DIGICOMP KIDS

DIGICOMP KIDS: CO-DESIGN AND USABILITY TESTING OF A HOSPITAL-TO-HOME INTERVENTION FOR CHILDREN WITH MEDICAL COMPLEXITY

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Lay abstract

Children with medical complexities are a group of young people who live with serious illness and require intensive medical care. Traditionally, healthcare for these children has been delivered in hospital settings such as clinics and inpatient wards, which is costly, inconvenient for families, and puts children at risk of medical errors and infections. This thesis aims to understand the needs of families and healthcare providers for using technology to virtually deliver hospital-to-home care for children with medical complexities. It includes a scoping review of the literature, an exercise to design a technology-enabled virtual care delivery system, and a usability test of the system, gathering feedback from families and healthcare providers. The results provide insight into the requirements for virtual care systems for children with medical complexities, which, once implemented, may help to improve health system costs, clinical outcomes, and quality of life for children and their families.

Abstract

Background. Advances in healthcare have resulted in a growing population of Children with Medical Complexities (CMC). Medical management of the complex needs of CMC has traditionally taken place in hospital settings, such as clinics, emergency departments, and hospital wards, by specialized teams of healthcare clinicians. While access to expert-level care is necessary, the hospital-based model of care is expensive and inconvenient and has resulted in harms such as medical errors conferred upon CMC. Models of care that allow for expert-delivered hospital-to-home care for CMC are needed. The aim of this dissertation was to investigate the needs, performance, and perceptions of CMC families and clinicians when using a hospital-to-home digital health system called DigiComp Kids.

Methods. This study was guided by A Holistic Framework to Improve the Uptake and Impact of eHealth Technologies, which attends to technological, human, and contextual variables influencing virtual care. A scoping review was conducted to provide an overview of how digital healthcare has been used with medically fragile children, before co-designing the DigiComp Kids system with CMC family members and clinicians. Usability testing of DigiComp Kids was conducted measuring user effectiveness, efficiency, satisfaction, and experiences.

Results. Across studies in this dissertation, technological, human, and contextual factors each played a role in the usability of digital health systems, including DigiComp Kids. In the scoping review, these factors influenced the acceptability, accessibility, and implementation success of digital healthcare systems for CMC. During DigiComp Kids co-design and usability testing, participants emphasized how these factors affected their willingness to engage with the system, how it fit into their lives and workflows, and where improvements could be made.

Conclusions. This study highlights the importance of engaging with end-users as well as attending to technological, human, and contextual factors when designing and testing digital health systems.

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List of Abbreviations and Symbols

APN: advanced practice nurse

bpm: beats per minute

CF: cystic fibrosis

CI: confidence interval

CINAHL: Cumulative Index to Nursing and Allied Health Literature

CMC: Children with Medical Complexities

COVID-19: coronavirus disease of 2019

CRI: chronic respiratory insufficiency

CSHCN: Children with Special Healthcare Needs

dallas: Delivering Assisted Lifestyles at Scale

DH: digital health

ED: emergency department

EMBASE: *Excerpta Medica* dataBASE

FO: family outcomes

GRIPP2: Guidance for Reporting Involvement of Patients and the Public-2

HiREB: Hamilton Integrated Research Ethics Board

HPO: health care provider outcomes

IQR: interquartile range

LOS: Length of Stay

MEDLINE: Medical Literature Analysis and Retrieval System Online

NG: nasogastric

NICU: neonatal intensive care unit

NIH: National Institutes of Health

OTN: Ontario Telemedicine Network

p: p-value

PedsQL: Pediatric Quality of Life Inventory

PO: patient outcome

RN: registered nurse

SD: standard deviation

SEQ: Single Ease Question

SO: system outcomes

SPROUT: Supporting Pediatric Research in Outcomes and Utilization of Telehealth

SUM: Single Usability Metric

SUPRQ: Standardized User Experience Percentile Rank Questionnaire

SW: social worker

T&A: title and abstract

US: United States

Declaration of Academic Achievement

This dissertation is a sandwich thesis which consists of three manuscripts (chapters 2-4) that have been submitted or published in peer-reviewed journals. The manuscripts consist of a scoping review (chapter 2), methodological framework (chapter 3), and usability testing results manuscript (chapter 4). Marissa Bird is the first author on all publications and was responsible for the development of research questions, study design, data collection and analysis, and interpretation and preparation of findings for publication. All work by Marissa Bird was directly supervised by Dr. Michael McGillion, as well as committee members Dr. Nancy Carter and Dr. Audrey Lim. Drs. McGillion, Carter, and Lim contributed invaluable feedback on the research process and thesis structure, as well as specific content and methodological guidance throughout. A Master's level student (Nadia Kazmie) was employed as a research assistant for the collection and analysis of usability testing data in chapter 4. As well, two Family Partners (Shannon Reaume and Elizabeth Chambers) were crucial advisories to Marissa Bird and committee members throughout the project, informing the team specifically on issues relevant to the care of medically complex children. This dissertation and its resulting publications represent the collective efforts of all members of the thesis committee and its collaborators, and all members have given their final approval.

Chapter 1: Introduction

Healthcare treatment advances have led to infants, children, and youth surviving accidents and illnesses to which they would have succumbed in years past. The epidemiological transition resulting from these increased survival rates has created a growing population of children living with lifelong medical conditions. Children with Medical Complexities (CMC) are a group of infants, children, and youth who live with medical fragility and intensive healthcare needs, with or without a reliance on technology for sustainment of life (Cohen et al., 2011). The following four factors characterize the global CMC population: (1) severe complex chronic conditions, (2) substantial family-identified service needs, (3) functional limitations, and (4) high resource use (Cohen et al., 2011). CMC may have a congenital or acquired multisystem disease, severe and long-lasting neurological impairment, and marked functional status limitations in multiple areas, requiring expert care and substantial resources to achieve optimal health outcomes (Cohen et al., 2011). Illustrative examples of CMC conditions include a child with an acquired severe brain injury who is reliant on a feeding tube and external ventilation, or an infant born with multiple congenital anomalies who requires non-invasive oxygen support, a complex medication regimen, and care from multiple speciality teams.

CMC prevalence and costs. In a given population, CMC generally constitute less than one percent of all children, yet they often consume the lion's share of pediatric healthcare resources (Amarri et al., 2021; Cohen et al., 2012; Yamada et al., 2020). In Ontario, a retrospective cohort study of hospitalized children revealed that CMC comprise 0.67% of the provincial pediatric population, yet account for one-third of child health spending (Cohen et al., 2012; Cohen et al., 2011; Dewan & Cohen, 2013). Financial resources expended on healthcare for CMC amount to $419 million per year in Ontario, with more medically complex children (those affected by a greater number of diagnosed conditions or requiring more technology assistance) consuming a higher proportion of resources (Cohen et al., 2012). Canadian data indicate that the majority of costs (79%) are related to hospitalizations, with homecare costs totalling approximately 11%, and outpatient costs totalling 6% (Cohen et al., 2012). Similarly, in the United States, 47% of CMC healthcare dollars are allocated to hospital-based care, while only 2% are allocated to home care (Foster et al., 2019). Data from the United States also indicate that CMC account for 43% of pediatric deaths, nearly half of pediatric hospital days, and 75-92% of pediatric assistive technologies such as gastrostomy tube or tracheostomy placements, or extracranial ventricular shunts (Orkin et al., 2019; Simon et al., 2010).

Gaps in care. CMC and their families experience numerous and frequent gaps in care, including but not limited to prolonged hospitalizations and extemporized courses of acute and critical care (Berry, 2015; Srivastava et al., 2005), financially under-resourced home and community supports (Cheshire et al., 2010; Fulton, 2022), and the need for frequent and expensive travel to receive care (Bradford et al., 2014). Contributing to these issues is the matter of CMC requiring care across multiple settings, including the hospital, clinic, community, school, and their homes. In each setting, CMC are at risk for iatrogenic harms due to a number of intersecting issues, including the multifaceted nature of their conditions and treatment regimes, lack of coordination across settings and care providers, and frequent communication breakdowns within and between treating teams (Dewan & Cohen, 2013). Examples of harms experienced by CMC due to these factors include adverse effects of an inappropriately administered medication, or procedural complications from devices such as indwelling urinary catheters (Slonim et al., 2003). Importantly, CMC experience higher hospital-related harms than children without medical complexity, and these harms are predictive of both increasing length of hospital stay (LOS) and death. For example, in one cohort study of pediatric hospital-reported errors in the United States, the mean LOS for patients without medical errors was 3.52 days [95% CI 3.39, 3.65], while the mean LOS for patients with medical errors was 10.77 days [95% CI 9.97, 11.57] (Slonim et al., 2003). Additionally, children without medical errors experienced a 0.39% mortality rate [95% CI 0.35, 0.43], while those children who experienced medical errors had a 2.03% mortality rate [95% CI 1.73, 2.36] (Slonim et al., 2003). In order to decrease avoidable harms to

CMC, including iatrogenic morbidity and mortality, solutions are needed to provide comprehensive care to CMC in their home environments whenever possible.

In addition to the need to provide care at home for CMC, care coordination efforts are urgently needed. Coordinated care is defined as organized care delivery with a clear division of responsibility (Berry, 2015). While most CMC have a central treatment team, often located at a tertiary pediatric centre, the treatment team may not include a dedicated individual whose role it is to act as a 'point person' in care coordination efforts for CMC families. The need to access care across settings and associated intensive care coordination efforts that are required to accomplish this often result in family caregivers taking on the expensive and labour-intensive tasks of care coordination. In a study of CMC in the United States, 46% of families reported spending more than $1,000 out-of-pocket on care-related needs including care coordination annually, and over half of CMC families reported that a family member left the workforce in order to provide care for the child at home (Kuo et al., 2011). Between family caregivers' extraordinary efforts to provide comprehensive day-to-day care to CMC and also coordinate care between settings, families of CMC report that the health system is fragmented and difficult to navigate (Kuo et al., 2011). Nearly half of CMC families report at least one unmet medical need, and one third have experienced difficulty in accessing non-medical services such as childcare, rehabilitation, and community programs (Kuo et al., 2011). Additional gaps in care for CMC include the focus of health systems on acute episodic care, family financial and psychological stress related to the need to travel extensive distances to obtain necessary care (Cohen et al., 2018), a reactive as opposed to proactive care delivery model, as reported by parents of CMC (Miller et al., 2009), and a serious workforce shortage of trained pediatric home healthcare providers (Foster et al., 2019).

The role of digital health. The gaps in care experienced by CMC and their families, including iatrogenic harms and unmet care coordination and CMC healthcare needs, are not easily solvable. Solutions to improving care and quality of life for CMC and their families need to span organizational and geographic boundaries in order to coordinate care (including personnel, supplies, care appointment scheduling, and clinician documentation needs), prevent hospitalizations of CMC where possible, and provide proactive, comprehensive care, as opposed to care that is reactive and episodic (Gordon et al., 2007). In other populations with complex health needs, hospital-to-home digital health technologies have been effective in lessening unmet health needs and use of acute care resources (Kroenke et al., 2010; Lewis et al., 2017; Maguire et al., 2015). Hospital-to-home digital health technologies allow for patient data acquisition in the home environment, and then transmit these data to hospital-based systems, integrating it into formats that make it readily available to hospital-based clinicians (McGillion et al., 2020). Examples wherein digital health technologies have been employed to assist in meeting the needs of patients with complex health issues include the use of technology-assisted patient reported outcome monitoring in patients with lung cancer, which decreased patient anxiety and improved self-care and self-efficacy (Maguire et al., 2015); as well as a primary-care-to-home virtual case management intervention for elderly persons experiencing acute illness, which decreased participant emergency department presentations (Lewis et al., 2017). These examples are illustrative of the utility of digital health technologies in meeting the needs of patients with complex health issues by enabling the delivery of care within patient homes by providers across varying settings.

