and means that after the study stage, an action is needed as to whether the change will be implemented. Literature surrounding the use of PDSA in quality improvement has returned mixed results related to demonstrating improvements.[50]

Figure 2.4. Plan-Do-Study-Act Cycle. Source: Langley et al (2009).

The PDSA cycle originated from the automotive industry in the 1930s by Walter Shewhart who wanted to bring the scientific method to the 20th century industry (i.e. hypothesis building, experimenting, and testing the hypothesis).[50,52] Shewhart's cycle included a three-stage iterative process which included specification – production – inspection, and was modified by Edward Deming in the 1950s to characterize a four-stage process that included design-produce – sell -test in the market and redesign through research.[53] Deming's cycle was later adopted and modified into the "plan-do-check-act" cycle by the Japanese Union of Scientists and Engineers in 1951 after Deming presented his cycle during quality control seminar.[53] In 1986, Deming modified the cycle to replace the word "check" with "study", but also believed the PDSA and PDCA cycles to be different.[53]

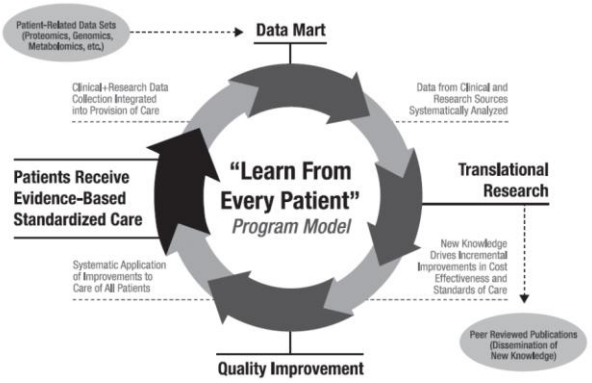


Figure 2.5. The "Learn From Every Patient" program model developed by Lowes et al. (2017) at Nationwide Children's Hospital.

Lowes et al. (2017) designed a LHS process model (**Figure 2.5**) through the Learn From Every Patient (LFEP) program at Nationwide Children's Hospital in Columbus, Ohio.[54] Lowes et al. also present their LHS model as a cycle to achieve the goal of systematically improving the use of evidence-based clinical care. The cycle denotes four spokes: 1) delivery of evidence-based standardized care; 2) a data

mart; 3) translational research; and 4) quality improvement. The LFEP model includes aligns well with basic research, but lacks several key characteristics compared to the Friedman model: a health problem, a learning community, and inclusion of supportive infrastructure. The data mart is not presented as infrastructure, rather it is more of a database than a facilitator of the entire LHS process, as opposed to the Friedman model which highlights four types of supportive infrastructure. The inclusion of both translational research and quality improvement in the LFEP model introduces these fields as subsets of LHSs.

Summary

The concept of a LHS evolved out of the continuous QIC work from the early 1990s. LHSs are critical to addressing the translation gap of research to practice, and health systems can serve as incubators to develop strategies to improve patient care and population health. Both LHS models presented include essential attributes of an LHS, with some overlapping content, but neither focuses on the primary objectives of the LHS: to improve patient care and patient outcomes. Feedback mechanisms are important to accomplish the goals of an LHS, especially to learn about clinician performance over time and to postulate how practice may be altered to meet demands of improved health outcomes; these models reinforce this belief. Large-scale multi-site systems, however, often fail to employ mechanisms to implement new standards and clinical practices, or routinely learn about their performance and their patients due to inadequate infrastructures. Assessing system infrastructures to ensure they would support large-scale rapid learning processes will be instrumental to the health system seeking LHS transformation.

SECTION 3. Infrastructure and Learning Health Systems

Overview of Infrastructure

Infrastructure is imperative to a functioning LHS.[5] Infrastructure exists as the supportive mechanism to "allow, facilitate, mediate, saturate and influence our surroundings".[55] The types of infrastructures we interact with are shaped by networks and systems of purpose; they are often heterogeneous and distributed in nature, and stretched across time and space. Examples of general concepts of infrastructure include the architecture that supports the physical flow of natural gas from source to user, the electric and power systems architecture supporting energy and telecommunications use, and the physical infrastructure for flow of water from treatment plant to spout, and transportation systems.

Star and Ruhleder, and Bowker and Star, defined the features of infrastructure which support the existence of large-scale systems (**Table 2.1**).[56-58] Hanseth, Monteiro, and Hatling (1996) took these principles a step further and applied them to information infrastructures; adding that infrastructure be characterized by openness to number and types of users, maintain interconnections of numerous modules/systems, include dynamically evolving portfolios of systems, be shaped by an installed base of existing systems and practices, and include many *actors* that intervene continuously in changing elements and in fixing them.[55,59]

Table 2.1. Dimensions of Infrastructure (reproduced from Star and Ruhleder, 1996).

- *Embeddedness* - Infrastructure is "sunk" into, inside of, other structures, social arrangements, and technologies;
- *Transparency* - Infrastructure is transparent to use, in the sense that it does not have to be reinvented each time or assembled for each task, but invisibly supports those tasks;
- *Reach or scope* - This may be either spatial or temporal -- infrastructure has reach beyond a single event or one-site practice;
- *Learned as part of membership* - The taken-for-grantedness of artifacts and organizational arrangements is a sine qua non of membership in a community of practice. Strangers and outsiders encounter infrastructure as a target object to be learned about. New participants acquire a naturalized familiarity with its objects as they become members;
- *Links with conventions of practice* - Infrastructure both shapes and is shaped by the conventions of a community of practice

- *Embodiment of standards* - Modified by scope and often by conflicting conventions, infrastructure takes on transparency by plugging into other infrastructures and tools in a standardized fashion.
- *Built on an installed base* - Infrastructure does not grow de novo; it wrestles with the "inertia of the installed base" and inherits strengths and limitations from that base. Optical fibers run along old railroad lines; new systems are designed for backward-compatibility; and failing to account for these constraints may be fatal or distorting to new development processes.
- *Becomes visible upon breakdown* - The normally invisible quality of working infrastructure becomes visible when it breaks: the server is down, the bridge

Infrastructure requires routine maintenance and repair to reduce system imbalances to maintain the flow and "invisibility" of infrastructure.[60] As infrastructure develops, further technical innovation is required as the system increasingly incorporates heterogeneous components.[60] Standards are central to a functional infrastructure and help maintain balance.[61] These standards are considered norms and rules; generically, infrastructures act like laws and are learned as part of membership in a system.[62] They set limits, both enabling and constraining populations, and promote some interests at the expense of others; thus resulting in tensions and conflicts.[62] Some deeply felt tensions and conflicts in systems may potentially be provoked during infrastructure development and innovation implementation.[57] As Edwards et al. review, large-scale systems may mask these tensions even after new infrastructures replace old ones, in order to make systems appear uncontroversial and harmonious.[57] Tensions and conflicts can be considered barriers and facilitators to infrastructural development and should be engaged and studied constructively.[57] Relations between system builders and system users continue to be sites of tension during infrastructure development, especially across different levels of scale.[57] Studying and navigating tensions and conflicts within large-scale health systems will be vital to ensuring the best implementation strategies for practice changes and for implementing new data infrastructures into clinical systems.

When infrastructure breaks down, its structures and importance for equilibrium in flow become visible. Hughes was instrumental in coining the term "reverse salient" when referring to

imbalance in a large technical system which results in a critical problem and possible infrastructure failure.[60] Invention and innovation of infrastructure stems from the occurrence of a reverse salient or critical problem, and is intended to correct the system to return to a period of stabilization.[60] These innovations and new infrastructures tend to also be *path dependent* on previous inventions and system designs. Implementation of EHRs across the US has been key to solving critical problems related to documentation and data collection and for evaluating outcomes across healthcare systems.[22] Therefore, the innovation of the LHS is path dependent on EHRs and reverse salients in documentation and fragmentation in patient medical records. When healthcare systems have shortages of supplies, inadequate staffing, poor workflow designs, discrepancies in EHR documentation standards or system maintenance requirements, the flow of patient care and quality is prone to breakdown. This breakdown inevitably impacts the function of research, practice changes, and any uses for clinical decision support tools which can support an economy of scale.

The optimal goal of infrastructure is to support an economy of scale[5] (e.g. increased scale at a decreased cost within a purposeful system[62]). An LHS seeks to achieve an "economy of scale". Nwaru et al. (2017) identified that for an LHS infrastructure to achieve an economy of scale, it must be capable of supporting multiple learning cycles where the cost of executing *N* learning cycles is far less than *N* times the cost of executing one cycle.[46] Friedman et al. address the importance of achieving an economy of scale for LHSs[5], but also highlight the other important features of infrastructure required to support an economy of scale and scope.

In order to achieve an economy of scale, LHS infrastructure must support the ability to collect and exchange information across multiple sites, reduce the time and increase the scale at which learning occurs, and replicate practices across large-scale networks of health systems. A critical

focus of the LHS is the 17-year gap to implement effective research into clinical practice and improve patient care.[63,64] LHS emphasizes an improved data infrastructure which connects multiple nodes, i.e. systems and sites, and enables knowledge exchange across the U.S. to build an economy of scale for large-scale implementation studies and practice transfer efforts.

Infrastructures enable multiple learning cycles within a LHS, and all learning cycles depend on infrastructures rooted in technologies, policies, and standards.[5,65] Multiple infrastructures are required to support the functions of an LHS, and each essential for future design of standards, frameworks and performance measures for LHS capability and accomplishment. Literature pertaining to underlying infrastructures of LHS is limited. Most research in this area apply the term "infrastructure" loosely to address the data structures and data architecture required for basic outcomes and comparative effectiveness research in a health system, rather than defining communities of practice, personnel, processes, and training required to interact with data, knowledge and design processes for enhanced replication of innovative practices.[32,66-82] To date, Friedman et al., Dixon et al., (2016) and Britto et al., (2018) are the only works to embed LHSs in infrastructure theory and concepts.[5,31,65,71] Britto et al., discuss the use of the network organizational model to achieve a LHS, while Friedman sheds light on the ways infrastructure supports the virtuous cycle of learning (**Figure 2.1**).[5,65] The data infrastructure is central to a functional LHS, and opportunities for practice and behavior change in a health system must extend outward and upward from the data infrastructure to other infrastructural elements.[5] Data infrastructures may be essential for accomplishing LHS goals of improving care, outcomes, reducing costs and gradually building an economy of scale through reusable and repurposed patient health data.

Learning Health System Data Infrastructure

The data infrastructure required for LHSs should facilitate the iterative cycle of data to knowledge to practice (D2K - K2P - P2D) (**Figure 2.1**).[5] Commonly, this data infrastructure includes multiple health systems exchanging patient information under a large decentralized network and is referred to as a distributed data network.[68,83,84] Distributed data networks have many names and scopes (data marts, data repositories, clinical data networks, distributed research networks) and come in different types; they can either be composed of population-based data from multiple heterogeneous health systems or one multi-site homogeneous system, disease-focused and/or controlled by patient-advocacy associations/foundations. These networks are a key component for addressing the lag in time between knowledge generation and knowledge translation in the U.S. health system. The feedback loop, population-based outcomes, and practice change central to a fully functioning LHS can be supported by distributed data networks; however, developing a standard for LHS practice must be considered.

An LHS requires the use of biomedical data to generate knowledge, however a hospital system does not have to be a part of a distributed data network to advance learning and improvement initiatives. A single health center can only generalize its care to the population it serves, therefore multiple healthcare centers and systems are necessary to produce population-scaled generalizable knowledge, otherwise understanding rare diseases and their processes and outcomes is difficult.[85] Presently, most self-promoted LHSs are designed to primarily support high-yield, single-domain disease states.[86] As such, findings and practices are difficult to disseminate across non-member, non-integrated institutions. Distributed networks permit multiple health centers or a multi-site system to aggregate data, develop research priorities and enhance external validity of findings**.** This aligns with the infrastructure principle of *openness to*

number and types of users, and emphasizes the importance of multiple health systems, patients, clinicians, administrators, policymakers, researchers, and information technology personnel to all be considered stakeholders in a LHS's development. Most important is that patients and clinicians have access to this expanding and evolving learning infrastructure. Furthermore, openness to multiple users allows a system to increase momentum and growth over space and time and permits more researchers and practitioners to intervene continuously in addressing any existing reverse salients and critical problems.

A primary feature of any infrastructure is that it is not organic; rather, it is built on existing infrastructure, and shaped by an installed base of existing systems and practices. Distributed data networks are generally built from existing data infrastructures such as health systems EHRs[31], claims data, and national disease registries supported by non-profits and charitable organizations. These networks are also built on the existing research and policy infrastructure related to ethics, review boards,[87] and sections of the Health Insurance Portability and Accountability Act (HIPAA).

The NIH Collaboratory Distributed Research Network (DRN) is an example of the capacity of data infrastructure to achieve a significant reach and scope to users and how it is built on existing infrastructures.[88] The NIH Collaboratory DRN enables researchers to collaborate with each other in the use of electronic health data from many institutions, while also safeguarding protected health information and proprietary data.[88] It supports both single and multisite research programs with data exchanged from partners such as Aetna, Kaiser Permanente Washington Health Research Institute, Harvard Pilgrim Health Care Institute, and HealthCore, Inc.[88] A caveat to the NIH Collaboratory DRN and other clinical data networks, is their primary emphasis on research rather than engaging in health system practice changes and

clinical learning. Furthermore, openness to multiple users allows a system to increase momentum and growth over space and time. More openness to users permits more actors to intervene continuously in addressing any existing reverse salients and critical problems.

Clinical Data Research Networks

The Patient-Centered Outcomes Research Institute supports the development of clinical data research networks (CDRNs) as a faster, easier, and less costly infrastructure for clinical research.[29] CDRNs are distributed data networks that extract routinely collected patient health data from EHRs from multiple healthcare centers in the U.S.[89] CDRNs have the capacity to serve as necessary infrastructure to support continuously learning healthcare. Learning healthcare, based on the National Academy of Medicine definition, is the process of leveraging routinely collected patient health data (real-world data) to develop biomedical knowledge and "real-world" evidence to support clinical practices.[41,90-95] These networks are built to ensure that aggregated clinical data are ready for research use,[28,68,84,89] to reduce direct queries of the EHR and to link data from multiple healthcare systems using a common vocabulary. This is accomplished by extracting data elements from the EHR, transforming these into a common data model and loading the model into a data warehouse for future research purposes.

A distributed data network such as a CDRN improves the security of information, as most data are maintained and stored by each data-contributing partner in a network.[68,83,84] In this case, facilities retain their own data, but are capable of sharing for large-scale learning purposes. Standards differ across network members in patient data collection and storage and impacts the ability for simplified exchange and querying of patient information. EHR data elements are critical for CDRNs; however, these networks primarily exist in a disparate healthcare ecosystem. This ecosystem comprises heterogenous healthcare systems using different EHRs. Different

EHRs not only complicates interoperability and exchange of health data, but it also contributes to other challenges related to variation in clinical documentation practices. These include deficiencies in accuracy and completeness of standardized data for medical diagnoses, procedures, encounters, treatment interventions across providers, organizations, and regions.[96] A common data model (CDM) is an information infrastructural approach to address these issues and build a common vocabulary of health-related data elements. A CDM is used as a standard to which all local data are mapped, and helps develop a standardized data taxonomy across disparate data systems[97], and several different types of CDMs exist, such as the Observational Medical Outcomes Partnership (OMOP) CDM, PCORnet CDM, and the PEDSnet CDM for pediatric research (**Figure 2.6**).

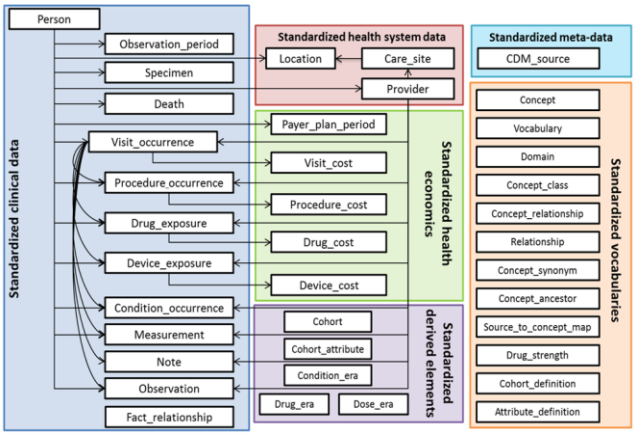


Figure 2.6. Observational Medical Outcomes Partnership (OMOP) V5

PCORI funds and sponsors PCORnet and its federated system of 13 CDRNs in the US, to improve the digital infrastructure for outcomes research and CER.[87,89,98-104] PCORnet and other large national data research consortia use this CDM approach to standardize data structures for heterogeneous partners.[97] Each PCORnet partner network is responsible for mapping data to a standard format (i.e., same variable name, attributes, and other metadata) to create a platform that enables rapid querying and responses to research-related questions.[97] Other healthcare systems participate in a CDRN and other distributed data networks as a part of a LHS or the infrastructure for a LHS.[3,66,69,78-80,98,102,105-109] Two of these are highly relevant to the purpose of this review because they surround pediatric healthcare; PEDSnet and Improve Care Now.

Although real-world examples of LHSs are sparse in the literature, the efforts by publicly and privately funded CDRNs and "health data marts" continue to support an extensive number of outcomes and comparative effectiveness research studies improves the literature base for developing a LHS.[65,79,110,111] Examples of these include PEDSnet, Improve Care Now Network, Learn From Every Patient, and Shriners Health Outcomes Network.[79,107,111,112] Private non-profit health systems such as Intermountain Healthcare, Nationwide Children's Hospital and Shriner's Hospitals for Children are the vanguard of the LHS movement, yet more work is needed.

PEDSnet

PEDSnet includes data integrated from a consortium of the eight largest pediatric hospital centers in the U.S. (Children's Hospital of Philadelphia (CHOP), Cincinnati Children's Hospital Medical Center (CCHMC), Children's Hospital Colorado, Nemours Children's Health System, Nationwide Children's Hospital, St. Louis Children's Hospital, Seattle Children's Hospital, and Boston Children's Hospital).[3] With over 2.1 million patients in this data network, maintaining security and privacy is crucial. Hospitals retain their own data for this reason but as noted above, use a common data model to ensure there is interoperability between children's hospital systems for data querying and sharing. PEDSnet is focused primarily on one disease state across its multi-system, non-integrated data network: inflammatory bowel disease. Although PEDSnet and other CDRNs have been successful with linking data across multiple hospital centers and systems using sophisticated data architecture methods and software programs, the extent that learning can be measured and achieved is relatively sparse.

In their classification of PEDSnet as a LHS, Forrest et al. do not address LHSs in the context of continuous learning, and subsequently report that PEDSnet is both a LHS and serves as the data infrastructure for a LHS.[3,107] Without any specified mode for continuous learning or

conceptual model/framework guiding this work, it remains unclear as to the efforts by PEDSnet to achieve a fully-functional national pediatric LHS. An investigation of the theories, frameworks and goals driving PEDSnet to help facilitate an LHS for its member health systems is warranted. Data quality procedures are commonly employed for CDRNs to ensure that data are accurate and complete, however CDRNs generally comprise heterogeneous healthcare centers with different EHR vendors and builds, which adds complexity to the transformation of data into a CDM. Based on an analysis of sources of data quality issues for PEDSnet, Khare et al. (2018) identify that approximately 35% of data quality issues are caused by the extract, transform, load code, and this may be due to the problems with heterogeneity of healthcare centers.[28]

Improve Care Now Network

Improve Care Now (ICN) is a distributed data network that supports learning efforts.[111] Similar to PEDSnet and LFEP ICN emphasizes the feedback loop in their work to improve the standardization of care for children with inflammatory bowel diseases (IBD), improve overall patient outcomes and patient care, and reduce complications and disease burden of IBD. Started in 2007 and based out of Cincinnati Children's Hospital, ICN grew from eight to 109 gastroenterology care centers around the U.S. over the past decade.[107,113] Initially established without PCORI funding, ICN is now funded by PCORI and aims to elevate clinical outcomes research for IBD**.**

Outcomes of implementation research efforts within ICN demonstrated an increase in remission rates of children with IBD by nearly 30% and reduced prednisone treatment in remission by 40% across its network.[113] The success of ICN resulted in the development of toolkits and dissemination of findings to help other facilities reach the same potential, and

parallels the concept of collaborative quality improvement groups previously discussed. Although ICN solely focuses on IBDs, it is an example of using standards and infrastructure to support large-scale learning. A recent study analyzed the data quality (completeness and accuracy) of medication lists between the abstracted data from ICN and data extracted from manual review of narrative portions of the EHR. Authors found variation in the accuracy and completeness in medication lists across sites and reported that their analysis may inform the improvement of site-level documentation practices to produce medication list data that are fit for quality improvement and research purposes.[19]

Learn From Every Patient

The LFEP program (**Figure 2.5**) at Nationwide Children's Hospital is just one type of local learning health facility that established a single-system clinical database and considers itself a LHS.[54] The LFEP program emphasizes the integration of clinical care, research and quality improvement through building a care coordination system for children with Cerebral Palsy (CP). The initial LFEP research was conducted in the Nationwide CP clinic over a two-year time-period. The goal of the LFEP program was to increase communication and minimize care fragmentation using interdisciplinary meetings after each clinic day to develop a care plan for each patient.[54] A care coordinator was also assigned to each patient to help the family navigate medical, insurance, and education-related issues.[54] The LFEP study published in 2017 by Lowes et al., was designed as a comparative effectiveness analysis at one site without randomization. Although main outcomes improved, these concerned aggregate level data regarding healthcare expenditures and rate of hospital utilization over the study period.[54] In the published work on LFEP, authors did report the use of a process model for guiding their work, but do not describe

an implementation plan or the practice changes designed and implemented, which limits its external validity. Thus, further investigation of LFEP to understand their LHS efforts.

As PEDSnet, ICN, and LFEP continue to scale and expand their scope, the data infrastructure may scale while other LHS infrastructures within partner systems lag. Furthermore, these networks demonstrate that data conversion and knowledge generation can be effectively supported, but a goal of conducting large-scale implementation-focused studies for clinical practice change and outcomes improvement is still distant. Chambers et al. (2016) and Nwaru et al. (2017) capture this problem well by highlighting that "Scientific breakthroughs remain incomplete until they are successfully, routinely implemented in clinical settings." [46,114] A primary step in achieving this feat requires knowledge of infrastructure and implementation research to dissect the structures supporting practice change and routine evaluation, and to investigate the perspectives of LHS practice by leading groups. These methods include: assessing mechanisms that support knowledge and practice transfer, identifying and investigating relationships, tensions and conflicts between stakeholders at different scales, and understanding strategies for scaling up, replicating practices, and supporting clinician behavior change across large-scale health systems.

SECTION 4. Computable Phenotypes from Electronic Health Record Data

Clinical documentation is important and can influence the care any patient receives, but what is more is the ability to leverage patient health data to measure clinical performance. Healthcare organizations currently struggle to leverage data stored within their EHRs to develop system-wide knowledge of care processes and to test and evaluate clinical interventions.[115] Data in their current state in EHRs or CDRNs, however, are also not conducive to simple measurement of clinical performance due to decreased documentation quality, missingness, or

the health conditions managed. Measuring performance, particularly from EHR data, requires an innovative approach to classify clinical features not easily conveyed by the current data elements. A new approach to leveraging these data is by re-use for LHS, monitoring, and research, and a helpful means to achieve these purposes is through developing computable phenotypes from these data elements.

Computable phenotypes are EHR-based definitions capable of identifying cohorts of patients with certain diseases or clinical profiles for disease management registries, quality improvement programs, evaluation studies, and interventional research.[116,117] While a phenotype is the physical trait expressed by conditions of a person's genes, a computable phenotype is a trait of a person expressed by the computable data in a person's medical record; that is, it is based solely on data elements from an EHR or CDRN and logic statements.[118] As Denny describes, data for phenotyping may include those routinely collected in the EHR, such as demographics, vital signs, laboratory tests, medication, diagnoses, procedures, and other documentation.[119,120] Some data elements may be stored in binary, categorical, free-text, or numerical forms. These forms comprise the value sets necessary to "AND, OR, NOT" Boolean logic for structured rules to classify.[96,119] Therefore, it is essential to determine the value sets for each data element being considered.[118]

Computable phenotype definitions enable continuous learning and research through cohort identification and can be thought of as infrastructure for LHS. These definitions help classify health conditions, characteristics and clinical features, but align well with dichotomous outputs, i.e. they have a condition, or they don't have a condition, based on value sets from standardized coding systems.[118] The innovation and importance of computable phenotypes surrounds the identification of patient populations with particular health-care related needs not

apparent by surveying the EHR. By creating a computable phenotype, data elements are consolidated that establish clinical features or building blocks of a computable presentation of a health condition or clinical state. We are then more apt to query large data resources like learning networks and produce an output containing generalizable knowledge.

Explicit, standardized phenotype definitions facilitate the reuse of clinical data and tools for population management, quality measurement, and research.[116] Further, the computable representation of knowledge—for example, knowledge embedded in clinical practice guidelines or drug-interaction databases—can support the dissemination and rapid adoption of automated clinical decision support tools, such as alerts, reminders, and customized order sets.[115] Although infrastructural solutions (CDMs) help mitigate much of the headache associated with the interoperability of these systems, there are differences in the types of data captured and how systems support clinical documentation practices. These differences may affect the reliability, validity, and overall reproducibility of computable phenotypes. Thus, whether across heterogeneous or homogeneous healthcare systems, documentation practices and the data produced for learning networks are critical to the development of high-quality computable phenotypes.

Richesson et al. and Denny describe the historical approach for using the method of expert-defined rules to develop a phenotype.[96,119] This is the most widely adopted method for computable phenotyping and begins with the manual development of an algorithm often using Boolean logic, scoring thresholds, or a decision tree and is based on domain expertise.[96] The structured rules of the condition are then iteratively enhanced through validation and chart review of EHR data.[96] Furthermore, the design of structured rules is included as one of the 10 Desiderata (**Table 2.2**) for computable phenotyping using EHR data developed by Mo et al.

(2015) and will guide this aim.[120] The first two Desiderata emphasize the importance of structuring data in a queryable form and ensuring that data are stored in a common data model.[120] The remaining eight Desiderata encompass the structured and systematic steps for developing, implementing and managing a computable phenotype.

Table 2.2. Desiderata for Computable Phenotyping, Mo et al. (2015).

Recommendations for clinical data representation to support phenotyping
1. Structure clinical data into queryable forms.
2. Recommend use of a common data model, but also support customization for the variability and availability of EMR data among sites.
Recommendations for phenotype representation models
3. Support both human-readable and computable representations.
4. Implement set operations and relational algebra.
5. Represent phenotype criteria with structured rules.
6. Support defining temporal relations between events.
7. Use standardized terminologies, ontologies, and facilitate reuse of value sets.
8. Define representations for text searching and natural language processing.
9. Provide interfaces for external software algorithms.
10. Maintain backward compatibility.

The latter eight recommendations characterize the process to build out a computable phenotype, evaluate it and operationalize it. The first three recommendations relate to the importance of developing a phenotype that uses structured rules that are both human and computer readable. As Mo suggests, temporal relations are ideal for studying response and side effects of medications,[120] and this should include accounting for progress in patients with physical impairments and response to therapy services. However, the purpose of the following work does not entail an analysis of the patient response to care and changes over time, thus this recommendation does not apply at this instance. The fifth recommendation applies to the proposed work in the sense that data elements and value sets need to conform to standard medical terminologies and ontologies to facilitate reuse by SHC and sharing with other pediatric-related CDRNs. Since SHOnet data are transformed into a common data model that already conforms to standardized terminologies and a controlled vocabulary, careful attention will be given to ensure that when evaluating value sets and data elements that labels and values maintain

their alignment with existing standards. Recommendations 6-8 do not apply because they concern the EHR support to implement and operationalize the computable phenotype in clinical practice.

Computable phenotypes are vital infrastructure for LHS because they can be queried and exclude researchers from the time-consuming process of sifting through the EHR. LHS activities can also improve the quality and completeness of data in CDRNs and other learning networks that are used to create computable phenotype definitions. Networks such as PCORnet and the NIH Collaboratory use computable phenotypes to identify patient cohorts and clinical events to conduct observational and comparative effectiveness research. Many computable phenotypes are built directly from EHR data elements. However, the preferred method is to build them from common data models (CDM) for scalable observational research.[118,120,121] Representing EHR data elements using a CDM is one of the primary desiderata described by Mo et al. for jumpstarting the phenotype process and ensuring data are structured in a queryable form.[120] A CDRN that uses a CDM (**Figure 2.6**) maximizes the generalizability and implementation of a computable phenotype in clinical settings across different clinical settings that participate in the CDRN.

Currently, scientific literature is limited on the power of computable phenotypes to aid learning and measurement of performance in healthcare systems. Although no single consolidated repository exists to share all computable phenotype definitions, several dozen phenotypes are publicly available in a phenotype repository at www.phekb.org. This site contains phenotype definitions and provides documentation and information on phenotype performance measures. After reviewing this repository, an overwhelming majority of computable phenotypes relate to physiological responses and disease classification, and most are produced

from PCORnet nodes. This provides an opportunity to construct computable phenotypes that classify or define health-related conditions such as physical function and disability. Currently, there is also no literature which applies the Desiderata for computable phenotyping to representing computable forms of motor function or any other variables pertinent to measuring functional performance for orthopedics and physical rehabilitation. This first aim will build the foundation for further development of functional performance phenotypes for conducting measurement and health outcomes studies that transcends the classification of disease or lab values.

SECTION 5. Shriner's Hospitals for Children, Cerebral Palsy, and the Shriners Health Outcomes Network

Shriner's Hospitals for Children System

Shriner's Hospitals for Children is (SHC)is a philanthropic network of 20 pediatric care sites in the US, one in Canada and one in Mexico, providing specialty services for orthopedic problems, burns, spinal cord injuries, cleft lip and other complex surgical needs.[122] The mission of SHC is three-pronged in the areas of 1) providing the highest quality care to children, 2) advancing the education of clinicians, and 3) conducting research to advance quality of care and patient quality of life. Each hospital has a specialty area in orthopedics, burn care, spinal cord injury and/or cleft lip and palate care, but is equipped to treat most pediatric patients.[122]

Shriners International, a society of freemasons established in 1870, passed a resolution in 1920 to create the hospital system.[122] The first SHC opened its doors in 1922 in Shreveport, LA, providing orthopedic care to children suffering from the crippling effects of the polio epidemic of the times.[123] Thirteen SHCs opened by 1930, and the first three burn treatment and rehabilitation centers were established in the early 1960s.[122] Many of the SHCs developed

partnerships with large academic medical centers to advance research efforts for developing and integrating innovative treatments into routine care. Most notably, the Philadelphia SHC has a partnership with the Temple University Medical Center, the Northern California SHC in Sacramento has a partnership with University of California-Davis Medical Center and the St. Louis SHC has a partnership with Washington University in St. Louis School of Medicine.

Overview of the Shriner's Health Outcomes Network

In 2015 SHC began building the Shriners Health Outcomes Network (SHOnet) to support LHS efforts for pediatric orthopedics and rehabilitation. SHOnet uses an "extract – transform – load" process, much like other learning networks (i.e. PCORnet), to extract existing data elements for all patients from EHRs at 21 SHC sites, transform them into a pediatric-specific CDM to support standard terminologies and data structures for observational research (OMOP (**Figure 2.6**) in pediatrics, and load these data into SHOnet.[124,125] The conceptual schematic of the SHOnet Learning Model is depicted in **Figure 2.7**. SHOnet stores these data on a secure server at SHC headquarters in Tampa, FL. SHOnet can be operationalized for system research and learning purposes and presents an opportunity to move the fields of learning health sciences and rehabilitation sciences forward to improve and innovate measurement of rehabilitation practice. One of the largest patient populations managed by SHC is Cerebral Palsy (CP), thus SHOnet supports many system-wide opportunities to generate meaningful knowledge and inform clinical practice for managing CP.

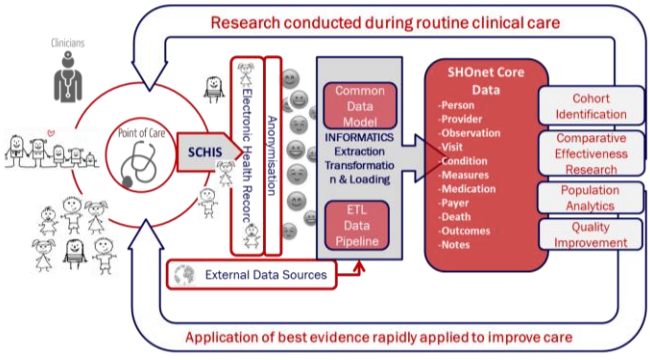


Figure 2.7. Schematic of SHOnet Learning Model.

Through collaboration with a community of SHC clinical and system leaders, patients, and their families, SHOnet supports large-scale system research studies to impact clinical practice and improve the health of children cared for by the SHC system.[125] The goal of SHOnet is to facilitate a LHS capable of rapid, continuous learning about its patient care and patient outcomes, and serve as an incubator for research on dissemination and implementation of new practices.[124,125] SHOnet was initiated in 2015 through Shriner's grant funding, and accomplished all of its initial phase 1 proposed objectives, including: 1) developing the data warehouse based on standardized terminology, a data model and data elements; 2) strict quality control and data validation processes to ensure the highest quality data; 3) scientific and regulatory process and procedures to guide data sharing, data security and data management; and 4) partnerships with clinicians, researchers, patients and families, and SHC stakeholders.[124,125]

SHOnet recently received a three-year grant, awarded in January 2020, to conduct its phase 2 work. It is focused on expanding, utilizing and sustaining the rapid generation of new, highly impactful knowledge about best practices for patient care and translate that new knowledge at the point of care.[125] The three primary aims of SHOnet phase two are to: 1) Expand the SHOnet informatics and scientific infrastructure to support learning; 2) Establish processes for using SHOnet resources to conduct research and knowledge generation and that support a learning health system culture; and 3) Establish a knowledge translation approach to reduce the gap between scientific discovery facilitated by SHOnet and SHC clinical care. [125]

The end goal of SHOnet is to have a fully-functioning and sustainable data and scientific infrastructure that is interoperable with other national LHS data networks, and that will serve as a mechanism to develop active research programs with a clear and measurable impact on patient care and outcomes across SHC.[124] Currently, SHOnet has six demonstration projects addressing

two primary disease states: osteogenesis imperfecta and cerebral palsy. As such, the subsequent work outlined in this document will focus on a developing generalizable knowledge and to indirectly support SHOnet demonstration projects that aim to understand clinician practice patterns to manage children with cerebral palsy (CP).

A core team of researchers are leveraging SHOnet data sources to optimize an understanding of practice patterns and patient outcomes for SHC to become an LHS. The SHOnet core team of researchers designated CP as a LHS research priority for SHOnet.[125] A CP collaborative research group (CRG) of 20 SHC investigators was formed to develop LHS-focused research priorities for children with CP.[125] The CRG drafted projects based on consensus criteria to test the value of SHOnet data resources. Subsequently, the CRG developed a demonstration project to understand clinician hip surveillance practice patterns for children with CP and hip dysplasia.[125]

SHC, although multi-site, is more a homogenous care system than the care sites that comprise most other pediatric CDRNs, and this bodes well for leveraging SHOnet data elements for measurement and learning purposes. Despite its potential differences regionally, SHC has uniformity in many areas: 1) it uses the same EHR vendor, 2) began EHR implementation in 2005 with full system-wide deployment in 2007, 3) maintains a similar EHR build and interface across sites, 4) provides specialty care to a narrow set of health conditions, 5) employs health professionals that share the organization's mission, vision and values, and 6) requires all clinicians to complete system-wide standardized trainings and competencies. All these factors help minimize, but do not eliminate, the variation in clinical documentation practices across SHC. Furthermore, given the SHC model of care includes more charity care than many other systems, some aspects of documentation are less mature than others, for instance CPT codes and

other billing technologies and requirements. Despite its homogeneity, recent queries of SHOnet demonstrates inconsistencies of key data elements for measuring functional performance of CP cohorts, which are instrumental to measure quality of care, patient health outcomes, and response to treatment interventions.

Cerebral Palsy

Cerebral Palsy (CP) is an exemplar condition to study as a use-case for SHOnet because it meets the following five criteria: 1) It is a condition that is prevalent across SHC and a high volume of patients annually. 2) The level of care involves a trans-disciplinary team (i.e. physician, nurse practitioner, physical therapist, occupational therapist, etc.). 3) Patients require multiple outpatient and inpatient care visits. 5) The condition results in impairments of body structures or functions, and restrictions in activities and participation in daily tasks.

CP is a heterogenous group of conditions that leads to dysfunction of motor control, movement, and posture. It affects the developing and immature brain, resulting in a permanent and nonprogressive dysfunction of the central nervous system.[126-129] Although CP is considered a nonprogressive disorder, it does result in progressive musculoskeletal dysfunction.[127] At its mildest form, individuals with CP present with mild unilateral spasticity and contracture in one arm and one leg.[126,127] Both inattention to sensory/environmental stimuli and a unilateral visual field deficit may also be present, depending on the disorder severity.[127] At its most severe, a child with CP may present with bilateral involvement of arm and leg motor dysfunction related to spasticity and contracture, while also displaying severe dyskinesias and postural instability.[127] Some forms of CP also associate with severe learning disabilities, high risk of infection, seizure disorders, and severe visual impairments.[127,129]

Etiology

Most CP cases result from an interference in brain development *in utero* (congenital) but can also occur post-neonatally (acquired). According to the U.S. National Institute of Neurological Disorders and Stroke (NINDS), congenital brain damage can result from the following events: damage to white matter in the brain; asphyxia; abnormal brain development; fetal stroke.[129,130]

Damage to the white matter of the brain around the ventricles (periventricular leukomalacia) can cause death of nerve cells necessary for motor control and is directly related to progressive muscle spasticity during child development.[129,130] A fetus is most sensitive to damage of the periventricular white matter between 26 and 34 weeks of gestation.[130] Asphyxia refers to a lack of oxygen in the brain caused by poor oxygen supply. A fetus or neonate is at severe risk of developing hypoxic-ischemic encephalopathy if the supply of oxygen is cut off or reduced for lengthy periods, which destroys tissue in the cerebral motor cortex and other areas of the brain.[126,127,129,130] Problems involving the umbilical cord or severe head trauma during labor and delivery can also result in asphyxia. Asphyxiation, however, is presumed to only account for 10–20% of CP cases.[127] Abnormal brain development related to mutations in the genes that control the developing brain, or infections, fevers, trauma to the mother could compromise the unborn baby's nervous system development, thus resulting in CP. Fetal stroke, either intracranial hemorrhaging or ischemia, due to blood clots (i.e. thromboembolism) in the placenta that block blood flow in and to the brain during development can occur, resulting in underdevelopment and even death of brain tissue.[129,130] Maternal hypertension and/or maternal infection both increase the risk of fetal stroke if not properly treated.

Acquired CP occurs in the event of brain damage during the first few months or years of life. Such brain damage can be sustained from brain infections (i.e. bacterial meningitis or viral encephalitis), poor perfusion of the brain with blood, or traumatic/anoxic brain injuries from traffic collisions, falls, child abuse, or asphyxiation.[130]

Epidemiology

The prevalence of CP globally is 2-3.5 cases per 1000 live births, or 1 in 323 births, and it is one of the most common motor disabilities of childhood.[127,128] Approximately 17 million people worldwide have a diagnosis of CP.[131] Over the past 30 years, prevalence of CP remained relatively stable with advances in technology and treatment of maternal infections during pregnancy and improvements in neonatal care.[132] Continued technological advances may contribute to an increased prevalence rate of CP due to more premature babies born, especially since 85-90% of all CP cases are congenital.

Prevalence of CP is inversely related to birthweight and gestational age; nine percent of cases are associated with low birthweight (< 2.2 pounds), and .15 percent of cases are associated with normal birthweight or heavier (≥ 5.5 pounds).[127,129,130] Having multiple pregnancies is often thought to be a major risk factor for CP, but its effect is often confounded by birthweight and gestational age.[127] The risk of CP increases in twins and more than doubles for triplets.[127] A 2013 systematic review reported several risk factors significantly associated with CP, these include: placental abnormalities, major and minor birth defects, low birthweight, emergency cesarean section, birth asphyxia, neonatal seizures, respiratory distress syndrome, hypoglycemia, and neonatal infections.[133]

CP is more prevalent in boys than girls, and it disproportionally affects African American children more than non-Hispanic white children.[129]Approximately 80 percent of children with

CP have spastic CP, while over 25 percent of children with CP commonly are afflicted with a seizure disorder.[130,131,134] CP is also associated with several types of impairments, and these can range from poor mobility and speech, to difficulty controlling oral secretions (i.e. saliva). Half of all children with CP have an intellectual impairment due to the global nature of the disorder to the brain.[131] Approximately one-third are unable to walk and a quarter are unable to talk or communicate effectively.[131] Over 75 percent of children with CP experience pain regularly due to muscle spasticity and/or joint instability related to hip dysplasia and severity of CP.[131]

Gross Motor Function Classification System

The severity of CP is assessed using the GMFCS, a five-level classification system developed to assess and describe the gross motor function of children and youth with CP on their ability to sit, walk, and/or manage a wheelchair.[135] The GMFCS levels are described in the illustrations in **Figure 2.8**.[135,136] Each level identifies specific functional abilities and captures the need for assistive technology and devices to enhance the performance. The GMFCS is used as part of the routine clinical evaluation for CP. This standardized tool enables clinicians to quickly classify a patient's abilities and limitations in gross motor function. The GMFCS primarily concerns a person's functional performance related to what they can do at home, school, and in community settings, and the levels provide a measurable entity for improvement and prognosis.[131,135,136] GMFCS level remains relatively stable after 2-years of age in CP patients.[137,138]

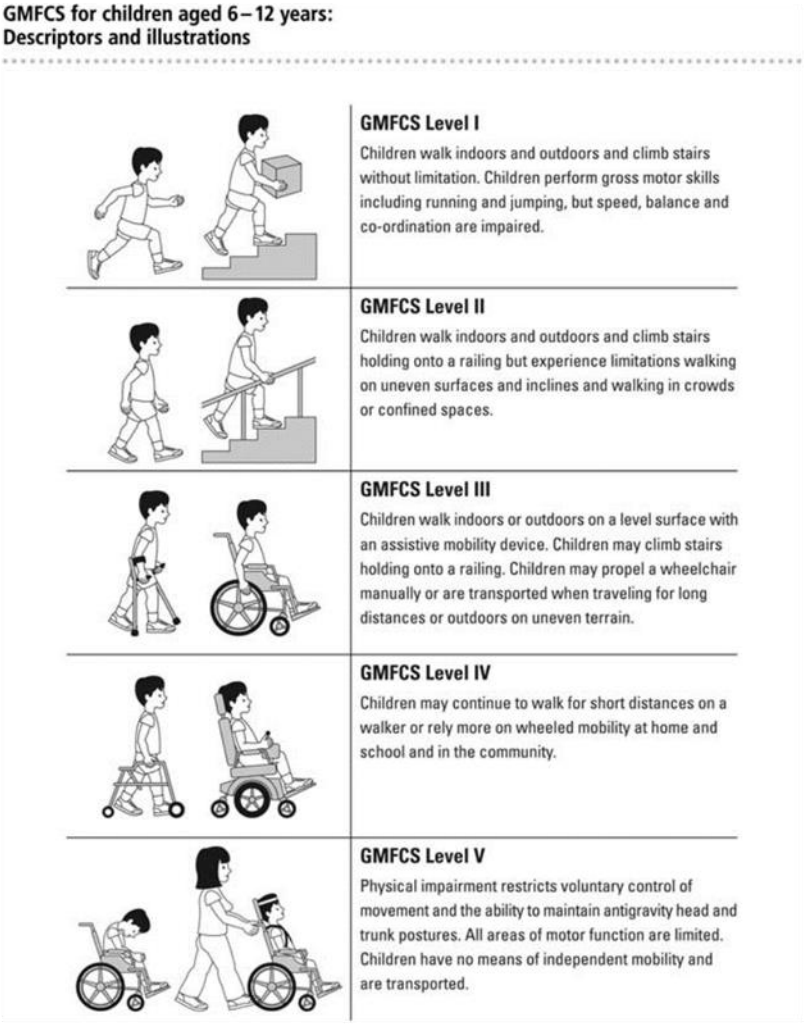


Figure 2.8. GMFCS descriptors for GMFCS 6-12 Years. Palisano et al. (1997) Dev Med Child Neurol 39:214–23. Illustrations copyright © Kerr Graham, Bill Reid and Adrienne Harvey, The Royal Children's Hospital, Melbourne.

Comparison Between GMFCS Levels

The following describes each GMFCS level based on the CanChild and Palisano et al. case definitions and the comparisons between levels.[136,139] First and foremost, there are age-based differences for GMFCS levels which are classified into five groups (before 2nd birthday, between 2-4 years, between 4-6 years, between 6-12 years, and 12-18 year). This work will only focus on two age bands (6-12, 12-18) which relate to school age and older children since children are developing gross motor skills from birth to 6 years old. For the purposes of

simplicity, since the distinction between GMFCS levels for age-bands 6-12 and 12-18 are relatively similar, these will be collapsed into one age-band for children 6-18 years-old.

Children at GMFCS I have the least severe dysfunction in motor performance for mobility and movement. A child classified as a GMFCS I should demonstrate, without difficulty, participation in activities at home, school, outdoors and in the community. They can negotiate curbs and stairs without physical assistance, a mobility device, or a railing. Although agility, balance and coordination are affected in children with CP at different gradations and limitations, children at GMFCS I can still perform running and jumping tasks without difficulty and participate in sports and other physical activities.

The primary distinction between a child classified as a GMFCS I versus a GMFCS II concerns mild limitations in balance, strength, and sustained activity tolerance in those at GMFCS II. These children may require the use of hand-held mobility devices, handrails, or minimal physical assist to negotiate stairs and curbs, uneven terrain and when in carrying objects. A child at GMFCS II may require a wheeled mobility device when traveling long-distances. The joint integrity level between children at GMFCS I and GMFCS II is reported as minimal difference, therefore when classifying GMFCS phenotype, there is consideration to collapse these levels into one level since for clinical significance to inform hip surveillance practice.

The distinction between GMFCS III and GMFCS II is clearer than GMFCS II versus GMFCS I. A child classified at GMFCS III may use an assistive device (unilateral or bilateral hand-held forearm crutches, rolling walker, etc.) for most mobility indoors (i.e. school, home), demonstrates decreased pelvic stability when sitting, and requires a wheeled mobility device for long distances outdoors and in the community. These children are strong enough to go up and

down steps, but they often require supervision or minimal physical assistance and hold onto a railing to negotiate stairs. These children may need minimal physical assistance or guarding and a supportive surface to transfer from sitting to standing or from the floor to standing because of generalized weakness and decreased motor control. Children are limited in their participation in sports and other physical activities due to impairment in mobility, often requiring adaptive equipment (manual or powered wheelchair) and/or adaptations to activities to participate.

The differences between children classified as GMFCS IV and III are more noticeable. Rather than using a hand-held assistive device for mobility in some indoor and outdoor settings, children at GMFCS IV require physical assistance from another person for mobility in all settings, and sometimes use powered wheelchair mobility. Children at GMFCS IV demonstrate decreased strength and balance in sitting and require adaptive seating and need physical assist to complete all transfers from sit to stand, bed to chair, floor to stand, and any transfers necessary to perform activities of daily living. While children at GMFCS III may need adaptations or adaptive devices to perform sports and other physical activities, children at GMFCS IV require adaptations, adaptative devices and physical assistance and/or a powered mobility device.

Children at GMFCS IV and V are not much different from one another. The primary feature distinguishing GMFCS V from GMFCS IV is the level of dependency these children require for completing all activities. This dependence includes the use of manual or powered wheeled mobility in all settings, the use of total physical assistance to complete all transfers and the use of assistive technologies to improve head alignment, seating, standing, and/or mobility. Movement and motor control are extremely poor, limiting performance of activities by these children, therefore they require total assistance from adults and activity adaptations to participate. Due to the severity in motor dysfunction and the corresponding weakness and

spasticity, children at GMFCS V have higher rates of displacement and dislocation of hip joints. They may require assistance and technologies to complete genitourinary function, medication management and feeding.

Hip Dysplasia and Complications in Cerebral Palsy

Hip dysplasia is a common complication of CP and occurs because of neuromuscular imbalance on the growth and development of the hip joint and is accompanied by significant pain and problems with gait, sitting, and hygiene.[128,140] Approximately 35 percent of children with CP have a hip dysplasia,[140] which results in pain due to the instability and abnormal migration of the head of the femur in the acetabulum of the pelvis. As hip dysplasia progresses in children with CP, it can lead to many functional limitations and hip disorders such as hip displacement, subluxation, dislocation, degenerative joint disease and can cause severe pain if not monitored.[140] The progression of hip dysplasia is a permanent process, occurs over several years, and once a hip begins to subluxate, frequent treatment is needed for correction.[128,141]

Research demonstrates that GMFCS level is a strong indicator of whether a child is at risk developing a hip dysplasia, hip displacement and/or dislocation.[140] Children with GMFCS level V have a 90 percent incidence rate of developing a hip dysplasia. Incidence of hip dysplasia is lower in children that demonstrate the ability to pull to standing by three years-old and have better associated outcomes if a hip disorder does occur[128] A child with spastic CP, muscular imbalance and poor motor control and function may be at risk for further complications and highly susceptible to hip dysplasia.[142] Spasticity refers to a velocity-dependent increase in resistance to passive muscle stretch (i.e. hypertonia).[142] Furthermore, spasticity in CP is often accompanied by weakness, hyperreflexia and clonus. Spasticity becomes prominent during periods of stress and can also be observed during sleep. Severity of tone and spasticity can be

assessed on a patient's upper extremity. A patient with spastic CP often presents with increased flexor or extensor muscle tone at rest and the arm becomes harder to move as more resistance is applied.[142] Spasticity generally occurs during this assessment as a resultant involuntary contraction of the muscle, characterized as stiff, jerky and imprecise. Spasticity in a child with hip dysplasia is also a "strong etiologic factor" of hip displacement, especially among patients with CP classified as GMFCS levels of IV or V.[128]

Hip displacement occurs because of continued contractures and spasticity of hip adductors, flexors and hamstring muscles which rotate the hip internally.[143] Clinicians apply the Reimer's method using X-Rays of the pelvis for determining hip displacement in children with CP. This method is a standardized technique to assess the percentage of lateral migration, i.e. migration percentage (MP), of the femoral head and is the primary radiographic measurement used for hip surveillance and treatment planning.[128,144-147] An MP of less than 25 percent at 4 years-old is considered normal.[128]

Hip displacement is more frequent in quadriplegia (four-limb) than in diplegia (two-limb), with a progression in MP found to be four times greater in the former.[128] This aligns with the GMFCS levels, as GMFCS IV and V concerns children that are wheelchair bound and require maximum physical assistance due to poor extremity strength and motor control. As a hip dysplasia progresses to dislocation, it becomes more painful because of degeneration in articular cartilage on the femoral head secondary to pressures from the surrounding soft tissues.[128] Increased spasticity and poor motor control of more complex patients also places them at increased risk for hip displacement and dislocation as they age. As patients with GMFCS level III and IV age and grow, they may become more prone to hip dysplasia, which will increase pain, reduce quality of life, and decrease participation in daily activities. Displacement generally

occurs before five years-old in children with a hip dysplasia, however research demonstrates children 4-12 years-old are at greatest risk of displacement.[128,148,149] In this case, emphasis on improving and standardizing hip surveillance systems at early ages for children with CP will maintain gross motor control through physical and occupational therapies and prevent future hip displacement and/or dislocation events.

Hip Surveillance in Cerebral Palsy

While over one-third of children with CP have a hip dysplasia, hip displacement affects between 25 and 60 percent of those cases, with approximately 10-15 percent leading to hip dislocation.[128] Hip surveillance is the process of monitoring and identifying the critical early indicators of hip displacement.[128,140,150,151] Hip surveillance pathways are designed to promote early detection and treatment of hip dysplasia in children with CP to prevent future displacement and/or dislocation. Hip surveillance may be delivered by trained professionals working in small tertiary health centers where children with CP receive specialized care and services; or it may be mandated from a centralized entity and implemented in regional centers, which aligns with the structure of SHC.[152] Recommendations constitute serial radiographs of a patient's hip joint MP. National hip surveillance recommendations and standards were developed and implemented in Australia (**Figure 2.9**) and Sweden (**Figure 2.10**) and date to the mid-1990s.[153,154] Hip surveillance guidelines are limited in the U.S.; in September 2017 the American Academy for Cerebral Palsy and Developmental Medicine (AACPDM) adapted recommendations from Australia and created their own Hip Surveillance Pathway. Implementation success of the AACPDM Pathway in the US is unknown. Although few studies analyzed the results of hip surveillance pathways, available evidence supports the implementation of surveillance programs for children with CP.[128,143,145,155] Internationally, programs established that hip joints with a

Figure 2.10. Australian Hip Surveillance National Recommendations. Guidelines recommend the following screening protocol:

All Patients	• Establish a baseline GMFCS Level and Winter, Gage and Hicks Gait Type • A pelvic X-Ray between 1 and 2 years-old for all children diagnosed with CP
GMFCS I	• Additional physical screenings at 3 and 5 years-old • No additional radiographic follow-up unless the GMFCS Level changed
GMFCS II	• Follow-up clinical exams with pelvic X-Rays one year after initial evaluation, again between 4 and 5 years-old, and again between 8 and 10 years-old • If the MP remains stable (no change >10 percent over a 12-month period) and the GMFCS Level is unchanged, these patients will continue with evaluations every four to five years • If the MP is unstable, then yearly assessments and pelvic X-Rays should be performed
GMFCS III, IV	• Follow-up evaluation six months after initial screening. • If the GMFCS Level is the same and the MP is stable, pelvic X-Rays should be obtained every 12 months. • If the MP is unstable, then clinical and radiographic evaluations should be performed every six months. • If the MP is less than 30 percent and stable and the GMFCS is unchanged at 7 years-old, pelvic X-Rays may be discontinued until prepuberty (typically age 11 for girls and 13 for boys).
GMFCS V	• Follow-up clinical examinations and X-Rays should occur every six months • If the MP is stable and less than 30 percent at 7 years-old, X-Rays should be performed every 12 months.

Figure 2.9. Swedish Hip Surveillance Guidelines.

GMFCS I – No radiograph unless clinical deterioration.

GMFCS II – Radiograph at ages 2 and 6; if no deterioration and MP <33% continue to monitor clinically.

GMFCS III-V – Annual radiograph to age 8 after confirmation of CP diagnosis, >8 y old, monitor clinically.

migration pattern greater than 30 percent are at risk for progressive displacement and dislocation.[146,152] Migration of greater than 50 percent will not reduce spontaneously and over one-third of those will progress to dislocation.[128,141]

Hip surveillance is an important practice to standardize in the U.S. for several reasons. The incidence of hip subluxation and dislocation is correlated with severity of CP, as measured using the GMFCS.[145,146,155] Hip displacement occurs in less than five percent of children with a GMFCS level I, i.e. independent mobility; however, a hip displacement occurs in over 60 percent of children with no walking capacity, or GMFCS level IV and V.[149,156] Current research is limited regarding the extent that pediatric clinicians adhere to measuring key indicators for hip

surveillance, i.e. GMFCS and routine radiographs at indicated time points based on severity and age, in clinical care settings.

Overall, clinicians treating hip dysplasia in children with CP focus on maintaining a flexible, reduced, and painless hip.[128,140,157] The goal of a hip surveillance program is for clinicians to assess patients at risk for progressive displacement and seek to intervene early enough to prevent pain, decreased motion, and decreased quality of life associated with painful dislocated hips.[153,154] Institutions in Australia and Sweden are at the forefront of improving the knowledge base of risk factors related to hip displacement and dislocation among children with CP through their national hip surveillance programs.[143,153,154,158] Specific recommendations for screening points over time vary across these hip surveillance programs, but all maintain the use of GMFCS level and MP for guiding screening procedures. The Australian and AACPDM guidelines also emphasize the use of the Winters, Gage, Hicks Gait Type (WGH) for children with hemiplegia.[159] This is a four-level classification system of walking patterns that become prominent at 4-5 years old. Gait type levels of I-III require standard hip surveillance protocol as indicated by GMFCS level. A child with WGH level IV gait pattern indicates decreased mobility and hip-joint integrity; thus, a child is at risk for late-onset progressive hip displacement and requires ongoing surveillance, irrespective of GMFCS.[160] Pruszczynski et al. (2016) conducted a systematic review to develop a simplified version of consensus hip surveillance recommendations based on existing literature (**Figure 2.11**).[143]

Figure 2.11. Pruszczynski et al. (2016) simplified hip surveillance recommendations.

GMFCS Level (Migration Percentage)	Children age 2-8 years:	Children age 8-18 years:
GMFCS I and II (MP <30%)	One radiograph	None
GMFCS I and II (MP >30%)	Annual radiograph	Every 2 years
GMFCS III, IV, V (MP<30%)	Annually	Every 2 years
GMFCS III, IV, V (MP>30%)	Every 6 months	Annually

Although sparse, literature demonstrates that implementation of a comprehensive hip surveillance program results in an increase in early soft tissue surgeries and skeletal hip reconstructions and decreases the incidence of hip dislocations and salvage surgeries over long periods of screening.[152] Hip surveillance system studies conducted in Australia and Sweden demonstrate the extent that early screening and routine surveillance can help prevent displacement and dislocation events. Connelly et al. (2009) found that, of the 208 children who participated in an Australian hip surveillance program, only 15 children developed a hip dislocation over a 12-year period.[158] Two patients with hip dislocations underwent salvage procedures, while six were found on follow-up exams or were the result of surgical intervention. Kentish et al. (2001) also evaluated Australian hip surveillance recommendations over a five-year period and, of the 1240 people included in the hip surveillance data, only one patient developed a hip dislocation.[161] Hagglund et al. (2014) reported on a study to examine Swedish hip surveillance.[145,155] Their 20-year retrospective cohort study of 689 patients assessed a hip surveillance protocol pre-post implementation and found that early screening and routine surveillance of children with spastic CP was beneficial in reducing the number of dislocation events.

British Columbia (BC) is leading the Canadian effort to develop and implement a provincial consensus on hip surveillance, which was updated in 2017 to align with AACPDM. The initiative is guided by Child Health BC, a provincial health network composed of leaders in pediatric health from all of BC's health authorities, and fully launched in Fall 2016 after five years of planning and pilot testing.[162] The primary purpose of the Child Health BC hip surveillance initiative is to facilitate province-wide implementation and integration of recommended hip surveillance standards into clinical practice, and to provide a standardized

approach to management of needs for this patient population .[162] The network provides resources and tools on its website regarding how it developed standards, and is currently building its hip surveillance database, recruiting patients and facilities, and continues to disseminate the consensus across BC.[162] As of March 2018, total provincial recruitment of children with CP was 686, which accounts for approximately 32 percent of children with CP in BC born between 2000-2016.[163] The network publishes brief quarterly reports regarding program efforts to build awareness and infrastructure for hip surveillance and care delivery. Furthermore, Child Health BC has other initiatives and programs for related to other pediatric health concerns; many of which align with LHS concepts at a national level.

Hip surveillance is a less reactive and more proactive approach to preventing future complex surgeries and has the potential to reduce costs of complex care if properly implemented and adherence is maintained.[152] Hip surveillance for CP is a high priority for SHC to address critical infrastructure issues and to test their potential for LHS transformation. Shriner's does not have a standard for hip surveillance practice, however, Northern California SHC pediatricians Jon Davids, MD, and Vedant Kulkarni, MD, are currently assisting with the development of hip surveillance guidelines for the State of California that may translate to use across SHCs. Information on these guidelines is not yet available. Documentation standards are essential to building an improved system of learning and care delivery; however, little is known surrounding the documentation and practice patterns by clinicians treating children with CP. Initiating approaches to assess these processes and implement standards for GMFCS and hip surveillance may contribute to reduced complications associated with hip dysplasia. Outcomes following surgical management of hip disorders are also improved when performed earlier in the course of the disease process.[140,145,155,164,165] Implementing improved practice standards for hip

surveillance, therefore, could trigger early surgical intervention and improve participation and quality of life for children with CP.

SECTION 6. Implementation Research Approaches for Learning Health Systems

Health systems may have infrastructures to develop new knowledge and seek efforts to change practice, but oftentimes adoption of new practice standards does not occur.[54] On one hand, in a traditional health system, managers and system administrators often vacillate between addressing system problems[54] and making small fixes over time based on familiarity with a specific strategy, with little participation from clinicians. The focus is often on whole hospital performance indicators (i.e. readmission rates, infection rates, etc.) and aggregate data as outcomes.[166] The proposed solutions occur with limited knowledge of the antecedents, relationships and tensions within systems, and without environmental scans that help to understand the breadth of clinical practices in motion and barriers to optimal clinician performance. They also, unfortunately, do not result in the idealized reach and scale of new practices and protocols. An LHS, on the other hand, emphasizes building infrastructure to support continuous assessment of practice patterns and disease-specific patient outcomes, and the design of projects to understand and evaluate variation in patient care and health outcomes to determine what and how evidence-based practices should be implemented. Achieving these efforts is critical for LHS researchers and requires knowledge and skill regarding implementation science.

Implementation and Implementation Research

Implementation is classified in the literature as both an event and a process, depending on the field one subscribes. In the organizational studies literature, Linton (2002) subscribes to

implementation as the culmination of activities between the adoption phase of an innovation and the point where the innovation becomes routine or is abandoned in an organization.[167] May and Finch push Linton's definition further, adding that implementation also embeds the techniques and technologies required for implementation evaluation.[168,169] This perspective of implementation should be considered when seeking clinical practice transformation.

In the health informatics community, according to Cresswell (2016), the barriers to successful implementation of health information technology (HIT) comprise both social and technical factors. Research on the implementation of HIT, however, is limited to installation and adoption by clinicians and practice settings, focused on technical use, and surrounds the technology's physical influence on general care processes. Implementation of new documentation standards in clinical settings using EHRs should account for the social and technical interrelationships that exist in the healthcare system. Understanding how clinical documentation is performed EHRs and what is documented, rather than the EHRs disruption or transformation of care delivery[167] significantly contributes to the field of implementation and implementation research.

The field of implementation research surrounds the translation of knowledge and replication of innovations into practice. While implementation is integral to the LHS cycle, learning cannot be achieved or known without studying clinician behavior change surrounding the implementation of an intervention, technology, or new clinical practice. Eccles and Mittman (2009) define implementation research as the scientific study of methods to promote the adoption and uptake of research findings and other evidence-based practices into routine practice.[170] It aims to improve the quality and effectiveness of health services through the study of factors influencing healthcare professional and organizational behavior.[170] Implementation efforts

across a large-scale healthcare network requires supportive infrastructures with the necessary components for enabling the smooth transfer and replication of practice patterns to improve care delivery and patient outcomes, and to address the barriers influencing practice adoption. This is accomplished only through using environmental scans and applying an ethnographic approach to understand how people perform in clinical settings. Studying how clinicians perform documentation offers insight into the factors influencing documentation practices and data quality, and subsequently the opportunity to develop effective implementation strategies to improve documentation of key data elements for LHS activities.

Implementation science emphasizes the use of theory-informed systematic approaches to optimize the effectiveness of an intervention or practice change in improving patient care and patient outcomes.[171] Specifically, these approaches help to understand critical factors influencing intervention implementation and to characterize how a new treatment or intervention should be tailored for clinicians within one system, or across multiple systems.[171] The use of a systematic approach ensures that each step of the implementation process can be evaluated and maximizes the external validity, while a theory-informed approach maximizes the replicability of the treatment intervention to other settings.

Identifying and understanding barriers influencing successful the adoption, implementation, evaluation, and scaling of practice change garnered increased support over the past decade; however, literature relevant to implementation science in the context of LHS remains sparse. The Cochrane Effective Practice and Organization of Care group categorized barriers into nine groups that could potentially impair the effectiveness of an intervention to improve professional practice: information management, clinical uncertainty, sense of competence, perceptions of liability, patient expectations, standards of practice, financial

disincentives, administrative constraints.[172] Furthermore, individual clinician resistance, organizational culture and climate, communities of practice, absence of using a theory-informed approach or a practice framework/model all influence successful knowledge translation and practice change. A change strategy may also fail to take the intended effect or result in unintended consequences if contextual and infrastructural factors are not considered. Implementation science methods may be the solution to this barrier.

The systematic approach to implementation described by Grol and Wensing[173] and the use of five categories of theories, models and frameworks (process models, determinants frameworks, classic theories, implementation theories, and evaluation frameworks) described by Nilsen, provide guidance for conducting implementation research.[171] These theoretical structures are important to understand and explain how and why implementation of new programs and practices succeed or fail, and foregrounds factors which may be relevant for successful implementation.[171] Theories, whether classic or implementation focused, provide the initial concepts to understand and explain phenomena related to implementation. Models emphasize guidance through the steps/phases of implementation and help with planning and executing the knowledge transfer process. Frameworks provide a structure and plan aimed at understanding the descriptive categories of factors (i.e. concepts, constructs, variables, domains, and their interrelationships) leading to behavior and practice change.[171] Two types of frameworks exist: determinants frameworks and evaluation frameworks. Determinants frameworks will be discussed below, and primarily help researchers understand what influences or influenced implementation, as well as understand barriers and facilitators influencing current practice; and, evaluation frameworks help determine implementation success.[171]

Implementation research commonly uses frameworks to guide the systematic process of assessing the barriers and facilitators throughout the stages of implementation: pre-implementation, implementation, post-implementation, and evaluation. The three ladder stages are beyond the scope of the following dissertation. Pre-implementation requires an initial assessment of variation and gaps in clinical practice and health outcomes using a mixed methods approach. Qualitative methods for implementation research commonly employ ethnographic approaches to study the context, processes and interactions which produce the practices or behaviors under investigation. Quantitative methods are valuable in implementation research, especially to help identify problems related to health outcomes, documentation of care delivery, care quality, and patient performance. While the quantitative analyses reveal gaps, many contextual and socio-technical factors cannot be observed using quantitative methods. An ethnographic approach, therefore, allows researchers to understand what, how and why a practice does or does not become routinized in healthcare settings.

Many types of models and frameworks exist for conducting implementation science, as demonstrated by Tabak et al. (2012), which describe 61 models and frameworks that exist specifically for facilitating dissemination and implementation research. Process models commonly used for implementation science include the Implementation of Change Model and the Knowledge to Action (K2A) model. Common implementation determinants frameworks include the Consolidated Framework for Implementation Research, the Theoretical Domains Framework, and the Normalization Process Theory.

Implementation Models and Examples

Knowledge to Action Model

The K2A model (**Figure 2.2**) was developed in Canada by Graham et al. (2006), as a conceptual model to identify key elements of the knowledge translation process and provide clarity to the dissemination and implementation field.[49] The model includes two components: Knowledge Creation surrounded by an Action Cycle. Three generations of knowledge exist within the Knowledge Creation component, knowledge inquiry, knowledge synthesis, and knowledge tools/products, and knowledge can be tailored at each phase to meet the needs of users. The Action Cycle consists of seven steps of activities necessary for knowledge translation, and include: 1) identify gaps, 2) adapt to local context, 3) assess barriers to knowledge use, 4) select, tailor and implement interventions, 5) monitor knowledge use, 6) evaluate outcomes, 7) sustain knowledge use.[49] The K2A model is primarily used in Canadian healthcare research, however the model is widely cited. Russell et al. (2010) applied the K2A in their work on facilitating the use of four evidence-based measurement tools in clinical practice designed to evaluate and understand motor function in children with CP.[174] The K2A model was used to design the implementation intervention through its seven key elements. Results indicate that the K2A model was effective in supporting the design of the implementation intervention, as reported use of three of the four measurement tools increased, while changes in uptake were sustained one year later.[174]

Implementation of Change Model

Grol and Wensing (2013) developed the Implementation of Change Model for practice change in healthcare (**Figure 2.12**) that assists with the development of a proposal for change.[173] The model follows a seven-step process, beginning with the fruition of new scientific evidence,

practices, protocols and/or guidelines for improving patient care, and identification of practice gaps and problems in clinical care.[173]

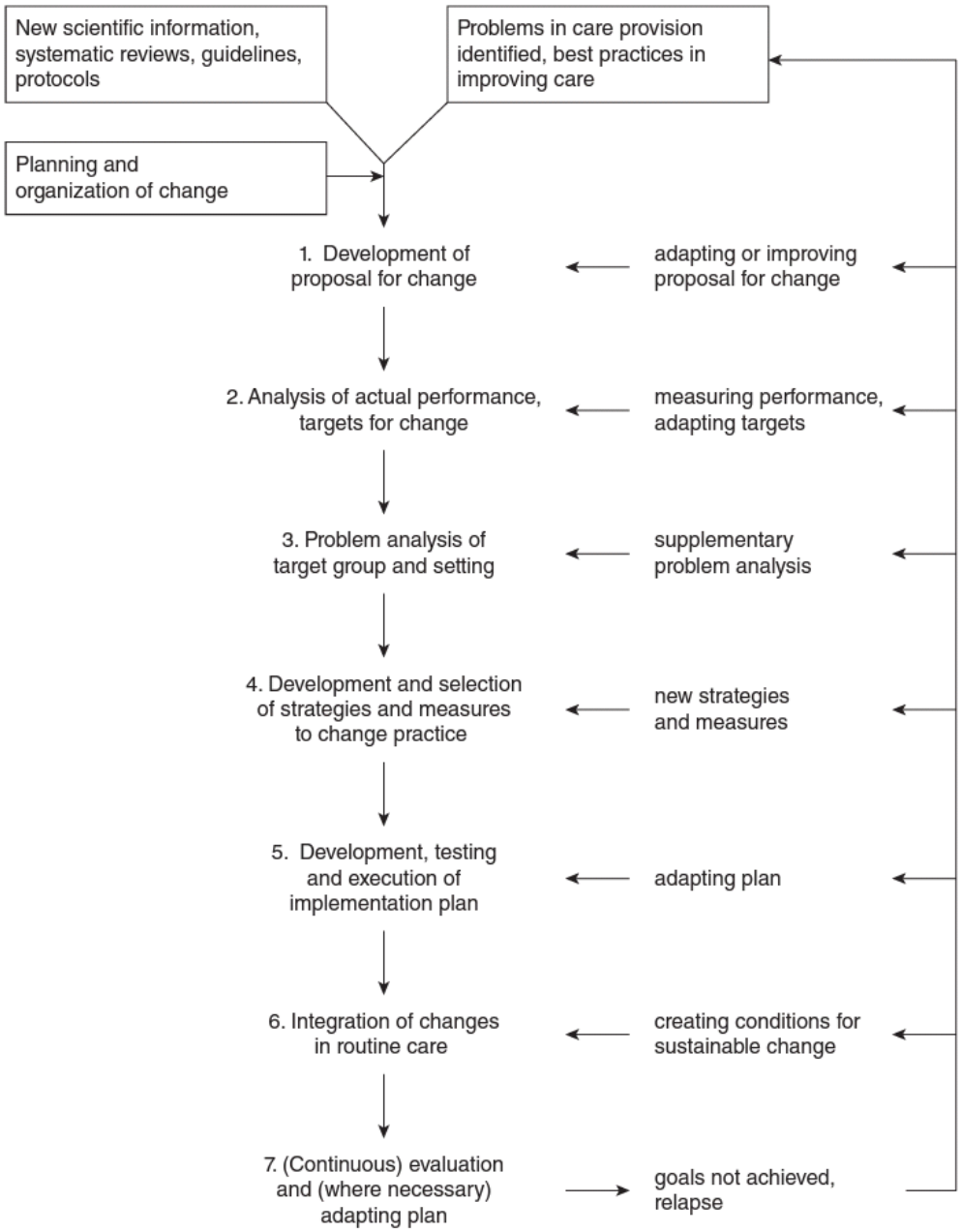


Figure 2.12. Grol and Wensing Implementation of Change Model.

The Grol and Wensing model outlines the importance of measuring current practice performance and identifying potential areas where change may be warranted, assessing the

problem through mixed method tools and assessments of barriers and facilitators.[173] Steps four through seven emphasize the development and selection of implementation and behavior change strategies, the development of an implementation plan surrounding the change strategies and designing a study to determine feasibility and later effectiveness of the implementation interventions and finally implementing the effective change strategy into routine practice and evaluating the implementation success.[173] This model has not been tested in the field of LHS work, but its application may provide helpful guidance through key phases of the examining phases of a LHS.

Meerhof et al. (2017) applied the Grol and Wensing model to design and implement a data registry in the Netherlands to increase physical therapist (PT) contribution to and use of outcomes data for patient care.[175] The registry was also used as a potential method of audit and feedback to improve patient outcomes. Their study included 355 PTs from 66 practices enrolled in three consecutive individual pilots to address the feasibility of an implementation strategy.[175] Each step of the Grol and Wensing model was discussed in depth. This included an initial assessment of preconditions using mixed methods with interviews used to select and modify outcome measures for musculoskeletal conditions, a tailored approach to implementation of a data registry, and an evaluation of the feasibility post-implementation.[175] Results indicated an improvement in the PT contribution to the registry and increased patient-reported outcome measure use in practice following the tailored implementation.[175] The study demonstrated the utility of the Grol and Wensing model to design and implement a practice change strategy, however improvement in their study design and evaluation is warranted.

Implementation Determinants Frameworks and Examples

Theoretical Domains Framework

The Theoretical Domains Framework (TDF) was developed to make behavioral theory useful to researchers in a range of disciplines.[171,176] It has demonstrated success in contributing to problem solving in implementation research. The TDF is an overarching determinants framework that addresses 128 explanatory constructs from 33 theories of behavior.[176,177] The TDF was developed using an expert consensus process and validation to identify psychological and organizational theory relevant to health practitioner clinical behavior change.[176,178] The TDF has 14 domains covering the main factors influencing behavior and behavior change, and includes: knowledge; skills; social/professional role and identity; beliefs about capabilities; beliefs about consequences; goals; intentions; optimism; reinforcement; memory, attention and decision processes; environmental context and resources; social influences; emotion; behavioral regulation.[178,179] These domains provide an extensive framework that has greater coverage of potential barriers to change and a greater range of potential intervention components.[171]

The TDF is primarily used to assess factors at the individual level of scale, however it has elements for use at the organizational level. Interview questions and questionnaire items may be designed using the TDF to explore the specific content of domains in relation to implementation problems,[171] and for the design of implementation interventions.[178] The TDF has demonstrated utility for the development of qualitative and quantitative measurement tools to assess potential implementation behavior determinants,[179] and as a coding framework for analysis. Taylor et al., (2013) used the TDF to guide the design and implementation of patient safety interventions across three hospitals to reduce the risk of feeding into misplaced nasogastric feeding tubes.[180] They demonstrated the TDF was feasible and acceptable for supporting the design of patient

safety interventions, and helped identify target behaviors, elicit local barriers, and select change strategies.[180]

Consolidated Framework for Implementation Research

The Consolidated Framework for Implementation Research (CFIR), developed by Damschroder et al. (2009), is a conceptual determinants framework with a comprehensive typology used to understand variation in implementation of a practice and to facilitate interviews/focus groups to understand barriers and facilitators related to specific theoretical domains and constructs.[181] The CFIR is also used to guide the development and implementation of an intervention and inform the evaluation process following implementation.[181,182] The CFIR consists of five domains related to an organizational setting and an implementation intervention: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation.[181,183]

CFIR domains comprise constructs that are measured through qualitative methods such as thematic coding and analysis. Intervention characteristics includes eight constructs related to the intervention features that might influence implementation. The outer setting considers four constructs pertinent to the external context or environmental factors that may affect implementation. The inner setting concerns 12 organizational constructs that influence implementation. Characteristics of individuals considers five constructs related to knowledge and beliefs about an intervention. Eight constructs are associated with the implementation process and are related to strategies that influence implementation success. The use of the CFIR throughout the pre-implementation, implementation and evaluation phases improves fidelity, validity, and increases the replication and scalability of the implementation and evaluation process.[183]

Damschroder et al. (2013), used the CFIR to retrospectively evaluate the MOVE! program.[182] MOVE! was designed by the Veteran Affairs (VA) National Center for Health Promotion and Disease Prevention, and is a patient-centered, multi-tiered set of tools and treatment options based on published guidelines for obesity management. The CFIR was used to guide development of the interview guide, as a coding framework and during analysis in order to identify contextual factors that explain variation in implementation success of the MOVE! program by VA medical facilities. All interview questions pertained to four CFIR domains, excluding the individual level domain. Authors assessed domain constructs by rating each construct on a -2/+2 scale to identify patterns in ratings of the CFIR constructs that distinguished between high and low MOVE! implementation effectiveness. The team assessed 31 CFIR constructs and found that 12 constructs manifested more positively in the high implementation compared to low implementation VA facilities. Eight of these constructs nested under the inner setting domain, demonstrating the important roles and interrelationships for implementation in an organizational setting such as leadership engagement, resource availability and relative priority of the practice change. The benefit of applying the CFIR in this constructive way is that findings can be used to help organizations focus internal efforts on constructs associated with implementation success.[182]

Keith et al. (2017), applied the CFIR to guide data collection, coding, analysis, and reporting of findings related to the implementation of the Comprehensive Primary Care (CPC) initiative.[183] The CPC initiative is a 4-year multi-payer initiative launched by CMS designed to improve health, lower costs, and patient-provider experience by strengthening primary care. This goal is achieved through emphasis on five primary care components: 1) access and continuity of care, 2) planned care for chronic conditions and preventive care, 3) risk-stratified care

management, 4) patient and caregiver engagement activities, 5) care coordination across the medical "neighborhood".[183] Authors describe how the CFIR can be used to systematically assess barriers and facilitators to CPC implementation for iterative learning in which actionable findings are shared with stakeholders during the implementation process. The study objective was to understand how participating practices experience the implementation process in the five primary care component areas. Researchers conducted interviews of 21 participating practices to understand the following areas of the implementation process of the CPC initiative: 1) the operationalization of each CPC component, 2) the support each component received by practice functions and workflows, 3) challenges with operationalizing each component, 4) strategies that helped operationalize each component, and 5) patient reactions to each component. The CFIR was not used to design interview questions, but rather helped guide the field observations, inform the coding process of interviews, and analysis. Limitations abound in the Keith et al. paper, however, authors were able to explore applicability of the CFIR to code, develop analytic matrices to compare the implementation experience between participating sites, and as a taxonomy to investigate barriers and facilitators influencing primary care transformation across 21 heterogeneous practices.[183]

Normalization Process Theory

The Normalization Process Theory is the final framework discussed and will be the most applicable to the proposed dissertation study on clinician documentation practices. Clinical documentation is one type of care delivery process whereby its practices are highly routinized in clinical settings and understanding these may inform the development of LHSs. In order to develop strategies to improve clinical documentation practices, it is necessary to study how clinicians document based on their responses to conditions of constraint in clinical settings.

These constraints may include standards, technology and established workflows, and organizational structure, climate, and culture. The NPT is described as a middle-range action theory that explains processes and routines relevant for implementation of complex interventions.[168,169,184] The NPT helps investigators understand system-level constraints and their influence on human agency. A website is also maintained by the team that developed the NPT at http://www.normalizationprocess.org/ and is considered the NPT Toolkit. This toolkit helps researchers learn how to use the NPT in their qualitative research activities.

What, how and why routines develop for clinical documentation and the factors influencing implementation of practice transformation strategies can all be deconstructed using the NPT. NPT consists of four primary constructs that describe actions in organizational environments: coherence, cognitive participation, collective action, reflexive monitoring. Each construct comprises four distinct components that can be useful in supporting qualitative data collection and analysis (**Table 2.3**). NPT can inform the development of interview questions and direct aspects of field observations and serve as an integral component of framework analysis for qualitative research.

Table 2.3. Constructs and Components of the Normalization Process Theory.[184]

Constructs	**Components**	**Definition**
Coherence	Differentiation	Understanding the difference between different ways of working in a context
	Communal Specification	The process groups of users employ to share and create an understanding of a practice
	Individual Specification	The process individual users employ to create an understanding of a practice.
	Internalization	The process of attaching meaning to a practice.
Cognitive Participation	Initiation	Motivation to start or continue a practice
	Enrollment	The process of engaging others to participate in a work practice
	Legitimation	The process of validating a practice's legitimacy to use
	Activation	The process of users building efforts to sustain a practice
Collective Action	Interactional Workability	Doing the practice in context
	Relational Integration	How and when to use a practice and understand how practice influences others
	Skillset Workability	The process for how a practice is distributed and operationalized
	Contextual Integration	How a practice is incorporated and exists in different contexts
Reflexive Monitoring	Systematization	The process of determining how effective and useful a practice is
	Communal Appraisal	The collaboration of individuals to evaluate the worth of a practice
	Individual Appraisal	The individual evaluation of the effects of a practice on themselves and the context the practice is used
	Reconfiguration	The process of redefining and modifying a practice after appraisal to maximize utility

Coherence surrounds the process of people cognitively negotiating the practices they execute both individually and collectively in a work setting. It will be important to leverage the four components of the coherence to illuminate how providers make sense of EHR data and information. These components include differentiation, communal specification, individual specification, internalization. In the context of this dissertation, coherence and its components may be mapped to initial stages of a provider's or collective providers chart review practice or help distinguish the differences between providers sense-making strategies. Cognitive participation consists of four components: initiation, enrollment, legitimation, activation. This domain focuses on the commitment, enrollment or engagement of the necessary participants to deliver an intervention.[185,186] Collective action consists of the following components: interactional workability, relational integration, skill set workability, contextual integration. This domain focuses specifically on the necessary work or tasks that need to be completed in order to achieve implementation success. Reflexive monitoring is considered the on-going process of modulation or adjustment by the participants and the intervention to maintain success.[185] This domain can be considered feedback and how people respond to feedback, and includes four components: systematization, communal appraisal, individual appraisal, and reconfiguration.

A recent systematic review of 29 studies using the NPT demonstrates it is a beneficial theoretical framework to explain social processes in healthcare related to e-health and telehealth, and to guide implementation processes.[187] The most closely related study using the NPT was by Pope et al (2013). This team of researchers applied the NPT in a cross-case comparison study to describe how the use of a clinical decision support system became embedded in three different healthcare settings in the UK.[185] They demonstrated how similar processes and social

relationships existed in these settings and how each setting employed strategies to ensure successful implementation of the system.[185]

Ethnography for Implementation Research and Learning Health Systems

Infrastructures are central to implementation, operationalization, and the design of continuous learning systems of healthcare. The EHR not only serves as a document and data repository, it also serves as key technology infrastructure to facilitate the processes, communication and decisions performed by clinicians. Data and information managed and represented by technological infrastructures can inform the care delivery process and produce measures of quality and patient outcomes. However, in most cases, infrastructure and implementation studies focus not on the measures or outcomes these infrastructures *produce*, but the labyrinths, technology, mechanisms and processes *of* the infrastructures, the relational approaches to *understand* the infrastructure that produces an outcome, and how infrastructures are created and enacted.[15]

The EHR supports the storage of routinely structured and unstructured data for clinical use while clinician actions concurrently build the data and information infrastructure. The clinician relationship with these infrastructures is multi-faceted and requires further dissection. Star writes that "the ecology of the distributed high-tech workplace…is profoundly impacted by the relatively unstudied infrastructure that permeates all of its functions…Study an information system and neglect its standards, wires, and settings and you miss equally essential aspects of aesthetics, justice, and change (p. 379)."[15] The relational nature of infrastructure, that "one person's infrastructure is another person's topic or difficulty (p. 380)"[15] foregrounds the importance of studying constraints, tensions and conflicts that exist for people within and interacting with infrastructure.[188] In the context of LHS and computerized clinical

documentation, this relational approach focuses on studying infrastructure through a socio-technical lens using ethnographic methods and case-studies to understand technical infrastructure and the surrounding relationships.

In ethnography, emphasis is placed on the collection of observational and interview data about real-world interactions, practices and processes through pragmatic, reflexive and emergent ways to understand what is actually happening in a clinical setting.[189,190] An ethnographic approach is required because it will provide an interpretive perspective to describe the values, beliefs, practices, and attitudes surrounding clinical documentation practices of encounters in pediatric clinics, as well as understanding the dynamics of clinic workflow.[189] Although there are limited studies using ethnography for LHS research, literature in health informatics and infrastructure studies demonstrates the benefit of using ethnography to understand relationships in a socio-technical system.[1] Ethnographic methods will be key to understand the clinician-infrastructure relationships and how these are influenced by differences in practice, context and technological innovations. Therefore, exploring what, why and how clinicians document and the factors that support and inhibit their documentation is essential to classifying the barriers to optimal performance.

How clinicians document using EHRs in their daily practice is not easily captured by survey assessments or strict analysis of EHR data. Although many studies on the use of health information technology in healthcare settings are designed to measure how a variable changes as a result of some deployment of a technology, these positivist and post-positivist methodological approaches are scrutinized by social scientists for oversimplifying how a new technology or process involving a technology is adopted/resisted and used/abandoned in social settings.[189] An ethnographic approach, however, can help a researcher understand these issues surrounding

reflexivity by focusing more on the social, cognitive and contextual influences on the use of technologies.[189] An ethnographic approach focuses on the more process-related aspects of clinical care, i.e. documentation that produce the data in an EHR and subsequently extracted, transformed and loaded into a network like SHOnet.

Field observations also help to describe the work environment where clinicians conduct their daily practices and determine how and when clinicians document patient encounters. There are two primary types of field observations: participant observation and non-participant observation. Participant observation is a method whereby the observer participates in activities and daily life of those being studied. Observers may do this either openly as a researcher or in a covert or disguised role, taking measures to ensure they don't "go native".[191] Non-participant observation considers the researcher analyzing the daily life and activities of those under study, however there is no active participation on the part of the observer and the role. Field interviews may occur during these observations and this generally includes informal conversations with active participants under study. Semi-structured interviews are also a data collection method in ethnography and generally includes an initial set of questions that may be open or closed-ended and occur with key informants related to a research interest, but allow for more rich discussions and illumination of phenomena than highly structured or unstructured interviews. For the purposes of the following work, non-participant observation and semi-structured interviews will be used as a field method to collect information related to how clinicians document during clinic.