While digital health systems can theoretically help to meet the needs of CMC by providing comprehensive, continuous care in a home environment, applications of digital health interventions for CMC remain largely underexplored. Despite this, preliminary data from a number of studies show positive effects of digital health technologies in terms of easing the burden of care on families and reducing health system resource use. For example, a study using videoconferencing to support parents of children with complex congenital heart defects at home showed a significant reduction in parental anxiety (median reduction of 6 points in State and Trait Anxiety Inventory score, $p < 0.05$, $n = 78$) (McCrossan et al., 2008). Parents in this study commented that they were reassured by the ability to access highly-trained clinicians from their home, and that the use of video to provide care in the home was not intrusive (McCrossan et al., 2008). Additionally, a care coordination nursing intervention for CMC showed a reduction in unplanned hospitalizations over time spent in the program (mean unplanned hospitalizations in Year 1: 1.7, SD: 2.5; mean unplanned hospitalizations in Year 2: 0.8, SD 1.7; $p = 0.007$) (Cady et al., 2009). Despite a relatively constant rate of planned hospitalizations for CMC in this study (Cady et al., 2009), a reduction in unplanned hospitalizations may represent a more proactive and comprehensive approach to care provision and coordination, resulting in less disruption to CMC and family lives and decreased risk of iatrogenic harm over time.

These early studies demonstrate that digital health-enabled care for CMC can indeed improve outcomes for children, families, and the health system. Despite this, there remains a lack of scalable, standardized digital health-enabled care models for CMC. This shortage of successful and sustained models suggests that a deeper exploration of factors influencing adoption, scalability, and spread of digital health-enabled care models for CMC is warranted. To date, no published studies have explored such factors with CMC, their families, and clinicians. As such, the optimal attributes and implementation factors of digital health-enabled interventions designed to provide comprehensive home-based care to CMC remain unknown.

Thesis Aims and Research Questions

The aims of this thesis are to: a) determine the optimal attributes of a digital health-enabled intervention for CMC, their clinicians, and families; and b) examine the usability and user experiences of such an intervention. In meeting these objectives, the research questions to be answered in this thesis are:

1) How have digital health interventions been used to care for medically complex children, and what are the attributes, barriers, and facilitators of these interventions that have affected their success?
2) What are the optimal processes, features, and workflows for a digital health intervention that aims to provide integrated home-based care for CMC, as defined by families of CMC and their clinicians?
3) What is the usability and user experience of CMC family members and clinicians using a co-designed digital health intervention to virtually care for CMC in simulated scenarios?

Conceptual Framework

This dissertation is informed by The Holistic Framework to Improve the Uptake and Impact of eHealth Technologies (the eHealth Holistic Framework) by van Gemert-Pijnen and colleagues, which examines the gap between the postulated benefits of digital health interventions for complex populations and the lack of supporting empirical evidence from sustained models of digital health-enabled care (van Gemert-Pijnen et al., 2011). Within this framework, authors report that digital health technologies are often developed by research teams without adequate involvement of end-users in the design of interventions, resulting in a lack of adoption, scale, and spread (van Gemert-Pijnen et al., 2011). Lack of attention to the ways in which people interact with technology in specific contexts when designing and implementing digital health technologies results in a failure of these technologies to meet the needs of their intended end-users, and subsequent intervention non-adoption or abandonment (Greenhalgh et al., 2017; Huckvale et al., 2019). In order to combat developing digital health interventions that do not meet the needs of intended end-users, and are thus not amenable to scale and spread, the eHealth Holistic Framework argues that complex interactions between technologies, humans, and the contextual environment must be accounted for when developing, implementing, and evaluating digital health interventions (van Gemert-Pijnen et al., 2011). These interactions are best illuminated by the voices of end-users themselves, which should be incorporated into all stages of intervention design, development, and implementation (Sanders & Stappers, 2008; van Gemert-Pijnen et al., 2011).

Approach

As described by the eHealth Holistic Framework (van Gemert-Pijnen et al., 2011), the lack of careful attention paid to the interactions between technologies, human factors, and the contextual environment during the design, development, and formative testing of digital health interventions has resulted in a mismatch between the postulated benefits of digital health interventions and the lack of adoption seen in practice (Andersen, Bansler, Kensing, Moll, & Nielsen, 2014; van Gemert-Pijnen et al., 2011). As such, this thesis project was designed to focus specifically on investigating these interactions from the perspectives of those involved in the care of CMC (end-users, i.e., family members, hospital-based clinicians, home-based clinicians), and using these perspectives to inform the development and usability testing procedures for a digital health-enabled hospital-to-home intervention for CMC. To undertake this process, this project began with a scoping review in order to understand the state of the science of hospital-to-home digital health intervention use in caring for medically complex children; before moving on to a process of co-designing and subsequently usability testing a hospital-to-home intervention for CMC.

Thesis Content

Chapter 2: Scoping review. Chapter 2 in this dissertation is a scoping review which describes the various models of synchronous hospital-to-home digital health that have been used in pediatric populations with special health care needs, their outcomes, and implementation barriers. This review has been published in *JMIR Pediatrics and Parenting* (Bird et al., 2019). In this review, the focus was on synchronous (real-time) digital health interventions in order to understand if digital health interfaces could reduce the need for some real-time in-person care provision for CMC, as in-person care has been shown to confer risk for this medically fragile population. In addition, the search strategy employed in this review purposefully cast a wide net by capturing studies that focused on the broad category of Children with Special Healthcare Needs (CSHCN), of which CMC make up a small subset. CSHCN are a group of children with or at risk for chronic physical, developmental, behavioral, or emotional conditions, often requiring substantial use of health and social services— comprising approximately 17-20% of the pediatric populations in Canada and the United States (McPherson et al., 1998; Newacheck et al., 2006; U.S. Department of Health and Human Services, 2013). CMC represent the most medically fragile subset of CSHCN. The working hypothesis when beginning this review was that far fewer studies of synchronous digital health had been completed with CMC than with CSHCN, and indeed, this was found to be the case. However, it was felt reasonable that the innovation strategies and results from studies with CSHCN could be extrapolated to CMC populations, which would serve to inform the thinking for later stages of this doctoral project. In this review, a special area of focus was placed on the engagement of end-users in the design and implementation of hospital-to-home digital health innovations and this engagement was evaluated using the IDEO Human-Centred Design Framework (IDEO, 2015). Because the literature search for this scoping review was run a number of years ago on June 30, 2018, a brief summary of updates to the literature can be found in the concluding pages of Chapter 2 of this thesis.

Chapter 3: Co-design framework. Chapter 3 consists of a methodological framework that was developed from undertaking the co-design of a digital health hospital-to-home innovation for CMC, entitled, DigiComp Kids. The impetus for the creation of this framework was a gap in the literature concerning engaging end-users in creative health innovation design. The methodological framework, now published in *Research Involvement and Engagement* (Bird et al., 2021), provides structured scaffolding for end-user engagement in the design of healthcare products, systems, and services. In seven steps, readers are guided through the processes of challenge identification, forming a co-design team, undertaking co-design using creative methods, and analyzing the data, as well as translating co-design findings into actionable items. This framework aims to assist healthcare innovators, applied health science researchers, clinicians, and quality improvement specialists to elicit the viewpoints of end-users while distilling practical considerations for healthcare innovation and design.

Chapter 4: Usability testing results. In Chapter 4 of this dissertation, the process and results of usability testing the DigiComp Kids intervention are presented. This manuscript, now submitted to *JMIR Formative Research* describes the process and outcomes of undertaking usability testing with hospital-based clinicians, CMC family members, and home-based clinicians. The manuscript describes participant effectiveness, efficiency, and satisfaction while using the DigiComp Kids intervention to complete a set of simulated tasks, as well as participant experiences solicited via qualitative interviews. Quantitative metrics are statistically combined into a single, summated score, representing the overall usability of the DigiComp Kids intervention, while interview findings are analyzed using thematic analysis techniques. The combination of quantitative and qualitative data presented within this manuscript add important contributions to the literature, as few usability testing studies have been completed in pediatric populations, with none found for CMC populations specifically.

Some overlap in content exists in Chapters 2-4. For example, definitions of CMC populations, clinical issues facing medically fragile children and families, and the importance of end-user engagement when innovating with this population are discussed in each chapter. In Chapter 5, this entire body of work is synthesized and implications for clinical practice, education, research, and policy are discussed.

Chapter 2

Care of Children with Special Healthcare Needs and Their Families via Synchronous Digital Health Technologies: A Scoping Review

Bird M., Li L., Ouellette C., Hopkins K., McGillion M, and Carter N. (2019). Care of Children with Special Healthcare Needs and Their Families via Synchronous Digital Health Technologies: A Scoping Review. JMIR Pediatrics and Parenting. 2(2), e15106. DOI: 10.2196/15106

Overview

Chapter 2 in this dissertation is a published scoping review summarizing the current body of literature surrounding the use of synchronous digital health technologies in caring for children with special healthcare needs, their implementation, uptake, and evaluation. Following the methods of Arksey and O’Malley for scoping reviews, this review was undertaken by identifying the purpose of the review, searching for and selecting relevant studies, charting the data, and collating, summarizing, and reporting the results (Arksey & O'Malley, 2005). The aims of this review were to provide an overview of the literature in this area as well as practical information for healthcare decision makers considering digital health implementation or expansion. To this end, barriers and facilitators to the design, implementation, and maintenance of successful digital health programs were highlighted. Informed by the eHealth Holistic Framework, a special focus was also placed on reporting the engagement of end-users in intervention co-design and implementation. Results drawn from this review argue that co-design and formative testing principles should inform the work of those designing and implementing digital health interventions for children with special healthcare needs in order to create feasible interventions that meet the needs of intended end-users.

Abstract

Background: Use of synchronous digital health technologies for care delivery to children with special health care needs (having a chronic physical, behavioral, developmental, or emotional condition in combination with high resource use) and their families at home has shown promise for improving outcomes and increasing access to care for this medically fragile and resource-intensive population. However, a comprehensive description of the various models of synchronous home digital health interventions does not exist, nor has the impact of such interventions been summarized to date.

Objective: We aim to describe the various models of synchronous home digital health that have been used in pediatric populations with special health care needs, their outcomes, and implementation barriers.

Methods: A systematic scoping review of the literature was conducted, guided by the Arksey and O'Malley Scoping Review Framework. MEDLINE, CINAHL, and EMBASE databases were searched from inception to June 2018, and the reference lists of the included systematic reviews and high-impact journals were hand-searched.

Results: A total of 38 articles were included in this review. Interventional articles are described as feasibility studies, studies that aim to provide direct care to children with special health care needs, and studies that aim to support family members to deliver care to children with special health care needs. End-user involvement in the design and implementation of studies is evaluated using a human-centered design framework, and factors affecting the implementation of digital health programs are discussed in relation to technological, human, and systems factors.

Conclusions: The use of digital health to care for children with special health care needs presents an opportunity to leverage the capacity of technology to connect patients and their families to much-needed care from expert health care providers while avoiding the expenses and potential harms of the hospital-based care system. Strategies to scale and spread pilot studies, such as involving end users in the co-design techniques, are needed to optimize digital health programs for children with special health care needs.

Introduction

Background. Advances in neonatal and pediatric care for complex medical conditions have contributed to the increased survival of children who live with chronic health care needs [1]. Although definitions of this group vary, children with special health care needs are generally considered to be those with or at risk for chronic physical, developmental, behavioral, or emotional conditions, often requiring substantial use of health and social services [2,3]. In the United States, the prevalence of children with special health care needs is estimated to be 19.8% of the pediatric population [4]. Canadian provincial administrative data report a similar prevalence rate of 17.5% [5].

Children with special health care needs often require care from specialists, typically located in urban tertiary centers [6]. In between specialist visits, children with special health care needs frequently experience the need for urgent care, often delivered by health care providers unfamiliar with their complex histories, intersecting conditions, and intricate care regimens [7]. This scenario often leads to extemporized courses of clinical management as well as recurrent emergency department visits and hospital admissions [8]. Such unpredictability confers vulnerability for children with special health care needs in terms of exposure to medical errors and other nosocomial harms such as infection [9].

Although children with special health care needs comprise less than 20% of the pediatric population in the United States, they account for 41% of total pediatric health expenditures [10]. Substantial time and resources are also contributed by families who care for children with special health care needs, estimated at 1.5 billion hours of care in the United States in 2015 [11]. Were these care hours provided by health care aides, the cost would approximate to US $35.7 billion or US $6400 per child [11]. Foregone income due to caregiving responsibilities in the home, as well as out-of-pocket expenses for parent and family members, add to the cost burden. Losses in parental earnings are estimated at US $3200 per child per year, and annual out-of-pocket expenses have been documented at over US $1000 per year in 20%-25% of children with special health care needs families [12].