Summary

Evidence-based practices abound in healthcare research; however, a critical problem facing healthcare is the absence of effective transfer and replication of these practices across both homogenous and heterogenous health systems. Implementation research and the use of

ethnographic methods provide the knowledge and theoretical basis to navigate systems and develop effective dissemination and implementation of knowledge practices across large-scale systems. Replication of practices is difficult in healthcare due to the complex infrastructure, interdependent relationships, communities of practice, and the difficult process of synthesizing the literature to determine the best evidence. Thus, infrastructure must encourage this flow to occur. Research on healthcare system infrastructures is critical to achieve a point where the right research question, the right data, the right personnel, technology and processes intersect to taking to change clinical practice, improve quality in care delivery, and improve patient health.

Chapter 3

Dissertation Research Proposal

Research and learning in healthcare systems using real-world data presents major concerns related to data quality and veracity of findings because these data are rarely collected systematically or with a clear collection procedure. While CDRNs hold much promise in measurement and translatability of a clinical practice in a healthcare system and patient outcomes, at a granular level, documentation of data in the EHR varies as part of routine care delivery.[6,11,16-18] Studies using CDRNs for research identified heterogeneity and variation in documentation practices across different systems as key barriers to accurately measure clinical performance.[3,18,19] These clinical documentation practices are known to vary by healthcare systems, regional geography, and due to the design and implementation of EHRs**.** The extent that clinical documentation practices can be evaluated and their influence on researching clinical performance and patient outcomes using CDRNs requires further study.

CDRNs and EHRs are also currently used to classify and develop computable representations of health conditions, patient populations and measure changes in patient outcomes over time using current diagnostic data structures of physiological function, medication information and ICD-9/10 codes.[111,116,117,119-121,192] Physiological function may include markers of endocrine, metabolic, and cardiovascular function, such as measuring clinical management of chronic kidney disease, hypothyroidism, diabetes, etc. These types of conditions comprise clinical indicators established through scientific study to determine normal ranges of

function. Aside from these diagnostic markers of the presence or absence and management of disease, sparse literature exists on using real-world data resources such as CDRNs to classify and measure physical disability and functional performance of complex and multidimensional disorders.

One such disorder is CP, which is a group of heterogeneous conditions resulting in varying degrees of impaired motor function that impact mobility, movement, and performance of activities of daily living.[126,127,129] Many CP-associated complications are managed by orthopedic surgery and physical medicine and rehabilitation clinicians. Standardized measures and approaches exist to classify severity of impaired motor function for mobility, movement, and performance of self-care tasks related to CP, however, these are inconsistently performed and/or documented by clinicians or collected as patient-reported outcomes in the EHR. These data are critical to measure the clinical management and health outcomes of a disorder like CP and offer an opportunity to develop computable phenotypes of disability and motor function.

CDRNs are not oriented around the measurement of orthopedic and rehabilitation-related data elements for CP and documentation practices.[9] Rather, many data resources such as networks and registries leverage health data to develop computable knowledge to classify the presence or absence of diagnoses, study readmissions, or surround pharmacotherapy interventions.[96,118,121] These real-world data natworks also primarily comprise heterogeneous healthcare centers; however, more distributed, homogeneous healthcare systems are establishing their own data resources to become learning organizations. Distributed and homogeneous healthcare systems may be better suited to address research and learning activities that reduce variation in clinical documentation practices.[6] SHOnet is exemplary to both conditions.

Initial SHOnet queries revealed over 32,000 unique CP cases (classified according to ICD-9/10 codes) seen across SHCs from 2011-2018. Since CP is a complex set of conditions resulting in motor dysfunction and impairments of body structures, functions, and restrictions in activities and participation in daily tasks,[126-129] these children also require a level of care that involves a trans-disciplinary team (i.e. physician, nurse practitioner, physical therapist, occupational therapist, etc.) and commonly require multiple outpatient and inpatient care visits. Results of the queries revealed that care for these patients was provided by 1,743 clinicians over approximately 14,000 encounters.

The extent of motor dysfunction of CP is often classified according to a patient's age and level of gross motor function using the Gross Motor Function Classification Scale (GMFCS) screen, a five-level (I-V) scale with level V being most severe. As described in Chapter 2, the GMFCS level informs treatment recommendations and long-term management related to functional performance and mobility.[193] There are five age-bands for GMFCS which parallel stages of child and youth development: before 2 years-old, 2-4 years-old, 4-6 years-old, 6-12 years-old, and 12-18 years-old. GMFCS level is known to remain stable after 2-years-old.[193] While all children with CP seen across SHC are known to have one or more GMFCS levels recorded in the SHC EHR (SHC Information System (SHCIS)), variation exists in the documentation location of GMFCS level. For the EHR location with the greatest frequency of GMFCS documentation as a discrete data element, SHOnet queries resulted in over 7,100 distinct GMFCS records for 5,530+ unique cases. Of the patients with a GMFCS documented as a discrete data element in SHOnet, approximately 60% also have variability in GMFCS levels that appear to be misclassifications.

As patients with GMFCS level III and IV age and grow, they may become more prone to hip dysplasia.[140] Hip dysplasia leads to an abnormal migration of the head of the femur in the acetabulum of the pelvis. Approximately 35 percent of children with CP have a hip dysplasia,[140] which results in pain due to the instability, reduced quality of life, decreased participation in daily activities. Children with GMFCS level V have a 90 percent incidence rate of developing a hip dysplasia. As hip dysplasia progresses in children with CP, it can lead to many functional limitations and hip disorders such as hip displacement, subluxation, dislocation, degenerative joint disease and can cause severe pain if not monitored.[140] Initial displacement of the hip generally occurs before 5 years-old in children with a hip dysplasia and is reduced, however, early displacement may lead to chronic displacement and possible dislocation.[128,148,149]

Research demonstrates children 4-12 years-old with GMFCS level III-V are at greatest risk of displacement and dislocation.[128,148,149] Careful monitoring of hip dysplasia, referred to as hip surveillance, is informed by a patients age and GMFCS level. Hip surveillance involves routinely monitoring the gap and rotation of the hip joint using serial pelvic x-rays and is commonly performed by orthopedic surgeons to either manage children surgically or conservatively (non-surgical) as the child develops. The extent of missingness of the GMFCS as a discrete data element in SHOnet compared to the volume of patients with CP influences the research and quality improvement, for example in the ability to stratify patient cohorts by individual GMFCS levels to evaluate management of patient treatment outcomes.

Based on these preliminary results of GMFCS in SHOnet, it appears that documentation practices may differ in terms of what and where data are documented in the EHR by clinical providers. Therefore, the dissertation revolves around several research questions such as “To what extent are discrete data in the EHR complete?”, “Who produces this data and how?”, and

"Why does missingness occur?". Preliminary qualitative interviews with providers in SHC point to the lack of feedback that clinicians receive related to their documentation practices, especially documenting discrete data. Moreover, clinicians are not able to see trends over time in patient performance related to key evaluation criteria nor do they have knowledge of how their documented data are used for research and learning. Providers also reported difficulty finding or reading documentation by their colleagues. Providers across SHC continue to document a high volume of data in EHRs to capture patient events and do so using different strategies and preferences. This presents a complex socio-technical and infrastructural problem that requires further interviews and in-depth study of this qualitative data to elucidate factors that influence documentation and data completeness.

The preliminary descriptive findings of GMFCS and the CP population demonstrate that SHOnet can be used to identify the problems or deficiencies in care delivery and documentation processes at different levels of scale. SHOnet may also be used to build multi-class computable representations for characterizing functional performance and physical disability such as imputing GMFCS levels to address limited documentation of the GMFCS as a discrete data element. Since the GMFCS level is integral to hip surveillance practice, the collection of these data and all other routine discrete data elements about gross motor function may inform the design of a computable representation of the GMFCS level.

Knowledge is limited regarding whether data networks like CDRNs can support the classification of functional performance, as well as what variables are necessary to classify functional performance and the extent that variables are present as discrete data elements. Based on initial descriptive statistics of GMFCS levels outlined above, discrete data are missing extensively in the EHR of a distributed pediatric healthcare system. This indicates a socio-

technical problem related to clinical documentation and the types of data elements routinely collected in EHRs. The extent that GMFCS levels and other discrete data about gross motor function are documented in the EHR requires further study. Research is needed surrounding pediatric rehabilitation settings and the extent that documentation practices differ between providers, vary across regionally different clinical settings, and how these practices along with system and professional factors contribute to data missingness in the EHR. These issues are necessary to explore to improve the collection of key data for conducting more robust research and learning activities in pediatric rehabilitation settings.

Based on the previous information, this dissertation proposal outlines the process to produce generalizable knowledge that informs pediatric rehabilitation settings, specifically related to clinical documentation practices and missingness of data in the EHR. This work intends to expand knowledge on documentation of data stored in real-world data resources like CDRNs, mechanisms for leveraging data on physical disability and functional performance for children with CP to aid in the development of strategies to improve the veracity of healthcare outcomes research findings produced using data infrastructures. This dissertation supports future work, in CP and other disease states, to understand the variability in documentation and the extent that CDRN data can be used to classify functional performance and evaluate documentation practices. This work also builds a foundation for future research into studying clinical documentation practices for LHS and better understand data quality in a variety of pediatric settings.

SPECIFIC AIMS

The **objective** of this proposed dissertation is two-fold: 1) To determine the extent that existing data from EHRs can be leveraged to create a standards-based typology of gross motor

function for patients with CP. 2) To gain an understanding of documentation practices used to develop these data and how they contribute to missingness of data in the EHR. The objective of this work surrounds a socio-technical problem of clinical documentation and missingness; therefore, quantitative and qualitative methods are integral to understand this problem. Furthermore, the exemplars and use-cases to study this problem are SHOnet, SHC, and CP.

This dissertation provides a critical analysis of SHOnet data elements and documentation practices. This work is necessary to support the development of computable biomedical knowledge and infrastructure in rehabilitation settings, especially as SHOnet becomes operationalized for CP research and learning across SHC. The **long-term goal** of this work is to instantiate and iterate infrastructures for a sustainable and robust LHS. The development, refinement, and replacement of infrastructure in healthcare has the potential to support clinical decision-making and the measurement of 1) clinical care, 2) translation of new clinical practices into routine care, and 3) patient outcomes and response to care.

The specific aims of the proposed dissertation are:

Specific Aim 1: To map case definitions of GMFCS levels to indicator variables of gross motor function and identify the extent these are observed in the SHOnet Common Data Model in order to create a phenotype model of gross motor function to classify GMFCS levels.

Specific Aim 2: To describe the documentation completeness of GMFCS levels and data elements in the gross motor function phenotype model established in Aim 1, for patients 6-18 years-old with a diagnosis of cerebral palsy (CP) seen as an outpatient between 2015-2019, and determine the variation in documentation of these discrete data by SHC site.

Specific Aim 3: Explore the factors, from a socio-technical perspective, that influence missingness and variability of GMFCS level and gross motor function phenotype model variables using qualitative methods.

RESEARCH APPROACH

The following proposed aims and tasks of this dissertation will build the research foundation to address the following research questions:

1) To what extent can data networks (CDRNs) be leveraged to build classifiers of patient functional performance and physical disability?
2) How can discrete clinical data on gross motor function be used to draw conclusions about clinical documentation practices in the EHR for cerebral palsy?
3) Why does missingness of discrete data in the EHR occur?

Specific Aims 1 and 2 will address these questions in the context of SHC pediatric clinical care for managing CP, specifically related to developing phenotypes for the GMFCS. The present data and information infrastructure across SHC are limited in its supports of clinicians to learn about their own performance, consistently document patient encounters, and improve their clinical practice. SHOnet can help to bridge this gap. As preliminary analyses demonstrate, the discrete data element for GMFCS is not routinely documented across SHC. Approximately 18% of unique cases of all-ages of CP had GMFCS level documented in the highest frequency discrete location in the EHR, with observed variability within patient records. Developing a mechanism to identify the routinely documented data elements necessary to auto-classify GMFCS level for patients would help to address this problem. Furthermore, this dissertations focus on developing a phenotype model of gross motor function will serve as the foundation for building "functional" computable phenotypes for research and clinical learning in pediatric rehabilitation settings.

Specific Aim 1 of this dissertation is organized around the development of a phenotype model of gross motor function discrete data elements. Specific Aim 2 switches gears to assess data quality, where the phenotype model data elements are evaluated for data completeness and missingness. Specific Aim 3 then explores how clinical documentation practices and generative mechanisms influence the extent of missingness in discrete data and focuses specifically on the GMFCS and phenotype model data elements.

Specific Aims 1 and 2 will focus on: 1) Mapping GMFCS level case definitions to SHOnet observed discrete data elements to establish a human and computer readable representation of GMFCS levels. 2) Assessing the completeness and variability in documentation of GMFCS levels and phenotype model data as discrete elements by SHC sites. Additionally, the Aims help determine the considerations for a computable classifier of gross motor function. GMFCS computable phenotypes present an opportunity to identify and represent trends in variables that relate to the classification of patient physical function and mobility. The long-term impact of a GMFCS phenotype would support research and quality improvement surrounding the management of hip dysplasia in children with CP (i.e. hip surveillance). A phenotype model of gross motor function inches us closer to determining the extent that EHR data about dimensions of patient function are fit for use to support these types of auto-classifiers to distinguish between proxy levels of functional performance.

Specific Aim 3 will require qualitative methods of semi-structured interviews and field observations to elucidate the processes of documentation and the clinician perceptions of EHRs, and understand how and what data are collected for managing patients with CP. Several factors are associated with poor EHR implementation such as processes of training, time management, staffing and contextual factors in clinics, EHR system design, expectations, and standards. These

factors may influence the differences in how and what data are documented, resulting in missingness and variability in data element values. At a granular level, missingness may result from the technical standards and processes for how data are transferred from the EHR into SHOnet; however, due to consistent quality control and monitoring, this seems to be less of a concern for SHOnet but necessary to explain. Furthermore, the SHC system has many elements of homogeneity (i.e. one EHR (Cerner) mission, vision, values, specialty patient population, etc.) and regional differences by SHC sites that provides a unique opportunity to study the contributing factors to data completeness and missingness in the EHR.

Methods for Specific Aim 1

To map case definitions of GMFCS levels to indicator variables of gross motor function and identify the extent these are observed in the SHOnet Common Data Model in order to create a phenotype model of gross motor function to classify GMFCS.

A phenotype model is a group of patient characteristics that, if present in a patient record, may be able to predict a patient's level of function. Fried et al. developed a phenotype model of frailty using data from a large-scale cardiovascular study.[194] This phenotype model is semantically interoperable because it focuses on general patient characteristics such as ambulation quality, reduced strength, unintentional weight loss and reduced activity tolerance.[195] Due to this, studies frequently cite it as a mechanism to identify data elements in clinical data networks, registries and EHRs to develop site-specific frailty indexes.[196-199]

In similar fashion, a phenotype model of gross motor function may be constructed from similar patient characteristics plus others about presence of muscle tone, extent of range of motion, performance in activities of daily living, and other clinical indicators like presence of drooling, tracheostomy, gastrostomy and or prescribed medications. The difference between the

frailty model and the gross motor function model is the presence of GMFCS case definitions. These definitions are proxies that inform the breadth and depth of patient characteristics that can be mapped to an ensemble of EHR data elements. Therefore, a phenotype model creates an abstraction of the GMFCS levels based on existing standardized data elements. This work may also support the development of a computable phenotype of GMFCS levels in the EHR. Computable phenotypes are EHR-based conditions capable of identifying cohorts of patients with certain diseases or clinical profiles for disease management registries, quality improvement programs, evaluation studies, and interventional research.[116,117] As such, Specific Aim 1 includes the process of mapping the definition for each of the five GMFCS level definitions to data elements and identifying the presence of these variables in the SHOnet CDM. This process will produce a phenotype model of gross motor function data elements and sub-models that correspond to levels of the GMFCS. Furthermore, the phenotype model also supports structured rules to distinguish between different levels of gross motor function represented by the GMFCS.

The development of structured rules will characterize the conditions of data elements that describe a person's level of gross motor function. Richesson et al. and Denny describe the importance of using the method of expert-defined rules to develop a computable phenotype.[96,119] This is the most widely adopted method for developing a computable phenotype and begins with the manual development of an algorithm often using Boolean logic, scoring thresholds, or a decision tree and is based on domain expertise.[96] The structured rules of the condition are then iteratively enhanced through validation and chart review of EHR data.[96] Much of this process is described in the 10 Desiderata for Computable Phenotypes using EHR data developed by Mo et al. (**Table 2.2**), and many of these Desiderata inform this first aim.[120]

Since a phenotype model is not a computable phenotype, this work does not employ the validation process or operationalize the phenotype for use in the EHR. Instead, the multiple phenotype sub-models can differentiate between GMFCS levels and characterize the extent that discrete data from the EHR can classify deviations in gross motor function. Although the latter eight Desiderata characterize the process to build out a computable phenotype, evaluate it and operationalize it, only Desiderata 1-3 and 5 apply to Specific Aim 1 objectives. These selected Desiderata are the core process steps to develop the phenotype model.

Desiderata 1-3 relate to the importance of developing a phenotype that uses structured rules that are both human and computer readable. As Mo suggests, temporal relations are ideal for studying response and side effects of medications[120], and this should include accounting for progress in patients with physical impairments and response to therapy services. However, the purpose of the following work does not entail an analysis of the patient response to care and changes over time, thus this recommendation does not apply at this instance. Desiderata 5 applies to the proposed work in the sense that data elements and value sets need to conform to standard medical terminologies and ontologies to facilitate reuse by SHC and sharing with other pediatric-related CDRNs. Since SHOnet data are transformed into a CDM that already conforms to standardized terminologies and a controlled vocabulary, this work also maintains the existing standards for the labels and values for each data element in the CDM. Desiderata 6-8 do not apply because they concern the EHR support to implement and operationalize the computable phenotype in clinical practice.

Objectives for Specific Aim 1

Objective 1: Identify the indicator variables of gross motor function.

Objective 2: Map the indicator variables to data elements in SHOnet corresponding to gross motor function and determine the value sets for each data element.

Objective 3: Define the structured rules according to data elements and data value sets for each GMFCS.

Objective 1

Objective 1 of Specific Aim 1 will identify the indicator variables of gross motor function. A phenotype model that distinguishes between levels of functional performance requires careful examination of the potential variables which may represent gradations in a patient's gross motor function status and indicate their cohort membership in each GMFCS level. Therefore, Objective 1 defines the routinely collected variables that may inform severity or gradations in gross motor function. Although not all statements in GMFCS level case definitions[136,139] (Appendix A) match a specific variable collected as discrete data in the EHR, many other discrete data elements are observed in the EHR and collected during routine patient encounters. As Denny describes, data for phenotyping may include those routinely collected in the EHR, such as demographics, vital signs, laboratory tests, medication, diagnoses, procedures, and other documentation.[119,120] However, this objective only focuses on the discrete data that providers collect about dimensions of physical functional performance.

Two clinical domain experts will identify an initial list of variables to support the classification of gross motor function. Variables will be drawn from both the common data elements of CP described by the National Institute of Neurological Disorders and Stroke and types of current procedural terminology (CPT) and ICD9/10 codes related to CP and hip surveillance practice (i.e. X-Ray, visit dates, surgical history). Important indicator variables may include body structures and functions (body movement, muscle coordination, strength, balance

status, mobility status, range of motion), use of external devices such as a roller walker or wheelchair, visit dates, activities of daily living, oral motor skills, genitourinary and gastrointestinal dysfunction, and muscle tone. These are not data elements, rather they are examples of *attributes* corresponding to the case definitions for each GMFCS level and many of these variables are routinely collected in EHRs by SHC clinicians. Objective 1 will result in a human readable definition comprising variables that inform classification of general gross motor function but is still irrespective of gradations in GMFCS.

Objective 2

Objective 2 of Specific Aim 1 will map the indicator variables to data elements in the SHOnet CDM corresponding to gross motor function and determine the value sets for each data element. Objective 2 concerns the identification and mapping of selected indicator variables for gross motor function to data elements stored in SHOnet. Many computable phenotypes are built directly from EHR data elements, rather than CDRNs which transform and store EHR data in a CDM for scalable observational research.[118,120,121] Representing EHR data elements using a CDM is one of the primary desiderata described by Mo et al. for jumpstarting the phenotype process and ensuring data are structured for queries.[120] Since SHOnet is built using OMOP, it maximizes the generalizability of a phenotype model to other CDRNs that are built using OMOP.

SHOnet team members routinely extract data from SHCIS every month and transform these data into research ready data using the PEDSnet pediatric-specific CDM to support standards for observational research in pediatrics. SHOnet also includes many observational, surgical and measurement data elements that PEDSnet does not transform. These data may be integral to physical rehabilitation and disability studies for LHS. The mapping process to identify

GMFCS data elements will include a review of the SHOnet CDM and identification of data elements that may explain each indicator variable of gross motor function. Each variable may not be labeled accordingly in the CDM and each variable may correspond to multiple CDM data elements.

Some data elements may be stored in binary, categorical, free-text, or numerical forms. These forms comprise the value sets necessary to "AND, OR, NOT" Boolean logic for structured rules to classify a GMFCS.[96,119] There is not much granularity between GMFCS I and II definitions and between GMFCS IV and V definitions, and hip surveillance practice manages these two sets similarly. Therefore, for the purposes of this dissertation, the GMFCS level case definitions can be collapsed into three classes based on how each class is clinically managed: Class 1 (GMFCS I and II), Class 2 (GMFCS III), and Class 3 (GMFCS IV and V).

Each data element and corresponding value set will be scrutinized for its applicability to distinguish between GMFCS Classes. Data elements will be a mix of categorical/discrete and numerical/continuous variables. Consideration will be given as to whether value sets for categorical data elements can or need to be collapsed into fewer categories but are able to maintain standard medical terminologies and ontologies of the CDM. Procedure code names and medications will be transformed to a simplified terminology using labels such as surgery, x-ray, Level_# (for GMFCS), and general medication names. Domain experts are necessary to classify both the deviations in data element values by GMFCS Classes. Approximately 4-5 clinicians and researchers across SHC will be recruited as a panel to complete an exercise to rate the extent that data elements selected differentiate between GMFCS Classes. For each data element, panelists will also select and apply the performance value that best resonates with each GMFCS Class.

The final list of data elements will be determined based on consensus ratings of data elements by panelists.

Objective 3

Objective 3 of Specific Aim 1 will define the structured rules for each GMFCS Class according to final list of data elements and value sets selected in Objective 2. This Objective will evaluate the panelists responses to the rating exercise outlined above and then determine how panelists allocated the data element values to each GMFCS Class. The consensus value for each data element will be used as the condition that satisfies each rule. The inclusion, exclusion and intersection of data elements and value sets will be identified to correctly classify each GMFCS Class.[117,120] This serves as the basis for developing structured rules that are human and computer readable. Each increase in a person's GMFCS level is graded based on increases in physical assist and use of external devices to support mobility and movement. The structured rules should emulate this thinking.

Often, the increase in physical assistance and external devices for mobility decreases participation and independence in activities of daily living such as self-care tasks, play and activity tolerance in a variety of settings (home, school, community, outdoors). At a granular level, the decrease in functional performance of these activities relates to impairment in strength, range of motion in extremities, and may also reveal increased tone and spasticity of extremities. Cases of spastic CP often impair functional performance and require spasticity medication to reduce and manage spasticity and seizure medications to prevent seizures. More severe cases may have poorly controlled seizure and spasticity and events may result in displacement and dislocation of joints. Severity of impaired strength, range of motion, tone and spasticity may result in poor motor control, balance, and coordination essential to maximize participation,

independence, and quality of performance in daily activities. Understanding the gradation between GMFCS case definitions for children with CP is an important step to develop the rule-based logic for each GMFCS Class computable phenotype. The structured rules for each GMFCS Class will be evaluated by CP clinical domain experts to ensure the logic makes sense.

Summary

GMFCS case definitions can be deconstructed, mapped to indicator variables, and therefore mapped to data elements and value sets stored in SHOnet. A rule-based logic can be developed for each of these definitions based on the characterization of gradations in performance of mobility and daily activities. The inclusion, exclusion and intersection of these data elements and value sets (based on Boolean logic) that correspond to body structures and functions, participation, the environment, and activities will ultimately produce a phenotype model for each GMFCS Class. Currently, there is no literature which applies the Desiderata for phenotyping to represent computable forms of motor function or any other variables pertinent to measuring functional performance for orthopedics and physical rehabilitation. This first aim will build the foundation for further development of functional performance phenotypes for conducting measurement and health outcomes studies.

Ethics and Institutional Review Board

Development of a GMFCS computable phenotype received IRB approval in December 2017 from the SHC/WIRB (PI: Tucker).

Data Element Analysis

The case definitions for each of the five levels of GMFCS will be deconstructed into components of potential features that may map to SHOnet data elements. The SHOnet CDM will

be obtained and inspected. Data elements will be selected as to whether they generalize to any of the components of GMFCS levels. These data elements will then be mapped according to whether each is present or absent for GMFCS levels. The value sets for each data element will be inspected. Although an initial list of data elements was previously drafted (Appendix C), this list will be expanded further and to include all value sets. Value sets will be classified as categorical/discrete variables, such as levels of mobility status, or continuous variables like range of motion. The panelist responses will be evaluated to determine the extent that data element values map to each GMFCS Class. One clinical domain expert on the SHOnet team will serve as the final arbiter to break a tie in responses or if there is any incongruity in panelist responses. The final set of data elements serve as the basis for the structured rules. These rules require reflexivity, with feedback provided by informaticians to ensure the rules are stated clearly and logically for each data element and GMFCS Class phenotype sub-model. Opinions on the structured rules will be solicited from clinical domain experts via email communication.

Outcome of Aim 1

A phenotype model for overall gross motor function and three phenotype sub-models of gross motor function that correspond to three GMFCS Classes (i.e. meets the criteria for all GMFCS levels in the 6-18 age-band).

Methods for Specific Aim 2

To describe the documentation completeness of GMFCS levels and data elements in the gross motor function phenotype model established in Aim 1, for patients 6-18 years-old with a diagnosis of cerebral palsy (CP) seen as an outpatient between 2015-2019, and determine the variation in documentation of these discrete data by SHC site.

All data elements in the EHR are collected by clinicians nested in clinical specialties which are further nested in SHC sites. These data may present issues of incompleteness and variability. Often, this may be a result of how clinicians document, what clinician specialty is documenting, the geographic location of the site and the volume of patients seen with a specific condition.[12,96] Specific Aim 2 of this dissertation will describe the completeness and SHC care site variability of all data elements identified in the gross motor function phenotype model constructed in Specific Aim 1. This second Aim will also identify the extent of completeness for the GMFCS as a discrete data element and how this varies by SHC site. This is not a study solely on data quality; therefore, the focus of this work is on understanding the breadth of documentation of key discrete data elements that may contribute to representing distinctions between GMFCS levels for patients with CP.

Objectives for Specific Aim 2

Objective 1: Describe the completeness of GMFCS as a discrete data element and all data elements in the phenotype model of gross motor function developed in Specific Aim 1 for outpatient-related patient encounters across SHC.

Objective 2: Evaluate the sources of missingness by describing the extent of differences in documentation of discrete data elements by SHC site for the GMFCS and data in the phenotype model of gross motor function.

Objective 1

Objective 1 of Specific Aim 2 will describe the completeness of SHOnet data elements identified in the phenotype model of gross motor function developed in Specific Aim 1 as well as the GMFCS as a discrete data element. All data elements identified in the SHOnet CDM that can differentiate between GMFCS Classes will be extracted from SHOnet using a general query.

Data completeness will be assessed for each data element in the phenotype model irrespective of whether that data element satisfies conditions developed for each GMFCS Class identified in Specific Aim 1. Objective 1 will provide a general overview of the extent that structured data entry is used across SHC care sites. Patients may have more than one visit included in the four-year time-period chosen. Due to this, completeness will be evaluated for each unique visit and for all outpatient visits for a unique patient.

Data completeness is dependent on the object of interest. Weiskopf et al. (2013) recommend this be either the patient or a healthcare.[200] In the case of the proposed study, the object of interest is a healthcare process, i.e. documentation, but at a more granular level related to completeness in documentation of specific data elements following patient encounters.[200] Hogan and Wagner's definition of completeness will be used to describe completeness, which is, "the proportion of observations that are actually recorded in the system."[7,200] Therefore, completeness will be calculated for each data element as the presence of each data element divided by the total number of subjects. This will return two completeness percentages for each data element at the unique visit level and unique patient level. In addition, the mean completeness percentage will be calculated as the average of the completeness percentages for each visit and for each patient. After evaluating completeness for unique visits and unique patients, the mean completeness percentage will be described for each GMFCS level. All patients will be grouped based on the presence or absence of a documented GMFCS level as a discrete data element, and then the mean completeness will be compared between groups. The mean completeness will then be evaluated across these five GMFCS levels for the sample of patients.

All patients with CP that do and do not have a GMFCS level documented will be included in the analysis of completeness in this objective. Analysis of completeness is used to describe a component of data quality monitoring as a measure of the extent that data are successfully extracted from the EHR for a CDRN and can be used for the purposes of conducting observational research.[6] Sparse literature exists related to understanding structured entry of data documentation across a distributed healthcare system. This objective will help to understand the deficiencies in collection of discrete data elements for CP management across SHC and will demonstrate the extent that EHRs are utilized for structured data entry.

Objective 2

Objective 2 for Specific Aim 2 will assess the variability of completeness in outpatient visits by describing the extent of differences in discrete data documentation by SHC care sites. This objective builds on the prior objective in analyzing both unique patient and unique visit levels by further stratifying the discrete data by SHC care sites. The objective will describe the distribution of structured patient data collection by these clinics and elicit potential hypotheses as to the patterns and sources of data element missingness. Structured entry documentation of phenotype model data elements may differ based on clinicians, clinical specialty and/or SHC sites, but only SHC care sites are included due to inconsistencies in provider identifiers in SHOnet.

The regional distribution of SHCs presents an opportunity to study the sources and variability of structured data incompleteness within a large-scale healthcare system. While documentation differs based on EHR type, regional location, level of training, etc., SHC and SHOnet allow for analysis of documentation differences across one regionally distributed healthcare system with a diverse staff of clinical specialists using one similar EHR build.

Although the previous objective measures completeness at each row such that each corresponds to a patient visit date, Objective 2 will measure completeness using a descriptive analysis and multi-level regression of the nested nature of the data elements (visits nested in patients, patients nested in SHC sites). An analysis of this nesting would provide important results surrounding the extent of variability in completeness of phenotype data elements by SHC care sites. The variability of data completeness by SHC site will then be evaluated and compared to the volume of patients and visits with CP at each SHC site.

By explaining the multi-level variability of incompleteness of structured data entry for these phenotype model data elements, this objective will help pinpoint the specialties and SHC sites that are high and low performing in structured data entry. Each clinician employs a documentation practice that includes different methods of data entry (structured, unstructured, dictation). A majority of clinicians in a clinical specialty or clinical specialties in a SHC site may use unstructured or narrative means of data entry and documentation, meaning many structured data elements could be produced by a small minority of clinicians or weighted towards specific clinical specialties. If higher volume sites demonstrate a higher percentage of completeness or missingness, then there may be consideration for implementation strategies to improve documentation of discrete data.

Summary

The discrete data stored in CDRNs has the potential to support LHS research and practice. Current studies that leverage these data elements demonstrate the significance of patient health data to inform the development of real-world evidence and clinical practice changes. These studies, however, limit their focus to observable changes in measured continuous or binary outcomes mostly aligned with medicine. Some computable phenotype work has impacted the

LHS field; however, there remains a limited purview of the clinical care fields and disciplines covered in LHS research. Developing innovative methods to measure and classify patient functional performance and outcomes using real-world patient data will greatly influence the future direction of the physical medicine and rehabilitation field and develop real-world evidence for its disciplines.

Sites

Data from all 21 SHCs in North America will be included in the analysis for this aim. Sites differ regionally and by volume of children with CP treated annually. All sites use the same Cerner EHR build. Not all sites hold specific outpatient clinic days for treating patients with CP, and this may influence the completeness of data elements documented. Sites such as Northern California and Chicago hold CP clinic, while Portland and Philadelphia treat patients with CP in a general pediatric orthopedic clinic. For orthopedic and CP clinics, each includes an orthopedic surgeon, nurse practitioner, medical residents, physician assistants, and nurses, and patients then are seen in outpatient rehabilitation clinics by physical, occupational and speech therapists when consulted by physicians. Outpatient rehabilitation services for these patients occur in therapy gyms.

Subjects and Selection Criteria

Subjects will comprise patients with a diagnosis of CP seen at each SHC site over the past four years between 2015-2019. Patients will not be engaged in this study. SHOnet will be queried to extract data elements for patients that meet the following criteria: any ICD-9/ICD-10 codes corresponding to a diagnosis of CP, an outpatient related visit, between 6-18 years-old at time of visit. Each patient in SHC is given a unique SHOnet identifier that is different from their

medical record number. **Table 3.1** includes the ICD 9/10 codes used to classify the patient population with CP across SHC using SHOnet data.

Table 3.1. Cerebral Palsy ICD 9 | 10 Diagnosis Codes.

343 | G80.1	Diplegic Infantile CP, Spastic diplegia, CP, diplegic
343.1 | G80.2	Hemiplegic Infantile CP, Spastic hemiplegic CP, CP, hemiplegic
343.2 | G80.0	Quadriplegic Infantile CP, Spastic quadriplegic CP, CP, quadriplegic
343.8 | G80.8	Other Specified Infantile CP
343.9 | G80.9	CP
344.89 | G83.89	Other Specified Paralytic Syndrome, Spastic triplegia
G80.4	Ataxic CP
331.89 | G31.89	Other Cerebral Degeneration

Data Preparation

Gross motor function phenotype model data elements will be processed and extracted from SHOnet by writing queries for patients that meet the selection criteria outlined above. All data elements for SHC care site will also be pulled from SHOnet to correspond to each observation (patient visit date). This will result in a de-identified dataset for analysis. Using R statistical software, the dataset will be transformed into a usable data frame to conduct an analysis of completeness for Objective 1. The data frame will be dichotomized into those with and without a documented GMFCS and will support subsequent analyses of the data requirements for all five GMFCS levels. The analysis for Objective 2 will require further transformation of the data frame to arrange and group by SHC sites.

Data Analysis

All demographic data will be reported first to describe the patient population with CP. Measures of central tendency will be calculated for all continuous data elements for the purposes of presenting the distribution of key features of the population. Frequencies for all categorical

data elements will be calculated and then visualized using graphical representation. For each phenotype model data element, completeness will be calculated by dividing frequency of values documented by the total number of observations (patient visits and patients) and then reporting the result as a percentage to depict the extent that values for data elements are complete. The mean completeness will then be calculated for the aggregate data elements by completeness for unique visits and completeness by unique patients across all their respective outpatient visits. The relationships between data elements will be further represented through data visualizations. All observations will then be stratified by GMFCS documented and GMFCS not documented as a discrete data element. For each group, mean completeness will be calculated for all data elements and compared between groups at both the patient and visit levels. Those with a documented GMFCS will then be further stratified by the five GMFCS levels and mean completeness will be calculated for each level to compare completeness between each GMFCS level.

Objective 3 will analyze the extent that mean completeness may be attributed to factors specific individual SHC care sites by evaluating the hierarchical levels between visits, patients and SHC sites. The mean completeness will be calculated for each SHC site along with the volume of unique patients and unique visits for each site. The mean completeness is a continuous variable and the volume of CP patients is a frequency, therefore, Pearson correlations will be calculated between these variables to obtain the extent that patient and visit volumes are related to mean completeness percentage of the phenotype model discrete data elements. Visits are nested in patients and patients are nested in care sites, therefore, a multi-level linear regression model is the most appropriate statistical tool to account for this nesting and determine the extent of variation in mean completeness potentially attributed to factors at individual care sites. The

extent of other covariates included in this model besides the three hierarchical levels will depend on the correlations and other data obtained. All findings will be interpreted to describe the extent of completeness of the GMFCS and phenotype model data elements. R software will be used for all analyses.

Outcome for Specific Aim 2

A descriptive analysis of the completeness and variability of the GMFCS and discrete data elements in the gross motor function phenotype model.

Methods for Specific Aim 3

Explore the factors, from a socio-technical perspective, that influence missingness and variability of GMFCS level and gross motor function phenotype model variables using qualitative methods.

Specific Aim 3 explores the factors that influence missingness and variability of discrete data in the EHR. The phenotype models for GMFCS Classes are meant to both aid and eventually circumvent the issues surrounding missingness in documentation of the GMFCS as an easily extractable discrete data element. By exploring potential factors influencing missingness and variability of data in the EHR, this third Aim supports future work to build the knowledge base and understanding regarding *how* and what factors surrounding documentation of discrete data may be addressed using implementation science methodology. The ultimate question is whether missingness of discrete data like the GMFCS level occurs because it is just not accessed or because there are other more latent and unobservable factors that influence how providers think about discrete data elements and documentation in the EHR. This Aim takes an infrastructural and sociotechnical approach to understanding the phenomena of missingness.

Since missingness is often attributed to individual level factors and often managed by statistical methods to manufacture a "complete" sample of record, this aim identifies the system-level and professional factors of the healthcare system that produces missingness.

Infrastructures are central to implementation, operationalization, and the design of continuous learning systems of healthcare. The EHR not only serves as a document and data repository, it also serves as key technology infrastructure to facilitate the processes, communication and decisions performed by clinicians. Data and information managed and represented by technological infrastructures can inform the care delivery process and produce measures of quality and patient outcomes. However, in most cases, infrastructure and implementation studies focus not on the measures or outcomes these infrastructures *produce*, but the labyrinths, technology, mechanisms and processes *of* the infrastructures, the relational approaches to *understand* the infrastructure that produces an outcome, and how infrastructures are created and enacted.[15]

The EHR supports the storage of routinely structured and unstructured data for clinical use while clinician actions concurrently build the data and information infrastructure. The clinician relationship with these infrastructures is multi-faceted and requires further dissection. Star writes that "the ecology of the distributed high-tech workplace…is profoundly impacted by the relatively unstudied infrastructure that permeates all of its functions…Study an information system and neglect its standards, wires, and settings and you miss equally essential aspects of aesthetics, justice, and change (p. 379)."[15] To some extent, missingness is often a forgotten product of the healthcare system infrastructure, and literature is sparse as to the causes of missingness in the EHR. The relational nature of infrastructure, that "one person's infrastructure is another person's topic or difficulty (p. 380)"[15] foregrounds the importance of studying

constraints, tensions and conflicts related to power, control and interprofessional relationships that exist for people within and interacting with health system infrastructures.[188] In the context of LHS and computerized clinical documentation, this relational approach focuses on studying infrastructure and missing data through a socio-technical lens using qualitative methods and case-studies to understand technical infrastructure and the surrounding relationships.

Specific Aim 3 uses qualitative methods of observations and interviews to explore the aforementioned relationships and complement Specific Aims 1 and 2. The first two aims focus on the extent that CDRNs of EHR data can support the construction of classifiers for gross motor function based on existing clinically documented discrete data. Specific Aim 3 investigates how clinicians document overall, their perceptions of documentation, and how they document discrete data, all to gain a better understanding of the factors that influence missingness. This aim is divided into two objectives:

Objectives for Specific Aim 3

Objective 1: Characterize the transformation of data from the SHC EHRs to SHOnet.

Objective 2: Understand the perceptions, processes, and routines of documentation by clinicians (MD, NP, PA, PT, OT) using EHR systems and managing patients with CP across three regionally different SHC clinics.

Objective 1

Objective 1 of Specific Aim 3 examines the transformation of data from the SHC EHRs to SHOnet. Objective 1 for this aim focuses strictly on the technical consideration for incompleteness in GMFCS computable phenotype data elements. This objective will use document analysis and informal interviews to understand the process by which EHR data are transformed into a controlled vocabulary for observational research and stored in SHOnet. The

findings from this activity will help me describe the flow of data from initial documentation through the transformation into the pediatric-specific CDM and to the quality monitoring process at SHC headquarters. This will serve as key background to demonstrate that data missingness and variability may be due to the source of data (i.e. documentation) rather than the data transformation process. Data quality procedures are commonly employed for CDRNs to ensure that data are accurate and complete, however CDRNs generally comprise heterogeneous healthcare centers with different EHR vendors and builds, which adds complexity to the transformation of data into a CDM. Based on an analysis of sources of data quality issues for PEDSnet, Khare et al. (2018) identify that approximately 35% of data quality issues are caused by the extract, transform, load code, and this may be due to the problems with heterogeneity of healthcare centers.[28] It is anticipated that data in SHOnet extracted from EHRs across a homogeneous healthcare centers in one system and one EHR may exhibit less data quality issues of missingness related to the extraction and transformation of EHR data. Documents related to the extract, transform, load code and process, along with data quality control processes of SHOnet will be obtained and reviewed. Furthermore, key informants of the SHC Headquarters involved in Quality Measurement and Performance Excellence will be informally interviewed to better understand the SHOnet technical infrastructure and the flow of data from EHR documentation to storage in SHOnet. Objective 1 is more operational in that it will result in a refined understanding of the ETL process and SHOnet technical infrastructure, rather than produce empirical findings.

Objective 2

Objective 2 of Specific Aim 3 explores the perceptions, processes, and routines of documentation by clinicians (i.e., MD, NP, PT, OT, RN) using EHR systems and managing

patients with CP across three regionally different SHC clinics. Objective 1 examines documentation practices in order to better characterize the sources or causes of missingness in discrete data entry. As described in previous sections, missingness of discrete data is evident in the EHR, notably in GMFCS levels. Missingness has the potential to influence the quality and performance of measurement and overall validity of research results, especially in dynamic and unpredictable healthcare settings without highly standard processes of data entry. This objective investigates the extent that missingness is actually a product of the healthcare system and more external forces and that these factors manifest in clinical documentation and its practices.

Clinical documentation is the process of creating clinical notes that record the observations, impressions, plans and other activities surrounding patient-clinician encounters in a healthcare system.[10] Computerized documentation is a process whereby the clinicians interact routinely with a computer interface (EHR) to describe a patient encounter. Clinical notes are generated to achieve numerous goals: recordkeeping and prompting; communication between collaborating clinicians; to justify reimbursement by third-party payers for service provided; a record to be used in the court of law; and to support clinical research and quality-improvement efforts.[10-12]

Exploring the factors that contribute to missingness and variability in data elements for classifying gross motor function requires inquiry into what is deemed heteropraxial and heteroglossial.[15] This is especially true when one EHR-build is used across a distributed yet homogeneous system like SHC. Clinical providers often have discretion regarding how, when and what they document: whether narrative/dictation, structured or unstructured entry; during, directly after an encounter, or after all patient encounters in a day. *What* is documented may be influenced by department, organization, state and federal policy, however this often relates to

reimbursement and other financial incentives: documentation of quality measures, CPT codes, ICD-9/10 codes, and requirements by the Centers for Medicare and Medicaid Services (CMS). The variability in how and what clinicians document in a large-scale system requires qualitative methods of ethnography related to interviews with providers and field observations of their actual documentation practice.

Objective 2 also begins the initial phases of dissemination and implementation research by understanding the factors producing variability of documentation processes and practices in a clinical setting.[178] Understanding and pinpointing these factors will inform further work in order to develop and implement strategies to improve the collection of data elements that are integral to measurement of system performance and development of real-world evidence. Although the proposed work will not develop the specific dissemination and implementation strategies, future work should support optimal clinical and documentation practices by clinicians.

Optimal documentation will be considered as the consistent and accurate reporting of clinical encounters in designated narrative and structured data fields in the EHR. Optimal clinical practice will be considered as the compendium of practices which produces consistent performance of and adherence to clinical recommendations; in the case of the exemplar, to manage hip dysplasia in CP patients by documenting the data elements critical for classifying gross motor function. This objective is an important step to develop a dissemination strategy for research findings and how to address interprofessional relationships and tailor clinical practice changes to optimize documentation and measure care across SHC. While Rosenbloom et al. discuss the tension between expressivity and structured documentation, and the benefits of allowing clinicians to choose their documentation method based on factors such as workflow and

note content requirements, the extent that expressive/narrative text and structured data entry should and can be balanced requires further study.[10,12]

This objective will use qualitative methods to conduct a thematic analysis that includes data collection through non-participant field observations and semi-structured interviews to better understand clinical documentation practices in clinics at SHC. Much of this objective aligns with ethnography to conduct a thematic analysis. In ethnography, emphasis is placed on the collection of observational and interview data about real-world interactions, practices and processes through pragmatic, reflexive and emergent ways to understand what is actually happening in a clinical setting.[189,190] An ethnographic approach is required because it will provide an interpretive perspective to describe the values, beliefs, practices, and attitudes surrounding clinical documentation practices of encounters in pediatric clinics, as well as understanding the dynamics of clinic workflow.[189] Although there are limited studies using ethnography for LHS research, literature in health informatics and infrastructure studies demonstrates the benefit of using ethnography to understand relationships in a socio-technical system.[1] Thematic analysis will then be used to interpret and construct the latent themes related to the clinician and infrastructure relationships and how these factors contribute to missingness of discrete data in the EHR.

Philosophical Framework for Objective 2

This objective draws on the philosophy of Critical Realism and uses this as a philosophical framework to understand the generative mechanisms that influence the documentation of discrete data in the EHR. Critical Realism considers the *real* mechanisms that generate the *actual* and *empirical* conditions or events researchers can observe.[201,202] Based on the writings of Bhaskar, the architect of this theory of science, the *real* is not something that can

be observed because it exists independent from human perceptions, theories, and constructions.[202] These unobservable structures and factors are considered generative mechanisms that give rise to observable and experienced phenomena. The literature that uses Critical Realism in healthcare systems research is sparse; however, a general example of this Critical Realist thinking is capitalism (real) and how its effect on institutions results in poverty (actual) and housing evictions (empirical). Zachariadis et al. (2013) explain that Critical Realism observes reality as an open and complex system that comprises numerous mechanisms and conditions.[201] Therefore, in conjunction with the structures, powers, and liabilities of a complex system, we should study the conditions in which "generative mechanisms" are experienced.[201] The structure of this philosophy in depicted as a stratified ontology (**Figure 3.1**) in a hierarchy of three domains: real, actual and empirical. The healthcare system is not closed off from the real-world, like laboratories with highly controlled experimental conditions; therefore, a positivist and even a post-positivist theoretical approach is inappropriate if the goal is to understand the numerous causal mechanisms associated with missingness of discrete data in the EHR. Rather, healthcare systems are open to the complex array of both observable events and unobservable structures and mechanisms that inform and shape processes and performance.[201-203]

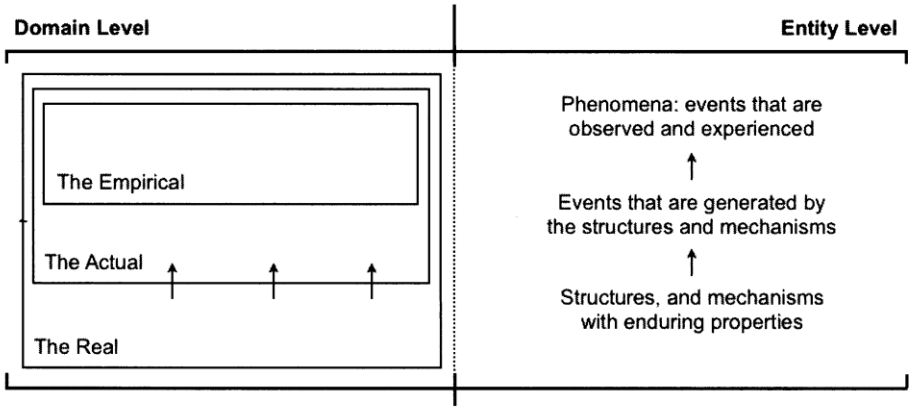


Figure 3.1 The Stratified Ontology of Critical Realism (Reproduced from Zachariadis et al., 2013; Bhaskar, 1975).

Interview Guide Development Using Normalization Process Theory

Clinical documentation is one type of care delivery process whereby its practices are highly routinized in clinical settings and understanding these may inform the development of LHSs. In order to develop strategies to improve clinical documentation practices, it is necessary to study how clinicians document based on their responses to conditions of constraint in clinical settings. These constraints may include standards, technology and established workflows, and organizational structure, climate, and culture. The Normalization Process Theory (NPT) is a middle range action theory organized in a matrix-based framework that helps investigators understand these constraints and their influence on human agency. A recent systematic review of 29 studies using the NPT demonstrates it is a beneficial theoretical framework to explain social processes in healthcare related to e-health and telehealth, and to guide implementation processes.[187] The most closely related study using the NPT was by Pope et al. (2013). This team of researchers applied the NPT in a cross-case comparison study to describe how the use of a clinical decision support system became embedded in three different healthcare settings in the UK.[185] They demonstrated how similar processes and social relationships existed in these settings and how each setting employed strategies to ensure successful implementation of the system.[185] Although analyses are not directly comparing care sites, the properties and theoretical foundations of the NPT around dimensions of work processes are instrumental and informative to develop and localize the interview questions for semi-structured interviews.

This theoretical framework (**Table 2.3**) includes constructs and components which structure an assessment of processes and routines relevant for implementation of complex interventions.[169,186] The NPT is necessary for this dissertation because it will guide the development of questions grounded in a theoretical frame of reference to elucidate the constraints and tensions which explain differences and preferences of clinical documentation

practices that influence missingness. The NPT helps explain these aspects and consists of four primary constructs that describe actions in organizational environments: coherence, cognitive participation, collective action, and reflexive monitoring.[168] Each construct comprises four distinct components that can be useful in supporting qualitative data collection and analysis, but the NPT is only uses to inform data collection.

Summary

How and why documentation is performed by clinicians using EHRs in their daily practice is not easily captured using survey assessments or strict analysis of EHR data. Although many studies on the use of health information technology in healthcare settings are designed to measure how a variable changes as a result of some deployment of a technology, these positivistic methodological approaches are scrutinized by social scientists for oversimplifying how a new technology or process involving a technology is adopted/resisted and used/abandoned in social settings.[189] An ethnographic approach and thematic analysis, however, can help a researcher understand these issues surrounding reflexivity by focusing more on the social, cognitive and contextual influences on the use of technologies.[189] Therefore, this objective uses these approaches and is informed by Critical Realism to describe the more process-related aspects of clinical care and documentation that influence the extent of discrete data production in an EHR. Field observations also help to describe the work environment where clinicians conduct their daily practices and determine how and when clinicians document patient encounters. These are critical components to understand several factors which may influence the quality of data produced and the success of a practice change strategy, such as the environmental constraints limiting optimization of EHRs and the tensions surrounding organizational requirements and individual agency with how to perform work tasks.[12,204] Not only are these components critical to

data documentation and practice change, but they may also influence responses to changes in technologies and the dissemination and adoption of new guidelines and real-world findings from research via SHOnet.

Setting

Three regionally diverse SHC CP clinics will participate in Specific Aim 3. Each clinic treats the primary condition of CP and subsequent complications. There are generally two attending physicians on service for each clinic with residents, nurse practitioners and physician assistants present. Two SHC CP clinics, Northern California, and Chicago, participated in field observations and interviews during site visits. These clinics see a high volume and diverse population of children with CP. Children present with their parents in the waiting room, check-in and are either transported to Radiology for X-Ray or taken to a patient room for evaluation by nursing and the physician. The Northern California SHC has a highly specialized group of clinicians for treatment of CP, is located in Sacramento, CA, and manages patients traveling primarily from Nevada, Oregon, and Idaho. The Chicago SHC treats patients primarily from the upper Midwest in the states such as Illinois, Michigan, Wisconsin, and Minnesota.

Subjects and Recruitment for Interviews

Approximately 7-10 subjects will be recruited from each site (n~20) to participate in interviews. Subjects will comprise a range of key informants from each site: a variety of clinicians (physicians, physician assistants, nurse practitioners, nurses, occupational therapists, and physical therapists) and clinic managers. These informants offer a unique perspective surrounding the use of EHRs and different experiences managing clinical documentation. Specifically, to be considered a key informant, subjects must have working knowledge of CP,

documentation responsibilities using the EHR, and experience using EHRs. Patients will not be directly engaged during field observations, as the primary subject of this work is the provider and their use of health information technology to support and document patient-provider encounters.

Convenience sampling will be used to recruit subjects and assisted by liaisons at each SHC care site. Each site liaison or clinic manager will develop a list of key informants working in each participating clinic and key informants will be contacted via email, providing study and interview details. Key informants may also be recruited on-site and provided details about the present study. Video-conference interviews will also be offered as an option. Site field observations will be scheduled during the same visit as semi-structured interviews. Observations will include field interviews with clinicians. These clinicians will primarily include orthopedic surgeons, physical medicine and rehabilitation physicians, nurse practitioners and nurses in clinic.

Data Collection and Management

Semi-structured interviews will be approximately 30-45 minutes and audio recorded. Field observations will occur over approximately 50 hours total across 2-3 clinics because the small clinic size and low patient census may result in less time to achieve saturation in observed processes. Field interviews will occur throughout observations and intermittently audio recorded. Data collection via semi-interviews will occur at each SHC site with key informants in a reserved conference room. Field observations will occur in the physician workstations and the patient rooms of each clinic. Observations will not occur in the waiting room, front-desk area, laboratory office, or general nursing stations. Each SHC site has its own clearance process for clinical observers to conduct field observations. The necessary clinical observer materials will be provided, and clearance obtained.

All interviews will be conducted with a variety of key informants as detailed above. Verbal consent will be obtained from subjects to be audio-recorded. The interview guide (Appendix B) for semi-structured interviews was informed by existing literature across organizational studies, health informatics, dissemination and implementation science and the NPT toolkit (http://www.normalizationprocess.org/). The interview guide covers seven topic areas: clinic/organizational environment and workflow; clinical documentation practices; adaptation to health information technology; CP management; data governance; knowledge pertaining to data use by health systems; and evidence-based healthcare and knowledge dissemination. Each question from the interview guide is mapped to a component(s) of the NPT to ensure optimization of the NPT and that each question addresses the NPT constructs and components. The interview guide and subsequent revisions were previously circulated with subject-matter experts to achieve good structure and clarification in questions. Although the interview guide consists of enough questions for a two-hour interview, many questions will be used to guide follow-up questions to follow the phenomena under study. In additions, the Think-Aloud Method[205,206] will also be employed by having participants use the EHR, as able, to better understand how they think about, use, and navigate the EHR interface. Identifiable patient information will not be observed during these encounters because the focus of this work is on how the clinician uses the EHR system and the fields they use to document their clinical encounters.

The notes obtained from field observations and interviews will be used to stimulate conversation during further observations of EHR use and participant interviews. This will add an element of participatory research into the data collection phase because this participation provides reflexivity in the initial construction and curation of themes. These multiple sources of

data provide sufficient depth to crystallize the types of semantic and latent themes that may explain the occurrence of missingness of discrete data. All audio-recorded interviews will be transcribed using NVivo 12 software. All field interviews and observational notes will be written electronically using an Apple iPad tablet and then transcribed. All audio-recordings and transcriptions will be stored securely and password-protected on a laptop at the University of Michigan.

Data Analysis Plan

The analyses for Specific Aim 3 follow a thematic analysis process. A thematic analysis will be conducted of the final dataset using an iterative approach to ensure validity and convergence in the constructed themes. The thematic analysis follows the six-step approach described by Kiger and Varpio[207] and Braun and Clarke.[208] The six stages are sequential: "Step 1 – Familiarizing Yourself with the Data", "Step 2 – Generating Initial Codes", "Step 3 – Searching for Themes", "Step 4 – Reviewing Themes", "Step 5 – Defining and Naming Themes", and "Step 6 – Producing the Report/Manuscript".[207] The process for Objective 3 includes compiling and transcribing field notes and audio-recorded interviews to gain familiarity with the dataset. Initial codes will then be generated throughout the transcripts. Codes will be iterated on for 2-3 passes to ensure veracity in the constructed codes. Final themes, or factors, will be constructed from an examination of the relationships between codes factors associated with missingness. These themes will be reviewed and revised to ensure they best interpret the respective codes. This process will produce semantic and latent themes about the generative mechanisms surrounding healthcare work processes of clinical documentation that contribute to missingness of discrete data. Once analyses are complete and results are interpreted, participants

may be contacted if there is a need for follow-up questions. The last step of this process is to write-up the manuscript in monograph form and extract quotes/excerpts, as necessary.

Outcome for Specific Aim 3

Identification of factors that contribute to missingness in documentation of GMFCS and other discrete data essential for classifying and managing patients with CP.

SUMMARY

The following proposal provides three specific aims to explore and better understand key infrastructural and informatics issues in healthcare surrounding documentation to generate usable data and meaningful knowledge. Specific Aim 1 uses a mapping approach to create a phenotype model of gross motor function for children ages 6-18. Specific Aim 2 builds on this and uses quantitative methods to describe the missingness and variability of discrete data elements in the phenotype model and for the GMFCS that are stored in SHOnet. Specific Aim 3 then uses qualitative methods to explore the causes of the missingness in these data using field observations and semi-structured interviews informed and guided by Critical Realism and the NPT. Specific Aim 3 uses an investigative approach to explore the processes by which EHR data are produced and the how factors that shape documentation contribute to missingness of data in the EHR.

Clinicians continue to use a broad palette of methods to document clinical encounters[10,12], but at the expense of usable data. The re-use of existing structured data from EHRs in CDRNs may support the development of cohorts of patients based on their characteristics of functional performance. However, the missingness of these data elements in such data resources needs to be explored in order to characterize the extent of structured data collected, its availability and

quality for re-use. As LHS initiatives continue to develop, we need to expand the knowledge of the infrastructure supporting LHS. Clinical documentation has a role as LHS infrastructure, but it is understudied in the literature and rarely considered in the context of LHS. Studies consistently demonstrate data quality issues in healthcare; therefore, we need to understand mechanisms surrounding clinical documentation and how these influence both missingness and the types of data documented for research and learning.

Chapter 4

Development of a Standards-Based Phenotype Model for a Gross Motor Function Classification System

INTRODUCTION

The Gross Motor Function Classification System (GMFCS)[136] is a critical element in hip surveillance protocols to monitor and improve outcomes in children with Cerebral Palsy (CP) who are at risk for developing hip dysplasia, displacement and dislocation. [128,140,153,154,209,210] GMFCS is commonly documented as part of routine clinical care of children with CP by orthopedic surgeons, physiatrists, occupational and physical therapists, and nurse practitioners. It is also used to inform rehabilitation professionals about post-surgical rehabilitation treatment intensity. Hip surveillance protocols rely on identifying candidate cohorts of patients based on GMFCS levels to inform and evaluate perioperative care processes and outcomes. Unfortunately, GMFCS is not always documented as a discrete data element in the electronic health record (EHR), but rather it is often embedded in free-text and dictated clinical notes, making cohort identification difficult. Technical strategies to improve the identification of cohorts by GMFCS level would be a great benefit to research, quality improvement and clinical practice in pediatric rehabilitation settings.

The GMFCS, as described by Palisano et al.[136], includes a standardized phenotype case definition for each of its five levels that depict gradations in gross motor functional performance. These definitions inform the breadth and depth of patient characteristics that can be mapped to an ensemble of EHR discrete data elements to create an abstraction of the GMFCS levels for

pediatric CP populations. Therefore, this chapter focuses on constructing an abstraction of these phenotype definitions using discrete data elements in the EHR to create a phenotype model of gross motor function. A phenotype model is a group of patient characteristics that, if present in a patient record, may be able to predict a patient's level of function.[195] This type of model can be semantically interoperable if it is built from standardized data elements of patient characteristics. This differs from conceptual models, information models and concept maps because those entities model the relationships between concepts, data or develop a theory about a process or behavior, which is beyond the scope of this chapter. The development of a gross motor function phenotype model supports the design of a computable phenotype to identify cohorts of patient populations[116,117,120] based on distinct levels of gross motor functional performance for large-scale observational and comparative effectiveness research in pediatric rehabilitation.

Currently, evidence that applies computable phenotyping methods to identify patient cohorts by functional performance in pediatric rehabilitation is sparse, while only limited studies exist that develop or use phenotype models from health data.[194,196,198,199] Fried et al. (2001) developed a phenotype model of frailty using data from a large-scale cardiovascular study[194], and incorporated such patient characteristics as ambulation quality, reduced strength, unintentional weight loss and reduced activity tolerance to develop an index of frailty.[195] A phenotype model of gross motor function could be similarly built and leveraged for pediatric rehabilitation.

Pediatric rehabilitation relies on an interprofessional team to provide patient-centered care for patients with physical disability and functional performance deficits. Many aspects of patient care are impacted by characteristics of the patient's functioning across multiple physical health domains related to mobility and gross motor functioning. If researchers can identify and stratify cohorts of patients by gross motor function status, then they are better situated to study

how these patient groups respond to surgical intervention and rehabilitation treatment intensification. A phenotype model for gross motor function constructed from standardized EHR discrete data elements would support cohort identification in pediatric rehabilitation research and quality improvement. The re-use of patient health data in rehabilitation advances and supports a key area of a Learning Health System (LHS): real-world knowledge from real-world data collected during routine patient care.[33,68,109] Therefore, in this chapter, we present the design of a phenotype model of gross motor function based on a theory and expert-informed approach and created from discrete data elements in a standards-based pediatric data model readily available in an EHR.

RESEARCH QUESTION AND OBJECTIVES

The research question that drives this study is, "To what extent can real-world data networks be leveraged to build classifiers of patient functional performance and physical disability?" The primary objective of this chapter is to construct a phenotype model of gross motor function by identifying clinically sensible EHR discrete data elements that differentiate between GMFCS levels for children with CP. A secondary objective is to define three classes of the gross motor function phenotype model by structured rules based on a consensus set of data elements available in an EHR and corresponding value sets. For this work, the existing GMFCS level case definitions serve as the gold standard phenotype definitions of gradations in gross motor function in children with CP of which data elements are mapped.

MATERIALS AND METHODS

Gross Motor Function Classification System

The GMFCS[211] is a standard screening tool to classify performance of gross motor functional activities for children with CP. The GMFCS follows a five-level ordinal classification structure: I, II, III, IV, V.[211] Each level includes a phenotype definition that describes the key features of a person's gross motor performance, general mobility, activities of daily living (ADLs), device use and capacity to engage in activities and play at school (**Figure 2.8**). The GMFCS is also considered a better indicator of hips leading to displacement in a surveillance program than classification by subtypes of CP by the traditional system based on body region involved (spastic hemiplegia, diplegia, tetraplegia and quadriplegia), because it describes performance and participation rather than physical impairment.[209]

The GMFCS level definitions provide a description of current functional status, and also has predictive value for future functioning level for children with CP.[211-213] A higher GMFCS level indicates increased level of physical assistance and use of external (assistive or mobility) devices required to complete functional activities. For example, patients at GMFCS V require total physical assistance to perform all activities and are unable to propel their own wheelchair; thus, they require a manual wheelchair with trunk support that is propelled by family or caregiver. Patients at GMFCS I are independent in all mobility activities, can run, jump, and play without physical limitations, and do not require the use of external devices. Given this initial effort in what may be a more difficult classification, i.e. function rather than diagnostic, we chose three classes rather than the five GMFCS classes. GMFCS levels collapse to three clinically sensible classes related to hip surveillance in CP and informing care patterns: Class 1) GMFCS I and II; Class 2) GMFCS III; and Class 3) GMFCS IV and V. The GMFCS is further

refined by age groups (birth-2, 2-4, 4-6, 6-12, and 12-18) that reflect age-related gross motor development and mobility skills. For the present study, we focused on the GMFCS for ages 6-18 years old. The other age-range specific GMFCSs reflect the same underlying concepts GMFCS level is considered stable after age 2.[211,213]

Setting

In the past decade, federal funding and non-profit organizations supported establishing LHS in pediatrics by developing several national clinical data research networks. PEDSnet, a patient centered outcomes research institute (PCORI) funded effort, is one example of a general pediatric care data network to support LHS activities. The Shriners Hospitals for Children (SHC) Health Outcomes Network (SHOnet) is specific to specialized care and pediatric rehabilitation. SHOnet includes data resources that are derived primarily from discrete data elements contained in the EHR. SHOnet maintains a common data model (CDM) that harmonizes EHR data elements across 21 pediatric specialty hospitals in the SHC System. SHCs provide specialty services for a variety of diseases and disorders, most notably management of CP.

SHOnet includes extensive mappings to EHR data elements for describing care delivery and outcomes common in pediatric rehabilitation, including surgical data, as well as physical and occupational therapy observational data elements. SHOnet adapts the existing pediatric-specific CDM for PEDSnet which is based on the Observational Medical Outcomes Partnership (OMOP) structure.[3,107,214,215] All SHOnet data elements for observational data are stored as OMOP concept identifiers (IDs). Medications are all stored as RxNorm concept IDs. Initial queries of SHOnet for children 6-18 years-old with CP returned approximately 32,000 distinct cases across SHC hospitals since 2011. The SHOnet team defined cases of CP as the presence of any ICD-9/10 or CPT codes related to CP for a given patient. For the purposes of this study, we only

considered available structured data elements stored in SHOnet that could be queried and support GMFCS phenotypes. In our initial SHOnet queries, we determined inconsistent capture of GMFCS level across SHC. Of the roughly 32,000 unique CP patients managed across SHC, 15% include a GMFCS level documented as a discrete data element.

Procedure

Our methods are divided into the two objectives of this study. 1) To construct a gross motor function phenotype model by identifying clinically sensible EHR discrete data elements that differentiate between GMFCS levels for children with CP. 2) To define the classes of gross motor function by structured rules based on a consensus set of data elements available in an EHR and corresponding value sets. The scope of this work is informed by the first five Desiderata for computable phenotyping using EHR data developed by Mo et al. (**Table 2.2**).[120] We adapted the next three Desiderata to the present study by defining a four-phase iterative process which were informed by Westra et al. and their work in modeling EHR data for secondary use.[216]

Objective 1: To identify clinically sensible EHR discrete data elements of the gross motor function phenotype model that differentiate between GMFCS levels

Phase 1: Initial Selection of Data Elements

In phase one, two clinical domain experts on the SHOnet team selected concept IDs for data elements and value sets from the SHOnet CDM that aligned with gradations in gross motor function. We selected data elements if they could be queried in SHOnet (as discrete data) and based on existing knowledge of routine care, evaluation and treatment by SHC therapists and nurses, and the extent the value set can distinguish between GMFCS classes. We reviewed 10000+ observational structured data elements in the SHOnet CDM, which resulted in our initial selection of 540 data elements clinically relevant to gradations in GMFCS levels. Then we

eliminated redundant data elements and ones that appeared extraneous to gross motor function. This resulted in a final set of 89 data elements which we compiled into an Excel workbook.

Phase 2: Development of Variable Classification Exercise

In phase two, we collapsed the selected concept IDs into 28 variables to form the basis of the expert-panel exercise. We accomplished this by grouping concept IDs into "derived" variables if many referred to a similar concept with overlapping value sets. For example, one concept ID corresponds to "feeding ability", however, nine qualifier codes exist which classify gradations in feeding ability performance (i.e., independence to no oral feeding). This contrasts the concept ID for "ambulation level," which is a unique data element and already maintains a standard 6-level value set from independent to dependent performance. These 28 variables included 14 corresponding to unique data elements and value sets, and 14 derived from multiple data elements and value sets. All concepts informed severity or gradations in gross motor function.

For the purposes of clarity in the panel classification exercise, we modified two variables prior to distribution: Gross Motor Concerns, and Mobility Device Used. The derived variable "Gross Motor Concerns" comprised seven unique data elements all clinically evaluated using a "yes/no" value set: ambulatory with assistance; assistive devices needed; household ambulation; tires easily; trips/falls frequently; unable to sit independently; and, does not perform household ambulation. The other derived variable, "Mobility Device Used," included four data elements: wheelchair independently; manual wheelchair; power wheelchair; and, unable to propel own wheelchair. We divided this variable into two distinct concepts: mobility device type (none, manual, power, or both manual and power) and level of independent mobility (does not use

wheelchair, wheelchair independently, or unable to propel wheelchair). The final exercise comprised 31 variables for expert review.

Phase 3: Expert Panel Review Exercise

In phase three, we recruited a panel of domain experts to review the 31 variables and independently complete a two-step evaluation exercise to assess variable differentiation. Four licensed clinicians and researchers with extensive knowledge of CP from three different SHCs formed the expert-panel. The panel provided expert opinion on the extent that variables differentiated across the three GMFCS classes. The panel averaged over 20 years of clinical experience.

Each panelist classified performance for each of the three GMFCS classes for patients 6-18 years-old by assigning values to each variable. selecting multiple values for each variable if warranted. Panelists assigned values to the 31 variables for each GMFCS class, thus completed 93 distinct classifications. Panelists then rated their perception of how well each variable distinguished between GMFCS classes by applying a 5-point rating scale (1- does not distinguish at all, 3 – distinguishes moderately, 5 – distinguishes very well) to each variable in step two. Examples of these two processes are provided in **Figure 4.1** and **Figure 4.2**. At the end of

Figure 4.1. Example process for applying rating classifiers for variables by each GMFCS Class.

DOMAIN CONCEPT	RATING CLASSIFIER	GMFCS I and II	GMFCS III	GMFCS IV and V
1. Mobility Device Used	0 = None 1 = Manual wheelchair 2 = Power wheelchair 3 = Both	0	1	3
2. Wheelchair Independent Mobility	0 = Does not use wheelchair 1 = Wheelchair Independent 2 = Unable to propel own wheelchair	0	1	2
3. Primary Mobility	0 = No device 1 = Ambulation with device 2 = Independent manual/power wheelchair 3 = Dependent	0	1,2	3

DOMAIN CONCEPT	RATING CLASSIFIER	RATING
1. Mobility Device Used	0 = None 1 = Manual wheelchair 2 = Power wheelchair 3 = Both	4
2. Wheelchair Independent Mobility	0 = Does not use wheelchair 1 = Wheelchair Independent 2 = Unable to propel own wheelchair	5
3. Primary Mobility	0 = No device 1 = Ambulation with device 2 = Independent manual/power wheelchair 3 = Dependent	4

Figure 4.2. Example process for rating (on 5- scale) how well each variable differentiates between GMFCS Classes.

the exercise, panelists had the option to recommend additional variables they felt may distinguish between GMFCS levels. Each panelist completed the exercise independently and did not review other panelists responses. Results of this exercise form the basis of the development of structured rules to stratify the phenotype model by GMFCS classes.

Data Analysis

This study used an iterative approach to analyze the responses to the expert-panel exercise. Step one of the panelist exercise supported panelist decision-making for step two described in objective two below. To analyze step one, we reviewed the values that individual panelists assigned for each variable. Then, based on panelist consensus, we determined an overall assigned variable value. If a panelist assigned multiple values to a variable, then the breadth of values they selected was considered the assigned value. This accounts for the potential cascading of performance within a GMFCS class. If a variable incurred a tie, then both values were included as the final value. If panelist consensus or a tie did not occur, all assigned values were included in the overall value. For exercise step two, we analyzed panelist responses to determine how panelists rated the extent that each variable differentiated between the three GMFCS classes. We retained a variable when a consensus of panelists rated it ≥ 3. If a variable was split, for example if it received two ratings of ≤ 2 and two ratings of ≥ 3, then we retained the variable. If a variable received a consensus rating of ≤ 2, then we did not retain the variable in the final list of variables.

In addition to variable selection, we analyzed each variable for conformance between the panelist assigned values and how the variables were rated across the three GMFCS classes. If a variable included the same assigned value across all groups, then the variable was not retained, as this indicates the variable does not differentiate between GMFCS classes. The final list

included variables retained and their overall assigned values for each GMFCS class. We used Microsoft Excel to complete all analyses.

We allocated the final variables into domains of gross motor functional performance that were informed by GMFCS phenotype definitions and components of the ICF (International Classification of Function, Disability and Health). These domains included but were not limited to neurologic function, motor performance, activity performance, mobility performance, devices used.

Objective 2: To define the classes of gross motor function by structured rules based on a consensus set of data elements and corresponding value sets

Phase 4: Determination of Structured Rules by GMFCS Classes

In phase four, we evaluated the overall gross motor function phenotype model constructed in objective one to create three sub-models based on GMFCS classes. Each model comprised the same variables and value sets to design structured rules that instantiate membership to one of the three GMFCS classes. We organized the variables by their respective value sets and then constructed rules based on the gradations in how the panelists assigned performance values to each variable. Each rule has human-readable logic and contains a stem, logic statement and qualifier stratified by value sets. For each rule, we included the OMOP concept IDs for data elements and values to encourage semantic interoperability and generalizability with other health system data warehouses, networks and registries built based on OMOP. To distinguish between each GMFCS class, we selected variables to create the primary root rules that partition the classes. Two SHOnet team members with informatics and clinical domain expertise reviewed the veracity of the rules for the assignment of values and logical operators in each GMFCS class.

RESULTS

Objective 1: To identify clinically sensible EHR discrete data elements of the gross motor function phenotype model that differentiate between GMFCS levels

The final gross motor function phenotype model consisted of 82 discrete data elements found in the EHR. The expert panel identified 23 of 31 variables that at least moderately (≥3) differentiated between GMFCS classes. The three data elements for "Gross Motor Concerns" and "Mobility Device Used" returned to their respective derived variables which resulted in 20 total variables. These variables corresponded to 65 data elements; therefore, the panel agreed with approximately 73% of data elements selected by the SHOnet team. In post-exercise discussions, two panelists verbalized the importance of including variables for gastrointestinal medications and anti-epileptic/muscle relaxant medications because these medication types help distinguish between high and low GMFCS levels. Upon review of the SHOnet CDM, 17 RxNorm concept IDs referred to these two medication variables. This resulted in a total of 82 data elements for the overall phenotype model. A list of all 82 data elements and value sets is provided in Appendix C. These data elements were collapsed into 22 variables, of which 16 variables are derived from multiple data elements.

The analysis of conformance revealed inconsistent ratings for two variables. For the variable "General Lower Extremity Muscle Tone," panelists perceived this variable was able to, at least, moderately differentiate between GMFCS classes (≥ 3). However, panelists assigned the same performance value to each GMFCS class without any gradation in the performance. This variable was not retained for this inconsistency, however panelists also selected two joint-specific variables related to lower extremity muscle tone (i.e. "Knee Tone" and "Ankle Tone"), which are scored on a standardized scale that better differentiates between GMFCS classes. The other variable was the derived variable "Elbow Tone," which included the two data elements of

flexor tone and extensor tone. Two panelists rated the variable ≤ 2, one panelist declined to rate the variable, and another rated it a 3. The overall performance values applied to this variable followed a clear gradation across each GMFCS class [i.e. by Modified Ashworth Scale (MAS) score (Class 1: 0,1,1+; Class 2: 1,1+, 2,3; Class 3: 2,3,4)]. At the discretion of the investigator, this variable was retained in the phenotype model.

Domains of the Phenotype Model

The final list of 22 variables identified by panelists spanned six domains: Medication Use, Neurologic Function, Mobility Performance, Activity Performance, Motor Performance, and Device Use. **Table 4.1** provides the list of 22 variables that are sorted by domains and data elements for each GMFCS Class. Activity Performance includes four variables (19 data elements) for current reported performance of ADLs (feeding, toileting and dressing, bathing, and grooming) and home treatments. Motor Performance includes six variables (10 data elements) for gross motor strength and muscle tone for both upper and lower extremities, and presence of drooling/oral secretions. Mobility Performance includes four variables (10 data elements) for performance of general ambulation, stairs performance and the primary mode of mobility. The Device Use includes four variables (20 data elements) for mobility and assistive devices used by patients, to include walkers, wheelchairs, forearm crutches, and canes. Medication Use includes two variables (17 data elements) for gastrointestinal, anti-epileptic and muscle relaxant medications. Neurologic Function includes two variables (six data elements) for general sensory, cognitive, and communication deficits.

Table 4.1. Variables, data elements and value sets for each GMFCS domain.

Domain	Variables	Data Elements	Value Set
Medication Use	Gastrointestinal Meds	Ranitidine (4)**;** Famotidine (5)	Yes/No
	Anti-epileptics/Muscle Relaxants	Diazepam (6); Valproic acid (2)	Yes/No
Motor Performance	Drooling	Drooling; Drooling oral motor function	Yes/No
	Sitting Balance	Sitting balance	Intact; Impaired
	Knee Tone	Knee extensor tone; Knee flexor tone	0, 1, 1.5, 2, 3, 4
	Ankle Tone	Ankle dorsiflexor tone; Plantar flexor tone	0, 1, 1.5, 2, 3, 4
	Elbow Tone	Elbow Extensor Tone; Elbow flexor tone	0, 1, 1.5, 2, 3, 4
	Neck Strength	Neck Strength	WFL; Limited
Neurologic Function	Cognitive Concerns	Cognitive deficits; Speech deficit	Yes/No
	Communication Concerns	Language delay; Language impairment; Speech delay; Speech impairment	Yes/No
Devices Used	Assistive Devices Used	Walker; Cane; Crutches	Yes/No
	Mobility Device Used	Wheelchair independently; Manual wheelchair; Unable to propel own wheelchair; Power wheelchair	Yes/No
	Ambulation Device Used	Gait trainer; Swivel walker; Walker pickup; Walker reverse; Walker wheeled; Crutches forearm; Cane, quad; Cane, single point; Cane, tripod; Crutches axillary; Stander; None	Yes/No
	Stair Railings	Stair Railings	Bilateral; Rail on left going up; Rail on right going up; None
Activity Performance	Current Home Treatments	Respiratory support; Trach care; Tube feeding; Urinary catheterization	Yes/No
	Fine Motor Concerns	Dressing; Feeding; Grooming; Bathing	Yes/No
	Toileting Habits	Toilet trained; Diaper at night	Yes/No
	Feeding Ability	Feeds self; Complete independence; Modified independence; Supervision; Minimal assistance; Moderate Assistance; Maximal assistance; No oral feedings; Total assistance	Yes/No
	Gross Motor Concerns	Ambulatory with assistance; Assistive devices needed; Household ambulation; Tires easily; Trips/falls frequently; Unable to sit independently; Non-ambulatory	Yes/No
Mobility Performance	Ambulation Level	Ambulation Level	Independent; Stand-by assistance; Minimal assistance; Moderate assistance; Maximum assistance; Dependent
	Stairs Assistance	Stairs Assistance	Complete independence; Standby assistance; Contact guard assistance; Minimal assistance; Moderate assistance; Maximal assistance; Dependent
	Primary Mobility	Primary Mobility	Independent wheelchair – manual; Independent wheelchair – power; Ambulation with device; Ambulation without device; Dependent wheelchair mobility; Other

Objective 2: To define the classes of gross motor function by structured rules based on a consensus set of data elements and corresponding value sets

Class 1 and 2 comprised 82 data elements (22 variables), while Class 3 only consisted of 78 data elements. Two derived variables, "Stair Railings" and "Assistive Devices Used," differentiated Class 1 from Class 2, but these variables did not apply to Class 3. Patients at GMFCS IV and V rarely operate the devices included under the "assistive devices" variable (i.e. canes, crutches, and walkers). GMFCS IV and V rarely negotiate stairs, thus, presence and use of railings does not apply for these levels.

The variables resulted in structured rules for each GMFCS Class model. The panelists did not scrutinize the medication data elements in their exercise; therefore, the investigator wrote the rules for the two medication variables based on prior clinical domain expertise. Two unique variables served as the primary root rules to partition the GMFCS Classes; these included, "Ambulation Level" and "Stairs Assistance." Based on Palisano's illustrations[136], patients in GMFCS Class 1 and 2 are both ambulatory except Class 2 (GMFCS III) uses assistive devices more frequently for distance and community ambulation. Patients in GMFCS Class 3 primarily use mobility devices (i.e. manual or power wheelchairs) and are considered limited to non-ambulatory.[136] The structured rules for variables in each Class are provided in Appendix C. Further details are provided below about domain variables and rules for each GMFCS Class. As an exemplar, **Table 4.2** provides a matrix view of the domain for Activity Performance and includes rules, variables, data elements, and value sets stratified by each GMFCS Class.

Table 4.2. Example: Activity Performance Domain

Variable	Data Element Concepts	GMFCS I and II	GMFCS III	GMFCS IV and V
Current Home Treatments	Respiratory support (2500010257) Trach care (2500010258) Tube feeding (2500010259) Urinary catheterization (2500010260)	**No treatments**	**No treatments**	**Any one treatment**
Fine Motor Concerns	Dressing (2500010181) Feeding (2500010178) Grooming (2500010182) Bathing (2500010180)	**No fine motor concerns**	**Concerns with any one fine motor activity**	**More than one fine motor concern**
Toileting Habits	Toilet trained (2500000137) Diaper at night (2500000135)	**Toilet Trained**	**Toilet trained or diaper/assistance**	**Diaper at night, assistance needed**
Feeding Ability	Feeds self (2500000144) Complete Independence (2500000143) Modified independence (2500000148) Supervision (2500000150) Minimal Assistance (2500000146) Moderate Assistance (2500000147) Maximal Assistance (2500000145) No oral feedings (2500000149) Total assistance (2500000151)	**Feeds self, Independence**	**Feeds self, Independence, Supervision, Minimum to Maximum Assistance**	**Minimum to Total Assist, or No Oral Feedings**

Activity Performance Domain

Activity Performance included 19 data elements for toileting, bathing, grooming, dressing, and feeding ability that are compiled into four rules. Many of these ADL data elements are available on nursing, speech language pathology, and OT forms in the EHR but other than feeding, most are generally completed with and formally evaluated by an OT during a clinic visit. Only the ADL data elements from nursing EHR forms were included in the phenotype model. This occurred for two reasons. First because these are collected during nursing intake exams for doctor-patient outpatient clinic visits and surround current patient-reported function. Second, because the value set is binary for each data element and specifies whether a patient (or patient family) has difficulty or concerns completing these ADL tasks. Four of these data elements (feeding, grooming, dressing, and bathing) were grouped into a derived variable and rule for “Fine Motor Concerns.”

Three variables include a data element for feeding: one as included in the “Fine Motor Concerns” variable, and the other two to characterize the quality of feeding oral motor skills. The extent of feeding performance is important because presence of a feeding tube or oral feeding restrictions corresponds to higher GMFCS levels. The first variable, “Feeding Performance,” is based on a 9-level ordinal value set from ‘Feeds self’ and ‘Complete independence’ to ‘Total assistance’ and ‘No oral feedings’. The second variable, “Current Home Treatments,” comprises four data elements, one of which specifies whether a patient requires tube feedings at home. The derived variable for “Current Home Treatments” is presented as a rule in Equation 1. This variable includes three other data elements about home treatment needs, such as respiratory support, tracheostomy, and urinary catheterization. Based on panel ratings, presence of one of these data elements may classify a patient as a GMFCS III. Patients at higher subclassifications of GMFCS V are known to present with a gastrostomy tube and a tracheostomy and would require either total assistance for feeding or do not receive oral feedings.[217]

Derived variable: Current Home Treatments = YES if 3 or more of the following 4 variables below are NO:

Respiratory support (2500010257)
Trach care (2500010258)
Tube feeding (2500010259)
Urinary catheterization (2500010260)

NO = If 2 or more are stipulated as YES

MISSING = If one variable is stipulated NO, AND one or more variables are MISSING

Equation 1. Example rule for "Current Home Treatments" variable in the Activity Performance Domain for GMFCS Class 2.

Toileting is a full-body activity where the patient transfers, manages lower extremity undergarments, and performs perineal hygiene, all while maintaining balance in both sitting and standing. The “Toileting” variable includes two data elements to distinguish between whether a

child is toilet-trained and/or requires a diaper at night. This is important because children between ages 6-18 years-old that are toilet-trained without a diaper may be interpreted as performing toileting independently. Presence of a diaper at night for this age range may signify increased assistance, incontinence. A patient that requires increased assistance to complete toileting will demonstrate decreased gross and fine motor function and subsequently a higher GMFCS level. Children in GMFCS Class 1 are likely to perform toileting tasks with independence or supervision. For GMFCS Class 2 and 3, value sets gradually increase in assistance level and signify movement and performance impairments.

Motor Performance Domain

Motor Performance included six variables corresponding to 10 data elements. Strength and muscle tone are clinical concepts routinely collected by OTs, PTs, and nursing professions as discrete data elements. Lower extremity tone and strength influences the tolerance and quality of movements for mobility and panelists rated a clear gradation for these variables across GMFCS Classes. Neck strength and sitting balance indicate the quality and gradation in trunk strength, sitting ability and posture. The value set for all strength data elements followed a binary standard terminology: within normal limits (WNL) and limited. Panelists rated variables for "Sitting Balance" and "Neck Strength" as limited for GMFCS Class 3 because these patients commonly require seating and head supports in a wheelchair and total assistance to complete mobility transfers and ADLs.

Variables for muscle tone comprise joint-specific tone at the "Elbow", "Ankle", and "Knee". Tone is measured in extension and flexion to assess the extent of rigidity of a muscle and commonly evaluated by providers using the MAS. This 6-point scale (0,1,1+,2,3,4) characterizes the severity of tone from no increase in normal tone (0) to rigid and immovable

(4).[218] The MAS is commonly assessed on the elbow, but it can be assessed on the knee and ankle. Although the GMFCS strongly applies to mobility related data elements, elbow tone is routinely assessed by physicians and therapists and may be a good indicator of patient functional performance. Further, GMFCS levels positively correlate with the Manual Ability Classification System levels (also an ordinal classification I-V), a sister screen of the GMFCS that assesses quality of handling objects.[193] While increased tone in the lower extremities indicates decreased mobility performance and a higher GMFCS, hypertonia at the elbow influences the quality and speed of movement of the upper extremities and may also influence the use of handheld mobility devices and manual wheelchair propulsion. A patient at MAS 2 or 3 may have spasticity and increased flexor tone at the knee and present with a "stiffness" of the knee during passive range of motion. This level of tone degrades functional performance mobility activities, and the patient would classify at a higher GMFCS, while patients at lower GMFCS levels have milder tone or spasticity. The variable for "Knee Tone" is presented as a rule in Equation 2.

Variable: Knee Flexors/Extensors (Concept IDs: 2500010279/ 2500010278) = YES if the following values are selected on the Modified Ashworth Scale:

0, 1, 1.5

NO = if one of the following values is selected:

2, 3, 4

MISSING = if no value is stipulated in this variable.