Prior Work. Recent attention has been given to synchronous digital health technologies, designed to increase access for patients and families to clinical teams in real time from their homes. Synchronous digital health technologies refer to the use of audio, video, and health information interfaces to facilitate the provision of health care remotely, in real time [13]. Both randomized and nonrandomized studies of digital health interventions in children with special health care needs to date have shown improved clinical, economic, and quality of life outcomes [14-16]. Synchronous digital health technologies have also been documented to improve parental caregiver outcomes such as quality of life, psychological health, satisfaction with care, and social support. One systematic review reported that 62 of 65 studies (95%) of synchronous digital health technologies observed significant improvements in these outcomes for caregivers of children and adults with chronic and degenerative diseases [17].

A national survey in the United States documented 51 digital health programs providing care to pediatric populations [18], supporting the momentum for such programs. At this time, the number of existing digital health pediatrics programs in Canada is unknown. Although the evidence base in support of the effectiveness of pediatric synchronous digital health interventions is growing [16,19-21], a comprehensive description of the ways in which synchronous home digital health solutions are used to care for children with special health care needs and support for their families is not yet documented.

Purpose and Objectives. The purpose of this review is to summarize the current body of literature in order to describe how synchronous digital health technologies are used in the care of children with special health care needs and their families and to provide practical information for health care decision makers, considering digital health program implementation or expansion.

Methods

Scoping Review Phases. A scoping review was undertaken to allow for examination of the breadth of research activity on the design of digital health interventions for children with special health care needs, implementation, uptake, and evaluation of these programs as well as health care provider and family involvement in digital health solutions. Levac and colleagues' [22] revision of Arksey and O'Malley's [23] original methodology was used to conduct this work in five phases: (1) identifying the research question; (2) identifying relevant studies; (3) study selection; (4) charting the data; and (5) collating, summarizing, and reporting the results.

Search Strategy. The search strategy was designed to capture a wide breadth of literature related to the research question, irrespective of study design. We included any type of article, book, dissertation, or report describing the use of synchronous digital health technologies to provide direct care to children with special health care needs or aimed at parents or caregivers with the intention of affecting outcomes in children. With the assistance of a librarian, a comprehensive search of the MEDLINE, CINAHL, and EMBASE databases was conducted by the first author (MB). Subject headings and keywords were used to locate articles describing the use of digital health in home settings for pediatric populations. The indexes of four key journals were also hand-searched for relevant articles. The initial literature search was run on June 30, 2018, with no date, age, or geographical limits set in order to increase the breadth of results. During the screening and data extraction phases, reference lists of highly relevant studies and reviews were scanned, and additional studies were screened for inclusion.

Inclusion and Exclusion Criteria and the Review Process. Inclusion was based on four criteria: (1) the population of interest was children (<18 years) or children's caregivers; (2) the population met the definition of children with special health care needs articulated by Newachek et al [68], i.e., having a chronic physical, behavioral, developmental, or emotional condition in combination with high resource use; (3) care for the child was ongoing and occurring in the home setting; and (4) care for the child was delivered by synchronous digital health. All studies included at least one synchronous intervention element (eg, real-time phone call or video visit.). However, included studies could feature multifaceted interventions that included nonsynchronous components as well. Papers were excluded if they were not published in English, no full text was available, or if they were published prior to 2008 in order to ensure that the interventions described were relevant to stakeholders today. In accordance with scoping review methodology [22,23], no quality assessments were completed on the selected articles.

Screening and Data Extraction. A two-stage screening process using screening forms developed by the team was employed for this review. Prior to screening, a validation test of the title and abstract screening tool was first completed by two authors (MB and NC). Validation screening resulted in 90% agreement, with conflicts resolved through discussion and consensus between authors. After refinement of the screening tool, title and abstract screening was completed by one author (MB). Prior to full-text screening, all authors met to arrive at a consensus on the inclusion criteria. Test screening of three articles per author was performed, and discrepancies were resolved via email communication. Each author was then assigned articles to screen and extract data from using a standardized survey template. Authors were in frequent communication during the screening process, and weekly emails with updates, group questions, and discrepancies were circulated to ensure consistency.

Analysis

Frameworks Used. Our interest in providing decision makers with relevant information related to digital health program implementation or expansion prompted us to extract and analyze practical considerations of these applications. To this end, we analyzed digital health intervention characteristics, end-user involvement (patients, families, and health care providers) in digital health intervention design, and barriers to implementation. Data extracted from relevant articles were downloaded into Excel (Microsoft Corporation, Redmond, Washington) files and reviewed by research team members. We used two frameworks to guide analysis: Data from feasibility studies are presented using a framework by Bowen and colleagues [24], and end-user involvement in co-design and implementation was evaluated using the Human-Centered Design framework from IDEO [25]. The two frameworks are described briefly below.

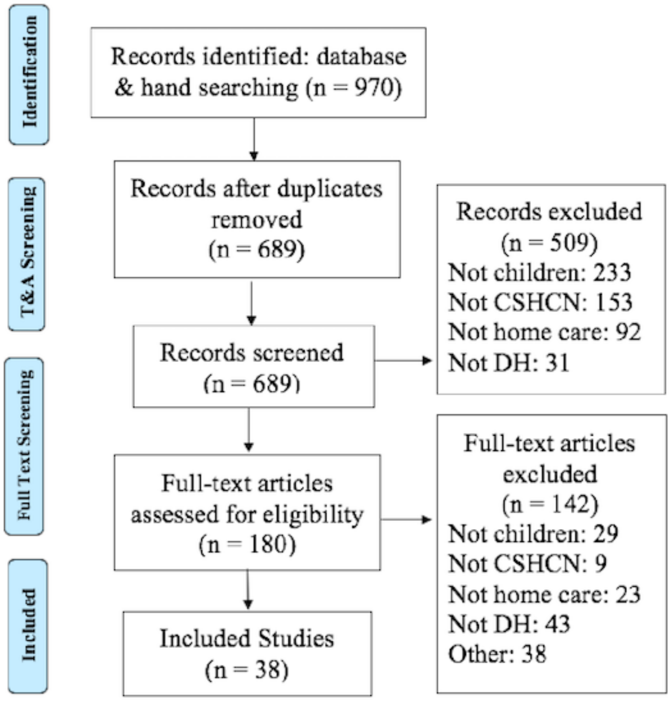
Feasibility. Our use of the term “feasibility” is broad in nature, in keeping with work by Bowen and colleagues [24], suggesting that feasibility trials encompass any study that assists investigators to prepare for a full-scale trial of intervention effectiveness. Using this definition, feasibility outcomes may be grouped into eight general areas of focus, which include acceptability (intervention recipient feedback), demand (intervention use), implementation (success of intervention deployment), practicality (interference with resource use), adaptation (necessary modifications), integration (fit of intervention to context), expansion (intervention applications to new context), and limited-efficacy testing (preliminary outcomes) [24].

Human-Centered Design. We sought out information from all papers related to the inclusion of end users in digital health intervention design and implementation using the IDEO Framework as a guide to this data extraction. Consisting of a six-stage, iterative cycle, the IDEO Framework aims to increase the relevance and appropriateness of interventions [25]. End users are included in the stages of observation (understanding the end user), ideation (brainstorming ideas), prototyping (creating rough intervention mock-ups), user feedback (soliciting input from end-users), iteration (intervention refinement), and implementation (deployment into practice) [25]. In the health care sector, the IDEO Human-Centered Design framework has been used to generate solutions such as helping patients remember to take their prescription medications and communicating messages of support to women recovering from surgical procedures [26]. Finally, consideration was given to issues of digital health implementation in relation to technological, human, and system-level factors.

Results

Numbers, Sources, and Types of Papers. Results of the screening process and overall yield of papers are presented in Figure 1. Of the 38 papers included in the review, as shown in Table 1, 50% originated in the United States—an expected result, given the size and population base. Eleven articles originated in Australia, where the use of digital health may represent a solution to timely care delivery for the country's large rural and remote population.

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.



CSHCN: children with special health care needs
DH: digital health
T&A: title and abstract

Table 1. Yield of papers by country of origin.

Country of origin	Number of papers	References
United States	19	[15-17,19,27-41]
Australia	11	[7,14,42-50]
United Kingdom	3	[51-53]
Germany	1	[54]
Israel	1	[55]
The Netherlands	1	[56]
New Zealand	1	[57]
Scotland	1	[58]

Table 2 depicts the variation in study design, as reported by the authors. The majority of the papers reported on evaluation of digital health initiatives through feasibility studies (n=12), program evaluations (n=8), randomized controlled (n=6), nonrandomized controlled trial (n=3), mixed methods (n=1), and cohort studies (n=1).

Table 2. Yield of papers by stated research method (N=38).

Research method	**Number of papers**	**References**
Feasibility studies (n=12)	12	[29,30,42,44-46,48,50,52,55-57]
Program evaluation (n=8)	8	[7,15,28,32,37,39,47,49]
Randomized controlled trial (n=6)	6	[16,19,31,34,53,54]
Nonrandomized controlled trial (n=3)	3	[27,36,43]
Discussion paper (n=2)	2	[33,58]
Review (n=2)	2	[17,41]
Cost minimization analysis (n=1)	1	[14]

Descriptive (n=1)	1	[35]
Mixed methods (n=1)	1	[51]
Cohort (n=1)	1	[40]
Qualitative (n=1)	1	[38]

Studies Reporting on Digital Health Interventions. A major focus of this review was on empirical studies that evaluated the use of digital health in caring for children and families. A large number of the empirical studies included were feasibility trials, leading us to report these separately from full-scale studies. Here, we first describe feasibility trials and then studies that used digital health interventions to provide direct care to children with special health care needs (such as employing video consultations for physical assessments), followed by interventions aimed at supporting families to care for children at home. Where possible, we have included information on published statistical results; however, many studies were performed with small samples, and therefore, the results were not analyzed for statistical significance. Feasibility Studies. Table 3 provides details of the feasibility studies using digital health interventions. Based on Bowen and colleagues' [24] definition of feasibility studies, we identified 12 articles that reported feasibility-related outcomes. Of note, five of these studies were conducted with hematology/oncology/palliative care populations, whereas the remaining interventions targeted diverse disease groups. One intervention used telephone calls and a blog for communication [57], another used "Skype" and "WhatsApp" for video chats and text messaging [55], and all other studies utilized video formats with either embedded audio or separate telephone audio. There was a wide range of uses for digital health, including assessing acute clinical issues, providing routine care and follow-up, facilitating case conferences, providing psychosocial support, delivering therapy, and monitoring progress and adherence.

Among the included studies, six of the eight dimensions of feasibility were measured, and these outcomes are reported in Table 3. Ten studies looked at *acceptability*, with seven studies measuring family-reported acceptability [30,44-46,52,55,56], and five studies measuring health care provider acceptability [44-46,50,52]. Overall, most families and health care providers reported high satisfaction with digital health interventions and found the equipment to be easy to use. The *demand* for digital health was reported in seven studies by describing the number and length of calls made over the study period [30,42,44,45,48,52,56]. Two of these articles also measured changes in demand over time, with both studies observing an increase in the utilization of digital health over the study period [48,56]. A total of seven studies reported *implementation* and *integration* issues in the form of technical difficulties [29,44-46,50,52,55]. These technical problems were both human related (eg, confusion with using equipment) and technology related (eg, firewall settings, poor internet coverage in remote areas, and bandwidth limitations). In terms of *practicality*, three studies conducted cost analyses [44,45,48], and two studies found that patient and staff availability, workloads, and scheduling influenced how the intervention was implemented [44,55].

Four studies conducted *limited-efficacy testing* of their interventions [30,52,55,57]. Gur and colleagues [55] piloted the use of text messaging and video chats with individuals with cystic fibrosis, but found no statistically significant differences in measured outcomes between the control and intervention groups. The remaining three studies did not have control groups but reported benefits of improved child functional outcomes [57], reduced parental anxiety (median State and Trait Anxiety Inventory score reduction: 6 points; *P*<.05) [52], and prevention of health care visits/admissions [30]. Among all the feasibility studies identified, none adapted a previously established program or reported on outcomes related to the expansion of an already successful intervention. Additionally, four studies led to future publications describing larger-scale interventions [29,30,42,52].

Table 3. Feasibility studies.