Equation 2. Example rule for "Knee Tone" variable in the Motor Performance Domain for GMFCS Class 1.

Drooling was also included as a data element. Two data elements correspond to drooling that may be routinely populated by nursing or therapies. If drooling is present in children with CP, then it is commonly attributed to poor oral motor function and control. Drooling is typically

presented in children with increased gross motor dysfunction such as GMFCS IV and V; therefore, drooling is most likely present in patients designated as GMFCS Class 3.

Mobility Performance Domain

Mobility Performance included 10 data elements across four variables: “General Ambulation”, “Stairs Assistance”, “Gross Motor Concerns”, and “Primary Mobility”. The rules that correspond to each variable are designed to account for the gradations in mobility performance between each GMFCS Class. Patients in GMFCS Class 1 ambulate independently and do not require physical assistance when negotiating stairs. While children run and jump and play at in GMFCS Class 1, speed, balance, and coordination may be limited, while strength and range of motion of the lower extremities are WNL. The panel replicated this thinking in their ratings. The values they assigned for mobility concepts gradually increased in need for physical assistance from GMFCS Class 1 to Class 3. Patients in GMFCS Class 3 are not primary ambulators and require the use of mobility devices. A distinction between Class 2 and 3 is that, while both use mobility devices, GMFCS Class 2 patients can independently use a manual wheelchair, but often use assistive and ambulation devices such as forearm crutches and walkers to ambulate. This is specified in the Device Use Domain. Class 3 patients generally have more severe motor dysfunction that impairs their ambulation. As demonstrated by the GMFCS phenotype definitions, patients at level IV may require assist with manual propulsion in a wheelchair, or may navigate independently in a power wheelchair, while level V patients require assistance to for manual propulsion.

Device Use Domain

Device Use included 20 data elements for four variables. These variables addressed the types of ambulation and mobility devices used by patients, and include walkers, wheelchairs, forearm crutches, and canes. The four variables are “Assistive Device Used”, “Mobility Device Used”, “Ambulation Device Used”, and “Stair Railing Use”. Four data elements in the device domain do not apply to GMFCS Class 3, which include the general use of assistive and ambulation devices such as canes, walkers, and forearm crutches, but also the use of railings to negotiate stairs. As previously mentioned, GMFCS Class 3 patients do not ambulate frequently, rarely negotiate stairs and are limited in their use of assistive devices. Panelists replicated this clinical thinking by rating the data elements for “Stair Railings Used” and “Assistive Device Used” as ‘Not Applicable’ for Class 3. Patients in GMFCS Class 1 may or may not require the use of at least one railing when negotiating stairs, while GMFCS Class 2 patients require the use of both railings. All other data elements are grouped into one variable called “Ambulation Device Used” which describes an array of devices. While patients in Class 1 and 2 use any type of walker (wheeled, standard, reverse), canes (single point, tri, quad cane) or crutches (forearm, axillary), patients in Class 3 do not. Rather, GMFCS IV patients may use a gait trainer and GMFCS V patients may use a stander to facilitate upright posture, blood circulation, bear weight, and maintain strength and joint integrity in the lower extremities.

Medications Domain

Medication use is not explicitly described in the GMFCS phenotype definitions, but the inclusion of these concepts in the medical record supports our ability to differentiate between GMFCS Classes. Two medication variables were included in the phenotype model. The first variable consisted of antiepileptics and muscle relaxants. Patients that take antiepileptics and

muscle relaxant medications (Diazepams, Valproic Acid) would indicate the presence of seizure activity and spasticity, both of which are established features of patients in GMFCS Class 3. Patients with severe spasticity may be subject to hip displacement and dislocation due to the increased involuntary motor control and laxity in their hip joint stability. The second variable included antacids and other gastrointestinal medications (Famotidine, Ranitidine). These medications signify bowel mechanism issues. Patients at higher GMFCS levels are limited in activity and mobility and tend to demonstrate slower motility and increased bouts of constipation, thus increasing risk of gastroesophageal reflux. Treatment intensification (i.e. dosage and frequency) of these medications may explain the severity of seizure, spasticity, and constipation; however, medication dosage was not considered for the current study.

Neurologic Function Domain

Neurologic Function included two variables for cognition, communication, and speech deficits. These two variables comprised six data elements. One variable contains two data elements for cognitive and speech concerns to assess general deficits. A specific data element exists for presence/absence of cognitive deficits; however, the final list did not included data elements that explain the extent or quality of patient cognitive function. A recent study of the subclassifications of GMFCS V phenotype identified nonverbal status as a key classifier of this level.[217] Therefore, if speech deficits are present, then these six data elements captured by nursing during routine intake evaluation would help to determine speech deficit concerns. Speech-Language Pathologists and OTs collect and document much of the finer details of patient cognitive and speech function in the EHR; however, these data are not as applicable to gross motor function levels. Data elements for "Communication Concerns" provide explicit reference to the speech and language issues that a patient or patient's family may report. These elements

are collected in nursing EHR intake forms during outpatient visits. The derived variable for "Communication Concerns" is presented as a rule in Equation 3.

Derived Variable: Communications Concerns (Concept ID: 2500010797; Qualifier: 2500000271) = YES if any one of the four below is YES:

Language delay (4039748)
Language impairment (4041822)
Speech delay (4047123)
Speech impairment (435642)

NO = If all four are stipulated as NO
MISSING = missing if any of the four are missing with the others coded as NO

Equation 3. Example rule for "Communication Concerns" variable in the Neurologic Function Domain for GMFCS Class 3.

Data Elements Not Selected

By way of consensus, the panel agreed that eight variables did not distinguish between GMFCS Classes. The eight variables spanned data elements for orthotic types, strength variables for upper and lower extremity, trunk, abdominal and back, ankle clonus and general muscle tone for the upper extremity, and four data elements for consultation referrals.

DISCUSSION

The results of this chapter demonstrate a standards-based, expert informed phenotype model of gross motor function that offers flexibility across three clinically sensible GMFCS Classes. This is also the first instance that compiles real-world observational data elements from a CDRN to support the development of a functional performance phenotype in pediatric rehabilitation. The findings of this work ground gross motor function and the GMFCS Classes in a model capable of semantic interoperability with other CDRNs, data registries, and data warehouses for cohort identification activities. The design of the phenotype model and three sub-models applies an interoperable and standard terminology (i.e. OMOP, RxNorm) to support the classification of

gross motor function for CP based on an ensemble of real-world patient data elements. This work supports future population research and quality improvement studies for CP in pediatric rehabilitation settings.

The rigorous approach to construct the phenotype model and rules was rooted in the computable phenotyping Desiderata developed by Mo et al., but work by Westra et al. informed the iterative approach based on their concept of an information model to organize EHR data for secondary use.[120,216] Westra et al. published work on the development of an information model of structured flowsheet data elements to support secondary data use in health systems research.[216] However, Westra's work uses a data-driven consensus process informed by the available structured data across a large hospital system, rather than a theory-driven approach that compiled data elements that support semantic interoperability.[216] The application of these and other systematic methods supports the theory-based selection of common data elements and corresponding interface terminologies to design the structured rules for each GMFCS class. The iterative approach to design this phenotype model provides an innovative application of existing methodologies. This work also underscores the complexity of modeling functional performance using standardized data elements and the rigor necessary to develop similar models for computable phenotyping functional performance in the future. Much like Westra, the design of this phenotype model helps simplify the representation of EHR data for specific research and evaluation purposes.[216]

Evidence demonstrates that the re-use of EHR data improves patient cohort identification and may be essential to support pragmatic prospective cohort studies with economy of scale. Fried et al. as well as many others have used the phenotype model of frailty to support the construction of a frailty index[194,196,199], most recently by Pajewski et al. (2019). This group

developed and tested a frailty index using EHR data to screen Medicare patients in an accountable care organization as prefrail or frail.[198] In terms of computable phenotypes, Richesson et al. describe the variation of computable phenotypes for classifying type II diabetes by comparing the outputs of patient populations retrieved using seven heterogeneous phenotype definitions developed from different sources.[219] Phenotype definitions identified 7-13% of patients had type II diabetes, however the discrepancy between definitions and overall impact points to a need to improve the identification and agreement of clinical characteristics for diabetes. Denny also writes extensively on computable phenotypes for genomic studies using the eMERGE network to capture candidate cohorts for genome-wide association studies.[119,220] Geva et al. demonstrate that an EHR-based computable phenotype can improve the ascertainment of a patient population of pediatric pulmonary hypertension compared to the population in a pulmonary data registry.[221] The gross motor function phenotype model, although not operational in an EHR, builds infrastructure from CDRN observational data elements to identify pediatric patient cohorts by distinct categories of gross motor function for research and quality improvement.

Although various clinical providers collect the GMFCS level, they do not all record the GMFCS as a discrete data element. In the context of SHC care sites, the GMFCS is documented in clinical notes as either a structured data element, unstructured/free-text or via dictation. While natural language processing of such unstructured, free-text and dictated notes would allow for discretization of the GMFCS or additional data elements, the process is not widely implemented, especially for rehabilitation terminologies, and concerns exist about ensuring de-identification of data elements. Therefore, this study was organized around the available discrete data elements stored in SHOnet that can be queried to support phenotype models for GMFCS Classes.

The list of selected data elements may be extensive, but due to unpredictable workflows and processes in clinical settings, many patient records and/or patient clinical events may not have populated values for many of these discrete data. The phenotype model supports an essential step to evaluate data element availability in SHOnet and its readiness for building auto-classifiers. Therapists (OT and PT) and nurses across SHC document these discrete data in the EHR, but it is unknown as to the extent that these data elements are complete and accurate, or how their missingness should be interpreted in rehabilitation settings. This missingness may occur either because of a lack of data collection or documentation by the provider or because the data element did not apply to a specific patient. Such issues of missingness may arise for a motor issue, mobility impairment, or device that is absent or not used. Wells et al. reports that differentiating between the lack of a comorbidity, the lack of documentation of a comorbidity and the lack of data collection regarding the comorbidity can be difficult, but typically missingness should indicate a negative value.[222] But this may not always be the case. Hripcsak and Albers report that during a manual review of charts, providers, residents particularly, do not use negation in their notes, rather they only document what is present.[223]

Missingness of EHR data is viewed differently from missingness of research data, and improper handling of missing EHR data may introduce significant biases.[222,224] The extent that this is true in SHOnet for GMFCS and phenotype model data elements is critical to evaluate in order to determine how care processes may influence the collection of key data elements for classification. This also means that the breadth of data elements may be pared down in future iterations based on the availability and accuracy of discrete data elements and to evaluate the extent that certain data elements are stronger classifiers compared to others.

This expert-informed phenotype model of gross motor function may support future imputation efforts of GMFCS for research; however, two limitations of this study exist. The first limitation of this work includes investigator blinding to completeness or availability of populated data elements in the initial review and selection process. This was a deliberate effort. The initial mapping procedure and selection of data elements was agnostic to the current volume of populated data elements in SHOnet because knowledge of data completeness and availability in the EHR could bias the theory-based selection of data elements.

Building an auto-classifier for GMFCS consists of structured data that may also be inconsistently collected during routine clinical care. What, how, and when data are documented may be influenced by structural, system and exogenous factors. Furthermore, the mode of documentation may differ across clinical provider groups. Physicians may choose to dictate or free-text their clinical notes, thus producing unstructured data; however, OTs, PTs and nursing are relegated to point and click, dropdown features and free-text fields to collect patient data and compile notes. Therefore, the data on these patient attributes may be collected in other unknown locations of the EHR. The benefit of using a theory-driven approach to develop these models is that the 82 data elements correspond to OMOP and RxNorm concept IDs are expert-informed and not constrained by what data *are collected*. Instead, the phenotype model is optimized for semantic interoperability with other pediatric data resources and foregrounds what data *should be collected* by clinicians and systems to classify clinically sensible classes of gross motor function.

The second limitation is generalizability. The expert-review panel only included internal clinicians and researchers to rate and select an ensemble of data elements that may classify classes of gross motor function. These panelists are experts both in evaluating functional performance dimensions and how these dimensions are influenced by CP. Their organizational

membership, though, may present potential biases in the prioritization of and attention to specific data elements. Although panelists all work for SHC, biases in their ratings are mitigated because they all work at three regionally different SHCs. Another way to reduce bias was by using a standardized terminology of concepts based on OMOP. This CDM includes widely accepted reference terminology standards and publicly available concept IDs which further supports opportunities for generalized use.

This work informs other CDRNs supporting pediatric populations (i.e. PEDSnet, Improve Care Now) of the opportunities to afforded by building out their observational data elements for conducting critical LHS research in rehabilitation and recovery. Future work should stress both an understanding of documentation practices and perceptions and an analysis of completeness of the data elements in this gross motor function phenotype model. More research is needed to evaluate the overall generalizability of these data elements to other care settings and processes corresponding to managing complications in patients with CP. This can be achieved by studying how well these data elements are documented in routine care settings to understand the extent the phenotype model translates to other care facilities and can support a generalizable auto-classifier of gross motor function.

CONCLUSION

This study leverages a standard terminology composed of common data elements to construct a gross motor function phenotype model capable of instantiating clinically sensible GMFCS Classes. This model is essential to design computable phenotypes in pediatric rehabilitation that generate candidate cohorts of patients stratified by GMFCS Classes. This work supports future research to study and improve care delivery and management of medical complications associated with CP. This work presents systematic and iterative methods to construct phenotype

models of functional performance and supports future efforts to develop “functional” computable phenotypes to aid rehabilitation research. More research is needed to study the availability and quality of the data elements in this phenotype model and the extent that these data can validly differentiate classes of gross motor function.

Chapter 5

A Descriptive Analysis of Data Completeness Using the Gross Motor Function Phenotype Model for Pediatric Rehabilitation

INTRODUCTION

A significant infrastructural barrier to generate new biomedical knowledge to support Learning Health Systems (LHS) is data completeness.[3,6,225] Completeness in biomedical informatics is defined as the proportion of data elements that are actually recorded in the electronic health record (EHR) without reference to actual values.[6,7] Data completeness studies for pediatric rehabilitation are absent from the literature and there is a lack of large-scale real-world data sources to support rehabilitation research. The recent National Institutes of Health (NIH) and National Institute for Child Health and Human Development (NICHD) strategic plans emphasize robust research infrastructure and resources to support large-scale medical and pediatric rehabilitation research.[226,227] Data quality studies, particularly completeness, would be a great benefit to expand pediatric rehabilitation LHS capacity.

Data completeness studies are important to clinicians and informaticians because these personnel are producers and consumers of clinical data and knowledge in healthcare systems.[200,228] Several studies of data completeness are present in the informatics literature, most notably to evaluate quality of data from EHRs and clinical data research networks (CDRN) built using data from multiple EHRs and support large-scale observational research.[2,19,21,28,29,39,41,69,80,89,90,92,100,200,225,229-233] Completeness, or missingness, drives critical conversations about whether, and what, process changes are necessary to improve systems of

learning. An analysis of data completeness is task-dependent, i.e. based on the question asked by a researcher or consumer of EHR data.[21,200] Weiskopf et al. provide a framework to study completeness at four dimensions: documentation, breadth, density and predictive completeness.[200] Each dimension requires a critical appraisal of documented data elements based on their "fitness for use", or the extent that the data are of sufficient breadth, depth and scope for the problem at hand.[200,228] Weiskopf et al. also make the distinction between assessing data completeness for the patient record versus the patient encounter. The patient record may be viewed as complete if a data element(s) is present at any encounter.[200] The patient encounter is process-oriented and may be incomplete if a data element(s) is not present irrespective of its documentation during another visit. Again, this is all dependent on the data elements under consideration.

Task-based studies of data completeness are essential to understand how and what data are collected (i.e. clinical documentation) following routine patient-provider encounters. This study takes the approach that the extent of data completeness explains potential patterns of clinical documentation. Completeness of unique visits and whole patient-records not only clarifies documentation patterns, but explains the readiness of data resources to build, improve and refine cohort identifiers, measurement instruments and feedback necessary to support routine health system research and learning.

Data completeness studies such as these are critical to ensure data are of sufficient quality to produce valid and actionable knowledge and advance LHS science for pediatric rehabilitation. Only one data network currently supports pediatric rehabilitation LHS activities: the Shriners Hospitals for Children (SHC) Health Outcomes Network (SHOnet). SHOnet harmonizes data from 21 pediatric hospitals in the SHC system. SHOnet stores data elements in a common data

model (CDM), or standard terminology for semantic interoperability and large-scale observational pediatric health research. The SHOnet CDM was built using the Observational Medical Outcomes Partnership (OMOP) CDM and PEDSnet CDM.[3,107,214]

This chapter builds on Chapter 4 and uses the phenotype model of gross motor function constructed from the SHOnet CDM as an exemplar task-based mechanism to measure data completeness in pediatric rehabilitation settings. The phenotype model of gross motor function generalizes to patients aged 6-18 years-old with cerebral palsy (CP). The construction of the phenotype model used an expert-driven, iterative review process to select discrete data elements that are available in the EHR and are mapped to a standard reference terminology (OMOP). The phenotype model contains 82 discrete data elements about patient characteristic that align with case definitions of the Gross Motor Function Classification System (GMFCS)[136,139]. Sixty-five of these data elements are performance-related discrete data types collected by nurses (RN), occupational therapists (OT) and physical therapists (PT). The primary purpose of this phenotype model is to support cohort identification by GMFCS Classes when the discrete data element for GMFCS is unavailable.

This chapter provides a critical examination of data completeness in pediatric rehabilitation settings, elucidates data readiness, and implicates the role and further study of clinical documentation for LHS. The frequency of available data elements significantly impacts how healthcare systems can achieve continuous and routine learning. Completeness is a fundamental indicator of priorities in care delivery and drives the development of knowledge. While accuracy of data element values is important for predictive analytics and development of clinical decision support tools, data availability and the pattern of data capture for rehabilitation settings foregrounds opportunities to develop innovative changes to clinical documentation.

Since rehabilitation studies are largely absent from LHS and informatics fields, this work fills an important gap and presents a natural synergy between LHS and rehabilitation.

RESEARCH QUESTION AND OBJECTIVES

The primary research question driving this paper is, "How can discrete clinical data on gross motor function be used to draw conclusions about clinical documentation practices in the EHR for cerebral palsy?" To address this question, this chapter analyzes the extent of data completeness in the context of the CP-specific gross motor function phenotype model. We do this through three objectives: 1) To evaluate completeness of gross motor function as a discrete data element represented by the Gross Motor Function Classification System (GMFCS)[211]; 2) To evaluate the completeness of discrete data elements in the phenotype model for unique patient visits, unique patients and unique data elements; and, 3) To evaluate variability in completeness of discrete data elements in the phenotype model.

METHODS AND MATERIALS

Study Design and Data Source

To address the above research question and objectives, this chapter employed an exploratory descriptive design using retrospective observational data to describe completeness of discrete data elements represented in the gross motor function phenotype model. This project was undertaken as a Quality Improvement project at Shriners Hospitals for Children and as such, was not considered research.

SHOnet (**Figure 2.7**) is the exemplar LHS data resource for pediatric rehabilitation to study completeness in this chapter. SHC has managed more than 274,746 unique patients, 6-18 years-old for over 1,369,075 unique visit occurrences between 2015 and 2019. Approximately

6.73% (n = 18,508) of these patients have a diagnosis of CP. The SHOnet team previously defined cases of CP as the presence of any ICD-9/10 or CPT codes related to CP for a given patient. An estimated 80,000 unique visit occurrence numbers exist for this CP population, and 90% of these occurrence numbers are for outpatient or outpatient-related visits. For each patient-provider encounter, the SHC sites assign a visit occurrence identification number and codes the visit as one of 18 visit types. Multiple visit dates may map to the same occurrence number for a patient, but the visit type does not change. All visit information is extracted from the EHR, transformed to a CDM then loaded into SHOnet and stored in separate tables (**Figure 2.6**). Six outpatient-related visit types were collapsed into the general category of outpatient visits. These included outpatient visit, outpatient surgery, outpatient clinic, outpatient rehab, recurring visit, and pre-registration.

Selection of Study Sample

The patient sample of record from SHOnet comprised patients with CP, ages 6-18 years-old who had an outpatient clinic visit between September 2015 through 2019 to obtain a sample of record to analyze. Outpatient visits were included if the associated patient was ≥ 6 or <19 years old at the time of the visit during the 4-year period. The cutoff of < 19 years old was chosen to account for patients being classified as 18 during their 19th year.

Data Preparation

Data Extraction

An informatician on the SHOnet team queried the data resource for patients with any of the 65 performance-related data elements in the phenotype model, plus patient demographics (birthdate, gender, race and ethnicity), other metadata (SHC care site, clinical encounter dates for

every data element, clinical encounter types (outpatient, inpatient, etc.), and whether a visit included an occupational and physical therapist). RxNorm data elements were not analyzed for completeness because they require an assessment of the coded medications through manual chart review and thus are beyond the scope of this paper.[19] The dataset transformation was conducted using R Studio and R v3.6.2.[234]

Data Element Properties

The 65 discrete data elements in the phenotype model (**Table 4.1**) were collected and stored as coded or codable text data in SHC EHRs prior to being mapped to SHOnet. The distinction between these two data types is described by Benson and Grieve (2016); however, these data types are transformed into unique discrete data in SHOnet.[235] Discrete data in the phenotype model are captured in EHR forms that are populated separately by PTs, OTs and RNs. Each discrete data element in SHOnet is considered an observation and includes a unique identifier, concept name, concept value code, qualifier code, and observation date. Observations are mapped to metadata such as visit encounter codes and dates. These metadata provide details about a patient visit and care delivery patterns.

Demographics

Primary patient demographics included gender, race, ethnicity, and age for this analysis to describe the CP patient cohort. While gender, race and ethnicity variables are all stable across time and analyzed as frequencies, age was calculated differently due to the multiplicity of patient visits. Mean age was calculated for each patient's first and last visit to describe the average patient age at defined points of time in the study, rather than the average age across the entire study period. Age at each visit was calculated as the patient encounter date minus the patient

birth date. The SHOnet informatician time-shifted all birth dates and visit dates during extraction to ensure the dataset was de-identified for analysis.

Data Analysis

The methods to analyze data completeness are described in the literature by Kahn et al. and Weiskopf et al.[6,21,200] The present study used three hierarchical methods to examine completeness. The highest order of completeness, referred to simply as *data element availability*, is abstracted from Kahn's data quality framework and considers the frequency of query-able data elements available for gross motor function.[6] We calculated the frequency of phenotype model data elements available in SHOnet. The next level of completeness, referred to as *documentation* by Weiskopf et al., is evaluated as the frequency or proportion of data element values captured in a patient-provider clinical encounter.[200] This study also analyzed frequency and proportion of phenotype model data elements documented at the level of unique patient visits. A unique patient visit was considered the combination of the unique patient visit date and visit occurrence number, since multiple visit dates may have the same visit occurrence number. The last level of completeness is referred to by Weiskopf et al. as *density* and is evaluated in two ways: the number of data elements in a patient record and the temporal relationship between data elements over time.[200] This analysis applied the former concept of *density* to calculate the frequency and proportion of phenotype data elements documented in a patient's outpatient record over the study time period. While Weiskopf et al., also evaluate the regularity of documented data elements, that level of analysis is beyond the scope of this paper.

The first step to this analysis was recoding the available data element values. Each visit-data element cell and patient-data element cell was recoded either 1 or 0 to denote the presence or absence of a data element value, since the analysis only included the frequency and percentage

of data elements present.[6] Unique patients may contain multiple instances of the same data elements after collapsing unique visits into unique patients. In this case, data elements maintained the same 1/0 binary convention above to classify its presence or absence for a given patient record. All visits included in the analysis required either one populated phenotype model data element and/or GMFCS level. The analyses for each of the three study objectives are described below.

Objective 1: Evaluate completeness of GMFCS as a discrete data element

The first objective evaluated the completeness of GMFCS. GMFCS is a five-level classifier of gross motor functional performance in children with CP.[136] It is collected in discrete or narrative forms by physicians, nurse practitioners, physicians assistants, RNs, PT and OT for the CP patient population. The study analyzed completeness of GMFCS as a discrete data element in SHOnet, which maps to a designated field on a PT/OT form in the SHC EHR. We calculated the frequency and percentage of these GMFCS values documented for unique visits and unique patients, and then stratified these counts by the five GMFCS levels. We then calculated the extent of clinician rater agreement in GMFCS level documentation by surveying the number and percent of visits and patients where GMFCS levels agreed and disagreed during the 4-year study time-period. GMFCS level is known to be stable after 6-years-old, therefore, agreement should be near unity for this population.[211,213]

Objective 2: Evaluate completeness of phenotype model data elements by unique data elements, unique patient visits, and unique patients

The second objective examined completeness of data elements in the gross motor function phenotype model using two methods. The dataset was organized with data elements in the columns and patient encounters corresponding to each row. The first method used a column-

based analysis to calculate the percent completeness for each data element by dividing the frequency of populated values for each data element by the total number of rows. The second method used a row-based analysis to determine mean percent completeness. We calculated a completeness percentage for each unique row as the sum of all populated data elements in a row divided by the total number of available data elements. We completed both analyses for unique visits and unique patients to evaluate variability in data completeness within these groups.

Mean completeness percentage for visits and patients was stratified by SHC site and by GMFCS levels and for groups with and without a GMFCS documented as discrete data. This enabled us to explore differences in documentation completeness by care sites, GMFCS levels and the presence/absence of a discrete GMFCS value. For care sites, we calculated the total number of visits and patients for each SHC care site, then used Pearson correlation to evaluate the relationship between mean completeness and care site CP volume. Spearman correlations were also calculated between GMFCS levels and mean completeness percentage because of the ranked nature of the GMFCS. Mean completeness should not differ by GMFCS levels and between those with or without a GMFCS, as this may demonstrate a disequilibrium in the standard of care. However, data completeness may differ between SHC care sites due to regional variability in roles, routines, and documentation practices with the EHR. [3,6,11,16-18,28]

Objective 3: Evaluate variability and clustering in completeness of phenotype model data elements

The last objective explored variability in completeness by analyzing the clustering of data element documentation. We first used a two-step process to identify and verify clusters computationally and visually. In the first step, we computed a heat-density correlation matrix of Pearson correlations for all data elements. We then reorganized the heat-density matrix to visualize clusters of highly correlated data elements along the diagonal. In step two, we verified

the pattern of clusters using k-means clustering.[236] K-means clustering is an accepted unsupervised machine learning method that uses distance measures to identify clusters. Correlations in the full Pearson correlation matrix are an appropriate distance measure to study clustering of documentation; however, they are not widely cited in k-means analyses.[237] The k-means method requires the user to state the number of hypothesized clusters or centroids, the algorithm then approximates the closest mean distance for each data element from each centroid and assigns each data element to the nearest centroid by minimizing the within cluster sum of squares for each cluster.[237] Data visualizations using *factoextra*[238], *cluster*[239] and *ggplot2*[240] packages in R Studio verified the clusters.

In addition to clustering of data elements, the dataset includes 21 clusters of SHC care sites, and patients and visits are nested within these sites. This means our dataset is hierarchical and that data completeness for unique visits may be influenced by specific care site. We employed an intercept only mixed effects linear regression model[241] to survey the extent of variance in data completeness that may be attributed to SHC care site. Mixed effects models include both fixed and random effects, where the random effects control for the nesting in a dataset.[241,242] Intercept only models do not include any covariates and the constant (β_0) is our only fixed effect. The output of this model includes estimates of variance for each level of nesting and allows us to calculate the percent of variance in data completeness attributed to unique care site, also known as the intraclass correlation coefficient (ICC). The ICC is a measure of effect size to determine how similar the outcomes are within a cluster relative to those of other clusters on a scale of 0-1. An ICC=1 indicates 100% of the variance in outcomes is attributed to the group level, whereas an ICC=0 indicates 0% of the variance in outcomes is attributed to the group level. All analyses were done in R 3.6.2.[234]

RESULTS

Nineteen of the 65 data elements in the phenotype model contained populated values. The study population comprised 6,192 unique patients across 19,880 unique outpatient visits had at least one of the 19 data elements captured and/or a GMFCS level collected as a discrete data element since 2015. The total outpatient visits comprised 12,644 unique visit occurrence numbers. **Figure 5.1** is a flowchart of the patient population. The following examines GMFCS, data element completeness, and cluster analysis of data element relationship patterns.

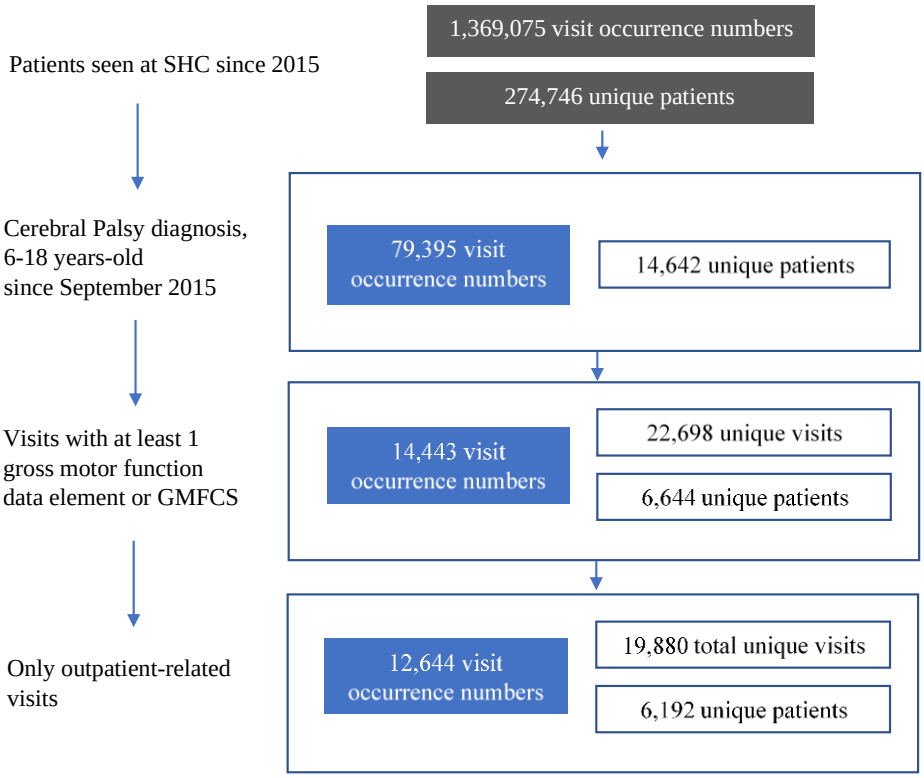


Figure 5.1 Flowchart of the CP population for the present study.

Demographics

Demographics of the study population are provided in **Table 5.1**. Approximately 57% of patients were male. The majority of patients were White (63%), 12% were Black or African

American. Of this population, approximately 22% identified as Hispanic. The mean age at first visit was 12.20 years (median = 12.15). The mean age at last visit was 11.50 years (median = 11.35).

Table 5.1. Demographics of CP patient population (n = 6,192) and visits since 2015.

Variable	Category	n (%)
Gender	Male	3,548 (57.3)
Race	White	3,903 (63.0)
	Black	738 (11.9)
	Other	1551 (25.1)
Ethnicity	Hispanic	1269 (20.5)
	Not Hispanic	3966 (64.1)
	Other	957 (15.4)
		Mean (Median)
Age (years)	Age at First Visit	12.2 (12.15)
	Age at Last Visit	11.5 (11.35)

Objective 1: Evaluate completeness of GMFCS as a discrete data element

Only 21% (n = 4,220) of unique outpatient visits had a GMFCS level documented as discrete data. Approximately 96% of GMFCS levels were documented as discrete data elements in outpatient visits compared to all other visits (i.e. inpatient). Mean completeness percentage did not differ between visits with and without a discrete GMFCS level, 7.0% and 7.8%, respectively. The mean completeness also did not differ between unique patients with and without a discrete GMFCS level, 11.2% and 10.7% (**Table 5.2**).

Table 5.2. Completeness by category of GMFCS documented, unique patients, and unique visits

Group Level	Overall			With GMFCS	Without GMFCS
	n	Mean Completeness % (Median)	GMFCS %	Mean Completeness % (Median)	Mean Completeness % (Median)
Unique Visit	19,880	7.6 (5.3)	21.2	7.0 (5.3)	7.8 (5.3)
Unique Patient	6,192	10.9 (10.5)	38.6	11.2 (10.5)	10.7 (5.3)

GMFCS was available for approximately 39% of unique patients (n=2,393). Of these patients, 16% were GMFCS level I, 28% GMFCS level II, 18% GMFCS level III, 18% GMFCS level IV, and 20% GMFCS level V. An estimated 12% of these patients had inconsistencies in their assigned GMFCS level during the 4-year period, reflecting different providers documentation or assessment of GMFCS. Patients have multiple visit dates that fall under the same visit occurrence number. Only 1% of unique visit occurrence numbers had disagreement in the assigned GMFCS level.

Objective 2: Evaluate completeness of phenotype model data elements

Completeness of Unique Data Elements

The results for completeness frequency and percentage by individual data element for visits and patients are provided in **Table 5.3**. No complete cases of these 19 data elements were present at the patient or visit level. At the visit level, of the available data elements, ambulation assistance was approximately 75% complete (n = 14,927), followed by sitting balance (~17%, n = 3,537), and neck strength (~13%, n = 2,568). All remaining data elements were less than 7% complete. Eight data elements were less than 1% complete, and seven of these data elements are found on RN outpatient intake forms in the EHR.

Data element completeness was analyzed at the unique patient-level for all 19 data elements available in the phenotype model. Ambulation level was approximately 76% complete (n = 4,704), followed by sitting balance (~29%, n = 1,797), neck strength (~25%, n = 1,528), stairs assistance (11.5%, n = 707), and knee flexion tone (10.5%, n = 651). All remaining data elements were less than 10% complete. Seven data elements were less than 2% complete and were identical to those above found on RN data forms in the EHR.

Table 5.3. Completeness percentage for individual data elements by unique visits and patients.

Data Element	Unique Visits		Unique Patients	
	n	Completeness %	n	Completeness %
Language Delay	7	0.04	7	0.11
Speech Difficulty	12	0.06	10	0.16
Drooling - First Location	57	0.29	51	0.82
Toileting	90	0.45	73	1.18
Feeding Ability	108	0.54	62	1.00
Drooling - Second Location	130	0.65	72	1.16
Speech Delay	148	0.74	115	1.86
Ankle Dorsiflexion Tone	186	0.94	145	2.34
Elbow Extensor Tone	353	1.78	242	3.91
Elbow Flexor Tone	705	3.55	428	6.91
Knee Extensor Tone	757	3.81	539	8.70
Walker	810	4.07	472	7.62
Ankle Plantar Flexion Tone	856	4.31	611	9.87
Knee Flexion Tone	985	4.95	651	10.51
Stair Railing Use	1117	5.62	597	9.64
Stairs Assistance	1364	6.86	707	11.42
Neck Strength	2564	12.90	1528	24.68
Sitting Balance	3532	17.77	1797	29.02
Ambulation Assistance	14842	74.66	4704	75.97

Mean Completeness by Unique Visits

The mean completeness percentage across unique outpatient visits was 7.6% (median = 5.3%; range = 0 – 47%) (**Table 5.2**), interpreted as ~1-2 data elements per visit. Mean completeness percentage was stratified by GMFCS levels; however, there was no observed difference in completeness between these levels. The median completeness percent for unique visits of 5.3% means half of all visits in the study population have ≤ 1 documented phenotype model discrete data element. The Spearman correlation between mean completeness percent and the five GMFCS levels was (r = -.078), demonstrating no linear relationship between these two variables. Therefore, the extent of completeness, or rather missingness of data elements, does not appear related to a patient's classified GMFCS level.

Mean completeness percentage was also no different for unique outpatient visits from year to year in the study period (**Table 5.4**). In Table 5.4, four full years (2016-2019) are included since the initial study period started in September 2015 and ended in December 2019. The total volume of visits and patients for this study population steadily decreased from year to year. This decrease may be due to a variety of reasons, such as patients exceeding the age band, aging out of pediatric care, or a reduced frequency of therapy and orthopedic clinic visits.

Table 5.4. Mean completeness percentage and volume of unique visits by year.

Year	Unique Visits	Unique Patients	Mean Completeness % (Median)	Max Completeness %
2016	6033	2710	7.9 (5.3)	47.4
2017	5323	2501	8.0 (5.3)	37.0
2018	4014	1989	7.2 (5.3)	42.1
2019	2180	1191	6.5 (5.3)	37.0

Mean Completeness by Unique Patient Records

The mean completeness across patient records for outpatient visits was 10.9% (median = 10.5%; range = 0 – 63%) (Table 4.2), interpreted as ~2 data elements per patient record. Mean completeness was no different at the patient's first recorded visit (8.0%) compared to the last recorded visit (7.7%). The Spearman correlation between GMFCS levels and mean completeness percentage for unique patients also demonstrated no linear relationship between these variables (r =.045).

Care Site Case Analysis

The descriptive statistics for mean completeness percent, volume of patients and visits, and GMFCS presence as a discrete data element by each SHC site are provided in **Table 5.5**. No linear correlation was observed between mean completeness and SHC care site volume of unique visits. The range of mean completeness for unique visits by SHC care sites was ~2-16%, and the Pearson correlation between site completeness and volume of outpatient visits was r = -.06,

demonstrating no linear correlation. The range of mean completeness for unique patients by care site was ~3.1-20.7%. The Pearson correlation between site completeness and volume of unique patients was r = -.10. This indicates that a weak, yet insignificant negative linear relationship exists between the number of patients managed at a care site and mean completeness percentage of discrete data elements related to gross motor function. Pearson correlations between the presence of GMFCS as a discrete data element and the SHC care site volume for both patients and visits also revealed a strong correlation between the volume of CP patients and visits (r = .80 and r = .81, respectively) and the extent that GMFCS would be documented as discrete data.

Table 5.5. Mean completeness percentage for unique visit and patient volume by care site.

Care Site	Patients	*Mean Completeness % (Median)	Visits	**Mean Completeness % (Median)	***Patients GMFCS (%)	****Visits GMFCS (%)
Site A	19	13.0 (10.5)	82	7.19 (5.3)	1 (5.3)	1 (1.2)
Site B	272	10.6 (5.3)	720	7.63 (5.3)	159 (58.5)	260 (36.1)
Site C	447	13.8 (10.5)	1144	9.91 (10.5)	135 (30.2)	176 (15.4)
Site D	3	5.3 (5.3)	22	5.26 (5.3)	0	0
Site E	222	20.7 (26.3)	376	16.03 (15.8)	143 (64.4)	174 (46.3)
Site F	3	17.5 (15.8)	16	9.87 (8.0)	0	0
Site G	493	15.7 (15.8)	1620	9.89 (5.3)	59 (12.0)	78 (5.0)
Site H	194	10.2 (5.3)	1438	7.07 (5.3)	33 (17.0)	93 (6.5)
Site I	216	7.8 (5.3)	327	6.81 (5.3)	4 (2.0)	4 (1.2)
Site J	125	8.7 (5.3)	707	6.51 (5.3)	5 (4.0)	5 (0.7)
Site K	314	9.6 (5.3)	745	6.99 (5.3)	65 (21.0)	107 (14.4)
Site L	179	14.2 (15.8)	551	9.85 (5.3)	7 (4.0)	8 (1.5)
Site M	178	14.5 (10.5)	1145	7.18 (5.3)	2 (1.1)	2 (0.2)
Site N	547	10.4 (5.3))	2140	5.91 (5.3)	320 (58.5)	921 (43.0)
Site O	530	3.1 (0)	905	2.08 (0)	426 (80.4)	607 (67.1)
Site P	973	12.5 (10.5)	3691	8.76 (10.5)	739 (76.0)	1416 (38.4)
Site Q	128	11.0 (5.3)	298	7.81 (5.3)	26 (20.3)	32 (11.0)
Site R	304	9.4 (5.3)	1024	6.39 (5.3)	133 (44.0)	199 (19.4)
Site S	457	7.0 (5.3)	1499	5.79 (5.3)	24 (5.3)	18 (0.1)
Site T	331	9.6 (5.3)	574	7.66 (5.3)	57 (17.2)	63 (11.0)
Site U	257	10.3 (5.3)	856	7.31 (5.3)	55 (21.4)	58 (7.0)

*Pearson correlation between SHC site patient volume and mean completeness percentage: r = -.102

**Pearson correlation between SHC site visit volume and mean completeness percentage: r = -.058

***Pearson correlation between SHC site patient volume and presence of GMFCS as discrete data: r = .80

****Pearson correlation between SHC site visit volume and presence of GMFCS as discrete data: r = .81

Objective 3: Evaluate completeness by care site variability and clustering of phenotype model data elements

Intercept Only Mixed Effects Linear Regression Model of Completeness by Care Sites

Although mean completeness was not associated with patient volume, results demonstrated that completeness of unique visits differed by SHC care site. The intercept only mixed effects linear regression model evaluated the extent of variability in completeness attributed to nesting. Each visit is nested in a visit occurrence number, which is nested in patient, and a patient is nested in a care site. The model did not include three sites because of a limited number of patient and visit volume compared to all other sites (**Table 5.5**). The ICC for SHC care site was .245. This measure of effect size demonstrates that care site alone accounts for nearly a quarter of the variance in data completeness for outpatient visits.

Two SHC care sites stand out in the analyses of GMFCS completeness and data element mean completeness: Site E and Site O. Site E is the only SHC care site that has a mean completeness above 10% at the visit level (~16%). This means approximately three discrete data elements are documented during each Site E outpatient visit, and on average, at least one more than any other site. Although there was no correlation between mean completeness and volume of CP patients at each care, the number of unique visits at Site E over the past four years was 376 across 222 patients. Contrast this with Site O, where the mean completeness for unique visits was approximately 2% for over 900 visits across 530 patients. Site O has twice as many patients and nearly three times as many visits as Site E, however Site O barely averages one data element per outpatient visit and over half of all patients and visits have zero values for discrete gross motor function data elements. However, Site O has the highest rate of GMFCS documentation for unique visits compared to all SHC sites. Over two-thirds of all Site O visits have a GMFCS

documented, while nearly 80% of Site O patient records include a GMFCS documented. Less than half of Site E visits and nearly two thirds of patient records have a GMFCS.