Study identifiers: first author, year, country, sample size, reference	**Study purpose: objectives, uses**	**Intervention characteristics: technology used, diagnosis of sample, health care providers**	**Feasibility outcomes: acceptability, adaptation, demand, integration, implementation, expansion, practicality, limited-efficacy testing**
Ludikhuize (2016), Netherlands (n=21) [56]	• Determine feasibility of adding video to phone consultations in order to reduce the need for	• Home computer with webcam or tablet/phone to hemophilia treatment center • Hemophilia	• Acceptability: high satisfaction with video quality. Patients/parents reported adding video led to

	patients to travel long distances • Assessment and follow-up of acute bleeding	• Registered nurse, physician - specialist	better consultations; health care providers reported video helped them assess severity of bleeding. • Demand: 29 phone or video consultations took place over 13 months with 10 of 21 enrolled patients. Use of video consultations increased over the trial period.
Katalinic (2013), Australia (n=14) [50]	• Improve access to services, self-management of health conditions and health education; reduce social isolation for rural and remote patients. • Clinical review, case conferences, education and bereavement follow-up	• Home tablet (iPad) to clinical service • 4 clinical services, including pediatric palliative care • APN[a], physician (specialist), occupational therapist, SW[b]	• Acceptability: high usability ratings; portable and customizable • Implementation: low-cost and little set-up required. Complex licensing and application purchasing; difficulties with customizing implementation. • Technical problems: firewall outages, poor internet coverage, integration

			issues, bandwidth limitations
Bradford (2010), Australia (n=2) [42]	• Describe two case studies illustrating the value of home telemedicine • Clinical management, anticipatory guidance, and psychosocial support	• Computer and webcam (video only) and phone (audio) to telehealth center • Palliative care • Registered nurse, physician (specialist), “hospital clown doctors”	• Demand: case 1 had 37 calls lasting 10-20 minutes over 7 months (23 with Clown doctors and 15 with specialist team). Case 2 had one 45-minute call.
Bensink (2009), Australia (n=11) [45]	• Determine acceptability of videotelephony for families receiving pediatric palliative care. • Add video to existing telephone support provided by specialist nurses in the hospital to regional and remote families.	• Home computer with webcam (video) and telephone (audio), linked to a computer, webcam, audio-conferencing system in the hospital. • Palliative care • Specialist registered nurse, physician (specialist), SW	• Acceptability: 92% participant consent rate; high nurse satisfaction with video and audio quality. • Demand: 25 calls with 7 of the 11 consenting families. • Implementation: Technical problems were human related (*n*=3) and technology related (n=1). • Practicality: cost analysis reported.
Bensink (2008), Australia (n=8) [44]	• Test the feasibility of providing videotelephone-based discharge	• Home computer with webcam (video) and home or mobile phone (audio)	• Acceptability: high family satisfaction with service; high nurse

	support to families with a child newly diagnosed with cancer. • Provide practical, emotional, and symptom support to families.	• Oncology • APN, SW	satisfaction with audio and video quality. • Demand: 20 calls were made with 7 families over a 3-month period, totaling 400 minutes. • Implementation: problems with video were human related (n=1) and technical (n=2). • Practicality: calls required organization around ward workflows.
Gur (2017), Israel (n=18) [55]	• Assess the feasibility of using WhatsApp and Skype to improve treatment adherence by enhancing communications between patients/families and health care providers. • Evaluation and encouragement of treatment adherence, addressing barriers to adherence.	• Text messaging (WhatsApp) and video (Skype) • CF^{c} • Registered nurse, physician, physiotherapist, dietician, psychologist, SW	• Acceptability: patients were very satisfied with the intervention. • Practicality: scheduling difficulties. • Integration: technical issues with wireless internet in some remote areas. • Limited-efficacy testing: No difference in CF-related self-rated health, CF-specific knowledge, treatment

			adherence, or patient-rated relations with their teams between groups.
Casavant (2014), US (n=14) [30]	• Investigate whether telemedicine is feasible, affects confidence of families in clinical management, and supports clinical decision-making. • Routine health care visits, follow-up of clinical problems, and urgent assessment when home visit not possible.	• Family's existing computer with webcam to study team • Children with chronic respiratory insufficiency on home ventilation • Physician (specialist), respiratory therapist, APN, SW, program administrator	• Acceptability: families reported intervention ease of use, high audio and video quality, and no added costs. Families perceived health care providers were better able to assess their child and received better overall clinical management compared to phone • Demand: 27 video conferences with 14 families over 9 months; 15 calls were for routine care, 10 for follow-up of specific issues, and 2 for acute illness. • Limited-efficacy testing: prevented 23 clinic visits; 3

			emergency department visits, and 1 hospital admission.
Jury (2014), Australia (n=not reported) [48]	• Increase convenience for families, reduce physician travel, provide additional services, conserve physical space, and provide more equitable health care access. • Follow-up, outreach for remote communities.	• Web-based video-consultations • 37 departments at The Royal Children's Hospital in Melbourne have provided video-consultations • Mixed health care provider groups	• Demand: increase in consultations (from 14/month to 49/month); 92% of departments had provided at least one video consultation. • Practicality: 65 billed appointments per month are needed to fund a coordinator. 36% of booked appointments were not billed to Medicare.
Constantinescu (2012), Australia (n=17) [46]	• Provide access to therapy and reduced costs for children and families living in rural and remote areas. • Weekly planning and audio-verbal therapy sessions.	• Computer-based videoconferencing (Skype) • Children with hearing loss • Auditory-verbal therapist	• Acceptability: High parental and therapist satisfaction; parents and therapists reported moderate audio and video quality; parents reported more technical difficulties and less comfort with technology than therapists.

Miyahara (2009), New Zealand (n=7) [57]	- Develop and implement a family-focused intervention program to improve the coordination of children with developmental coordination disorder. - Progress monitoring of developmental coordination disorder.	- Workbook, DVDs, weekly telephone consultations, and a blog - Children with developmental coordination disorder - Physiotherapist	- Acceptability: parents voiced appreciation for the weekly telephone consultations and reported that telephone consultations encouraged program adherence. - Limited-efficacy testing: all families reported improvements in their children's functional motor skills.
Cady (2008), US (n=5) [29]	- Evaluate feasibility of videoconferencing between study office and family homes. - Assessment, management of acute and chronic conditions, dissemination of health information, coordination of services.	- Webcam (supplied) with family's own computer to study nurse - Children with medical complexities - APN	- Acceptability: unscheduled video visits were rated by nurses as providing more information than a telephone call. - Implementation: initial connections failed due to firewall settings—case-by-case resolution needed. - Integration: video quality in

			rural settings was insufficient for clinical assessment.
McCrossan (2008), UK (n=5) [52]	• Investigate the feasibility of videoconferencing using broadband transmission. • Assessment and provision of home support and advice after hospital discharge.	• Twice weekly videoconferences with pulse oximeter for 10 weeks • Complex congenital heart disease • Clinician (not specified)	• Acceptability: “good” to “very good” ratings by health care providers and parents. • Demand: 78 video conferences over a 6-month period with 5 patients. • Implementation: technical problems related to connectivity and video quality occurred in 10 videoconferences (13%). • Limited-efficacy testing: reduction in parental anxiety following video consultations.

[a] APN: advanced practice nurse.
[b] SW: social worker.
[c] CF: cystic fibrosis.

Interventions to Provide Direct Care via Digital Health. Ten articles representing seven studies described the use of digital health with children with special health care needs for the purposes of providing direct patient care or replacing in-person assessments (Table 4). Of these, six articles (four studies) examined digital health interventions for children with medical complexities [7,15,16,19,28,32], two articles (one study) focused on palliative care [14,43], one article focused on asthma [37], and one article focused on children with congenital heart disease [32]. Telephone was an interventional component in all studies; the next most commonly employed technologies were video [16,19,53] and email [32]. The makeup of digital health teams varied between studies: Some interventions were delivered by a single group of practitioners such as registered nurses [7,37] or advanced practice nurses [15,16,19,28], while others involved a multidisciplinary team [14,32,43]. One study did not specify the profession of the consultant involved in the intervention [53].

Studies that examined children with special health care needs–related outcomes had mixed results, while studies that examined family-related outcomes reported mainly positive results. Positive outcomes for children with special health care needs were constituted by parent-reported decreases in hospitalizations and quicker recovery from illness [28], reductions in unplanned hospitalizations (year 1 mean number of unplanned hospitalizations per child: 1.7; year 2 mean number of unplanned hospitalizations per child: 0.8; $P<.007$) [15], reduced health care resource use (37% lower in the video conferencing group compared to the control groups; $P<.05$) [53], and improved asthma severity scores [37]. In contrast, two studies found no change in emergency department visits (18.4% enrolled patients presented to the emergency department per month in 2003 and 15.0% per month in 2006; $P=.41$) or hospital admissions (8.0% of enrolled patients hospitalized per month in 2003 and 7.3% hospitalized per month in 2006; *P*=.67) [7], and no significant differences in health-related quality of life as measured by the PedsQL based on analysis of variance scores (*F*=0.90; *P*=.41) [16] for children with special health care needs. Family members reported overall high satisfaction scores with digital health interventions, for example, average scores reported were 8.3/10 [7], and 9.3/10 [32]. Parents participating in the intervention arm of a digital health study rated their satisfaction with their child's personal doctor (*P*=.001) and level of care coordination (*P*=.03) as significantly better than control groups based on the Consumer Assessment of Healthcare Providers and Systems Clinician and Group survey [19], and in an additional study, parents perceived availability of digital health to be "very important" in assisting them in managing their child's condition at home [28]. However, using descriptive analysis, Bradford and colleagues [43] found no change in caregiver quality of life in parents of children receiving palliative care via digital health.

Table 4. Interventions to provide direct patient care via digital health.

Study identifiers: first author, year, country, sample size, reference	**Study purpose: objectives**	**Intervention components: technology used, patient population, intervention, health care providers**	**Reported or perceived outcomes**

Graham (2017), US (n=320) [32]	• Describe the utilization and satisfaction of a program with 24/7 family-driven access to health care teams with the aim of providing comprehensive, individually tailored care to children with CRI[a]	• Telephone and email • Children with CRI • Home and clinic visits, care coordination, and ongoing access to physicians • Physician (specialist), respiratory therapist, APN[b], SW[c], program administrator	• SO[d]: Telephone calls accounted for 40%-50% of patient encounters over a 3-year study period, but telemedicine only accounted for 0.3%-1.1% of all visits. Average numbers of encounters per patient per year increased over the study period (increase mainly attributable to telephone and email communication); decrease in in-person visits over study period. • FO[e]: Family satisfaction rating of intervention was 9.3/10.

Cady (2014), US (n=27) [28] and Cady (2009), US (n=43) [15]	• Describe the attributes and effects of an APN-administered care coordination program for children with medical complexities and their families	• Telephone • Children with moderate/high intensity health care needs • Case management and care coordination • Primary care provider, APN, RN[f] coordinator, physician (specialist), support staff	• PO[g]: ≥80% of parents perceived their child to be hospitalized less frequently and recover from illness faster compared to before the program [28]. • SO: Over 3 years, the number of care coordination episodes tripled, with significant increase between years 1 and 2 (*P*<.001) [28]; 48% of episodes were initiated for acute and chronic condition management [28]; statistically significant reduction in unplanned hospitalizations between years 1 and 2 (*P*<.007), with stable rates of planned hospitalizations (*P*=.14) [15] • FO: 80% of parents were more comfortable being discharged home from the hospital [28].

Looman (2015), US, (n=148) [19] and Looman (2018), US (n=163) [16]	- Examine the effects of adding a high-intensity, APN-delivered digital health care coordination intervention within an existing medical home model	- Telephone or video - Children with medical complexities and their families - High-intensity care coordination APNs	- FO: Telephone group had significantly higher satisfaction scores on the global health care rating category (*P*<.05) and the health care provider communication measure (*P*<.01) compared to the control group [19]; parents rated care coordination and children's personal doctors as significantly better in both the video and telephone intervention groups, compared to the control group (*P*<.05) [19]. Intervention did not significantly improve child health-related quality of life or disease burden on family (all *P*>.05) [16].
Sutton (2008), Australia (n=220) [7]	- Determine if continuous mobile phone access to ED^h	- Telephone - Children with medical complexities	- FO: Family satisfaction with the program was 8.3/10.

	RNs can increase families' capacities to manage care of child at home and decrease ED visits and ED length of stay	• Enrollment in a program with access to advice and rapid emergency department care • ED RNs with extensive triage and resuscitation experience	• SO: Phone calls increased from an average of 0.24 calls/participant in 2003 to 0.3 calls/participant in 2006, 60% of which were after hours; no significant difference in the number of ED presentations as a percentage of enrolled patients (*P*=.41), number of hospital admissions as a percentage of enrolled patients (*P*=.67), or hospital admission rates after ED presentation (*P*=.70). Approximate cost of the program/child was AU $750 (£292)/year.

Bradford (2014), Australia (n=not reported) [14] and Bradford (2012), Australia (n=14) [43]	• Measure the effects of a home digital health program for pediatric palliative care consultations on caregiver quality of life. Compare in-person with video palliative care consultations	• Telephone and video • Children in palliative care • Specialist pediatric palliative care home video consultations to advise on symptom management, care planning, and emotional support. • RN consultant, physician (specialist), project officer	• FO: Descriptive analysis showed no differences in caregiver quality-of-life scores between intervention and control groups [43]. • SO: digital health intervention saves AU 244/year to AU $7598/year compared to outpatient or home visit appointments requiring road-only travel. Digital health intervention saves AU $23,758/year to AU $45,925/year compared to outpatient or home visit appointments requiring air travel [14].
Nelson (2009), US, (n=not reported) [37]	• Describe a severity-based nurse-administered asthma management protocol administered to children/families	• Telephone • Children with asthma • Access to a nurse-staffed call center after hours, weekends, and holidays for care advice and	• PO: Urgent calls had improved severity scores at follow-up; 28% of patients recommended home treatment were referred to ED at follow-up.

	at home via telephone	treatment recommendation - RNs	- FO: 95% parents reported implementing recommended home treatments.
McCrossan (2012), UK (n=83) [53]	- Evaluate a digital health intervention for clinical utility and intervention quality, and determine impacts on health care resource use	- Telephone or video - Children with congenital heart disease - Video or telephone consultations 1-2 times per week were conducted to assess patients with congenital heart disease and address parents' questions. - Clinician (not specified)	- PO: Probability of being admitted to hospital was significantly less in the video group compared with the telephone and control groups (*P*=.004). - FO: Parents reported video consultations were superior to telephone consultations with regard to facilitating communication and overall benefit (*P*=.001). - SO: Video consultation group used 37% fewer health care resources than either telephone or usual care groups (*P*<.001). - HPO[i]: Health care providers significantly more likely to report they could address parents'

			concerns in video versus telephone groups (*P*=.01).

[a]CRI:. chronic respiratory insufficiency
[b]APN: advanced practice nurse.
[c]SW: social worker.
[d]SO: system outcomes.
[e]FO: family outcomes.
[f]RN: registered nurse.
[g]PO: patient outcomes.
[h]ED: emergency department.
[i]HPO: health care provider outcomes.

Interventions to Teach and Support Parents and Families. Seven papers described digital health interventions intended to train or provide support to parents of children with special health care needs (Table 5). Four of these papers involved parents of children with autism spectrum disorder [27,36,39,40], two papers were focused on asthma [31,34], and one was focused on a mental health issue [54]. In four studies, behavior consultants or therapists used video to train parents of children with autism spectrum disorders to use autism specific interventions including applied behavioral analysis [27,36,39,40]. Reported outcomes of these interventions include reduction in problem behavior [36,39] and gains in communication skills for children [27]. For example, Lindgren and colleagues [36] found a mean reduction in problem behavior of over 90% for children with autism treated by specialists in their homes (mean reduction: 95.76%), by telehealth in a clinic setting (mean reduction: 91.00%), and via telehealth in their homes (mean reduction: 97.27%). Between-group differences based on analysis of variance scores were significant (*P*=.07).

Two papers used telephone consultation to support and train parents of children with asthma [31,34], with mixed outcomes reported. Neither study reported any benefit in patient outcomes: Gustafson and colleagues [34] found no difference in medication adherence (*P*=0.76) or number of symptom-free days for children (*P*>.99), while Garbutt and colleagues [31] found no improvements in either children's quality of life as measured by the Pediatric Asthma Quality of Life Questionnaire (between group difference: –0.17; 95% CI −0.47 to 0.12) or number of urgent events per year (between group difference: 1.15; 95% CI 0.82-1.61). However, at the family level, they reported that parental quality of life (measured using the Pediatric Asthma Caregiver's Quality of Life Questionnaire) improved with an asthma coaching program (between-group difference 0.38; CI 0.14-0.63).

Kierfeld and colleagues [54] used a telephone intervention with minimal therapist contact to train parents of children with externalizing problem behaviors. Results included improvements in the treatment group in problem behaviors, as measured by analysis of variance ($F_{1,44}$=21.14, *P*<.001, d_{diff}=1.22), parenting strategies ($F_{1,43}$=9.43, *P*=.002, d_{diff}=0.92), and parenting-related strains ($F_{1,43}$=12.28, *P*<.001, d_{diff}=1.03) [54].

Table 5. Interventions to train or support parents to deliver care (n=7).

Study identifiers: first author, year, country, sample size, reference	Study purpose: objectives	Intervention components: technology used patient population intervention health care providers	Reported or perceived outcomes

Lindgren (2016), US (n=107) [36]	- Determine whether challenging behavior in children with autism can be treated successfully at lower cost by using telehealth to train parents to implement applied behavior analysis	- Video (Skype) through the telehealth center - Parents of children with autism spectrum disorder - Weekly 60 minutes sessions where parents were coached to perform functional analysis and functional communication training - Behavior analysts or advanced graduate students	- PO[a]: reduction in problem behavior achieved but no different than traditional method (*P*=.74). - SO[b]: reduction of costs related to treatment compared to in-home therapy (for staff salaries and travel, facilities, and family costs including telehealth equipment, mileage, and time) (*P*<.01).
Suess (2014), US, (n=parents of 3 children) [39]	- Evaluate the fidelity with which parents of children with autism spectrum disorders implemented treatment procedures and the types of fidelity errors they made during coached and independent trials	- Video and Skype connection with telehealth center - Parents of children with autism spectrum disorder - Two sessions of didactic training, parent manual, weekly remote consultation, while parents implemented Functional Communication Training procedures - Behavioral consultant (psychology doctoral student experienced in behavior assessments and treatments)	- PO: all children showed substantial reductions in problem behavior during the final treatment trials and especially during the coached trials. - FO[c]: no consistent differences present in measurements of intervention implementation fidelity by parents across coached and independent trials.

Vismara (2013), US (n=8 families) [40]	• Teach parents to implement autism-specific interventions	• Video and self-guided website • Parents of children with autism spectrum disorder • Weekly 1.5-hour parent coaching sessions for 12 weeks with 3-month follow-up • Therapist with extensive training	• PO: overall improvement in rates of functional verbal utterances and nonverbal joint attention initiations, increased production and comprehension of words and gestures. • FO: steady gains in parental intervention skills, engagement style, and fidelity of intervention implementation.
Baharav (2010), US (n=2) [27]	• Assess the use of technology and telepractice as a tool for coaching parents of children with autism spectrum disorders.	• Home laptop with Web camera and health care provider laptop • Parents of children with autism spectrum disorder • Weekly 50-minute home-based and 50-minute clinic sessions over 6 weeks • Speech and language therapists	• PO: Gains in some communication and interaction skills. • FO: Parents report comfort with technology, willingness to continue to practicing strategies to deliver care to their child at home, and agree home services as valuable as those delivered by healthcare providers and would recommend to other patients
Gustafson (2012), US (n=301 parent-child dyads) [34]	• Support and train parents and improve asthma control and medication adherence.	• Telephone • Parents of children with asthma • Electronic health intervention with interactive tools and tailored content and	• PO: No significant difference in symptom-free days (*P>.99*), or medication adherence (*P*=.76) between groups.

		monthly support from nurse case manager	
Garbutt (2010), US (n=362) [31]	- Coach parents and children with asthma to improve disease-related quality of life and reduce incidence of asthma episodes requiring urgent care.	- Telephone from call center - Parents of children with asthma - 12-month coaching program to provide education and support - Call center RNs[d] with pediatric and asthma telephone care experience	- PO: No change in children's quality of life (95% CI −0.47 to 0.12) or number of urgent events per year (1.15; 95% CI 0.82 to 1.61). - FO: Significant improvement in parental quality of life with coaching program compared to control group (difference: 0.38; 95% CI 0.14-0.63). - SO: no change in number of urgent events per year (difference: 1.15; 95% CI 0.82-1.61)
Kierfeld (2013), Germany (n=48 families) [54]	- Support and train parents of children with externalizing problem behavior to administer interventions with minimal therapist contact	- Telephone - Parents of children with externalizing problem behavior - Self-help book and weekly phone calls (average 20 min) to enhance motivation by reviewing key concepts covered in the self-help book - Child psychologist trained and supervised by senior child psychologist	- PO: Improvements in parent-reported externalizing behaviors ($F_{1,44}$=21.14, *P*<.001, d_{diff}=1.22), and internalizing child problem behavior ($F_{1,44}$=13.52, *P*<.001, d_{diff}=1.01) - FO: Improvements in problem parenting strategies ($F_{1,43}$=9.43, *P*=.002, d_{diff}=0.92, and parenting-related strains ($F_{1,43}$=12.28, *P*<.001, d_{diff}=1.03).

[a] PO: patient outcomes.

[b] SO: system outcomes.

[c] FO: family outcomes.

^{d}RN: registered nurse.

Family and Health Care Provider Involvement in Design of Digital Health Interventions. Across the body of included literature, there were few studies that explicitly included families and health care providers (intervention end-users) in the design and implementation of digital health interventions. However, a few key examples showcased end-user involvement, most commonly, in the early stages of intervention design such as the *observation* or *ideation* phases, as well as by garnering *user feedback*. In one study by Miyahara and colleagues [57], the researchers actively involved families in the development, testing, and refinement of the intervention (*feedback* and *iteration*). An iterative process of two-way communication between the researchers and participants was used to evaluate and refine the intervention (a set of digital versatile discs, a workbook, and a website) throughout the study [57]. Authors reported that the impacts of end-user involvement increased participation in interventional components as well as the development of educational materials that were acceptable and useful to parents. Cady and colleagues [29] conducted a survey prior to initiating a videoconferencing intervention to find out what types of technologies were available to families (*observation*). Results of the survey supported that most families already had adequate home technology to support videoconferencing; however, apparent survey response bias led the researches to caution of a potential “digital divide” in access to technology between Caucasian and minority populations [29]. Finally, Sutton’s group [7] engaged in a formal parent survey and the collection of anecdotal feedback from parents, health care providers, and subspecialty staff about the current care model, which spurred the development of the intervention (*observation*). Researchers then developed a study advisory group, consisting of key stakeholders such as parents and a variety of health care providers (*ideation*). Although the exact responsibilities of the advisory group are unclear, the inclusion of an end-user advisory group can lend valuable insights into intervention content and structure, making interventions more user-friendly and feasible to implement [59].

Factors Affecting Implementation of Digital Health Technologies. In addition to implementation challenges reported in the feasibility studies section, we also examined included studies for factors that may impact implementation. These factors, which we categorized as *technological, human,* or *system*, stem from family and health care provider perceptions as well as lessons learned by the researchers.

Technological Factors. Many studies reported encountering technical issues, which affected the implementation and acceptance of digital health interventions if the quality of videoconferencing or health care provider workflow patterns are disrupted [29,50]. For example, a barrier to videoconferencing was the limited availability of devices and broadband internet [56]. To overcome barriers to access, some interventions supplied equipment or internet services to families in varying capacities such as webcams, software packages, and computers on loan from the study with prepaid wireless connections [16,19,42,45,50,52,53,56]. These practical considerations are vital to acknowledge and plan for prior to digital health intervention deployment.