K-means Cluster Analysis of Data Elements for Outpatient Visits

Five clusters of data elements had strong positive correlations as demonstrated in the heat-density correlation matrix (**Figure 5.2**). These clusters are circled on Figure 5.2. Based on

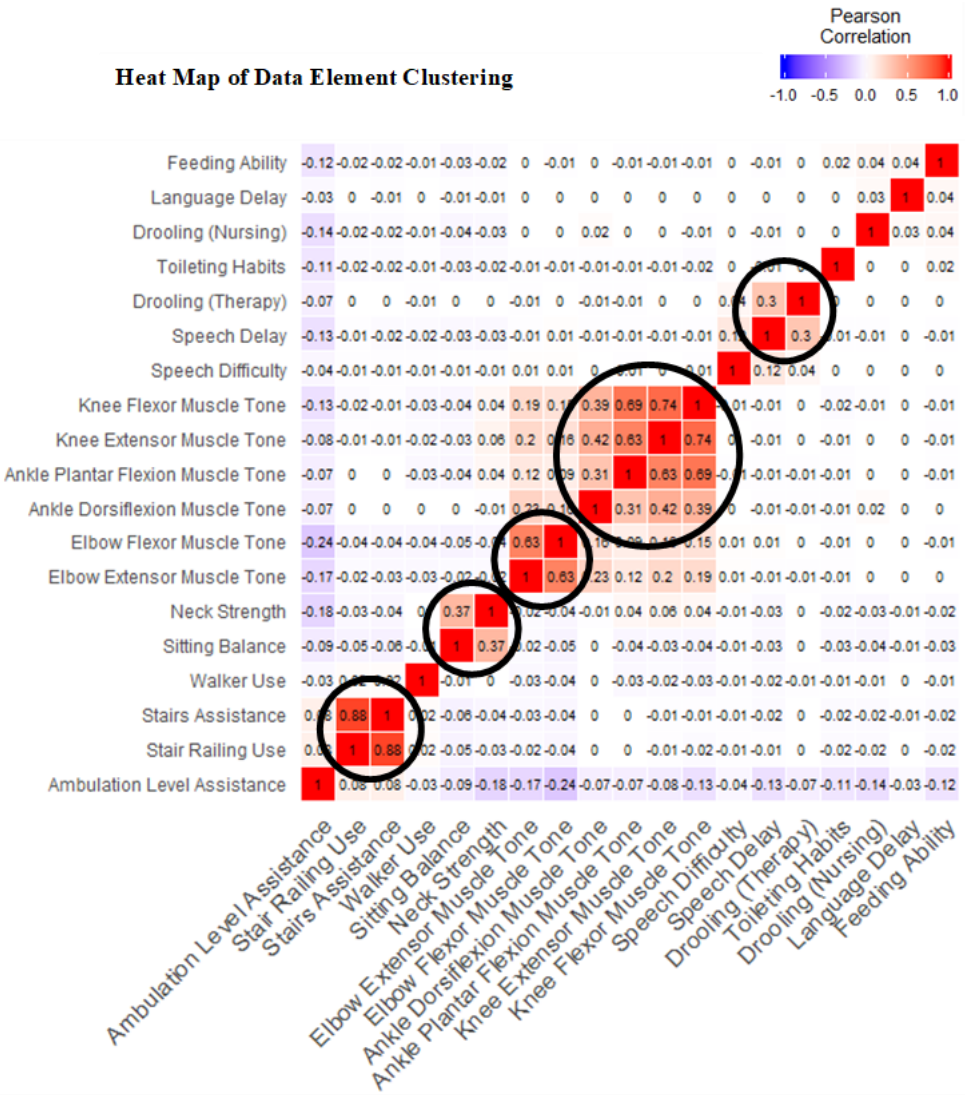


Figure 5.2. Heat-Density Map of Full Pearson Correlation Matrix. The figure above depicts a heat-map of the Pearson correlations for all 19 data elements with populated values for outpatient visit types. The correlations represent the relationship of presence and absence between each data element. Five clusters of data elements demonstrate. moderate to high positive correlation and are circled above. Stairs assistance and stair railing use demonstrate the strongest positive correlation at r = .88.

this matrix, all muscle tone data elements are highly correlated, however, there is some level of nesting based on upper and lower extremities. Elbow flexion and extension data elements are strongly correlated (r = .63), while data elements for ankle and knee muscle tone all moderately-strongly correlated with one another (ankle plantar and dorsiflexion = .31; knee flexion and extension: r = .74; ankle plantar flexion and knee extension: r = .63; ankle plantar flexion and knee flexion: r = .69; ankle dorsiflexion and knee flexion: r = .39; ankle dorsiflexion and knee extension: r = .42). Data elements for sitting balance and neck strength are moderately correlated (r = .37). Drooling and speech delay are moderately correlated (r = .30). Lastly, the relationship between stairs assistance and stair railings is strongly correlated (r = .88).

The optimal number of clusters was verified using k-means clustering analysis and two accepted methods to identify the optimal number of clusters. These included a Scree Plot of the total within sum of squares for each cluster to determine the elbow-bend[237] and a plot of the average silhouette width (**Figure 5.3**). The Scree Plot indicated the optimal number of clusters could be either 4 or 7. The plot for average silhouette width verified the number of clusters at 7.

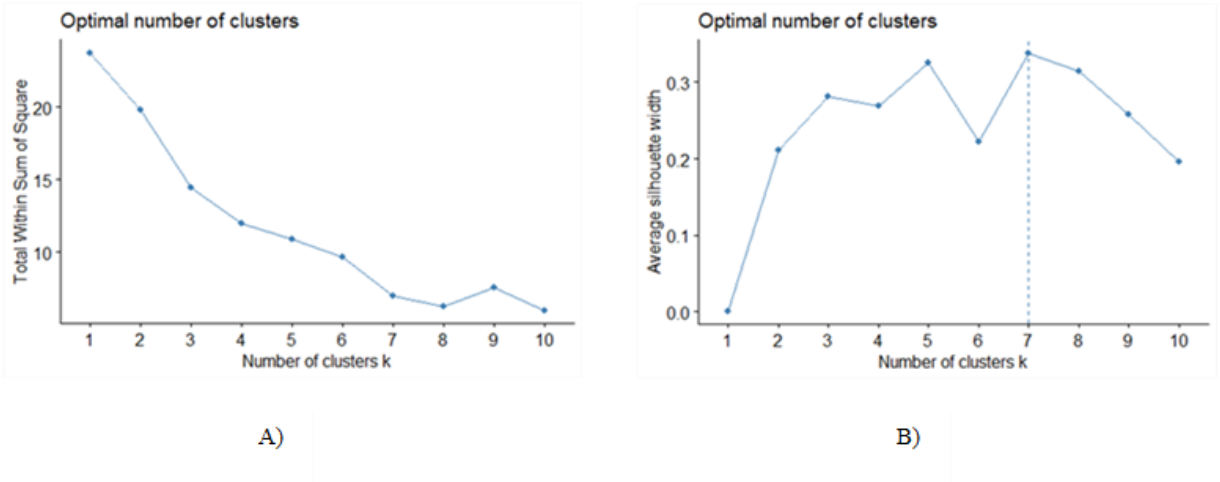


Figure 5.3. Plots to Determine Optimal Number of Clusters. The plots depict the optimal number of clusters. In A) the optimal number of clusters is determined by minimizing the total within sum of squares which is commonly observed as the elbow bend. The plot shows two instances where an elbow bend may occur (4 and 7 clusters), however the total within sum of squares does not appear to be minimized until cluster 7. In B) the optimal number of clusters is determined by a high average silhouette width. The average silhouette width is the measure of quality of the cluster and how well data elements fit in clusters. The plot shows that the optimal number of clusters to produce the highest average silhouette width is 7.

To visualize the assignment of data elements to clusters, 7 clusters were specified for the k-means algorithm. **Figure 5.4** provides a visualization of the k-means cluster analysis. The algorithm verified the previous 5 clusters, along with 2 others. Ambulation assistance is its own cluster but proximal to the cluster containing stairs assistance and railings, as depicted in the correlation matrix. Activities of daily living such as toileting and feeding clustered together with data elements for language delay and walker use. Based on these results, data elements with a significantly low completeness percentage tend to cluster together. This demonstrates a pattern associated with both the location of data elements on documentation forms and clinician routines and priorities to document specific data elements as narrative/free-text versus codified data.

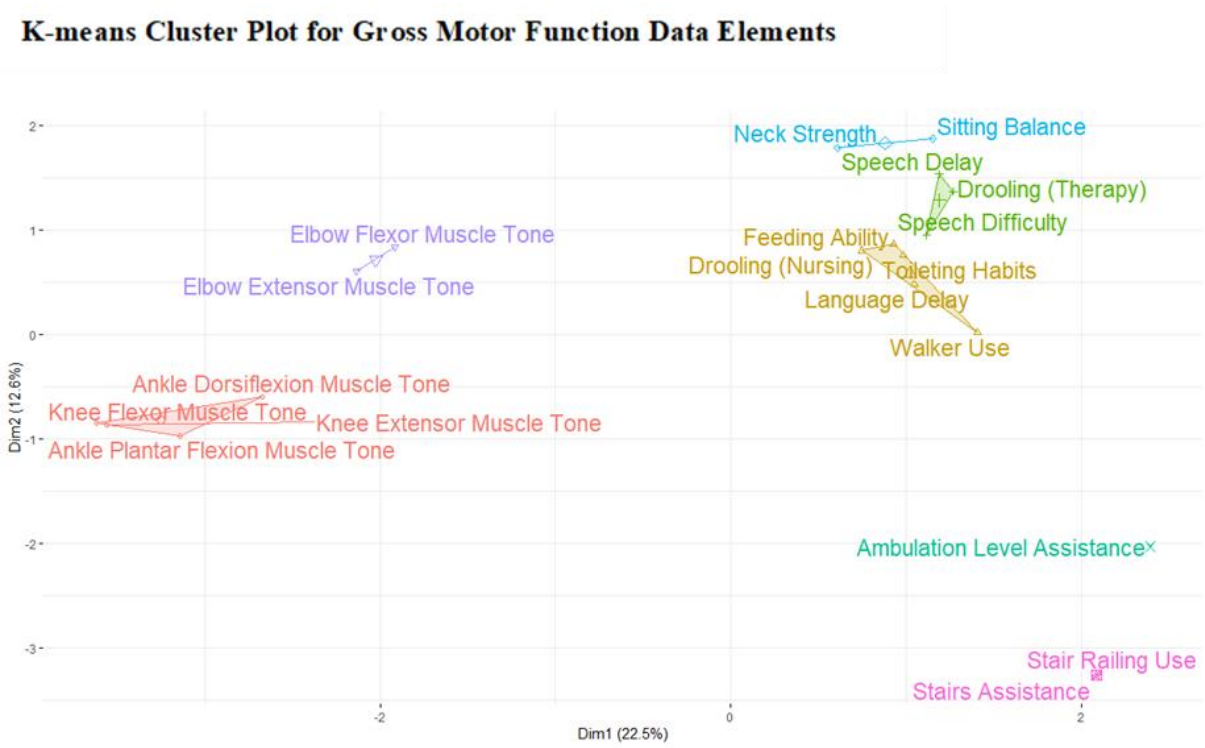


Figure 5.4. Cluster Diagram of Gross Motor Function Data Elements. The plot shows the 7 clusters identified by the k-means algorithm. Data elements cluster based on similar cluster means. The axes represent the two dimensions from a Principal Components Analysis that explain the most amount of information. The cluster and factoextra R packages automatically calculate a PCA and identify the two dimensions that explain the most variance.

DISCUSSION

This chapter analyzed completeness of data elements in an LHS data resource for the gross motor function phenotype model. The primary outcome of this study demonstrates low completeness of discrete data in the phenotype model, most notably in the average completeness percentage of outpatient visits (7.6%) and unique patients (11.4%). The missingness of phenotype model data and the discrepancy in GMFCS as a discrete data element by care sites that we observed in this study makes the use of existing EHR discrete data elements of limited value in such applications as hip surveillance for patients with CP. The data elements included in this study were limited to those that were available as discrete data elements in the EHR and previously selected by clinicians and researchers as essential to describe deviations in gross motor functional performance compared to existing GMFCS levels. Despite EHR support for discrete data elements and the robust EHR builds to capture salient data from patient-provider encounters, completeness of discrete data is quite low. Furthermore, the findings of this work indicate the need to consider data readiness and documentation of discrete data elements in phenotype model applications to develop accurate learning algorithms about functional performance.

The frequency of completeness and missingness may be explained by two phenomena: 1) Clinician priorities and preferences to capture patient health data, and 2) Site-specific care processes. Both phenomena require further investigation. However, what gets documented may be a feature of the site-specific documentation practices, as demonstrated by over one-quarter of the variance in data completeness attributed to SHC care site. Khare et al. in 2017 found that, within PEDSnet, 35% of the data quality issues were related to site-specific missingness in the EHR, while only 9% were related to problems with the ETL.[29] In contrast to significant

heterogeneity between PEDSnet sites, all SHC care sites use the same EHR build and version. SHOnet also adopted and stabilized the ETL convention created by PEDSnet for mapping EHR source data to standard terminologies. This magnifies the relationship between missingness in SHOnet and EHR documentation and informs the need to study the more structural factors that exist at individual care sites. Providers document most of these data elements, just not in locations for discrete data elements, so these data cannot be found and are missing in the context of EHR-based applications of learning. This biases the future use of these data for research and learning.[243]

Completeness is a central concept of Kahn's Data Quality Assessment Framework[6], but missingness requires equal attention. In the context of real-world data re-use, the meaning applied to completeness and missingness is much different than its characterization and management for research data. In fact, missingness tells a unique story about patient care processes. Therefore, what data elements are routinely documented or not can be just as important as the values. Data elements are often missing because they were negated by the value of a previous data element, or simply because it did not apply to a patient encounter.[223] The values inform treatment strategies at the next visit, while the presence and absence of specific data informs clinical decision making and clinician preference and priorities to document certain discrete data versus narrative data. Imputation methods, therefore, may not necessarily apply or account for the complexity of care processes and clinical thinking. Although this study did not analyze the data element values, the value of one data element could inform whether other data elements have or should have values. This thinking is also complicated by the significant missingness of data seemingly not at random.

This study only considers the extent of discrete data elements collected across a distributed healthcare system. From an infrastructure perspective, the SHC EHR supports customizations and choices to document essential patient health data. The EHR contains thousands of locations and formats to capture data (i.e. narrative, dictation, discrete, codable, etc.). The discrete data are primarily captured by PT, OT, and RN in the EHR using click-boxes and dropdown picklists. Discrete data enable and simplify many of the informatics, data science and quality improvement activities necessary for LHS, and, likewise, optimize existing clinical information system infrastructure. Standardizing and optimizing these discrete data for learning purposes in rehabilitation should be prioritized in health systems.

The EHR is a record of encounters to support communication, care coordination about specific patients, administrative processes, and as a future prompt about previous patient-provider interactions. Much of clinical care delivery is patient-oriented, and documentation surrounds the patient's response to treatment or a key finding or description of the clinical encounter. The medical record was not designed for population-centered research purposes and large-scale learning, as indicated by van der Lei.[20] Building LHSs means optimizing the EHR and documentation practices for dual-purposed learning, i.e. clinical and research. If specific data elements need to be populated in discrete form to conduct research on clinical care delivery and patient outcomes, then it becomes essential to ensure the necessary subset of data actually get captured in easily retrievable and shareable formats with all patient-provider encounters. This may be achieved by introducing documentation templates for specific diseases or broad physical function problems to ensure the optimal data elements are selected.

The results of this task-based study of data completeness demonstrate a significant need to improve the readiness of discrete data elements in SHOnet surrounding gross motor function.

While the EHR and SHOnet infrastructure already supports the collection of these data, the burden is somewhat reduced on the clinician to collect "more" or "extra" data. However, telling clinicians that their current performance is poor or that they need to document more will likely not be well-received. Thus, these results point to larger issues that future studies will address.

This study is not without limitations. The primary limitation is the absence of unique provider identifiers. Although the analyses included the specific visit dates and visit occurrence numbers, multiple different providers may be responsible for treating each patient within a specified visit occurrence number. Oftentimes, when a patient presents for an outpatient visit, they may be seen by multiple clinicians on the same day (MD, OT, PT, RN). Due to the lack of provider type metadata, the visit information for a specified encounter irrespective of clinical provider and specialty may be combined. A unique visit in these analyses may include data elements populated by an OT, PT, and nurse. Therefore, identifiers for different providers and provider types would inform another level of nesting at each clinical care site and further explain whether documentation of these data are attributed to one provider type versus another.

The second limitation of this work is in its generalizability. The study only evaluated outpatient visits for patients 6-18 years-old, and so the extent that missingness and clinical documentation of these data elements extends to inpatient visits should be studied separately for this population. This also means the documentation or lack thereof for many of these outpatient discrete data elements and GMFCS levels may be influenced by what providers read in previous inpatient notes or referrals in the EHR. The study also only includes SHC care sites; therefore, the results may lack generalizability to care settings outside of the SHC system. The data quality issues observed in this paper are consistent with those experienced in PEDSnet, a consortium of unaffiliated care sites; however, more research is needed in these pediatric health systems to

understand the factors influencing the data quality issues in order to optimize data capture and re-use. Lastly, the study only included data for the past four years. Many visits prior to 2015 and visits for patients that turned 6 years-old during the study period may have several of the data elements documented. This may affect the completeness percentage; however, the extent of data captured prior to age 6-years-old is outside the scope of this study since the gross motor function phenotype model corresponds to the GMFCS levels for children 6-18 years-old.

Pediatric rehabilitation relies on an interprofessional team to provide patient-centered care for patients with physical disability and functional performance deficits. Pediatric rehabilitation research and practice needs existing EHR discrete data to build actionable real-world knowledge around functional performance. Discrete data elements about patient function are also more easily accessible to patient families. With more complete data for necessary features like those in the phenotype model, patients and clinicians are better supported for shared clinical decision-making while researchers can identify cohorts of patients by gross motor function status and predict treatment intensity and progress.

This study advances the science of rehabilitation and LHS and provides a scientific account of variations in documentation of discrete data elements collected in a specialized pediatric rehabilitation hospital system. The systematic approach employed by this study to "learn" about data completeness advances knowledge of the breadth and density of discrete data documented across a pediatric hospital network. This examination of real-world data from previous clinical encounters demonstrates the need for qualitative research on EHR documentation practices and further learning activities using accessible discrete data elements to support LHS processes that improve care and outcomes. Future studies may consider questions

about the role of missingness and documentation in LHS, why missingness of EHR data occurs, and how clinicians perceive and develop documentation practices.

CONCLUSION

Data completeness is a challenge to ensure data readiness for conducting large-scale healthcare system research using real-world patient health data and is influenced by clinical documentation practices. The present chapter approached this problem using a learning health sciences process and task-based mechanism in the gross motor function phenotype model to link the extent of data completeness to the important role of clinical documentation practices. Although results demonstrate significant missingness in the phenotype data elements, the current SHOnet and SHC EHR infrastructure provide a foundation for additional data structures and resources. This work provides an opportunity to optimize this infrastructure and improve data readiness for LHS research. Future studies will focus on better understanding missingness of data and considerations for clinical documentation practices as critical infrastructure to improve the measurement of care delivery and patient outcomes in rehabilitation. Studies should also seek to understand conditions that dictate when discrete data elements can be collected and design implementation interventions to improve documentation of these data types.

Chapter 6

Exploring "Missingness": A Qualitative Analysis of Factors Influencing Documentation of Discrete Data in Pediatric Rehabilitation Settings

INTRODUCTION

Clinical data from the electronic health record (EHR) are an integral piece of learning health systems (LHS).[39] Such data are part of the LHS feedback loop which drives the outgrowth of discovery in clinical care in order to improve care delivery, patient health outcomes, and reduce costs.[5,41] However, sometimes data values are missing from the EHR, resulting in incomplete patient records. The extent of incomplete data in patient records is referred to as missingness. More specifically, for the purposes of the present chapter, missingness will be considered as the absence of discrete data in the EHR. Missingness of this clinical data influences data quality, data reuse for healthcare systems research and quality improvement, and generalizability of research results.[222 6,200,224,244-246]

Studies of data quality are common in the literature[6,68]; however, limited studies exist that use qualitative methods to explore the healthcare processes[247] and factors surrounding clinical documentation that influence missingness of re-usable real-world clinical data.[28,29] Wells et al. describe missing data as the result of either a lack of collection or a lack of documentation.[222] Several studies and perspective pieces on clinical documentation exist in the literature that describe its purposes and the tensions between structured (discrete; coded and codable)[235] and unstructured (narrative and free-text) documentation. Most notably, Rosenbloom et al. discuss this tension but recommend that reusable structured data fields be used by providers when

needed for research or researchers should rely on post-hoc text processing such as natural language processing to produce structured data, as appropriate.[12] The tension between structured and unstructured data types and the factors contributing to missingness is complicated to navigate and requires an understanding of existing healthcare processes[247] and provider perceptions and preferences of clinical documentation and the EHR systems. Few studies focus on factors influencing missingness of discrete data in the EHR. This chapter explores how and why missingness of discrete data in the EHR occurs and discuss the sociotechnical and professional factors that contribute to this missingness.

A proportion of EHR discrete data are produced for explicit reasons to support communication between providers in the present, as a historical record of the patient, and audit trails for billing, reimbursement and adjudication.[11,13,14] One recent reason is to support research and learning for LHS. It is important to optimize clinical data from patient-provider encounters for research in order to support routine learning about care delivery and develop evidence about and from these clinic visits. Clinical data research networks (CDRN), which are integrated or distributed data marts, are tools supported either by philanthropies or by the Patient Centered Outcomes Research Institute (PCORI)[69,89,97,248] to optimize these clinician-generated data to support LHS initiatives.[3,79,107,111]

One exemplar pediatric CDRN is the Shriners Hospitals for Children (SHC) Health Outcomes Network (SHOnet). SHOnet is an analog data repository of the SHC EHR system (Shriners Hospitals for Children Information System – SHCIS) that stores data from all 21 North American SHCs in a standardized terminology. SHOnet supports large-scale LHS efforts across SHC specialty care system that are specific to perioperative processes and pediatric rehabilitation settings. The data produced by rehabilitation professionals (physical, occupational and speech

therapies (PT/OT/SLP)), nurses and physicians are essential for measuring patient functional outcomes. These outcomes help shape pragmatic evidence about best-practices for perioperative care and rehabilitation. Data resources like SHOnet are instrumental to building infrastructure and communities of practice for scalable learning in pediatric rehabilitation; however, missingness, particularly of discrete data, is a critical issue that impacts the reliability, validity, and overall generalizability of findings.

In Chapter 4 and Chapter 5, SHOnet was used to learn about pediatric rehabilitation documentation by measuring the completeness of the Gross Motor Function Classification System (GMFCS) levels and gross motor function-related data elements captured in the SHC EHR. In Chapter 4, a domain experts and a panel developed the gross motor function phenotype model comprising discrete data elements to characterize the function for patients with cerebral palsy (CP), 6-18 years-old, seen as an outpatient across the SHC system. Results of Chapter 5 demonstrated that of the 65 performance-related data elements in the phenotype model, 19 included any populated values, while the mean data completeness percent per patient visit of these data was approximately 7.5%, or ~1-2 data elements per visit. Only 21% of unique outpatient visits had a GMFCS level documented as a discrete data element. Furthermore, results demonstrated that one-quarter of the variability in data completeness of phenotype model data can be explained by site level alone.

The findings of missingness in this prior report do not represent the extent of data and other information that rehabilitation therapists, nurses, and physician specialties document about patients in narrative forms and other free-text sections of the EHR. This information is stored in the EHR, albeit in unstructured formats. This incongruity impacts the generalizability of findings and validity in knowledge to support changes in care delivery and health system infrastructure.

The sparsity of available discrete data in therapy and nursing notes represented in our gross motor function phenotype model and the site-level variation impacts task-based learning activities and implementation of change in care delivery processes.

In addition to the background presented thus far, the concept of professions and professionalism are essential for the following analysis to understand missingness and clinical documentation. The consensus of theorists in the professions literature would define a profession as an exclusive occupational group with some special abstract skill that requires extensive training.[249] Physicians, nurse practitioners, physicians assistants, OT, PT, SLP, and nursing are all healthcare professions that maintain their own professional identity. As Abbott describes, each profession has activities under various kinds of jurisdictional boundaries.[249] Professions control techniques of structured work and the abstract knowledge that generates these techniques; however, each profession is competing constantly for control of further jurisdictions of abstract knowledge and techniques to exercise these abstractions and monopolize industry.[249] Professions do not exist on an equal playing field, and it is this competition that creates the subordination and super-ordination in many professions, for example in healthcare between physicians and others. The jurisdictions of documentation in clinical care among providers are not well-defined and may contribute to missingness in EHR data.

The background provided demonstrates the need to understand clinical documentation and develop strategies to improve completeness and accuracy of structured data documentation in EHRs to support research in LHS, especially in pediatric rehabilitation settings that influence child recovery, growth and development. In this paper, qualitative methods are used to explore and construct the themes (system-level and structural) surrounding clinical documentation which influence missingness of gross motor function structured data. The documentation of GMFCS as

a discrete data element is used as an exemplar to study documentation in a large-scale distributed pediatric rehabilitation healthcare system. These themes are then linked to perceptions, practices, and latent concepts of clinical documentation This qualitative work is an essential step to achieve improvements in completeness.

RESEARCH QUESTIONS

The primary research question of this chapter is to understand why missingness of EHR discrete data occurs. The objective, therefore, was to explore the relationship between missingness of the GMFCS discrete data element and clinical documentation practices, perceptions, and concepts for the purposes of managing patients with CP. This chapter elevates the GMFCS[136] as the exemplar data element because it is a normative data element for characterizing functional performance in patients with CP and is well-understood and documented by members of the interdisciplinary care team. The objective of this chapter is achieved by eliciting and interpreting clinician perceptions of documentation and the factors influencing their preferences and priorities to document narrative/dictation or structured data types around GMFCS. An extensive qualitative approach using thematic analysis resulted in the construction of two factors that shape our understanding of how and why missingness arises. These include such factors as the incongruity between the interface location of data elements in the EHR and provider perceptions and value of these data in the corpus of the clinical note, as well as the recognition that data documentation is influenced by a division of labor between provider specialties. The outcomes of this study support the development of future strategies for improving the collection of structured data in routine care delivery across a geographically distributed healthcare system.

MATERIALS AND METHODS

This project was undertaken as a Quality Improvement initiative at Shriners Hospitals for Children and as such, was not considered research.

Research Design and Philosophical Framework

The research design used for the following work was a multi-site case study that included field observations and semi-structured interviews. The data for this analysis come from 20 semi-structured interviews with clinical providers across three SHC care sites about their EHR documentation practices. This study used an iterative, qualitative approach to inductively develop semantic and latent themes to understand why missingness of EHR data (i.e. GMFCS) occurs across a distributed health system. Each care site operates under the same organizational mission, vision, and values of SHC, and effectively report to SHC headquarters, but sites maintain geographic differences. Thus, the research in this chapter was designed to obtain empirical qualitative data about provider documentation practices across the three SHC sites.

This research also draws on the Critical Realist philosophical framework to understand the generative mechanisms that influence the documentation of discrete data in the EHR.[201] The healthcare system is not closed off from the real-world, like laboratories with highly controlled experimental conditions; therefore, a positivist and even a post-positivist theoretical approach is inappropriate if we want to understand the numerous causal mechanisms associated with missingness of discrete data in the EHR. Rather, healthcare systems are open to the complex array of both observable and unobservable mechanisms that inform and shape processes and performance.[201-203] Critical Realism considers the *real* mechanisms that generate the *actual* and *empirical* conditions or events we can observe (**Figure 3.1**).[201,202] This philosophical framework allows us to formulate the factors that contribute to missingness.

Case Selection

The types of data documented, and documentation practices themselves may vary based on clinics, providers, and geographic location, as indicated, and discussed in several studies on data quality. [28,29,68,96,250] To account for this possible variation, the case selection was based on the geography of care sites with regionally diverse patient populations from a wide catchment area. Three SHC care sites were selected for study participation using theoretical sampling based on geographic distribution. The three SHC care sites, referred to here as Sites A, B, C, span the Western, Midwest, and Eastern regions of the US, and manage a moderate to high volume of patients with CP. These sites were selected using theoretical sampling prior to the analysis of data completeness in Chapter 5.

In the previous chapter, findings demonstrated that a quarter of the variance in completeness of GMFCS and gross motor function phenotype model discrete data elements for patients 6-18 years-old with CP seen between 2015-2019 could be attributed to care site level factors. **Table 6.1** compares the patient volume and data completeness across the three selected care sites. The table includes completeness percentages for the same group of patients between 2011-2015 to demonstrate consistency in missingness between time periods. While differences exist in data completeness between sites, results demonstrate a consistent theme across all sites

Table 6.1. Descriptive Statistics of Care Site Completeness.

	Site A	Site B	Site C
Completeness: 2015-2019			
Patients	334	476	197
Visits	745	1144	1145
% Mean Completeness	7.0	10.0	7.2
Mean Data Elements per Visit	1.30	2.0	1.33
% GMFCS Completeness for Visits	14.0	15.0	.002
% GMFCS Completeness for Patients	21.0	30.0	.01
Completeness: 2011-2015 Visits Only			
Visits	494	887	1058
% GMFCS Completeness	.02	19.0	.02
% Mean Completeness	9.0	8.4	6.8

of significant missingness of GMFCS as a discrete data element and overall missingness of discrete data in the gross motor function phenotype model.

Participants

Participants included clinical providers from each of the three SHC care sites. All participants have documentation responsibilities and treat patients with CP. Participants included a variety of clinical disciplines to encompass the interdisciplinary care team that manages patients with CP: PTs, OTs, SLPs, surgeons, physiatrists, nurse practitioners, and nurses. Participants were recruited for semi-structured interviews using a convenience sampling strategy with the support of care site liaisons. These care site liaisons are familiar with the procedures for visiting investigators to conduct on-site observations and interviews. They are also familiar with the variety of providers and provider schedules at respective sites to be able locate and recruit participants. The liaisons helped recruit providers whose primary clinical specialty was CP. Liaisons then scheduled interviews with willing and available providers prior to interviewer site visits, but also assisted with on-site recruitment if participants became unavailable. All participants received verbal details about the purpose of the study and verbally consented to participate in interviews and to be audio-recorded.

Twenty providers were interviewed across the three care sites: 7 at Site A, 10 at Site B, and 3 at Site C. Average duration of interviews was approximately 42.5 minutes. The 20 interviewees comprised 8 MDs, 5 PTs, 2 NPs, 2 OTs, 2 RNs, and 1 SLP. Three interviewees were observed performing a mock chart review and documentation process using the EHR. The initial findings demonstrated that providers could be collapsed into three broad disciplines according to their scope of practice and documentation typology: MDs, PAs, and NPs into the category “physicians”; PT, OT and SLP into “therapists”; and nurses.

As the findings will show, these three provider groups reported distinct documentation practices, and the differences between these practices help explain our previous finding that GMFCS and other structured EHR fields tended to be left empty, resulting in missingness at the population level. Therapists use a mixture of click-boxes, free-text fields, and other structured fields to document, and have a designated structured field to document GMFCS. Their EHR forms contain additional comment fields for them to expound on patient response to treatment. Therapists document either point-of-care or following a patient encounter. Nurses reported they only use structured fields to document during outpatient clinic encounters but there are free-text boxes to write comments, and that they do not have a nursing discipline-specific field to document the GMFCS. Physicians all dictate their notes in outpatient clinic settings, thus GMFCS is commonly captured as an unstructured format. These practice differences influence the types of data documented in the EHR and have implications for missingness of discrete data.

Data Collection

The data collection strategies included both non-participant observation and semi-structured interviews with participants. Interviews were guided by the study research questions surrounding a deeper understanding of clinical documentation practices and to determine factors influencing missingness of discrete clinical data. The research team included several members with previous medical background and knowledge of care delivery processes that provided much of the contextual knowledge necessary to conduct participant interviews.

Interviews were audio-recorded and occurred on-site at each SHC in a reserved conference room or provider office. Participants were asked to describe their typical documentation process, and subsequent questions referred to practices of GMFCS documentation, perceptions, and preferences of documentation, how providers learn and

receive/solicit feedback about their documentation, care delivery and patient progress. A list of questions from the interview guide are provided in **Table 6.2**. As applicable, participants engaged in the think-aloud method using the EHR system, SHCIS, during interviews to characterize the prototypical clinical documentation process. The think-aloud method is an established technique to capture the thought process a person endorses to navigate a problem or complete an action.[205,206] Those participating in this activity provided real-time, play-by-play analysis of navigating SHCIS to review the patient chart, previous notes, visit reasons, perceptions of colleague notes, switching between tabs, clicking boxes, and procedure for documenting. This provided insight into provider reasoning and perceptions about the multiple aspects of documentation.

Table 6.2. Selection of interview guide questions.

Where do you sit on the balance between structured forms and unstructured/free-text documentation in the EHR?
Do you think clinician documentation practices have any implications beyond ensuring good care for individual patients?
Describe your perceptions of the quality of clinical documentation at this clinic.
Is there a structured process you use for clinical documentation?
Describe your experience with and how you handle EHR updates and changes?
When do you document your clinical encounters?
How much time do you spend on clinical documentation during a routine workday?
What is the chart review process that you use? Is there a way you process the extent of information?
How do you think documentation practices become standardized in your clinic?
Where do you think you are strongest with your documentation?
Describe the aspects of clinical documentation with the EHR you like and dislike.
How comfortable are you with technology? Would you call yourself an early adopter?

Semi-structured interviews consisted of two primary activities: observations of EHR documentation followed by a set of interview questions. Interview questions were developed and circulated with study team members for review and revised for organization, structure, and clarity. During observations, the interviewer did not see any patient-specific EHR information, rather only the provider viewed the information in the EHR while the interviewer watched the provider. Interview questions were informed by existing literature across organizational studies,

science and technology studies, health informatics, dissemination and implementation science, and theoretical frameworks such as the Normalization Process Theory (NPT).

The NPT is a middle range action theory of implementation.[168,169] This theoretical framework is focused on understanding a work process by dissecting an activity into four processes of implementation: coherence, cognitive participation, collective action and reflexive monitoring. Each question from the interview guide maps to one of the four components of the NPT. While the NPT influenced the development of the interview guide, the interview transcripts were not deductively analyzed using the NPT; rather, the transcripts were analyzed inductively. Within implementation science, the NPT is primarily used to structure and understand the barriers and facilitators that influence a particular implementation intervention. However, the NPT structured the initial considerations of the potential factors that influence and shape practices of clinical documentation. The NPT informed the types of interview questions that providers could answer about a routine work process in order to understand the *real* generative mechanisms such as system level factors and practices and perceptions of documentation that result in missingness of discrete data.

Participant interviews occurred until the responses provided a sufficient account of documentation practices and considerations of the GMFCS in clinical care across provider groups. To determine sufficiency, data collection focused on obtaining enough overlapping details about the breadth and depth of documentation practices, the provider perspectives of documentation and their peers' documentation, and the interprofessional work of providers to construct cogent themes. Field notes were instrumental during interviews and observations to obtain key content that participants discussed surrounding the study research questions, particularly to capture instances when participants mentioned GMFCS, the documentation of

discrete data, or how providers conceptualize the GMFCS in the corpus of the clinical note. The data collection strategy revealed how provider groups document the GMFCS in the EHR and supported the construction of both semantic and latent themes that contribute to missingness. Each interview provided integral findings to identify more semantic themes and construct the latent themes more specifically; gaining a deeper understanding of how infrastructure supports, defines and stimulates the decisions of whether to document the GMFCS, as well as many other discrete data elements. Furthermore, the observations of patient-physician outpatient clinic visits informed how providers navigated and reviewed the previous clinical notes in the EHR and dictated their own clinical notes following a patient encounter. The data collection focused on how physicians and therapists describe and conceptualize patient functional performance using the GMFCS, and how this becomes idiomatic to both providers and provider groups that treat kids with CP.

The field notes and previous interviews stimulated conversation during further observations of EHR use and participant interviews. This added an element of participatory research into the data collection phase because participants became actively involved in the initial construction and curation of themes. These multiple sources of data provided sufficient depth to crystallize previous considerations for the types of semantic themes that may explain the occurrence of missingness of discrete data in the EHR.

Data Analysis

Thematic analysis was conducted on the final dataset and used an iterative approach to ensure validity and convergence in the constructed themes. The thematic analysis subscribed to a six-stage approach described by Kiger and Varpio[207] and Braun and Clarke[208]. All audio-recorded interviews were transcribed verbatim and coded using QSR International's NVivo 12

software. All interviews were transcribed by hand to ensure a rich understanding of the data corpus.

Once all the interviews were transcribed, the first pass analysis of the data corpus focused on grasping any variability in data collected. This first pass included highlighting passages and jotting notes and interpretations/paraphrased paragraphs on these possible data extracts. The initial pass focused on passages that linked to GMFCS, perspectives of discrete data, clinical documentation practices and purposes, and system level issues that may influence documentation. The second pass of the data corpus included a review of the highlighted passages to ensure data extracts were comprehensive enough to provide adequate context for further analysis. The data extracts, supporting notes and paraphrases were copied into a Microsoft Excel spreadsheet to visualize the breadth of data and support the coding process. The initial coding process used both inductive and deductive approaches to formulate the codes to build themes. The inductive approach focused on developing initial codes around the role of narrative data, the types of documentation purposes, and meanings applied to documentation. The initial results actually aligned with conditions of infrastructure described by Bowker and Star[58,61], and Edwards[251], because clinical documentation and missingness of GMFCS included definitions of infrastructure such as "built on an installed base," "linked with conventions of practice," and "learned as part of membership". While the extent that clinical documentation serves as a type of infrastructure for a healthcare system, sparse literature exists in this area. The argument can be made that this infrastructure supports, shapes and is shaped by the social and technical components of clinical documentation which influences the types of data that providers produce. Although these infrastructure codes align with a deductive approach these codes can be broken down into more specific entities that elucidate the types of factors influencing missingness. The

final pass of the data extracts resulted in new codes developed inductively but informed by concepts of infrastructure and professional factors that better captured the essence of the extracts, notes, and paraphrases and how they attribute to clinical documentation of GMFCS and missingness of discrete data.

Lastly, a four-step process was used to construct and refine the themes that address why missingness of discrete data occur in the EHR. First, since the focus of this chapter was on GMFCS as an exemplar for understanding missingness as a discrete data element, only those extracts that discussed the GMFCS were copied and pasted into a new spreadsheet and coded these at a semantic level. The themes were constructed from these codes related to the GMFCS by sorting the codes into similar groups. The initial codes about documentation and missingness in general were then mapped to these themes about GMFCS missingness. Finally, to enhance the specificity, the verbiage of the themes was revised, and the codes were re-sorted one last time. This resulted in two clear themes that function as generative mechanisms that shape the instances of missingness of discrete data in the EHR.

RESULTS

The thematic analysis resulted in the development of two latent themes, or primary factors, that explain missingness of GMFCS as a discrete data element in the EHR. 1) Missingness of GMFCS is influenced by the incongruity between how it is valued in the patient record and the GMFCS location in the EHR interface. 2) Missingness of GMFCS is influenced by a discordance in the division of labor of documentation responsibilities.

Factor 1: Missingness of GMFCS is Influenced by the Incongruity Between its Value in the Patient Record and its Location in the EHR Interface

The missingness of GMFCS as discrete data is influenced by the incongruity between the location of the GMFCS discrete data element in the EHR interface and how clinicians link the role or value of the GMFCS in the patient record. Therapists are the only providers documenting the GMFCS as discrete data. Nurses reported they do not document the GMFCS, therefore their perspective of the GMFCS and its documentation is not provided in this first factor. Physicians document the GMFCS, albeit in narrative form, and their perspectives are discussed below.

At the most semantic level, interviews revealed that therapists have a designated structured field in their EHR forms to document GMFCS located in the "Developmental Mobility" form. Chapter 5 demonstrated the infrequent use of this field an, while a checkbox for GMFCS level is located on this EHR therapy form, therapists do not routinely document in this field. Rather, when they document GMFCS, they insert the value in the free-text history of present illness (HPI) field on the first available EHR form. This contradiction resulted in a deeper question that asks why therapists choose to document GMFCS in the text-field rather than the designated structured field. Therapists indicate the HPI field is the first place the GMFCS is both considered and entered:

> [*Excerpt: Therapist, Site A*
> "If I'm not the first person to initiate a note, then [the GMFCS] might already be there. But if I'm starting [the note] too, then I'm almost always documenting, say for example, 'right hemiplegic cerebral palsy, GMFCS level I'…. On our note, on the first page, where you can kind of input 'why am I seeing them', we have that line for…history of presenting illness... so that [GMFCS] usually stays there. And I think we're pretty consistent now with people including things there..."]

The HPI section, found on the top of the first EHR form, is one of few populated sections, free-text or structured, that are actually carried over from note to note for a given patient in the therapy forms. So, if the GMFCS is already documented in the HPI, a simple

explanation for the missingness is that the therapist may not find it necessary to document the GMFCS again in the designated structured field. Furthermore, during a follow-up visit, the treating therapist may see the GMFCS documented in the HPI and choose not to populate the designated structured field again. This points to the role of the GMFCS as a phenotype of the patient and a key descriptor in the patient history, rather than a time-varying measurable entity. The GMFCS is valued by therapists so much so that they feel it *fits* in the explanation of the patient; that the GMFCS embodies the extent of a patient's functional performance in an ensemble of activities.

In reviewing the therapist documentation forms, the Developmental Mobility form, where the GMFCS field is located, is buried in the EHR interface. This location was pointed out by one therapist who participated in the think-aloud activity. The therapist described the location as problematic because a patient may not have impairments or concerns in developmental mobility if they are older, stating: "It doesn't make sense to me if you're not talking about [the patient's] developmental mobility, because this is something that's only for a younger child that I'm worried about." If a therapist treats patients who over 5 years-old, then they may hide (i.e. unselect) or not pull up the developmental mobility tab since most gross motor skills are mastered by 5 years-old.[252] As described above, this location actually limits the documentation of GMFCS because therapists may not need to access the Developmental Mobility form, and if it's already noted under the HPI, they may decline to document GMFCS a second time. These findings suggest that the GMFCS value is commonly missing from the structured field because its location in the EHR form does not match the way therapists view the GMFCS in the context of the patient and also the role of certain EHR forms as situational. This may also impact the documentation of many other structured data because some fields may not align explicitly with

the EHR form they fall under and may not be obvious or easily accessible by therapists. This incongruity creates a problem surrounding data collection for population-related versus patient-centered means and results in a substantial amount of missingness in discrete data for quality improvement and research purposes.

While therapists are not bound to only document discrete data elements, the infrequent use of the structured field for capturing GMFCS level in the EHR infrastructure introduces a contradiction about documentation: the incongruity between location of data fields and how providers conceptualize these data in the patient narrative. Therapists choose to document the GMFCS in the patient HPI not because of convenience, but because there is a mismatch between the technical and regulatory aspects of how the forms and clinical note in the EHR are built and the therapist conventions of practice and thinking. This evidence of professional autonomy is consistent with what Freidson considers a key feature of professionalism in medicine.[253] Professional autonomy enables providers to control the type of data they collect for the patient problems they are solving; however the EHR forms are designed in a way that limits this autonomy.[254] The forms in the EHR shape how data are perceived in the context of general patients across all disorder types, but these systems are not designed with the intent for therapists to document data that conform to their professional identity.

The physician perspective of GMFCS and documentation provides further evidence for why the location of GMFCS as a discrete data element in the EHR is important for therapists. The physician group generally reported that they acknowledge the GMFCS or some level of motor dysfunction in the HPI section for children with CP, commonly found in the Subjective section of the traditional problem-oriented SOAP (Subjective, Objective, Assessment, Plan) clinical note.[255,256] Providers like physicians, physicians assistants and nurse practitioners at SHC

care sites predominately use dictation for outpatient clinical notes rather than directly input patient data into the EHR. Dictation supports expressivity in the documentation and aligns with Freidson's and Abbott's concept of professionalism and the ability to create and present abstractions from clinical knowledge.[249,253] While not all physicians reported the explicit dictation of the GMFCS following routine clinic visits, all mentioned the importance of the classifier as a key entity in clinical decision-making and research and discussed how they classify patients by GMFCS.