Human Factors. In general, patients, families, and providers were satisfied with digital health interventions and were open to learning how to use new technologies if they thought it would save them time [50]. However, digital health was not always appropriate, depending on the clinical use case. For example, Constantinescu [46] reported that therapists had difficulty engaging with younger children with hearing loss during videoconferencing appointments. Additional human factor barriers noted by Edirippulige and colleagues [47] were that social workers preferred in-person appointments to facilitate a personal connection with patients, and Seuss' team [39] hypothesized that some parents may require face-to-face demonstrations of clinical skills for optimal treatment fidelity. With regard to human-technology interfaces, Casavant and colleagues [30] reported that the availability of real-time visual images was an important factor in decision making for health care providers treating children on home ventilator support, and a lack of visuals was cited as a concern for health care providers in two phone-only interventions [35,51]. Additionally, some studies cited barriers of scheduling, time constraints, and workload for both patients/families and health care providers [16,44,47,55,57]. Family commitment (i.e., history of good attendance in clinic) and health care provider engagement were crucial for successful implementation of the digital health interventions, with health care provider engagement being facilitated by strong leadership and rapid resolution of problems [49,50].

System Factors. Several studies reported system factor barriers to digital health related to funding, such as difficulties in obtaining consent to bill and restrictions on who could be reimbursed for delivering digital health interventions [31,48]. Additionally, connectivity issues [29,44,50,52,55] and device interoperability between systems [29,50] were additional barriers. System factors that facilitated implementation include detailed planning, high-level support, standardization and education, and adequate administrative support [49,50].

Discussion

Principal Findings. In this scoping review, we sought to synthesize the current available evidence on the use of digital health to care for children with special health care needs and their families. Our results draw attention to gaps evident in the knowledge base in this area, including the few full-scale randomized trials testing such interventions, and the dearth of literature discussing the involvement of end-users in intervention design and implementation. Despite national studies such as the SPROUT survey in the United States reporting 22 dedicated pediatric digital health programs, and an additional 29 programs providing digital health to mixed adult and pediatric populations [18], published research on such programs remains scarce.

Practical Considerations for Implementing Digital Health Technologies. This scoping review of the literature has demonstrated that digital health technologies have the potential to provide high-quality, effective interventions for children with special health care needs and their families in the convenience of their homes. Recent advances and widespread use of technology (eg, smartphones and tablets) have created an international landscape ready for implementation of digital health interventions. However, despite the pervasiveness of user-friendly technology, barriers to implementation continue to exist. Health care providers and health care administrators should consider the following implications when thinking about how to successfully implement digital health interventions.

Many of the included studies report the use of a digital health center or related infrastructure support, which may come with benefits such as having digital health–trained health care providers, dedicated technical support, and digital health–focused resources. Jury et al [49] reported the use of a website that contains staff and patient resources with how-to guides and troubleshooting material. However, other studies have demonstrated the effectiveness of interventions delivered by independent health care providers. For example, studies by Vismara and colleagues [40] and Baharav and Reiser [27] have shown therapeutic outcomes associated with interventions delivered by health care providers from their office computers. Although many studies reported technical issues such as connectivity or interoperability conflicts, it was often unclear whether dedicated ongoing technical support was available. When considering implementing digital health solutions, it is important to be aware of the type of infrastructure available, how technical support will be provided, and what effect program implementation will have on health care provider workflows. Explicit reporting of these vital factors in published journal articles or reports may assist in moving the field of digital health forward and achieving optimal digital health intervention integration into health systems.

In addition, some health care providers and administrators may be able to capitalize on available funding for the implementation of digital health interventions [49], which can assist in rapidly implementing or scaling a digital health program. To increase the uptake of digital health, decision makers should consider that funding must be available not only to set up infrastructure, but also to inform health care providers and families of digital health intervention availability on an ongoing basis, and to assist in day-to-day operational management of the program. For example, Jury et al [49] reported using a program manager and telehealth “champions” to facilitate implementation, promoting digital health to families, and referring general practitioners. The demand created by these promotional strategies may well neutralize the added costs of personnel involved in the digital health program in for-profit situations.

Finally, care equity deserves special consideration when implementing digital health interventions. For example, in rural and remote areas, poor internet connectivity may prove to be a significant challenge for digital health programs to overcome [50, 55].

One method that was used when bandwidth was insufficient for high-quality video was to utilize the Internet for video, while using the phone line for audio [42,44,45]. Using this strategy, fluctuations in picture quality were mitigated by clear and reliable audio components, and the call was not entirely interrupted. An additional care equity point to consider when implementing digital health programs is families' access to devices that are required for using digital health. Although some studies in this review excluded participants who did not have access to the required devices or sufficient internet speeds, others provided hardware or financial support to install high-speed internet. By excluding those who do not have access to devices or adequate internet, health care systems may be further marginalizing underresourced populations and exacerbate the "digital divide." Crucial to the successful implementation of digital health interventions is finding solutions to mitigate barriers to access. Modern technology options such as tablets are cost-efficient and easy to use, albeit reliant on Web-based software. Conversely, videoconferencing units that utilize phone lines are more expensive and require more technical support but may be more suitable for remote regions. Regardless of the types of devices and connection used, having requisite supports in place to rapidly overcome technical and user-related barriers in the provision of digital health is essential for intervention uptake.

Teaching Parents. A promising area of results of this review is the use of digital health to teach and support parents to deliver care to children with special health care needs. Across a multitude of clinical specialties, chronic disease self-management is heralded as promoting improved patient engagement and collaborative care [60]. For children with chronic conditions, self-management necessitates the involvement of parents or other caregivers to deliver requisite proactive planning, disease surveillance, and health maintenance. Lozano and Houtrow [61] highlight the need for children and youth with chronic conditions to participate in shared care management where possible while also allowing appropriate amounts of autonomy. The positive impacts of parental training noted in this review, particularly in studies examining the parental delivery of autism therapies, could have important implications for improving clinical outcomes and conserving health care resources.

Co-Design of Digital Health Interventions. Literature in the field of intervention co-design reports that the concerns of health care practitioners and patients are often fundamentally different and that aligning program goals is a prerequisite for the successful implementation of patient-centered digital health services [62]. No studies included in this review made explicit use of co-design principles in intervention development using an established framework or theory, although a small number did incorporate end-user feedback at various stages. Few of the feasibility studies identified moved on to larger trials, supporting that uptake and integration of digital health interventions into usual clinical workflows remains problematic. Mounting evidence suggests that patient-orientated research—the inclusion of end-users in co-design and coproduction of interventions—assists in the generation of ideas and products that are feasible, appropriate, and of value to end-users [63,64]. Interventions designed to meet the requirements of end-users are associated with improved intervention acceptance, reduced user errors, and an enhanced reputation [64]. Evidence from other populations validates these points. For example, a co-design study of a flexible hip protector garment for older adults in care facilities resulted in high levels of interest from residents and support from site managers [65]. In another study, a codeveloped tool designed to improve the communication about heart failure trajectory and palliative care resulted in nurses reporting increased knowledge, improved confidence, and enhanced skills in end-of-life conversations [66]. Future work in digital health for children with special health care needs should incorporate co-design principles into the development of digital health interventions in order to increase user acceptance and intervention integration.

Limitations of this Review. Although we attempted to be comprehensive in our search, missed studies may have limited the scope of this review. To be as comprehensive as possible, we followed a rigorous process using a predefined scoping methodology framework and assistance from an experienced librarian to develop our search strategy. We hand-searched reference lists of included articles and relevant journal databases to enhance the breadth of our search. However, we suspect that some organizations using digital health to care for children with special health care needs may be doing so without publishing their results. We did not contact experts in the field to inquire about known ongoing projects in this capacity; therefore, there is the possibility of some projects were missed.

Our team used an ongoing communication strategy, validation screening, and predefined study inclusion criteria and data extraction forms, contributing to the rigor of our data collection and extraction processes. However, due to time and resource constraints, we did not double screen the included studies. Thus, the potential for inappropriately including or excluding studies exists.

Additionally, we classified studies by methodology to the best of our ability, taking cues from authors' own descriptions or stated study type. However, some studies had methodologies that were ambiguous or not well detailed, leading to difficulty in classifying them. We suggest that authors publishing future work on digital health intervention implementation use clear language and reference a well-developed model for intervention stage such as the NIH Stage Model for Behavioral Intervention Development [67].

Finally, as per scoping review methodology, no quality appraisal was conducted on the included studies. The intent of our review was a broad overview of the literature; thus, omitting a quality appraisal was appropriate, as we did not wish to exclude smaller or less rigorously conducted studies. However, because of this, we would caution readers who are intending to use the evidence from this review to conduct their own quality appraisal of individual studies. Although we have preidentified articles for a variety of children with special health care needs, the utilization of high-quality evidence in practice is of equal importance.

Conclusions

The use of digital health to care for children with special health care needs presents an opportunity to leverage the capacity of technology to connect patients and their families to much-needed care from expert health care providers while avoiding the expenses and potential harms of the hospital-based care system. This review has summarized the use of digital health in providing care at home to children with special health care needs and their families while also highlighting challenges within the field. To move work in this important area forward, we strongly recommend the use of co-design and coproduction principles to involve end-users in meaningful ways in the design and implementation of digital health interventions. Additionally, much of the work in this area starts and ends with pilot and feasibility studies. Researchers should consider and integrate lessons learned from feasibility studies into large-scale interventions to operationalize programs with proven feasibility to better serve children with special health care needs and their families.

Conflicts of Interest

None declared.

Abbreviations

APN: advanced practice nurse
CF: cystic fibrosis
CRI:. chronic respiratory insufficiency
ED: emergency department
FO: family outcomes
HPO: health care provider outcomes
PO: patient outcomes
RN: registered nurse
SO: system outcomes
SW: social worker

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Summary of Updates to the Literature

The literature search for the scoping review published in the preceding chapter of this thesis was run on June 30, 2018 and as such, it was felt appropriate to include a brief summary of updates to the literature, as follows. An update to this literature search was run on December 3, 2021 following the search strategy methods described in Chapter 2. Subject headings and key words related to use of digital health in caring for pediatric medically fragile populations in MEDLINE, CINAHL, and EMBASE databases from 2018-2021 returned 401 relevant citations which were imported into Covidence review software. Title and abstract screening was performed using inclusion and exclusion criteria specified in Chapter 2 to retain 58 manuscripts, which were moved to full text review. 11 manuscripts representing ten studies were ultimately retained and included in this summary. A brief overview of included manuscripts is included below.

Similar to the distribution of manuscripts in the 2018 scoping review, six of ten studies conducted were from the United States (Crossen et al., 2020; Dykes et al., 2019; Jaclyn et al., 2021; Notario et al., 2019; Raphael et al., 2019; Wang et al., 2019). The remainder of studies originated from Australia (Benz et al., 2020), Canada (Amin et al., 2021), Italy (Onofri et al., 2021), and Spain (Munoz-Bonet, Lopez-Prats, Flor-Macian, Cantavella, Bonet, et al., 2020; Munoz-Bonet, Lopez-Prats, Flor-Macian, Cantavella, Dominguez, et al., 2020). All included studies were either pilot/feasibility programs, designed to test the utility of digital health interventions before full-scale implementation, or studies that aimed to deliver care to medically fragile children using digital health methods. In contrast to the findings of the 2018 scoping review, no included studies had a primary aim of teaching parents to deliver care via digital health. A large number of included studies were undertaken with CMC populations (Amin et al., 2021; Munoz-Bonet, Lopez-Prats, Flor-Macian, Cantavella, Bonet, et al., 2020; Munoz-Bonet, Lopez-Prats, Flor-Macian, Cantavella, Dominguez, et al., 2020; Notario et al., 2019; Onofri et al., 2021), while the remainder were undertaken with cystic fibrosis patients (Benz et al., 2020; Jaclyn et al., 2021), patients on home parenteral nutrition (Raphael et al., 2019), with nephrotic syndrome (Wang et al., 2019), heart transplant patients (Dykes et al., 2019), or patients with uncontrolled Type I diabetes (Crossen et al., 2020).

In many of these studies, authors cited the COVID-19 pandemic as being a major contributor to initiating digital healthcare with their specified population. All studies were undertaken with populations that were at increased risk of infection and potentially severe complications from respiratory infections due to the fragile nature of their conditions. Care delivered in the home environment was therefore seen as ideal, and in some cases where healthcare centres did not have the capacity to take on more patients (Onofri et al., 2021), delivery of care at home was the only option.

In order to facilitate synchronous home care that could replace in-person care for medically fragile children, many studies incorporated the use of video conferencing to facilitate “virtual home visits” as part of their intervention (Amin et al., 2021; Benz et al., 2020; Crossen et al., 2020; Jaclyn et al., 2021; Munoz-Bonet, Lopez-Prats, Flor-

Macian, Cantavella, Bonet, et al., 2020; Munoz-Bonet, Lopez-Prats, Flor-Macian, Cantavella, Dominguez, et al., 2020; Notario et al., 2019; Onofri et al., 2021; Raphael et al., 2019). However, in this scoping review update, some studies also used more “high-tech” digital health components than seen previously in the 2018 review. For example, one study used remote vital signs monitoring with ventilator setting configuration capabilities (Onofri et al., 2021), while another utilized an application with the ability to utilize mobile cameras for colorimetric analysis of urine test strips for nephrotic syndrome monitoring (Wang et al., 2019). Finally, in a third study, mobile echocardiography equipment was used by parents to monitor left ventricular function in pediatric heart transplant patients (Dykes et al., 2019). These advances in synchronous digital health technology components demonstrate the vast potential of this field to assist professionals and families caring for children with many varied conditions to improve outcomes while accessing comprehensive care at home and avoiding in-person care in some instances.

Finally, positive outcomes were noted in most studies, including acceptability of sound and image quality during digital health use (Notario et al., 2019), estimated cost savings when using digital health to replace some in-person care (Crossen et al., 2020; Notario et al., 2019), and high satisfaction ratings using digital health technologies (Crossen et al., 2020; Jaclyn et al., 2021; Wang et al., 2019). However, similar barriers to accessing and utilizing digital health technologies as were reported in this scoping review update as were reported in the 2018 scoping review. Common barriers encountered include exclusion of participants based on a lack of home WiFi (Notario et al., 2019; Onofri et al., 2021), technical difficulties with video applications and data sharing (Crossen et al., 2020), and a lack of home equipment for remote patient monitoring that led to concerns using digital health technologies to replace in-person care, in some cases (Jaclyn et al., 2021). The barriers reported in this update are common to digital health innovations and represent the intractability of the issues. Careful examination of the technological, human, and contextual factors contributing to these issues may help to tease out root causes so that solutions may be generated and barriers minimized for digital health innovations, going forward.

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Chapter 3

A Generative Co-Design Framework for Healthcare Innovation: Development and Application of an End-User Engagement Framework

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Overview

Chapter 3 in this dissertation consists of a published manuscript detailing the development and application of a methodological framework for engaging end-users in health innovation co-design. In searching for guidance when preparing to co-design our hospital-to-home intervention for CMC (DigiComp Kids), it was discovered that a framework did not exist for engaging end-users in creative health innovation efforts. To this end, this framework was developed, applied, and published to detail the process of co-designing DigiComp Kids and provide guidance for others undertaking creative co-design efforts . Consisting of three phases (Pre-Design, Co-Design, and Post-Design), this seven-step framework argues for employing co-design methods that solicit the voices of health innovation end-users using creative means, so as to encourage 'out-of-the-box' thinking and deep engagement in challenge identification and solution generation. Soliciting these contributions during co-design assisted us in designing DigiComp Kids in a way that prioritized solving the challenges that were identified as most important to end-users.

Abstract

Background: Challenges with the adoption, scale, and spread of health innovations represent significant gaps in the evidence-to-practice cycle. In the health innovation design process, a lack of attention paid to the needs of end-users, and subsequent tailoring of innovations to meet these needs, is a possible reason for this deficit. In the creative field of health innovation, which includes the design of healthcare products, systems (governance and organization mechanisms), and services (delivery mechanisms), a framework for both soliciting the needs of end-users and translating these needs into the design of health innovations is needed.

Methods: To address this gap, our team developed and applied a seven-step methodological framework, called A Generative Co-Design Framework for Healthcare Innovation. This framework was developed by an interdisciplinary team that included patient partners.

Results: This manuscript contributes a framework and applied exemplar for those seeking to engage end-users in the creative process of healthcare innovation. Through the stages of ‘Pre-Design’, ‘Co-Design’, and ‘Post-Design’, we were able to harness the creative insights of end-users, drawing on their experiences to shape a future state of care. Using an expository example of our own work, the DigiComp Kids project, we illustrate the application of each stage of the Framework.

Conclusions: A Generative Co-Design Framework for Healthcare Innovation provides healthcare innovators, applied health science researchers, clinicians, and quality improvement specialists with a guide to eliciting and incorporating the viewpoints of end-users while distilling practical considerations for healthcare innovation and design.

Key Words

End-user engagement, Healthcare innovation, Co-design, Patient and public involvement

Plain English Summary

Background: Continual improvements to health systems, products, and services are necessary for improvements in health. However, many of these improvements are not incorporated into everyday practice. When designing new health systems, products, and services, involving members of the healthcare community and the public with personal healthcare experience can help to make sure that improvements will be useful and relevant to others like them.

Methods: Together with healthcare workers and family members with healthcare experience, we developed and applied a step-by-step guide to involving those with personal experience in the design of health system improvements.

Results: Our guide has three phases— 'Pre-Design', 'Co-Design', and 'Post-Design'. This paper describes each of these phases and illustrates how we applied them to our own project, which is to use virtual healthcare methods to improve care for children with chronic healthcare conditions and their families. In our own work, we found that healthcare workers and family members with personal healthcare experiences were able to use their knowledge and creativity to help us imagine how to improve care for children with chronic healthcare conditions and their families. We have created action items from these family member- and healthcare worker-identified needs, which we will use to shape our virtual healthcare system.

Conclusions: This paper may be useful for those seeking to involve members of the healthcare community and the public in the creation of better healthcare systems, products, and services.

Background

Internationally, efforts to cultivate the inclusion of patient partners in research for the purposes of creating meaningful change in patient-important research outcomes have been driven by funding bodies, patient communities, and government initiatives (1). In support of these growing calls to action, the literature base detailing practical techniques for operationalizing patient partnership in health research is expanding (examples (2-4)). A 2019 systematic review by Greenhalgh and colleagues summarized over 65 frameworks designed to support, evaluate, or report on patient partnerships in health research (5). From these diverse frameworks, a taxonomy of five framework categories emerged, including frameworks that were focused on: power dynamics, priority setting, study processes, reporting, and supporting patient partnerships (5). Concomitant with increasing efforts to include patient partners in the aforementioned research endeavours, the need to include end-users in health innovation efforts is becoming increasingly recognized. This includes engaging patient partners and other stakeholders invested in the outcomes of health innovations in creative health innovation efforts such as the design of healthcare products, systems, and services (6, 7). When designing new health innovations, the value of creativity in the design process cannot be understated. Creativity is defined as the generation of new ideas, while design is a structured process, whereby creative ideas are transformed into specific products, systems, or services – serving as the link between creativity and innovation (8). Environments which encourage and nurture highly creative ideas have been linked to more robust research and development efforts, which in turn drive more successful innovation outputs (8). It is vital that innovation end-users including patients, caregivers, clinicians, and healthcare decision makers are included as partners within these creative innovation efforts, so that innovations may be influenced by end-users' knowledge as 'experts of their experiences' (9), thus shaping health solutions to focus on end-user priorities, ultimately leading to better patient outcomes and greater uptake (10). However, while a multitude of frameworks exist for gathering insight from end-users (e.g. the use of narrative interview techniques in Experience-Based Co-Design), none describe immersing end-users in highly creative environments and guiding them through a creative process of health innovation. Thus, end-user engagement frameworks specific to the field of health innovation and tailored toward creative innovation methodologies are largely absent in the literature. Building on the work of Greenhalgh et al. (5), we argue the need for a sixth category to be added to the taxonomy of patient partnership frameworks, focused on engaging end-users in the creative process of health innovation design. In what follows, we illustrate our search for, and subsequent construction of, an engagement framework for health innovation, using our work, The DigiComp Kids Project, as an expository example.

Methods

Our Project: DigiComp Kids. As a research team committed to engaging patient partners and other end-users in our work, we sought a framework to guide us in involving end-users in our health innovation effort, the DigiComp Kids Project. The aim of the DigiComp Kids Project is to co-design, develop, and test a virtual care program that enables children with medical complexities to receive comprehensive, integrated healthcare at home. A key objective of this project is to leverage digital technology to connect family members to home-based and hospital-based clinicians who care for medically complex children. To do so, we partnered with Ontario Health, Ontario Telemedicine Network (OTN) business unit, with the goal of bringing families and healthcare teams together virtually, in order to deploy a seamless and integrated approach to care at home.

The existing model of care for children with medical complexities and their families at our centre involves family members as well as specialized home-based and hospital-based clinicians providing care independently, but without the means to effectively communicate and operate as one cohesive team. The hospital-based Complex Care Team provides specialized interdisciplinary care via clinic and inpatient services to children with medical complexities and their families, while home-based clinicians provide close monitoring and care at home. Telephone, fax, and email are all used to intermittently communicate among siloed teams when necessary. For example, a family member may telephone a Complex Care Team member to help troubleshoot a problem with a piece of equipment, or a clinician from the Complex Care Team may fax a communication about a medication change to be carried out by a home care clinician. One of the key goals for a new model of care was finding a way to streamline communication and care processes amongst team members.

Our Approach to Co-Design. To accomplish our project aims of integrating care and connecting care teams, we set out to co-design a virtual program that would allow for a seamless care experience for children with medical complexities and their families. Through our co-design process, we aimed to answer the question: What are the optimal processes, features, and workflows for a virtual care intervention to provide integrated home-based care for children with medical complexities? Table 1 (Additional File 1) contains the definitions used in our work for processes, features, and workflows.

From the beginning of the DigiComp Kids Project, our research team agreed that a core value to guide our work would be the engagement of our innovation end-users including patient and family partners, hospital-based and home-based clinicians, and system navigators in co-designing a new virtual care model. In addition, as we aimed to design a new model for healthcare service delivery, we were interested in methods that would accommodate for creative approaches to idea generation. A diverse body of literature has exposed the integral role that creativity has in innovation work, with some citing creativity as the most central component of the process of innovation (11, 12). Within the creative design literature, a focus on generative techniques to solicit design requirements has emerged. Generative techniques aim to map participants' latent needs and desires by allowing them to explore challenges and create alternative future scenarios by solving those challenges (9). These techniques encourage participants to create an artefact, such as a story, about a future state in which present-day challenges are resolved. Through the creation of artefacts, participants are able to tap into their creative minds and express and harness their experiences to solve present day challenges. Generative techniques have been successfully used to gather patient insights in past examples of healthcare service design by allowing participants to imagine 'alternative future scenarios' or situations and contexts that are very different from their current reality (13). By employing generative methodologies with individuals with lived experiences of healthcare challenges through the co-design process, healthcare innovations which are relevant, acceptable, and context-specific may be created.

In searching for an existing model that would guide us in our project, we reviewed the work of Greenhalgh (5) and others (14, 15) to select a suitable framework for including our end-users in creative design work for health innovation. Through our focused literature search, we found that our values of patient partner and stakeholder engagement aligned closely with values guiding three categories of engagement frameworks— Participatory Action Research, Community-Based Participatory Research, and Experience-Based Co-Design.

In Participatory Action Research, participants engage in critically reflective exercises to understand and change systems and situations in which they find themselves (16). Researchers and participants in Participatory Action Research often seek to create more evenly distributed social justice via the actions taken through their work by using experience-based knowledge to change practice (17). In Community-Based Participatory Research, the collaborative work of researchers and laypeople focuses on addressing community-identified needs (18). An equitable relationship between laypeople and researchers ensues, with community members often helping to identify research priorities, as well as the research question and methods (19). The ultimate goal of Community-Based Participatory Research is the generation of information that will benefit the community and support community capacity-building (19). Finally, using Experience-Based Co-Design, patients and staff collaborate with researchers by participating in narrative interviews to detail their experiences with the current healthcare system and services, which are then used as a basis on which to improve future experiences for others (20).

While each of these frameworks provides valuable guidance for involving patient partners and stakeholders in the research process, none speak directly to the role of the creative process of end-users in health innovation. Operationally, we required guidance that specified how to channel deep engagement of end-users in co-design via creative methods, so as to reveal latent needs and generate alternative future scenarios. Our team thus developed and applied a new framework with these specific aims in mind, entitled— A Generative Framework for Healthcare Innovation. The three major stages of this framework (pre-design, co-design, and post-design) were conceptualized after our review of current frameworks revealed none that were suitable for our needs. Using these stages as a starting point, our team began the process of moving through these stages in turn, beginning with pre-design, and iteratively recording and refining the steps taken and operational decisions made in each phase. In this way, the phases of development and application of the framework reciprocally informed each other. In what follows, we describe the end-user engagement philosophy grounding our work, before presenting our seven-step methodological framework.