> [*Excerpt: Physician, Site B*
> "GMFCS for us is like a screen, like a blanket, easy…so I feel like I should be proficient in it. I think of the pictures; of that child with the box; can that person run. I basically think of the pictures and describe it and look at the patient. And when [the patient] is borderline, let's say a child that walks therapeutically, that's when it might get tricky, right. But if [they walk] therapeutically with a belt versus [not]...functionally if it takes me to get from here to that umbrella, or the Weber grill, that to me is therapeutic walking, that's not functional; that wouldn't be very fun. So then, I would classify that person as a 4, but I would note that the person can walk, etc."]

As the excerpt demonstrates, the simplest way that physicians (and therapists) classify patient GMFCS levels is by implicitly linking the patient presentation and current mobility status to one of the five (I-V) GMFCS levels developed by Palisano et al. (**Figure 2.8**).[136] Palisano et al. created five different graphics corresponding to five age ranges (0-2, 2-4, 4-6, 6-12, 12-18 years) for the GMFCS. The graphics of GMFCS functional levels support provider critical thinking about patient function, and engages patient families to understand the level at which their child may perform activities. This represents the embeddedness of the GMFCS in management of CP and the universality of the GMFCS as a standard language to describe patient gross motor function for CP. It also demonstrates providers' mental flexibility and abstract thinking about the ensemble of activities and functional performance that a single GMFCS level encapsulates.

The way physicians and therapists describe their GMFCS documentation practices demonstrates that the GMFCS is not wielded as a measurement tool or feature of treatment. Instead, the GMFCS is a phenotype of the patient and is an abstract representation of a patient's current functional motor performance. While the GMFCS may be an objective finding, it fits as a description of the patient presentation in the HPI, rather than a finding during examination. This holds true especially if the physician classifies the GMFCS prior to the therapist. If the GMFCS is perceived as a stable value, then the GMFCS may not be documented after initial evaluation by a therapist and physician during routine follow-up visits, and therefore the discrete data element is not considered in subsequent therapist notes.

Factor 2: Missingness of GMFCS is Influenced by Discordance in the Professional Division of Labor in Documentation Responsibilities

Although the location of the GMFCS field in the EHR is an important reason for its missingness as a discrete data element, this missingness can also be rooted in the discordance between providers about the professional division of labor in documentation responsibilities. Division of labor in healthcare is the organization of many technical and service workers around a central task of managing patient health[253], but this organization occurs at the level of specific practices and processes. In our case, these are the practices and processes of clinical documentation. So, the research question deepened a bit more to ask, "How is clinical documentation and the phenomena of missingness influenced by division of labor and professional identities in healthcare systems?" Physicians, therapists and nurses all document within their scope of practice and use different or varying formats, but subordination to physicians exists among the other professions. The initial patient history is often outlined by the physicians. Other services are consulted to then both reiterate and addend this patient history and

provide expert opinion, management, and interventions around their professional scope of practice. The care team builds a fragmented patient narrative of different opinions and abstract knowledge and specialized skills to tell the patient story and how the health problem can be solved. The variability and missingness in GMFCS and other gross motor function related data may be caused by a lack of articulated and agreed upon documentation responsibilities between professions.

Interviews suggest that therapists understand the division of labor in documentation responsibilities generally within their scope of practice, but the role of documenting the GMFCS, although concordant with their practice, is less clear. These findings suggest that therapists survey the patient chart for many data elements, but not explicitly for the GMFCS data element. During chart review, if the GMFCS is dictated in the physician note under the dictated HPI, it, among other things, prompts the therapists as to the physician's perspective of the patient's physical presentation. This does not automatically result in the therapist reproducing the GMFCS as a discrete data element. However, for therapy follow-up visits, the GMFCS may already be documented and carried over in the HPI of the previous therapist's note, thus there is no incentive for them to document the GMFCS again. If the patient is a new evaluation, the therapist may not see the GMFCS documented during chart review unless it was documented in the physician clinical notes. During the chart review process, the therapist focuses on developing their own narrative about the patient, whether the GMFCS is part of this is at their discretion. The chart review sets the tone for the consideration of what the therapist documents later:

> [*Excerpt: Therapist, Site C*
> "I look at the medical notes. I usually go back [in the chart] like two or three years just to kind of see how many times [the patient has] come in. And often if they had a recent procedure, then I can see there's a whole bunch of dates in a row. I also look in the Clinic Notes section, which lets me look back and ask, "where did they see another therapist?

And for what?" So, I'm basically doing a chart review, trying to figure out a picture of this kiddo."]

For therapists treating patients with CP, the documentation process requires them to source information from interdisciplinary care team notes in order to maintain care continuity, while also considering the patient deficits requiring skilled care. Prior to evaluating a patient for the first time, the therapist thoroughly examines the chart for previous physician and nurse notes to understand the patient typology. Therapists develop a mental picture of the patient's functional performance based on how providers characterize the patient phenotype in previous notes. The GMFCS parameterizes this patient function into specific bins based on mobility and activity performance, but therapists do not necessarily need this classifier to understand the patient motor ability and disability. They retain extensive professional knowledge and skills learned as part of their membership in the rehabilitation discipline to explain, understand and address patient deficits, which they prioritize and document in their clinic notes. But this knowledge, although important, tends to get replicated by other providers, as demonstrated in physician responses about documenting the GMFCS, creating further subordination and less control over their abstract knowledge.

[*Excerpt: Physician, Site C*
"I'm more details oriented. Instead of saying the patient is a 1, 2, 3, 4, I'll say they're ambulating this distance using this piece of equipment with modified independence. They're able to do this ADL with this amount of assistance, they're dependent for all ADL. I give more detail, but I probably should also list that. But if there was like a checkbox, I'd do it. That would be easy. I feel like the orthopedic surgeons probably dictate that more often than I do in my notes."]

Although this physician, a physiatrist, is not explicitly documenting the GMFCS, they, along with many other physicians prefer to narratively document the functional activities and assistance levels of a patient that correspond to a GMFCS level. They also defer to the orthopedic surgeon the responsibility to classify and document the GMFCS level. The last line

about the role of the orthopedic surgeons documenting the GMFCS indicates explicit understanding surrounding documentation responsibilities between physician specialties, whereby physician subspecialties document on a level playing field. Despite this acknowledgement, at this site, one therapist noted that they rarely see the GMFCS documented in physician notes, while an orthopedic surgeon also reported the GMFCS is only captured in their research and not in their EHR clinical notes. This also points to the view of the GMFCS as a research tool rather than a clinical tool. The consideration for the use of the GMFCS for research separates the GMFCS from the context of clinical care. Each provider knows the importance of the GMFCS, but as indicated, documentation jurisdictions of clinical data are not well-defined, which results in laissez faire documentation, frequent redundancy or extensive missingness whether discrete data or narrative. Furthermore, if one discipline relies on other disciplines to document key data and this is not effectively communicated, then requisite data, like GMFCS, are not routinely documented. Here the GMFCS is considered irrespective of the method of documentation (i.e. discrete vs unstructured).

To add to this discordance, some physicians are not sure which other professions document the GMFCS or where it is located in other parts of the EHR, and often stick to their traditional routines of referring to the most recent progress note to prompt treatment and patient classification. Even in these notes, physicians see inconsistencies in the reporting of the GMFCS and other classifiers:

> [*Excerpt: Physician, Site A*
> "Now, there are other parts of the EHR where [the GMFCS] is kept in a separate segregated fashion and I had no idea that those even existed. I have no idea who puts it in, and I've never used it."]

The physician does not know who documents the GMFCS or how it gets into the EHR, and this demonstrates the misalignment between disciplines in terms of GMFCS documentation

responsibility. It also demonstrates that effective, complete, and accurate documentation is built on trust between disciplines and acknowledgement of the division of labor in documentation. Therapists understand the importance of the GMFCS; however, whether they document GMFCS may hinge on whether it was previously documented by the physician. Therapists trust the physician's accuracy in classifying the GMFCS, but if the physician does not document the GMFCS, then this sets a precedent about its role and value of the GMFCS in clinical decision making and the patient record. Therapists also believe the GMFCS aligns best with the abstract knowledge they control as professionals.

The lack of clarity and standards in documentation leads to overextension and redundancy across the EHR and even within a clinical note, and these data are often not collected as structured forms or in a prescribed fashion. If we zoom out to the larger scope of discrete data documentation, we can also see how discordance in the division of labor of documentation responsibilities influences missingness.

> [*Excerpt: Therapist, Site B*
> "I feel like it's a little bit unclear what they're [Administration] looking for as far as documentation standards here. That's been a real struggle for us… Our notes are probably beyond thorough for anywhere else. For the chart for the activities, we're writing the activity, the reason for performing it and [the patient's] response. So, we're basically doing an assessment in our therapeutic log, and then doing an assessment again. It's frustrating and it's inefficient."]

This excerpt demonstrates that documentation responsibilities are built on standards and require sound communication between providers and between the system and provider to ensure the right data are documented by the right providers for the right patients. As a case in point, consider the documentation responsibilities established between therapies and nursing: These disciplines have overlapping structured fields to document gross motor function data; however, these fields are infrequently populated by both disciplines. The nurses interviewed for this study

reported that their documentation is all click boxes, and that their documentation is procedural; meaning they have established a routine to document the same data elements for each patient encounter. Nurses do not have a nursing discipline specific field for GMFCS and therefore SHC does not hold them responsible for documenting the GMFCS. Their EHR forms do retain several data about gross motor function which are located in the nurse outpatient intake form in the EHR. These data elements significantly overlap with therapist practice jurisdictions. Nurses reported that they are required to document in the outpatient intake form for every patient encounter.

> [*Excerpt: Nurse, Site B*
> "In the outpatient department, we are required to document in the outpatient intake form on a patient, which has certain categories of pain assessment, reason for visit, how they came in, do they have durable medical equipment, are they independent at home…it goes over toileting and other ADLs. [Headquarters] thought we only needed the outpatient intake form for the admission kids coming in for surgery or rehab, but we needed it for outpatients too. There's much more of them that never come in for a surgery."]

Many phenotype data elements are located on this form, but one nurse stated, "it is not a real fine place to document," and that data element values are not very granular. This is because often such data alone lack the context to synthesize findings. As one physician illustrates, we need to reconfigure the way data are viewed in clinical settings:

> [*Excerpt: Physician, Site B*
> "If the purpose is to have the [EHR] system built as a database to pull out data, then those discrete data elements become more important. But when you're a clinician and you have a problem and you're trying to solve that problem or trying to figure out the best way to solve that problem, the discrete data elements are not what's getting you there. It's the synthesis."]

This creates an interesting tension between the way we generally do quantitative research and the way that clinicians view the data in the realm of providing clinical care. These two excerpts also complement our first factor of aligning the data fields with the practice; however, they also

symbolize the recognition that nursing abstains from documenting these because the granularity of the data are better described and synthesized in therapy notes; thus, the deference to therapists for documenting these data. Many of these outpatient intake data elements are important to the care process and, based on the findings in Chapter 5, are rarely documented in structured forms during outpatient visits. Several of these structured fields exist for therapists as well, but many returned no populated values. Therapists are most likely documenting these data elements in unstructured fields; however, further evaluation of these textual fields using manual medical record review is warranted. This points to another discordance in the division of labor of documentation responsibilities between nursing and therapies, and forces us to ask, "What discipline is best equipped to document the GMFCS as a discrete data element?" Since nursing predominately documents in structured fields, their data collection and documentation practices are more malleable to standardize documentation of discrete data on patient baseline functional performance during intake. However, based on provider interviews, therapists commonly document these aspects as narrative formats, and this demonstrates that these professions seek to maintain control over the techniques and abstract knowledge to address patient gross motor functional performance issues.

DISCUSSION

The findings of this chapter resulted in two primary latent factors that shape missingness of GMFCS as a discrete data element in pediatric specialty care settings. The first factor relates to how the incongruity between the value of GMFCS in the patient record and its location in the EHR interface influences missingness. The second factor describes the discordance in the division of labor in documentation responsibilities among healthcare professions and how this influences the missingness of GMFCS both as a discrete data element and as free-text in the

EHR. This work only cracks the surface of the types of factors that influence the production and clinical data in healthcare settings but expands the conversation beyond rudimentary technical fixes. More research is needed to evaluate the generalizability of these factors beyond the scope of this paper to other care settings and diagnoses, and to build on the established factors influencing missingness of clinical data.

Much of the research on clinical documentation surrounds EHR usability, documentation purposes and finding a balance between structured and unstructured data from a semantic standpoint, while missingness of EHR data are commonly found in studies of data quality in biomedical contexts. Following a multi-site study, Embi et al. describe that the need for reusable structured documentation often conflicts with the need for highly reliable and accessible information from clinical notes to support clinical reasoning and workflows.[18] However, clinical documentation is much more complex than determining which data are structured versus unstructured, because the real social, economic, and policy factors of clinical settings generates variation in responses by the multiple healthcare professions.

Many data quality studies are quantitative analyses. These studies employ a positivist approach to analyze the extent of data quality, but this approach often leads to reductionist theories of missingness.[29,222,224,244,247] Agniel et al. identify that the extent of missing data is not due to randomness, but rather is the result of dynamic healthcare processes such as doctor and patient behaviors, clinic hours of operation, and when patients are seen.[247] However, the authors present this as merely conjecture and do not delve into these processes and only focus their analyses on highly structured laboratory test data. The theories result in three concepts of missingness that are widely considered in research and analytics: missing at random (MAR),

missing completely at random (MCAR), and missing not at random (MNAR). These studies are regularly reproduced and give way to the extent of missingness in EHR data.

In the clinical context, many of these studies only focus on anthropometrics and lab value data and developing imputation strategies, which neglects the specific encounter data that providers like therapists and nurses document about the patient phenotypic presentation and performance.[29,224,244] These studies do not represent the complexity of reality concerned with clinical documentation.[203] A recent study by Dixon-Woods et al. in the UK elucidates some similar concepts related to professionalism and professional control and ownership of data that contributed to improvements in overall completeness of clinical data for registries.[254] The authors, however, do not evaluate the factors that contributed to missingness in the first place, and UK documentation practices across professions are regarded as different from U.S. This does not mean the concepts surrounding professional identity and professionalism do not still apply. As demonstrated in this chapter, missingness of EHR discrete data such as the GMFCS occur because of conditions not visible to the naked eye and are not produced at random. The concept that real-world EHR data can be subject to three contiguous concepts of missingness distracts us from the relationships, conflicts, tensions and unobservable/external forces in healthcare settings that shape clinical documentation practices and perceptions and how these contribute to missingness.

In these findings, interviewees viewed the GMFCS not as a measurable and constantly changing value, but rather as a stable entity of functional mobility performance, consistent with existing literature that GMFCS is stable after 2 years-old.[213] The stability in this classifier prompts providers to consider the GMFCS as a key classifier of the patient in describing their gross motor ability in relation to their diagnosis of CP. In recent years, the classification of

children with CP shifted from designating cohorts of patients in terms of CP subtypes such as diplegia, hemiplegia and quadriplegia, to specifying these patients by functional phenotype along the GMFCS levels. Documenting the GMFCS level in the EHR helps characterize these cohorts without the focus on an ensemble of traits and attributes that also incur wide variability in completeness in the EHR. While there is a single existing designated place to document the GMFCS as a discrete data element, therapists do not find its location accessible or informative for other disciplines. The outcome of this impacts the ability to easily identify patient cohorts for future research and system learning. This signifies an incongruence between the EHR infrastructure design and 1) how therapists view the purpose of discrete data and 2) how they value these data in the context of the narrative of the patient and the patient encounter, i.e. SOAP note format. By documenting the GMFCS in the HPI free-text field, the therapist no longer needs to consider subsequent EHR fields or document the GMFCS in future notes because it is already included in the clinical note and patient record.

For physicians, they retain control over how they record the GMFCS in clinical notes, and this primarily occurs without the constraints of designated structured fields, as is the case with therapists. As the findings in Chapter 6 demonstrate, the physicians group maintains a superordinate position over all professions in healthcare systems in terms of clinical documentation. Their choice to freely dictate clinical notes and control the types of data that are entered in the EHR which overlap with many jurisdictions of healthcare professions demonstrates the subordination of other professions and professional identities despite the common goal of managing and improving the health of patients. To reduce redundancy, variability, and competition between providers for these documentation jurisdictions and to achieve goals of an LHS, professions require coordination and collaboration in documentation.

In the context of the GMFCS, it seems the GMFCS is an appropriate candidate to be collected once as a discrete data element and recycled many times as a cohort identifier for research, thus demonstrates the role of well-defined documentation responsibilities in increasing data quality. While the GMFCS is necessary for learning and research efforts for CP in pediatric rehabilitation, well-defined documentation responsibilities for this data element requires us to coordinate across healthcare professions to level the playing field and build collaborative documentation.

The disconnect in how the EHR emulates and supports provider practices like therapies represents a critical factor that shapes whether and where providers will populate specific data and the types of data documented. The EHR is a technological infrastructure capable of prompting providers to document the relevant data not only to directly inform clinical practice but also for learning and research. However, location of discrete data elements influences the likelihood of capturing specific data and their use in clinical practice. As the findings demonstrate, the GMFCS field in the EHR is embedded outside the therapist frame of reference in the Developmental Mobility tab. This forces the therapist to search for the GMFCS field rather than having the field align with their clinical thinking, thus influencing missingness. This forces us to ask a deeper question about how providers view the purposes of documentation and how these purposes shift in the context of LHS.

The findings from this paper provide an account of the sociotechnical factors that influence missingness of GMFCS and related structured data. Missingness in clinical data is a feature of the clinical documentation practice and should not be considered in the same vein as the normative analyses of missingness for research. These data cannot be subject to imputation and complete case analyses because of the variability in healthcare processes such as clinical

documentation, and thus we exclude a large swath of patients due to latent factors attributed to professional identity, power, control and divisions of labor that influence how, why and what data are documented. As Van Der Lei once wrote, "data should be used for the purpose for which they were collected," and warned of the reuse of clinical data for research.[20] However, with the advent of LHS, the paradigm surrounding the purpose of clinical data needs to shift to optimizing infrastructures and data sources for large-scale and continuous learning. Although clinical data are integral to discovery in an LHS, the extent of missingness impacts the quality and validity of LHS research, especially for rehabilitation purposes and data on patient function. Therefore, LHS scientists should focus on exploring these factors further and reshaping clinical documentation to optimize data capture and reduce missingness, while maintaining and improving efficiency of clinically meaningful documentation.

This chapter focused on generating hypotheses that challenge the way we think about missingness and clinical documentation; however, the study does have limitations that may influences the internal validity of the findings. While these findings force us to consider the unobservable forces that influence clinical documentation and missingness for GMFCS, they also attempt to inform the larger context of the external factors that shape work processes in healthcare settings. Although the perspectives on documentation were similar across the sample of interviewees, the sample of nursing providers was small compared to other provider groups; therefore, their responses may not encapsulate the breadth of nursing's role or perspectives surrounding the GMFCS. While this may challenge the veracity of the findings, early discussions and interviews revealed that nursing's role was limited in the collection of GMFCS, and so recruitment only focused on those clinicians whose work was organized around the GMFCS. Furthermore, instances of confirmation bias and interviewer bias are difficult to avoid in

qualitative data collection, but the iterative methodological process this study used to construct the codes and themes ensured fidelity to the interviewee responses. Furthermore, although liaisons helped recruit participants using a convenience sampling approach, these liaisons may have selected providers who were most vocal and willing to participate in interviews, thus introducing volunteer bias into the study and results. Lastly, although the study included three sites based on geographic location, the findings in this chapter may be confirmed or contrasted by providers at other SHC care sites in more disparate locations with more or less completeness of GMFCS and other discrete data elements related to gross motor function.

The findings of this qualitative analysis of missingness are foundational to understanding documentation practices that can lead to missingness in structured data fields in the EHR. While missingness may be attributed to negation or absence of a patient feature, trait, or performance in the clinical encounter, many discrete data elements that are missing reflect patient characteristics that can be documented as either patient-reported, discrete forms, or in narrative forms by members of the provider care team. Thus, missingness is actually produced by healthcare systems and the larger external and unobservable factors. Previous methods to manage missingness in research may not apply to the use of real-world data in LHS research because of the many other purposes for which clinical data are documented and the extent of missingness attributed to unknown causes. Therefore, new approaches are required to understand and reduce missingness in order to support validity in LHS research results.

CONCLUSION

In this qualitative study, findings demonstrated that two sociotechnical and professional factors surrounding documentation influenced and contributed to missingness of GMFCS as discrete data in the EHR. Missingness is an important phenomenon that has significant

implications for LHS research to improve care delivery, patient health and reduce system costs. Analyses such as this demonstrate that documentation is not a simple and mundane process in healthcare, but rather it is dynamic and subject to the external pressures of the healthcare system and this contributes to missingness. Qualitative studies such as this are needed to define the latent factors that shape documentation which results in missingness. Although this analysis was organized around missingness for one data element, further research is needed to determine the extent that these factors also apply to other types of data elements and disease states.

Chapter 7

Discussion

This dissertation revolves around three research questions that build knowledge about clinical documentation and data production in pediatric rehabilitation settings. 1) To what extent can data networks be leveraged to build classifiers of patient functional performance and physical disability? 2) How can discrete clinical data on gross motor function be used to draw conclusions about clinical documentation practices in the EHR for cerebral palsy? 3) Why does missingness of discrete data in the EHR occur?

Chapters 4-6 present a progressive and systematic research approach to answer these questions. The results of these three chapters illustrates the topography of clinical documentation infrastructure, from the available data elements to the extent of missingness of discrete data to the factors that influence missingness of these data types. The findings demonstrate that, while we can leverage data resources that comprise electronic health record (EHR)-based data to build gross motor function phenotype models, many of the discrete data organized around gross motor function, a critical aspect of rehabilitation, are missing in the EHR. As Martin et al. describe, easily captured and quantifiable data in care settings such as discrete data in structured fields are essential to the process of generating knowledge for healthcare quality and safety[257] and can be instrumental for a learning health system (LHS) for pediatric rehabilitation. Easily quantifiable data create foundational infrastructure for learning, but this process requires more complete discrete data. The variability in missingness and attribution to care sites also demonstrates that

missing data do not occur randomly, and that more structural and external factors are influencing how and what data are produced in clinical settings. Missingness in clinical contexts is affected by variations in clinical documentation practices and other health system infrastructures at multiple levels of scales. This infrastructure includes aspects of health profession development, identities, and technology. It shapes and is shaped by how clinical providers perceive and use technology and operationalize their professional knowledge and practices, which in turn influences the extent of structured and unstructured clinical data that providers produce. First, this discussion chapter explores many of these concepts and review how Chapters 4-6 intertwine to address the dissertation research questions. Then the chapter will expound on the implications of this dissertation for the larger scope of LHS and opportunities for the future study of clinical documentation and data production.

The phenotype model in Chapter 4 built the foundation to approach answers to the question about the data that are necessary to draw conclusions about both documentation practices and the extent that the data from a distributed pediatric CDRN can be leveraged for classifiers of physical disability and functional performance. The findings demonstrate that EHR-based data resources like the Shriners Hospitals for Children (SHC) Health Outcomes Network (SHOnet) contain discrete data elements that can be mapped to phenotype definitions of gross motor function and used to model functional performance in children with cerebral palsy (CP). The type of work presented in Chapter 4 is also different than the classical approach to construct phenotypes to develop an index or a binary classification for diagnostic purposes. Phenotype models and computable phenotypes surrounding functional performance and disability have to account for multiple ordinal classifications in patient body structures and function and activity performance. The type of classifiers presented are valuable and beneficial to rehabilitation

research because they leverage the nursing and therapy-related observational discrete data elements in the EHR and SHOnet that are often absent from other clinical data research networks (CDRN). Although the study resulted in one gross motor function phenotype model and three sub-models of Gross Motor Function Classification System (GMFCS) classes that determine membership based on data element values, more work is needed to determine the breadth of these data elements that may predict GMFCS class membership.

Chapter 4 also demonstrated the use of an expert-informed panel of clinicians and clinical researchers to construct the phenotype model. The methods used are easily replicable. The study mobilized domain experts to inform the selection of discrete data and values around gross motor function for the pediatric CP population. The expert-informed process described in Chapter 4 demonstrates the complexity and variability in assigning functional performance values to data elements, but also the care and complex theory-informed process to narrow the scope of data elements for these types of classifiers. Taken together, these methods should be considered essential for constructing further phenotype models related to physical function that also build infrastructure for the eventual design of "functional performance" computable phenotypes. The findings in Chapter 4 demonstrate the value in ensuring these discrete data elements are documented during routine care to classify cohorts of patients by levels of functional performance.

The phenotype model was leveraged as a task-based mechanism to study the completeness of these gross motor function data elements and determine the extent that these discrete data are documented in the EHR. Completeness of discrete data is important for learning applications and cohort identification but, based on the findings reported in Chapter 5, extensive missingness exists in the SHC EHR for discrete data on gross motor function and the GMFCS

for pediatric patients with CP between 6-18 years old. This analysis supported inferences about the extent of data production in healthcare settings and introduced the role of clinical documentation practices in missingness of discrete data in the EHR. The extent that these data types are documented routinely in the EHR by therapy and nursing providers is not well understood and sparsely reviewed in the literature. Therefore, this work adds to the reasoning for restructuring how we think about clinical documentation.

Furthermore, a majority of data elements in the phenotype model did not contain any populated values and completeness was highly variable across the SHC care sites. Over one-quarter of the variation in data completeness may be attributed to care site-specific factors. This indicates that differences may exist between care sites in how therapists and nurses document discrete data on gross motor function and that differences in these practices may contribute to missingness. The differences in documentation of the data described is not observed in the literature, it is consistent with the Sohn et al. description of the variation between clinical providers in documenting asthma, but this was also evaluated in free-text forms.[258] Other studies have also observed regional variation in the diagnostic practices, treatment, healthcare intensity, and documentation of data elements.[259,260] [261] In addition, geographic variation was also observed in the implementation and adoption patterns of EHRs by others[262], which may contribute to differences in documentation practices around "soft data".

The uptake of EHRs and how these systems are wielded in care settings may substantially influence data production and the extent of data stored in discrete forms. In the context of SHC, it was only within the past decade that SHC clinicians began billing insurance for services. This may also influence how providers perceive the role of discrete data in care practices if the need to justify reimbursement through metrics is relatively new. In the Chapter 5 study, the EHR was

not directly reviewed for these discrete data elements or surveyed for these data in unstructured locations because this would have been a costly and time-intensive process. SHOnet dramatically cut the costs and time to conduct this type of research, but possibly at the expense of comprehensiveness in the extent that these phenotype data are represented in the EHR. Therefore, missingness of discrete data does not challenge the extent or quality of care delivery, and it is unknown whether these data are documented in other locations and text formats of clinical notes in the EHR. Furthermore, SHOnet serves as both infrastructure and a conduit to store extracted EHR data to conduct observational population research without actively searching the EHR.

The data elements in the phenotype model and the GMFCS structured field exist in the EHR as the discrete attributes of patient function that can be used to design algorithms for characterizing three clinically relevant groups of GMFCS. This means that part of the technical infrastructure is in place to support classifiers that rely on discrete data, rather than developing methods of natural language processing for data extraction from dictated and narrative notes in the context of rehabilitation vocabulary. Although the common data model for learning networks like SHOnet organizes these data in distinct usable forms for research, this data model is a reference terminology system and differs from the interface terminology system which supports the EHR.[248] We cannot lose sight of the fact that learning networks like CDRNs are not exact replicas of the EHR, but rather are a consortium of data to conduct retrospective and prospective research and learning about healthcare systems from observational data. Based on these findings, these networks allow us to peel back layers of the healthcare system at various levels of scale to understand the extent of data documented and potentially make inferences about factors influencing missing data. The data we *can* extract from the EHR therapy and nursing forms that

are transformed into these standardized vocabularies demonstrates the breadth of opportunities to build functional performance computable phenotypes from existing infrastructures and supports rehabilitation research. However, the missingness of discrete data influences the ability to create classifiers of patient functional performance and may impact the validity and generalizability of future research results.

As indicated in Chapter 4 and Chapter 5, discrete data element locations exist in the EHR for providers like rehabilitation therapists and nurses, yet these data are often not recorded in the designated structured fields in the EHR interface. In the Chapter 5 analysis, we did not observe any complete cases of these discrete data for this population of CP patients, but the findings of the descriptive analysis demonstrate that further consideration is warranted as to the extent that clinical data conform to the three traditional concepts of missing data: missing completely at random (MCAR), missing at random (MAR), and missing not at random (MNAR).[8,263,264] Missingness of these discrete data, though, cannot be easily ignored and may not be managed with the traditional approaches to missing data due to the varied nature of how the data were produced in real-world, dynamic clinical settings. These settings are subject to external forces that shape providers and their work processes and thus data are not missing at random.

Based on the observations, findings, and knowledge of how data are collected and documented in healthcare settings, the one could argue that, in healthcare systems, missingness does not align with the designation of MAR and imputation would not be appropriate. We cannot assume that missing data are conditional on the presence or absence of discrete data when there is extensive missingness of discrete data elements due to the multiple different ways to capture data in other forms. The extent of missing data also does not support the complete case analysis and other statistical approaches to address data MCAR because this assumes that each data

element has an equal chance of being documented. The nature of these systems and the opportunities for providers to document in a variety of formats and locations in the EHR means that imputation or complete case analyses introduce biases based only on the providers that document data in discrete formats. That leaves us with the concept that data are MNAR. The variability by care sites and low completeness percentage for over three quarters of the 19 data elements in the phenotype model and the GMFCS indicates that considering the data as MNAR may be suitable, but this requires further investigation. Rubin (1976) describes that when dealing with real data the process that causes missing data should be explicitly considered[8], and in the case of real-world data missing in EHRs, we need to understand the causes of data MNAR to improve completeness. Furthermore, the presence of the structured data fields in the EHR provide the infrastructure to collect these phenotype model data elements but, as Chapter 6 investigates, improving the completeness of these fields is more complex than creating a new location or telling clinicians to document the data elements more.

In Chapter 6, the GMFCS discrete data element served as the exemplar data element of documentation and missingness because it is a composite value and proxy for how a patient physically performs in an ensemble of activities. In Chapter 6, the iterative analysis using qualitative methods of semi-structured interviews and field observations resulted in two primary sociotechnical and professional factors that influence missingness: 1) Missingness of GMFCS is influenced by the incongruity between how it is valued in the patient record and the GMFCS location in the EHR interface. 2) Missingness of GMFCS is influenced by a discordance in the division of labor of documentation responsibilities by healthcare professions. The findings in Chapter 6 demonstrate the importance of well-defined jurisdictions of documentation practices

and documented data by provider types to ensure the division of documentation responsibilities is concordant with the types of data that are fit for rehabilitation research and learning in an LHS.

The two factors influencing missingness point to larger questions about competition for professional jurisdictions of clinical knowledge systems, how professionals are steered to document this knowledge by the healthcare system, and how this affects the development of LHS. More specifically, we need to understand how to balance the clinical provider's professional autonomy in how they document and their discretion to document in overlapping jurisdictions of abstract knowledge systems to demonstrate their techniques to solve clinical problems. In their ethnographic analysis of why completeness of audit data improved in two UK data registries, Dixon-Woods et al. identified the role of professional responsibility in "data work" and its status as a professional activity to address for improvements.[254] While the authors discuss professional autonomy and discretion in data collection as well as continued variation in data completeness between clinical centers they observed, they refrain from discussing the professional competition that exists for knowledge jurisdictions in documentation. Furthermore, professional autonomy and the provider's claim to their knowledge systems may be attenuated by requiring providers to document discretely, and in affect this may minimize their ability to demonstrate value in addressing patient health problems and their role in an LHS.

Taken together, Chapters 4 and 6 indicate that, in an LHS, clinical documentation practices and standards in discrete data entry need to correspond to the health problems of interest for a specific patient population of which a learning community is formed around. The data and knowledge components of Friedman's LHS Cycle (**Figure 2.1**) require data that are documented in routine care. In his LHS Cycle, a learning community, data, knowledge, and performance elements are organized around the health problem of interest and supported by

infrastructure. Documentation incorporates the people, process, policy, and technology conditions of infrastructure evident in Friedman's model. The learning communities are ripe locations for stakeholders to consider clinical documentation as an essential part of the underlying infrastructure to support knowledge generation in an LHS. Early in the construction of learning communities, it is critical to mobilize providers and system-level administrators around the work processes of clinical documentation to ensure the right data are documented in the right place for the right patients to support LHS research and learning activities.

The latter point in the previous paragraph relates to an initial research question pertaining to the conditions when structured and unstructured data should be collected. This question may not have a definitive answer, but the findings in Chapters 5 and 6 suggest that data missingness is attributed to non-random factors. The missingness of discrete data does not instantiate missingness on the whole in the patient record or that data were not collected by these providers. Indeed, as interviews suggest, the GMFCS data element and many of the data pertinent to our phenotype model are collected and documented in physician, therapy, and nursing notes, albeit in unstructured formats.

The combination of structured and unstructured fields in therapy and nursing notes and the workflow, professional, and sociotechnical factors that influence documentation forces us to consider whether the traditional concepts surrounding missing data apply to the analysis of real-world clinical data. The values of these missing data elements exist in the EHR, just not in the prescribed structured locations of the EHR. The concepts of missing data assume that there exists only one method to record data, but this does not hold true in clinical care settings. The collection and documentation of clinical data are at the discretion of the clinical provider. Providers control how and what data are input into their clinical notes within their designated

documentation forms and sections in the EHR. Often many providers collect and document the same data in different ways in their respective sections of the EHR. The documentation of this clinical data occurs in real-world settings that are shaped by and shape many unobservable and external forces. These relate to the two primary factors identified in Chapter 6 and they demonstrate the breadth and flexibility required to construct a better understanding of clinical documentation for LHS. These sociotechnical and professional factors also serve as types of infrastructure we need to consider for LHS. Therefore, as a next step, we need to evaluate the extent that gross motor function data are truly missing in the EHR or documented somewhere else in the EHR to determine how documentation explains quality of care and whether data are actually missing at random or not missing at random. This would require an analysis of the data element values and medical record review as a comparator to understand how clinicians such as therapists and nurses decide which types of data get captured as discrete versus free-text or narrative forms.

While the GMFCS was the exemplar data element studied in Chapter 6, findings suggest that undefined roles in the division of labor in documentation responsibilities between professional provider groups influences missingness of GMFCS as a discrete data element in the EHR. This division requires clear jurisdictions of documentation responsibilities across providers to determine the best equipped professions to document data in structured and unstructured formats but is hindered by the power relations between professional identities. Central to a professional identity is the ability to control one's professional knowledge and its application. This is especially true in healthcare where physicians dominate knowledge and all other disciplines are viewed as subordinate professions. The choice to document in structured or unstructured formats is limited by the power struggle between the superordinate and subordinate

professions in healthcare. This is demonstrated further by the design of the EHRs, EHR forms and the decision by therapists, to the extent they have that choice, to document essential data on patient functional performance in free-text locations rather than the prescribed structured fields. Furthermore, in Chapter 5, the extent of missing data by therapies and nursing may be a response to the feeling that the professions in healthcare require a more equal playing field when it comes to jurisdictions of data documentation. This may prove significant for LHS, where cross-disciplinary collaboration is essential to accelerate knowledge growth and to support patient-centered care.

Although documentation practices were not directly compared between different healthcare professions, in field observations, interviews, and analyses, documentation is blended across several professions with unwarranted competition and redundancy in many areas or a lack of documented discrete data altogether. Concurrently, their care delivery is divided by jurisdictions of technical skills that use abstract knowledge systems specific to their profession and professional identity. For example, this is evident in the role of physicians in disease diagnosis and discharge planning, nursing in risk management, care coordination, recording medication dispensation and intravenous catheter placement, or physical therapy in treating gross motor and mobility quality, and occupational therapy is measuring, interpreting and managing activities of daily living. This is not to say that cooperation across these disciplines also does not occur in many of these areas, as professions wield their abstract knowledge systems to deepen the understandings and granularity of disease and disorders. While this does occur, in many instances there is consistent overlap and competition for jurisdictions of recording data, such as manual muscle testing, mobility and activity performance, and cognitive function to name a few. All of these data are collected by these healthcare professionals during their evaluations, and

consistency in reporting is important, but these data and many others are recorded in different formats and value sets and for different reasons that confounds and biases the types of research results we can produce from these data. At the same time, data elements may also be missing altogether based on pre-determined professional definitions, what is mandated by the system, or concern for creating new competitions between professions. However, it is still important to determine which professions are best equipped to collect the most granular, accurate and reliable data in the right format for the right patients for the research questions under consideration. This requires further investigation and is instrumental to LHS development.

The fact is that data for healthcare are documented in a dynamic and competitive system of professions that actually serves as a type of infrastructure in an LHS. In this system, the extent that professions document narrative or discrete data is subject to how they perceive, control, and reinvent their abstract knowledge systems that ultimately defines their profession and their justification for knowledge jurisdictions.[249] However, the interprofessional discordance in documentation discussed in Chapter 6 requires change. While professions need to ensure their distinct knowledge and skilled techniques are conveyed, the techniques surrounding care delivery are not the topic of this change. Instead, clinical documentation practices require a restructuring and reorganizing around interprofessional collaboration and the common goal of building a complete and accurate patient medical record to meet the demands of and economy of scale for an LHS and improve the quality and safety of care delivery. This is consistent with what Warner et al. refer to as "collaborative documentation"[265], and points to a need for the system administrative level to overhaul and reformat how we ensure providers communicate clinically meaningful content.

Many healthcare professions deliver a skilled service to the patient that only their respective professional knowledge system equips them to provide. This concept is considered a profession's jurisdictional claim to abstract knowledge systems and techniques. Yet, the extent that these providers document in overlapping jurisdictions and produce unique or redundant data may impact how we organize research around certain data, whose data are best curated or routinely queried and used for research, and which professions dominate the LHS space. If the concept of an LHS surrounds enhancing patient-centered care and shared decision-making through knowledge generation about the holistic care process, then documentation of the encounters should occur on a level-playing field and through collaborative data production process. Therefore, the question we should be asking is how to reconcile the clinical documentation jurisdictions between healthcare professions at a higher administrative level to optimize data production in LHSs, while also maintaining the division of labor between professions to control their existing jurisdictions of knowledge and techniques.

Healthcare professions often specialize in both existing and new jurisdictions through additional certifications, years of education, titles, examinations, professional associations, and so on, and this evolution in expertise can occur in an LHS. However, we need to really consider the extent that the production of data is and should be subjected to interprofessional roles in an LHS. We also need to deepen our understanding of how professions perceive discrete data and how these data formats reflect professional credibility and control of abstract knowledge systems. How does documenting in discrete forms impact professional identity and the capacity to claim jurisdictions and wield knowledge and skilled techniques? These concepts are alluded to in works by Dixon-Woods et al. and anticipated by Garfinkel[254,266], but we need to push this question further. In an LHS, healthcare data provide a window into the mobilization of

professions around patient health, especially in how these providers identify, interpret, and treat health problems. Thus, in LHS science, we need to establish a collective understanding and collaborative framework between healthcare professions to develop standards around who documents essential data for learning activities and how, without data entry being considered as a mundane task. This would build LHS infrastructure in data production for learning at economy of scale.

Since missingness is difficult to evaluate as a random phenomenon in the context of healthcare documentation, we need to focus our attention on improving the infrastructure to support data completeness. As Weed wrote in 1968, "Inherent in the problem-oriented approach to data organization in the medical record is the necessity for completeness in the formulation of the problem list and careful analysis and follow-through on each problem as revealed in the titled progress notes, requiring the proper data be collected and that the conclusions drawn from this data are logical and relevant" (p. 599).[267] Weed continues, "It can readily be seen that all narrative data presently in the medical record can be structured, and in the future all narrative data may be entered through a series of displays, guaranteeing a thoroughness, retrievability, efficiency and economy important to the scientific analysis of a type of datum that has hitherto been handled in a very un-rigorous manner" (p. 599).[267] While the technologies we currently have in healthcare systems simplify much of the front-end data entry and accessibility of clinical notes, we are still quite far from achieving the process Weed describes. Documentation practices are a key driver of this. Weed also elevates the concept of completeness as a primary concern for care delivery and for the ability to draw logical and relevant conclusions from the medical record data.

Many of the issues raised in this dissertation are longstanding problems in healthcare but are now crucial to an LHS. These issues now require innovative and systems solutions. In the context of LHS, if we assume that the EHR contains structured fields and that the variety of care providers are to document in these locations, then we need to understand how to improve documentation in these fields that crossover domains of clinical expertise. For LHS, we should focus on simplifying the breadth and depth of documentation for all clinicians by ensuring that evidence justifies the data elements that clinicians document.[268] We also need to consider the types of system-level infrastructural solutions surrounding interprofessional practice and jurisdictions that contribute to this problem. To do this we need to continue to advance our understanding of the extent that missingness is influenced by exogenous factors and unobservable forces within infrastructures and consider the role of implementation science to present a "just right" behavioral and technical solution for data missingness in the EHR.

The findings in this dissertation demonstrate the research that is needed to build capacity and infrastructure for LHS research in rehabilitation and clinical settings at-large, particularly with respect to clinical documentation and the professions that document. As demonstrated in Chapters 5 and 6, more research is necessary to determine the extent that existing structured fields within the EHR interface require further modification to increase completeness. This modification may include changes to depth, values, and language and location to improve the specificity of the data types for research and clinical learning. The decision to document structured and unstructured data inherently influences the data that we can leverage for research and learning and impacts the validity of results. Clinical documentation as a process and practice shapes the types of research we can conduct and requires continued examination in the areas discussed throughout this dissertation. We must also understand how behavioral and

technological interventions can influence data completeness and data quality overall. Clinical documentation is not easily evaluated and requires a multi-pronged analysis containing mixed methods approaches, as demonstrated by this dissertation. Further research on LHS should continue to expand these types of studies to understand the various infrastructures that shape and are shaped by healthcare processes and practices.

Chapter 8

Conclusion

This dissertation approaches answers to three research questions. Chapters 4-5 address questions about the data that are necessary to draw conclusions about both documentation performance and the extent that the data from a distributed pediatric learning network can be leveraged for classifiers of physical disability and functional performance. The dissertation research papers culminates with Chapter 6 in an analysis to understand why missingness of discrete data in the EHR occurs. The iterative process of this dissertation followed the data and revealed deeper questions about the causes of missingness, how to reduce missingness of data in the EHR occurs, and how healthcare professions documentation practices influence data completeness and missingness. It also forces us to restructure how we think about the concept of completeness, and rather than trying to achieve a "complete" sample of record through insufficient mechanisms, research should focus on understanding why missing data occurs and how to reduce missingness. The solutions to this problem that we eventually develop in real-world clinical settings will rely on our continued exploration of clinical documentation practices and processes.

The findings of this dissertation demonstrates the need to explore further questions such as, "What is a sufficient level of completeness for LHS?", "How do technical and service providers mobilize around the collection and documentation of biomedical data?", "How did variation in clinical documentation practices develop?", "How and when is infrastructure built and reshaped in healthcare systems?", and lastly, "How do divisions of labor and professional

jurisdictions of abstract knowledge systems influence which specialties or people document discrete clinical data in the EHR?" Based on the findings of this dissertation, we need to consider clinical documentation and professional jurisdictions in healthcare as critical infrastructures for LHS. Documentation is not just a mundane duty of care delivery to serve the hybrid purposes of communication, administrative, ethical, and legal obligations as mandated by health systems. The interprofessional roles and divisions between clinicians creates infrastructure through jurisdictions of abstract knowledge and techniques. This relationship between professionals causes cracks in clinical documentation because of how clinicians perceive the healthcare system values their work and knowledge. In this perspective, clinical documentation requires a restructuring or reorganizing of the social, policy, and technical components around its role as infrastructure for LHS research and how professions and system administrations define and divide documentation jurisdictions in order to improve the completeness and overall quality of data input into the EHR.

This dissertation is the foundation for my future career as an independent investigator in LHS. Future research will build off this work by conducting further studies of causes of missingness in the EHR, the role of professional identities and jurisdictions that function as generative mechanisms behind how data and knowledge are produced in an LHS, and developing and testing strategies to reduce data missingness and leverage clinical data for clinical comparative effectiveness research in pediatrics. The findings of this work have significant implications for advancing the science of LHS in terms of how we think about infrastructure, documentation by healthcare professionals, and missing data. As LHS evolves and becomes the reality for healthcare systems, there are many different areas where research is needed, and one is to better understand how clinical data are produced.

The findings in this dissertation demonstrate the importance of developing the science underpinning LHS. The evolution from a healthcare system to an LHS requires us to expand the concept of a LHS to incorporate the role of multiple competing professions that produce the data, and to understand how the documentation practices and the system of professions function as infrastructure for LHS. The beholder of large-scale clinical data does not equate to an LHS. LHS is not a thing or software; it is not something that an organization owns and operates; we do not *do* LHS. An LHS is a complex, multidimensional and dynamic effort that incorporates many stakeholders and professionals to scientifically produce new knowledge, generate and test hypotheses, innovate, and build infrastructure for many different functions across scales and scopes of the healthcare system.

This dissertation addresses an important infrastructural impediment for LHS that brings us closer to understanding the infrastructure for LHS. To bring LHS to a reality, we need to continue to develop the science of LHS both in the work presented in this dissertation as well as many other critical areas of ethics, social science, implementation science, and biomedical informatics. By continuing to build this science, LHS scientists control the narrative and definition of what it means to be an LHS and lay the groundwork for the healthcare systems and clinical research others can perform.

Appendices

Appendix A

Descriptions of Gross Motor Function Classification Scale Levels

Table A.1. Gross Motor Function Classification System Descriptions. Reproduced from CanChild and Palisano) 6-12 Age-band

GMFCS LEVEL	Phenotype Case Definition
Level I	Children walk at home, school, outdoors, and in the community. Children are able to walk up and down curbs without physical assistance and stairs without the use of a railing. Children perform gross motor skills such as running and jumping but speed, balance, and coordination are limited. Children may participate in physical activities and sports depending on personal choices and environmental factors.
Level II	Children walk in most settings. Children may experience difficulty walking long distances and balancing on uneven terrain, inclines, in crowded areas, confined spaces or when carrying objects. Children walk up and down stairs holding onto a railing or with physical assistance if there is no railing. Outdoors and in the community, children may walk with physical assistance, a hand-held mobility device, or use wheeled mobility when traveling long distances. Children have at best only minimal ability to perform gross motor skills such as running and jumping. Limitations in performance of gross motor skills may necessitate adaptations to enable participation in physical activities and sports.
Level III	Children walk using a hand-held mobility device in most indoor settings. When seated, children may require a seat belt for pelvic alignment and balance. Sit-to-stand and floor-to-stand transfers require physical assistance of a person or support surface. When traveling long distances, children use some form of wheeled mobility. Children may walk up and down stairs holding onto a railing with supervision or physical assistance. Limitations in walking may necessitate adaptations to enable participation in physical activities and sports including self-propelling a manual wheelchair or powered mobility.
Level IV	Children use methods of mobility that require physical assistance or powered mobility in most settings. Children require adaptive seating for trunk and pelvic control and physical assistance for most transfers. At home, children use floor mobility (roll, creep, or crawl), walk short distances with physical assistance, or use powered mobility. When positioned, children may use a body support walker at home or school. At school, outdoors, and in the community, children are transported in a manual wheelchair or use powered mobility. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports, including physical assistance and/or powered mobility.
Level V	Children are transported in a manual wheelchair in all settings. Children are limited in their ability to maintain antigravity head and trunk postures and control arm and leg movements. Assistive technology is used to improve head alignment, seating, standing, and and/or mobility but limitations are not fully compensated by equipment. Transfers require complete physical assistance of an adult. At home, children may move short distances on the floor or may be carried by an adult. Children may achieve self-mobility using powered mobility with extensive adaptations for seating and control access. Limitations in mobility necessitate adaptations to enable participation in physical activities and sports including physical assistance and using powered mobility.

Appendix B

Interview guide for semi-structured interviews

1. Verbal consent process
    a. Discuss the purpose of the research
    b. How long will it take? (30-40 minutes)
    c. This will be audio recorded
    d. What data will be collected?
2. Assurance of anonymity
3. Assurance that interviewees can skip questions or terminate interview at anytime
4. Inform interviewees that data will be protected on a computer stored at the University of Michigan and will be deidentified.

Topic areas: clinical documentation practices, adaptation to health information technology, management of cerebral palsy (CP) and hip dysplasia, clinical environment/workflow

First ask: healthcare specialty, years working as a clinician, years working with the SHC

Initial questions will pertain to your experience and knowledge of clinical documentation practices and routines here at your clinic.

Clinical documentation practice

- Is there a structured process you use for clinical documentation?
- Describe your perceptions of the quality of clinical documentation at this clinic.
- How do you think documentation practices become standardized in your clinic?
- Where do you think you are strongest with your documentation?
- What is the chart review process that you use? Is there a way you process the extent of information?
- When do you document your clinical encounters?
- How much time do you spend on clinical documentation during a routine workday?
- Do you think that providers' documentation practices have any implications beyond ensuring good care for individual patients?

Thanks for those responses. Next, I'd like to learn about how you and your clinic adapt to health information technology

Adaptation to health information technology

- (If prior to the use of the EHR) What were key challenges you identified during the transition from paper-based to electronic documentation?

- How comfortable are you with technology? Would you call yourself an early adopter?
    - Describe your experience with and how you handle EHR updates and changes?
- EHRs can be manipulated in many ways based on clinical field and setting through using structured and unstructured forms of data/information capture. Where do you sit on the balance between structured forms and unstructured/free-text documentation in the EHR?

Deeper Dive Questions

- How have these challenges evolved during the multiple updates and incarnations of the EHR?
- How do you think training influences EHR clinical documentation practices?
- How would further training improve documentation and standards for the SHC learning health system?

Now I'd like to ask you a few questions about your experience with hip surveillance and the electronic health record

Management of Cerebral Palsy and Hip Dysplasia (CP)

- On average, how many patients with Cerebral Palsy do you see in a given day?
- Can you describe your documentation and evaluation process for me for a patient with CP?
- Do you use any specific scales to classify hip function among your patients?
- Is it part of your clinical role to evaluate and document the GMFCS?
    - Describe your use of the gross motor function classification scale (GMFCS) in practice?
- When do you find surgical intervention appropriate for hip dysplasia in patients with CP?

Deeper Dive Questions

- Where do you find the GMFCS in the electronic health record (EHR)?
- How familiar are you with the different hip surveillance recommendations for children with CP?
- Do you to routinely look for the GMFCS score and other hip surveillance data elements in the EHR, and do you dictate these in your notes? Or are there instances that you cannot find them or must search the EHR?
- How do you think EHRs can be best utilized to provide decision support for clinical documentation and practice of hip surveillance?
- What strategies or decision support mechanisms do you use for hip surveillance?

Great, we are moving along. I'd like to move on to a brief discussion of your perceptions of the clinic/organizational environment and workflow

Clinic/Organizational Environment and Workflow

- How are new clinical practices or protocols disseminated in your clinic?
- How does the clinic environment and organizational climate influence your workflow?

Appendix C

Example Data Elements for GMFCS

Table C.1. Examples of candidate variables for inclusion in the gross motor function computable phenotype. This list of data elements was compiled prior to the study in Chapter 4, and this list was expanded and revised.

Concept	**Data Element**
Devices	Ankle foot orthosis
Devices	Lower extremity orthoses, not otherwise specified
Drugs	Diazepam
Drugs	Carbamazepine
Drugs	Aluminum Hydroxide
Drugs	Calcium Carbonate
Drugs	Cimetidine
Drugs	Dantrolene Sodium
Drugs	Esomeprazole
Drugs	Famotidine
Drugs	Glycopyrrolate
Drugs	Phenytoin
Drugs	Ranitidine
Drugs	Trihexyphenidyl Hydrochloride
Drugs	Valproic Acid
Measurements	PT: Range of motion
Measurements	PT: PODCI scores
Observation	PT: Muscle tone
Observation	PT: Ambulation - device utilized
Observation	PT: Ambulation - Orthoses/prostheses
Observation	PT: Ambulation - Gait deviations
Observation	PT: Assistive technology assessment
Observation	Outpatient history: Pregnancy/birth complications
Observation	Outpatient history: nutrition screen - drooling
Observation	Outpatient history: toileting habits (diaper)
Observation	Outpatient history: bowel management program
Observation	Outpatient history: functional - respiratory support
Observation	Outpatient history: functional - trach care
Observation	Outpatient history: functional - tube feeding
Observation	Outpatient history: functional - cognitive deficits
Procedures	Tenotomy

Gross Motor Function Phenotype Model variables with concept identifiers

Table C.2. All 82 variables in the Gross Motor Function Phenotype Model. This table includes the SHOnet variable name, the OMOP Concept ID and the corresponding value set if the value set is a categorical data element. Medications do not include a value set.

SHOnet Variable	Concept ID	Value Set
Ranitidine	961047	Medication
Ranitidine	19126405	Medication
Ranitidine	961168	Medication
Ranitidine	19003290	Medication
Famotidine	953076	Medication
Famotidine	19077241	Medication
Famotidine	19021074	Medication
Famotidine	19027493	Medication
Famotidine	953102	Medication
Diazepam	19076372	Medication
Diazepam	723013	Medication
Diazepam	19018909	Medication
Diazepam	19076374	Medication
Diazepam	723042	Medication
Diazepam	723020	Medication
Valproic acid	40237988	Medication
Valproic acid	40238017	Medication
Respiratory support	2500010257	Yes, No
Trach care	2500010258	Yes, No
Tube feeding	2500010259	Yes, No
Urinary catheterization	2500010260	Yes, No
Cognitive deficits	443432	Yes, No
Speech deficit	432730	Yes, No
Complete Independence	2500000143	Yes, No
Feeds self	2500000144	Yes, No
Maximal Assistance	2500000145	Yes, No
Minimal Assistance	2500000146	Yes, No
Moderate Assistance	2500000147	Yes, No
Modified independence	2500000148	Yes, No
No oral feedings	2500000149	Yes, No
Supervision	2500000150	Yes, No
Total assistance	2500000151	Yes, No
Drooling	2500000178	Yes, No
Diaper at Night	2500000135	Yes, No
Toilet trained	2500000137	Yes, No

Cane	4337514	Yes, No
Crutches	4179721	Yes, No
Walker	45767825	Yes, No
Language delay	4039748	Yes, No
Language impairment	4041822	Yes, No
Speech delay	4047123	Yes, No
Speech impairment	435642	Yes, No
Dressing	2500010181	Yes, No
Feeding	2500010178	Yes, No
Grooming	2500010182	Yes, No
Bathing	2500010180	Yes, No
Unable to sit independently	4106332	Yes, No
Non-ambulatory	2500010193	Yes, No
Ambulatory with assistance	2500010171	Yes, No
Household ambulation	2500010186	Yes, No
Tires easily	45881740	Yes, No
Trips/falls frequently	2500010215	Yes, No
Assistive devices needed	3039217	Yes, No
Unable to propel own wheelchair	4215087	Yes, No
Manual wheelchair	4045112	Yes, No
Power wheelchair	2616920	Yes, No
Wheelchair independently	4012670	Yes, No
Ambulation Level	2500010792	Independent-7 (2500000256), Stand-by assistance – 6 (2500000257), Minimal assistance – 5 (2500000258), Moderate assistance – 4 (2500000259), Maximum assistance – 2 (2500000260), Dependent – 1 (2500000261)
Stairs Assistance	2500010796	Complete independence (2500000143), Standby assistance (2500000269), Contact guard assistance (2500000270), Minimal assistance (2500000146), Moderate Assistance (2500000147), Maximal Assistance (2500000145), Dependent (4159760)
Railings	2500010795	None (4124462); Bilateral (2500000266); Rail on left going up (2500000267); Rail on right going up (2500000268)
Device Utilized, None	2500010164	Yes, No
Device Utilized, Cane, quad	2500010160	Yes, No
Device Utilized, Cane, single point	2500010161	Yes, No
Device Utilized, Cane, tripod	2500010162	Yes, No
Device Utilized, Crutches axillary	45772311	Yes, No
Device Utilized, Crutches forearm	2616479	Yes, No
Device Utilized, Gait trainer	3038446	Yes, No
Device Utilized, Stander	37396481	Yes, No
Device Utilized, Swivel walker	45764219	Yes, No
Device Utilized, Walker pickup	2616486	Yes, No

Device Utilized, Walker reverse	2500010165	Yes, No
Device Utilized, Walker wheeled	2616497	Yes, No
Primary Mobility	2500000268	Ambulation with device (2500000357), Ambulation without device (2500000358), Dependent wheelchair mobility (2500000359), Independent wheelchair mobility – manual (2500000360), Independent wheelchair mobility – power (2500000361), Other (9177)
Right Knee Flexors	2500010279	0, 1, 1.5, 2, 3, 4
Right Knee Extensors	2500010278	0, 1, 1.5, 2, 3, 4
Right Ankle Dorsiflexors	2500010262	0, 1, 1.5, 2, 3, 4
Right Ankle Plantar Flexors	2500010265	0, 1, 1.5, 2, 3, 4
Right Elbow Flexor	2500010267	0, 1, 1.5, 2, 3, 4
Right Elbow Extensor	2500010266	0, 1, 1.5, 2, 3, 4
Neck	2500010813	Limited (2500000040) WFL (2500000041)
Sitting Balance PT	4186717	Impaired, Intact
Drooling Oral Motor Function	28312333	Yes, No

Structured Rules of the Gross Motor Function Phenotype Sub-Models

GMFCS 1 & 2

Initial inclusion criteria: if a patient has the following data elements/value sets selected, then screen as GMFCS 3, 2, or 1.
If any of the following values are selected in Ambulation Level: Independent-7 (2500000256), Stand-by assistance – 6 (2500000257); Minimal assistance – 5 (2500000258); Moderate assistance – 4 (2500000259)
AND
If ANY of the following 5 values for Stairs Assistance is selected: Complete independence (2500000143), Standby assistance (2500000269), Contact guard assistance (2500000270), Minimal assistance (2500000146), Moderate Assistance (2500000147)

The following rules comprise derived variables composed of data elements and their value sets to satisfy the rules

ACTIVITIES DOMAIN 19 data elements, 4 variables

Derived variable: Current Home Treatments = YES if all 4 variables below are NO:
Respiratory support (2500010257)
Trach care (2500010258)
Tube feeding (2500010259)
Urinary catheterization (2500010260)

NO = If any variable is stipulated as YES
MISSING = If all the variables are MISSING

Derived variable: Fine Motor Concerns (CONCEPT ID: 2500010797; Qualifier: 2500000275) = YES if all the following four variables are any combination of NO or MISSING:
Dressing (2500010181)
Feeding (2500010178)
Grooming (2500010182)
Bathing (2500010180)

NO = if at least one of the four variables are stipulated as YES

Derived variable: Toileting habits (CONCEPT ID: 2500010700) = YES if the following variable is YES:
Toilet trained (2500000137)

AND the following variable is NO:

Diaper at night (2500000135)

NO = if the following variable is YES:
Diaper at night (2500000135)

MISSING = If “Diaper at night” is NO AND “Toilet trained” is MISSING

Derived variable: Nutritional Screen, Feeding Ability (CONCEPT ID: 2500010703)
= YES if any one of the following variables is YES:
Feeds self (2500000144)
Complete Independence (2500000143)
Modified independence (2500000148)

AND any of the following variables are NO:
Total assistance (2500000151)
Maximal Assistance (2500000145)
No oral feedings (2500000149)
Minimal Assistance (2500000146)
Moderate Assistance (2500000147)
Supervision (2500000150)

NO = if all the following variables are NO:
Feeds self (2500000144)
Complete Independence (2500000143)
Modified independence (2500000148)

AND any of the following variables are YES:
Total assistance (2500000151)
Maximal Assistance (2500000145)
No oral feedings (2500000149)
Minimal Assistance (2500000146)
Moderate Assistance (2500000147)
Supervision (2500000150)

MISSING = if all the following variables are MISSING:
Feeds self (2500000144)
Complete Independence (2500000143)
Modified independence (2500000148)

AND all the following variables are NO or MISSING:
Total assistance (2500000151)
Maximal Assistance (2500000145)
No oral feedings (2500000149)
Minimal Assistance (2500000146)
Moderate Assistance (2500000147)
Supervision (2500000150)

NEUROLOGICAL DOMAIN 6 data elements, 2 variables

Derived variable: Current Sensory Deficits = YES if both variables below are NO:
Cognitive deficits (443432)
Speech deficit (432730)

NO = If one variable is stipulated as YES
MISSING = If both variables are MISSING

Derived Variable: Communications Concerns (CONCEPT ID: 2500010797; Qualifier: 2500000271) = YES if all of the four below are NO:
Language delay (4039748)
Language impairment (4041822)
Speech delay (4047123)
Speech impairment (435642)

NO = If any of the four are stipulated as YES
MISSING = if one of the four are missing AND the others coded as NO

MEDICATIONS DOMAIN 17 data elements, 2 variables

Derived variable: Gastrointestinal medications = YES if none of the medications below are presently prescribed:
Ranitidine (Drug Concept ID: 961047, 19126405, 961168, 19003290)
Famotidine (Drug Concept ID: 953076, 19077241, 19021074, 19027493, 953102)

NO = If any are presently prescribed

Derived variable: Seizure/Muscle Relaxant medications = YES if none of the medications below are presently prescribed:
Diazepam (Drug Concept ID: 19076372, 723013, 19018909, 19076374, 723042, 723020)
Valproic acid (Drug Concept ID: 40237988, 40238017)

NO = If any are presently prescribed

DEVICES DOMAIN 19 data elements, 3 variables

Derived Variable: Assistive Devices Used = YES if all of the following variables are NO or MISSING, or one of the following three variables are YES:
Cane (4337514)
Crutches (4179721)
Walker (45767825)

NO = if two or more of the following variables is YES:
Cane (4337514)
Crutches (4179721)
Walker (45767825)

Derived variable: Mobility Device Used = YES if the all the following four variables are any combination of NO or MISSING:
Wheelchair independently (4012670)
Manual wheelchair (4045112)
Power wheelchair (2616920)
Unable to propel own wheelchair (4215087)

NO = if any variable is stipulated as YES

Derived variable: Ambulation Device Utilized = YES if any one of the following 7 variables are YES:
None (2500010164)
Cane, quad (2500010160)
Cane, single point (2500010161)
Cane, tripod (2500010162)
Crutches axillary (45772311)
Crutches forearm (2616479)
Walker wheeled (2616497)
Gait trainer (3038446)
Stander (37396481)
Swivel walker (45764219)
Walker pickup (2616486)
Walker reverse (2500010165)

NO = if two or more of the following variables are stipulated YES:
Cane, quad (2500010160)
Cane, single point (2500010161)
Cane, tripod (2500010162)
Crutches axillary (45772311)
Crutches forearm (2616479)
Walker wheeled (2616497)
Gait trainer (3038446)
Stander (37396481)
Swivel walker (45764219)
Walker pickup (2616486)
Walker reverse (2500010165)

MISSING = if ALL the following variables are MISSING:
None (2500010164)
Cane, quad (2500010160)
Cane, single point (2500010161)

Cane, tripod (2500010162)
Crutches axillary (45772311)
Crutches forearm (2616479)
Stander (37396481)
Gait trainer (3038446)
Swivel walker (45764219)
Walker pickup (2616486)
Walker reverse (2500010165)
Walker wheeled (2616497)

MOBILITY DOMAIN 11 data elements, 5 variables

Derived Variable: Gross Motor Concerns (CONCEPT ID: 2500010797; Qualifier: 2500010797) = YES if the all of the following variable is NO or one or more is YES:
Ambulatory with assistance (2500010171)
Tires easily (45881740)
Household ambulation (2500010186)
Assistive devices needed (3039217)
Trips/falls frequently (2500010215)

AND the following variables are NO:
Unable to sit independently (4106332)
Non-ambulatory (2500010193)

NO = If at least one of the following two is YES:
Unable to sit independently (4106332)
Non-ambulatory (2500010193)

MISSING = if "Unable to sit independently (4106332) and Non-ambulatory (2500010193) NO or MISSING and all other variables in this derived variable MISSING.

Variable: Ambulation, Ambulation Level (CONCEPT ID: 2500010792) = YES if the following value is selected:
Independent-7 (2500000256)

NO = if any of the following values are selected:
Stand-by assistance – 6 (2500000257)
Minimal assistance – 5 (2500000258)
Moderate assistance – 4 (2500000259)
Maximum assistance – 2 (2500000260)
Dependent – 1 (2500000261)

MISSING = if no value is stipulated for this variable

Variable: Stairs Assistance (CONCEPT ID: 2500010796) = YES if any of the following three values are selected:
Complete independence (2500000143)
Standby assistance (2500000269)

NO = if any of the following values are selected:
Contact guard assistance (2500000270)
Minimal assistance (2500000146)
Moderate Assistance (2500000147)
Maximal Assistance (2500000145)
Dependent (4159760)

MISSING = if no value is stipulated for this variable

Variable: Ambulation Railings (CONCEPT ID: 2500010795) = YES if any one of the following three values below is selected:
Rail on left going up (2500000267)
Rail on right going up (2500000268)
None (4124462)

NO = If the following value is selected
Bilateral (2500000266)

MISSING = if no value is stipulated AND stairs assistance variable has a value

Variable: Primary Mobility (CONCEPT ID:2500000268) = YES if one of the following two values is selected:
Ambulation without device (2500000358)

NO = if any of the following values is selected:
Ambulation with device (2500000357)
Dependent wheelchair mobility (2500000359)
Independent wheelchair mobility – manual (2500000360)
Independent wheelchair mobility – power (2500000361)
Other (9177)

MISSING = if no value is stipulated for this variable

MOTOR DOMAIN 7 data elements, 6 variables

Derived Variable: Drooling = YES if either of the following variables is NO or MISSING:
Nutritional Risk Factors (CONCEPT ID: 2500010706): Drooling (2500000178)
Drooling Oral Motor Function (28312333)

NO = if either of the following variables is YES

Nutritional Risk Factors (CONCEPT ID: 2500010706): Drooling (2500000178)
Drooling Oral Motor Function (28312333)

Variable: Sitting Balance PT (4186717, (Source Value 28295811)) = YES if the following value is selected:
Intact

NO if the following value is selected:
Impaired

MISSING = if no value is stipulated for this variable

Variable: Knee Flexors/Extensors (2500010279/2500010278) = YES if the following values are selected on the Modified Ashworth Scale:
0
1
1.5

NO = if one of the following values is selected:
2
3
4

MISSING = if no value is stipulated in this variable

Variable: Ankle Dorsiflexors/Plantar flexors (2500010262/2500010265) = YES if the following values are selected on the Modified Ashworth Scale:
0
1
1.5

NO = if one of the following values is selected:
2
3
4

MISSING = if no value is stipulated in this variable

Variable: Elbow flexor/extensor muscle tone (2500010267/2500010266) = YES if the following values are selected on the Modified Ashworth Scale:
0
1
1.5

NO = if one of the following values is selected:

2
3
4

MISSING = if no value is stipulated in this variable

Variable: General Strength, Neck (2500010813) =YES if the following value is selected:
WFL (2500000041)

NO = if the following value is selected:
Limited (2500000040)

MISSING = if no value is stipulated in this variable

GMFCS 3

Initial inclusion criteria: if a patient has the following data elements/value sets selected, then screen as GMFCS 3, 2, or 1.
If any one
Ambulation Level: Independent-7 (2500000256), Stand-by assistance – 6 (2500000257); Minimal assistance – 5 (2500000258); Moderate assistance – 4 (2500000259)
AND
If ANY of the following 5 values for Stairs Assistance is selected: Complete independence (2500000143), Standby assistance (2500000269), Contact guard assistance (2500000270), Minimal assistance (2500000146), Moderate Assistance (2500000147)

The following rules comprise derived variables composed of data elements and their value sets to satisfy the rules

<u>ACTIVITIES DOMAIN</u> **19 data elements, 4 variables**

Derived variable: Current Home Treatments = YES if all the following 4 variables below are NO:
Respiratory support (2500010257)
Trach care (2500010258)
Tube feeding (2500010259)
Urinary catheterization (2500010260)

NO = If any of the variables are stipulated as YES

MISSING = If one variable is stipulated as NO AND one or more variables are MISSING

Derived variable: Fine Motor Concerns (CONCEPT ID: 2500010797; Qualifier: 2500000275) = YES if one or more of the following four variables is YES:
Dressing (2500010181)
Feeding (2500010178)
Grooming (2500010182)
Bathing (2500010180)

NO = if all four are stipulated as NO
MISSING = if any of the four variables are MISSING with one coded as NO

Derived variable: Toileting habits (CONCEPT ID: 2500010700) = YES if one of the following variables is YES:
Toilet trained (2500000137)
Diaper at night (2500000135)

MISSING = If no variable value is stipulated

Derived variable: Nutritional Screen, Feeding Ability (CONCEPT ID: 2500010703) = YES if any one of the following variables is YES:
Feeds self (2500000144)
Complete Independence (2500000143)
Modified independence (2500000148)
Supervision (2500000150)
Minimal Assistance (2500000146)

AND any of the following variables are NO:
Moderate Assistance (2500000147)
Maximal Assistance (2500000145)
No oral feedings (2500000149)
Total assistance (2500000151)

NO = if all the following variables are NO:
Feeds self (2500000144)
Complete Independence (2500000143)
Modified independence (2500000148)
Supervision (2500000150)
Minimal Assistance (2500000146)

AND any of the following variables are YES:
Moderate Assistance (2500000147)

Maximal Assistance (2500000145)
No oral feedings (2500000149)
Total assistance (2500000151)

MISSING = if all the following variables are MISSING:
Complete Independence (2500000143)
Feeds self (2500000144)
Modified independence (2500000148)
Supervision (2500000150)
Minimal Assistance (2500000146)

AND all the following variables are NO or MISSING:
Moderate Assistance (2500000147)
Maximal Assistance (2500000145)
No oral feedings (2500000149)
Total assistance (2500000151)

NEUROLOGIC DOMAIN 6 data elements, 2 variables

Derived variable: Cognitive Concerns = YES if one of the two below is YES:
Cognitive deficits (443432)
Speech deficit (432730)

NO = If both are stipulated as NO
MISSING = If one variable is missing AND the other coded as NO

Derived Variable: Communications Concerns (CONCEPT ID: 2500010797; Qualifier: 2500000271) = YES if all of the following variables are either NO or one of the four below is YES:
Language delay (4039748)
Language impairment (4041822)
Speech delay (4047123)
Speech impairment (435642)

NO = If two or more of the four are stipulated as NO
MISSING = if any of the four variables are missing AND the others coded as NO

MEDICATIONS DOMAIN 17 data elements, 2 variables

Derived variable: Gastrointestinal medications = YES if none of the medications below are presently prescribed:
Ranitidine (Drug Concept ID: 961047, 19126405, 961168, 19003290)
Famotidine (Drug Concept ID: 953076, 19077241, 19021074, 19027493, 953102)

NO = If any are presently prescribed

Derived variable: Seizure/Muscle Relaxant medications = YES if none of the medications below are presently prescribed:
Diazepam (Drug Concept ID: 19076372, 723013, 19018909, 19076374, 723042, 723020)
Valproic acid (Drug Concept ID: 40237988, 40238017)

NO = If any are presently prescribed

DEVICES DOMAIN **20 data elements, 4 variables**

Derived Variable: Assistive Devices Used = YES if one or more of the following variables is YES:
Walker (45767825)
Cane (4337514)
Crutches (4179721)

NO = if all the variables are stipulated as NO
MISSING = if no variables values are stipulated

Derived variable: Mobility Device Used = YES if the following variable is YES:
Wheelchair independently (4012670)

AND the following variables is YES:
Manual wheelchair (4045112)

AND the following variable is NO or MISSING:
Unable to propel own wheelchair (4215087)
Power wheelchair (2616920)

NO = if "Unable to propel own wheelchair" or "Power Wheelchair" are YES and "Wheelchair independently" is NO

MISSING = if "wheelchair independently" is MISSING and "unable to propel own wheelchair" is NO; OR if all variables are MISSING

Derived variable: Ambulation Device Utilized = YES if one or more of the following 6 variables are YES:
Gait trainer (3038446)
Swivel walker (45764219)
Walker pickup (2616486)
Walker reverse (2500010165)

Walker wheeled (2616497)
Crutches forearm (2616479)
Cane, quad (2500010160)
Cane, single point (2500010161)
Cane, tripod (2500010162)
Crutches axillary (45772311)
Stander (37396481)

NO = if any of the following variables are stipulated YES:
None (2500010164)

MISSING = if ALL the following variables are MISSING and None is NO:
Gait trainer (3038446)
Swivel walker (45764219)
Walker pickup (2616486)
Walker reverse (2500010165)
Walker wheeled (2616497)
Crutches forearm (2616479)
Cane, quad (2500010160)
Cane, single point (2500010161)
Cane, tripod (2500010162)
Crutches axillary (45772311)
Stander (37396481)

Variable: Ambulation Railings (CONCEPT ID: 2500010795) = YES if one of the following three values below is selected:
Bilateral (2500000266)
Rail on left going up (2500000267)
Rail on right going up (2500000268)

NO = if the following value is selected:
None (4124462)

MISSING = if no value is stipulated for this variable AND stairs assistance variable has a value

<u>MOBILITY DOMAIN</u> 10 data elements, 4 variables

Derived Variable: Gross Motor Concerns (CONCEPT ID: 2500010797; Qualifier: 2500010797) = YES if one or more of the following variables is YES:
Ambulatory with assistance (2500010171)
Assistive devices needed (3039217)

Household ambulation (2500010186)
Tires easily (45881740)
Trips/falls frequently (2500010215))

AND the following variables are NO:
Unable to sit independently (4106332)
Non-ambulatory (2500010193)

NO = If all the following are NO or MISSING:
Ambulatory with assistance (2500010171)
Assistive devices needed (3039217)
Household ambulation (2500010186)
Tires easily (45881740) [AND/OR]
Trips/falls frequently (2500010215))

AND one or more of the following two is YES:
Unable to sit independently (4106332)
Non-ambulatory (2500010193)

MISSING = if "Unable to sit independently" AND "Non-ambulatory" are MISSING or NO and all other variables in this derived variable are NO or MISSING

Variable: Ambulation, Ambulation Level (CONCEPT ID: 2500010792) = YES if either of the following two values are selected:
Stand-by assistance – 6 (2500000257)
Minimal assistance – 5 (2500000258)

NO = if any of the following values are selected:
Independent-7 (2500000256)
Moderate assistance – 4 (2500000259)
Maximum assistance – 2 (2500000260)
Dependent – 1 (2500000261)

MISSING = if no value is stipulated for this variable

Variable: Stairs Assistance (CONCEPT ID: 2500010796) = YES if any of the following five values are selected:
Standby assistance (2500000269)
Contact guard assistance (2500000270)
Minimal assistance (2500000146)
Moderate Assistance (2500000147)
Maximal Assistance (2500000145)

NO = if any of the following values are selected:
Complete independence (2500000143)
Dependent (4159760)

MISSING = if no value is stipulated for this variable

Variable: Primary Mobility (CONCEPT ID:2500000268) = YES if one of the following three values is selected:
Independent wheelchair mobility – manual (2500000360)
Independent wheelchair mobility – power (2500000361)
Ambulation with device (2500000357)

NO = if any of the following values is selected:
Ambulation without device (2500000358)
Dependent wheelchair mobility (2500000359)
Other (9177)

MISSING = if no value is stipulated for this variable

MOTOR DOMAIN **10 data elements, 6 variables**

Derived Variable: Drooling = YES if either of the following variables is NO or MISSING:
Nutritional Risk Factors (CONCEPT ID: 2500010706): Drooling (2500000178)
Drooling Oral Motor Function (28312333)

NO = if one of the above variables is YES

Variable: Sitting Balance PT (4186717, (Source Value 28295811)) = YES if the following value is selected:
Intact

NO = if the following value is selected:
Impaired

MISSING = if no value is stipulated for this variable

Derived Variable: Knee Flexor/Extensor Tone (2500010279/2500010278) = YES if one of the following values are selected on the Modified Ashworth Scale:
1
1.5

2
3

NO = if one of the following values is selected:

0
4

MISSING = if no value is stipulated in this variable

Derived Variable: Ankle Dorsiflexors/Plantar flexors (2500010262/2500010265) = YES if one of the following values are selected on the Modified Ashworth Scale:

1
1.5
2
3

NO = if one of the following values is selected:

0
4

MISSING = if no value is stipulated in this variable

Derived Variable: Elbow flexor/extensor muscle tone (2500010267/2500010266) = YES if the following values are selected on the Modified Ashworth Scale for either of the above variables:

1
1.5
2
3

NO = if one of the following values is selected:

0
4

MISSING = if no value is stipulated in this variable

Variable: General Strength, Neck (2500010813) =YES if the following value is selected:

WFL (2500000041)

NO = if the following value is selected:

Limited (2500000040)

MISSING = if no value is stipulated in this variable

GMFCS 4 & 5

Initial inclusion criteria: if a patient has the following data elements/value sets selected, then screen as GMFCS 4, or 5
If any of the following 2 values are selected in Ambulation Level: Maximum assistance – 2 (2500000260); Dependent – 1 (2500000261)

AND

If any of the following 2 values for Stairs Assistance are selected or if the value is MISSING: Maximal Assistance (2500000145); Dependent (4159760)

The following rules comprise derived variables composed of data elements and their value sets to satisfy the rules

<u>ACTIVITIES DOMAIN</u> 19 data elements, 4 variables

Derived variable: Current Home Treatments = YES if one or more of the four below is YES:
Respiratory support (2500010257)
Trach care (2500010258)
Tube feeding (2500010259)
Urinary catheterization (2500010260)

NO = If all four are stipulated as NO
MISSING = missing if any of the four are missing with the others coded as NO

Derived variable: Fine Motor Concerns (CONCEPT ID: 2500010797; Qualifier: 2500000275) = YES if two or more of the following four variables is YES:
Dressing (2500010181)
Feeding (2500010178)
Grooming (2500010182)
Bathing (2500010180)

NO = if three or more are stipulated as NO
MISSING = if any of the four are MISSING with one coded as NO

Derived variable: Toileting habits (CONCEPT ID: 2500010700) = YES if the convention below is satisfied:
Diaper at night (2500000135) = YES

AND the following variable is NO**:**
Toilet trained (2500000137)

NO = if "Toilet trained" is YES

MISSING = if "Diaper at night" is missing "Toilet trained" is NO

Derived variable: Nutritional Screen, Feeding Ability (CONCEPT ID: 2500010703) = YES if any one of the following variables is YES:
Minimal Assistance (2500000146)
Moderate Assistance (2500000147)
Maximal Assistance (2500000145)
Total assistance (2500000151)
No oral feedings (2500000149)

AND any of the following variables are NO or MISSING:
Feeds self (2500000144)
Complete Independence (2500000143)
Modified independence (2500000148)
Supervision (2500000150)

NO = if all the following variables are MISSING or NO:
Minimal Assistance (2500000146)
Moderate Assistance (2500000147)
Maximal Assistance (2500000145)
Total assistance (2500000151)
No oral feedings (2500000149)

AND any of the following variables are YES:
Feeds self (2500000144)
Complete Independence (2500000143)
Modified independence (2500000148)
Supervision (2500000150)

MISSING = if all the following variables are MISSING
Minimal Assistance (2500000146)
Moderate Assistance (2500000147)
Maximal Assistance (2500000145)
Total assistance (2500000151)
No oral feedings (2500000149)

AND all the following variables are NO or MISSING:
Feeds self (2500000144)
Complete Independence (2500000143)
Modified independence (2500000148)
Supervision (2500000150)

NEUROLOGICAL DOMAIN 6 data elements, 2 variables

Derived variable: Current Sensory Deficits = YES if one of the two below is YES:
Cognitive deficits (443432)
Speech deficit (432730)

NO = If both are stipulated as NO
MISSING = missing if either are missing with the others coded as NO

Derived Variable: Communications Concerns (CONCEPT ID: 2500010797; Qualifier: 2500000271) = YES if two or more of the four below is YES:
Language delay (4039748)
Language impairment (4041822)
Speech delay (4047123)
Speech impairment (435642)

NO = If all four are stipulated as NO
MISSING = missing if any of the four are missing with the others coded as NO

MEDICATIONS DOMAIN 17 data elements, 2 variables

Derived variable: Gastrointestinal medications = YES if one or more of the medications below are presently prescribed:
Ranitidine (Drug Concept ID: 961047, 19126405, 961168, 19003290)
Famotidine (Drug Concept ID: 953076, 19077241, 19021074, 19027493, 953102)

NO = If any are presently prescribed

Derived variable: Seizure/Muscle Relaxant medications = YES if one or more of the medications below are presently prescribed:
Diazepam (Drug Concept ID: 19076372, 723013, 19018909, 19076374, 723042, 723020)
Valproic acid (Drug Concept ID: 40237988, 40238017)

NO = If any are presently prescribed

DEVICES DOMAIN16 data elements, 2 variables

Derived variable: Mobility Device Used = YES if one of the following two variables is YES:
Wheelchair independently (4012670)
Unable to propel own wheelchair (4215087)

AND any of the following variables are YES:
Manual wheelchair (4045112)

Power wheelchair (2616920)

NO = if “Unable to propel own wheelchair” and “Wheelchair independently” are NO

MISSING = Manual wheelchair and Power wheelchair are NO and “wheelchair independently” and “unable to propel own wheelchair” are MISSING

Derived variable: Ambulation Device Utilized = YES if one or more of the following 6 variables are YES:
Gait trainer (3038446)
Stander (37396481)
Swivel walker (45764219)
Walker pickup (2616486)
Walker reverse (2500010165)
Walker wheeled (2616497)

AND any of the following variables are NO:
None (2500010164)
Cane, quad (2500010160)
Cane, single point (2500010161)
Cane, tripod (2500010162)
Crutches axillary (45772311)
Crutches forearm (2616479)

NO = if any of the following variables are stipulated YES:
None (2500010164)
Cane, quad (2500010160)
Cane, single point (2500010161)
Cane, tripod (2500010162)
Crutches axillary (45772311)
Crutches forearm (2616479)

MISSING = if ALL the following variables are missing:
Gait trainer (3038446)
Stander (37396481)
Swivel walker (45764219)
Walker pickup (2616486)
Walker reverse (2500010165)
Walker wheeled (2616497)

AND any of the following variables are stipulated NO:
None (2500010164)
Cane, quad (2500010160)
Cane, single point (2500010161)

Cane, tripod (2500010162)
Crutches axillary (45772311)
Crutches forearm (2616479)

MOBILITY DOMAIN 10 data elements, 4 variables

Derived Variable: Gross Motor Concerns (CONCEPT ID: 2500010797; Qualifier: 2500010797) = YES if one of the following two variables is YES:
Unable to sit independently (4106332)
Non-ambulatory (2500010193)

AND if one or more of the five variables below are NO:
Ambulatory with assistance (2500010171)
Assistive devices needed (3039217)
Household ambulation (2500010186)
Tires easily (45881740)
Trips/falls frequently (2500010215)

NO = if "Unable to sit independently" AND "Non-ambulatory" are NO
MISSING = if "Unable to sit independently" is MISSING AND "Non-ambulatory" is MISSING and all other variables in this derived variable are NO or MISSING

Variable: Ambulation, Ambulation Level (CONCEPT ID: 2500010792) = YES if any of the following two values are selected:
Moderate assistance – 4 (2500000259)
Maximum assistance – 2 (2500000260)
Dependent – 1 (2500000261)

NO = if any of the following values are selected:
Independent-7 (2500000256)
Stand-by assistance – 6 (2500000257)
Minimal assistance – 5 (2500000258)

MISSING = if ANY of the above values are missing

Variable: Stairs Assistance (CONCEPT ID: 2500010796) = YES if the following value is selected or the variable is MISSING:
Dependent (4159760)

NO = if any of the following values are selected:
Complete independence (2500000143)
Standby assistance (2500000269)

Contact guard assistance (2500000270)
Minimal assistance (2500000146)
Moderate Assistance (2500000147)
Maximal Assistance (2500000145)

Variable: Primary Mobility (CONCEPT ID:2500000268) = YES if one of the following two values is selected:
Independent wheelchair mobility – manual (2500000360)
Independent wheelchair mobility – power (2500000361)
Dependent wheelchair mobility (2500000359)

NO = if any of the following values is selected:
Ambulation without device (2500000358)
Ambulation with device (2500000357)
Other (9177))

MISSING = if no value is stipulated for the variable

MOTOR DOMAIN 10 data elements, 6 variables

Derived Variable: Drooling = YES if either of the following variables is YES:
Nutritional Risk Factors (CONCEPT ID: 2500010706): Drooling (2500000178)
Drooling Oral Motor Function (28312333)

NO = if the above variable is NO
MISSING = if both of the variable values is MISSING

Variable: Sitting Balance PT (4186717, (Source Value 28295811)) = YES if the following value is selected:
Impaired

NO = if the following value is selected:
Intact

MISSING = if no value is stipulated for this variable

Variable: Knee Flexors/Extensors (2500010279/2500010278) = YES if the following values are selected on the Modified Ashworth Scale:
2
3
4

NO = if one of the following values is selected:

0
1
1.5

MISSING = if no value is stipulated in this variable

Variable: Ankle Dorsiflexors/Plantar flexors (2500010262/2500010265) = YES if the following values are selected on the Modified Ashworth Scale:
2
3
4

NO = if one of the following values is selected:
0
1
1.5

MISSING = if no value is stipulated in this variable

Variable: Elbow flexor/extensor muscle tone (2500010267/2500010266) = YES if the following values are selected on the Modified Ashworth Scale:
2
3
4

NO = if one of the following values is selected:
0
1
1.5

MISSING = if no value is stipulated in this variable

Variable: General Strength, Neck (2500010813) =YES if the following value is selected:
Limited (2500000040)

NO = if the following value is selected:
WFL (2500000041)

MISSING = if no value is stipulated in this variable

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