End-User Involvement in This Study. End-user involvement is integral to the design, conduct, and analysis of the entire DigiComp Kids project, and is reported here according to the GRIPP2 Long Form Checklist (21) (Additional File 2). The central DigiComp Kids project team includes two Family Partners (EMC and SVR, both mothers of medically complex children) who have been involved with the study since its inception. These Family Partners are part of the research team and are remunerated for their time spent on the DigiComp Kids Project, according to recommendations set out by the Strategy for Patient-Oriented Research Networks (22). The aim of including Family Partners within the co-design process as well as more broadly in the entire DigiComp Kids project is to ensure that our research prioritizes the concerns of medically complex children and their families, so that the DigiComp Kids intervention is relevant and useful to this community. Within the larger DigiComp Kids project, Family Partners have assisted in refining the research question, reviewing and contributing to a grant application to support this work, planning and preparing for the co-design day, and guiding the project development from their Steering Committee roles. In the overall project, Family Partnerships are situated at the 'Collaborate' and 'Involve' levels of the Levels of Patient and Researcher Engagement in Health Research, as identified by Manafo and colleagues (23). Within the co-design portion of the project specifically, they have also taken on a dual role as consenting research participants by joining in and facilitating a portion of the co-design session, as well as critically revising both our co-design findings and this manuscript. During these activities, their level of engagement in the research process aligns with the 'Participate' stage (23). Our team (including our Family Partners) chose to specifically separate the roles of our Family Partners into project team members (ongoing) and co-design participants (time-limited) by undertaking a process of informed consent for the co-design portion, in order for information shared through co-design to be protected by the rights afforded to research participants. Family Partners were under no obligation to participate in co-design and were informed that the choice not to participate would not affect their ongoing role as project team members, or their child's medical care.

Results

A Generative Co-Design Framework for Healthcare Innovation, presented here, was designed to be adaptable by healthcare innovators and end-users seeking to change a specific healthcare process or system. The importance of involving end-users in this process is critical— individuals living and working within a specific context have a deep understanding of the challenges they face and the intricacies of the environment in which these challenges are embedded. There exists a gap in the literature between the postulated benefits of health innovations, and the actual outcomes of these innovations when deployed in practice, which often fall short of their predicted benefits (24). In particular, health system transformation via virtual care technology innovations, which is the focus of the DigiComp Kids project, is often undertaken by research teams without adequate attention paid to involvement of end-users in the design of innovations, resulting in a lack of adoption, scale, and spread (24, 25). The complexity of both the health innovations themselves, as well as the environmental context in which they are implemented, results in interdependent human, socioeconomic, cultural, and technological factors that influence the outcomes of health innovation implementation (24).

These complexities have important implications for the implementation effectiveness of newly-developed health innovations, as relationships between humans and their contextual environment into which the innovation is introduced serve as mediating factors in how effective, acceptable, and usable those innovations are found to be (24, 26, 27). Therefore, health innovations developed with closer attention to real-world concerns of end-users will be more likely to be usable and sustainable by clinicians, families, and patients, for improving or maintaining health (24).

A Generative Co-Design Framework for Healthcare Innovation is divided into seven steps within three stages— 1) Pre-Design, consisting of 'Contextual Inquiry' and 'Preparation & Training'; 2) Co-Design, including 'Framing the Issue', 'Generative Design' and 'Sharing Ideas'; and 3) Post-Design, consisting of 'Data Analysis' and 'Requirements Translation'. Each stage is presented as a summary of activities and an example of how the stage was operationalized in the DigiComp Kids project. Figure 1 contains a summary of stages and their flow.

PRE-DESIGN

Summary. The Pre-Design phase of the Generative Co-Design Framework for Healthcare Innovation includes the Contextual Inquiry (Step 1), and Preparation (Step 2). Contextual Inquiry aims to help the research team familiarize themselves with the current state, including the usual practices and processes of the healthcare setting in which co-design is to be implemented. Contextual inquiry may include employing ethnographic research methods such as observing the practice setting, including professionals within the setting and their workflows; conducting informational interviews to gain an understanding of end-user current challenges; or value stream mapping/workflow mapping with healthcare practitioners within the practice setting (28). Shared team understanding of the current state is crucial for a productive co-design experience, and as such, even teams intimately familiar with the practice setting may wish to employ an abbreviated observational field experience, as appropriate. Next, Preparation aims to help future co-design participants and facilitators become acquainted with the project and begin to build rapport as a team. The Preparation phase may include the development and distribution of informational materials related to the project to future co-design participants and recruiting co-design session facilitators to help with co-design activities. Additionally, if co-design will be conducted virtually, testing the virtual system with future co-design participants will ensure connectivity and audiovisual issues are addressed before the co-design sessions are to take place, avoiding delays and frustrations during these sessions. Finally, regular group communication from the research team to co-design participants with informational materials and updates on preparations for co-design may help to build group engagement.

DigiComp Kids Operationalization: Pre-Design.

Step 1: During the Pre-Design phase of DigiComp Kids Co-Design, the lead author (MB) attended outpatient Complex Care Clinic appointments to obtain insights into the day-to-day rituals, habits, and workflows of clinic staff and patients. During these visits, field notes were kept detailing the needs of patients and families coming to clinic, clinic services provided, logistical, personnel, and space requirements for clinic functioning, and potential uses of virtual care technologies to facilitate clinic operations. Our research team (MB, MM, NC, AL) also conducted informal informational interviews with key stakeholders to discuss current state highlights, challenges, and visions for a technology-enabled future. In order to gain an understanding of diverse perspectives, we conducted these consultative meetings with a broad range of individuals, including parents of children with medical complexity, nurses, physicians, allied health professionals, as well as hospital and home-care administrators.

Step 2: In the Preparation phase, the DigiComp Kids research team met to collectively decide on which individuals should be invited to participate in co-design, with the aim of including participants who were representative of a wide variety of stakeholder groups. For the DigiComp Kids project, we selected 11 individuals to participate in our future co-design session who had experience in home and hospital-based care for medically complex children, system navigation, nursing practice support and leadership, as well as parents of medically complex children. After inviting participants to the project, we developed informational materials, including an agenda, a short pre-reading, and an instructional participant guide for the virtual platform to be used for co-design activities. These were distributed to future co-design participants to provide them with a background on the DigiComp Kids project, as well as the specific aims and structure of co-design. We also sent biweekly emails to future co-design participants with updates on project progress to keep them informed as co-design approached. Finally, each individual participant was contacted by the lead author (MB) ahead of the co-design day to gather informed consent for participation in co-design, answer outstanding questions, and conduct a technology test to ensure participants could log on and navigate the virtual platform to be used for co-design without issue.

A facilitation team was selected to assist with conducting synchronous activities during the co-design day, including five small group (CW, KL, CO, SM, CF) and three large group facilitators (MB, NC, MM). All facilitators were technologically savvy and had expertise in either relevant research methods or virtual healthcare design and implementation. Facilitators were briefed on the aims of the DigiComp Kids project and co-design day, and two mock co-design sessions were held with facilitators using the virtual co-design platform to practice the facilitation role before the co-design day.

CO-DESIGN

***Summary*.** Steps three, four, and five of the Generative Co-Design Framework for Healthcare Innovation (Figure 1) comprise the co-design phase, wherein participants and facilitators engage in activities to conceptualize a future state of care. The steps within the co-design phase consist of: Framing the Issue (Step 3), Generative Design Work (Step 4), and Sharing Ideas (Step 5). In the DigiComp Kids project, these steps took place on a single day, however, the timeframe for other projects may vary, according to project needs. Due to the short time frame of a one-day, immersive, co-design event, the preparatory steps taken during pre-design featured prominently during the DigiComp Kids co-design phase. For example, the research team had already developed a deep understanding of the context in which we were working, due to the time spent observing Complex Care Clinic workflows and conducting informational interviews. This context was vital for helping participants to frame the issues discussed during co-design, and to engage deeply with them. Additionally, preparing co-design participants by briefing them on the aims of co-design, providing them with informational materials to become familiar with the DigiComp Kids project, and ensuring technology needed to access the virtual platform was working before attempting to login on Co-Design Day ensured a smooth co-design process.

Co-design work starts by framing the issue to develop a mutual understanding of lived experiences and challenges faced by participants in the current state, as well as a shared vision for the work. Participants willing to share stories of their experiences and obstacles faced in the current state are encouraged to do so, as these stories will help to ground the team in understanding what must change. The research team is encouraged to facilitate conversations with participants around a commitment to improvement (the goals of co-design), and a shared vision for the work (the plan to achieve those goals).

Next, participants and facilitators undertake creative generative design work. Generative techniques aim to both consider explicitly stated needs of participants, as well as to reveal latent needs — those that people are not yet aware of in their conscious minds, and therefore are not always readily expressed in words (29). The rationale behind using generative techniques in relation to co-design is that if simply asked what is needed from a future healthcare system, participants may respond with solutions that improve current issues, but that do not respond to underlying root causes of problems. Root causes are not always readily identifiable— with generative techniques participants may be guided in stages to express deeper levels of knowledge about their experiences, challenges, and needs (29).

Many options exist for the selection of an appropriate generative technique, and the chosen exercise will depend on the needs of the research team and project. Examples of generative techniques used in co-design include a persona scenario exercise, which is undertaken to develop an understanding of participants' experiences and challenges, as well as a vision for the future via the creation of an ideal state (13); storytelling activities facilitated by illustrations and sketches (30); or a creative prototyping exercise, in which participants create a physical manifestation of a concept or idea. The central concept to generative design is that participants have the opportunity to creatively draw upon their experiences, and using that experience, make something (an artefact) that illustrates a future state. In this way, designers can harness the expertise of participants to both learn about the past, as well as to shape the future.

The artefacts created—be they stories, physical prototypes, illustrations, or other creative outputs—are then shared amongst the larger team in the final step of the Co-Design phase. The creation and sharing of artefacts allows participants to access their experiences in new and creative ways, and reflect on why they chose to create what they did (29). Within the Sharing Ideas sessions and associated dialogue, the research team should pay attention to similarities and differences of artefacts created by different groups, points of emphasis by participants, and stated priorities for the future state of healthcare. In order to capture the breadth of knowledge shared, it is recommended that these Sharing Ideas sessions are audio-recorded, with participant consent.

DigiComp Kids Operationalization: Co-Design

Step 3: In the co-design phase of the DigiComp Kids project, our Family Partners and two expert clinicians from the Complex Care Team presented accounts of challenges they had encountered in the current state. These stories were shared with the intention of building empathy, understanding the need for clinical change, and cultivating a shared sense of purpose among group members. Next, members of Ontario Health (OTN) presented case scenarios of healthcare solutions that they had previously helped to develop, in order to give examples of success stories and speak to the scope of change required for program implementation. During these case scenarios, technology was emphasized as an *enabler* of care, but participants were cautioned that implementing a new technology solution would not be sufficient to transform care in most cases, without consideration of context, workflows, and system integration.

Step 4: Subsequently, participants split into small groups, each led by a facilitator, to begin generative design work. For our generative design activity, we selected a persona scenario exercise, where participants worked together to develop a fictitious character that was representative of others 'like them'. To facilitate this, we grouped participants with similar experiences together (e.g. hospital-based healthcare practitioners), in order to encourage the development of detailed and authentic personas.

A 'persona' is a detailed and realistic character that is representative of participants' stakeholder group (13). Personas are meant to be fictional, yet draw on the expertise of the people creating them in order to construct a character that is representative of a ‘typical’ end-user for that group (31). Small group facilitators guided the development of personas using a worksheet (Additional File 3). Guiding questions asked included highlights and challenges of persona’s roles, their comfort levels and experiences with tablets, vital signs devices, and other technology types, and important tasks that they perform in their work with medically complex children.

During scenario work, groups selected an important challenge that their persona encountered, and then imagined a ‘future state’ where care would be delivered differently, to solve that challenge. To distil details of persona-technology interaction within the scenario, as well as requirements for a future state, guiding questions were used to direct group discussion. Specific questions asked by facilitators included “If your persona had remote access to healthcare providers and services, what would be different about the way that care is provided? How would this help to solve the challenge you’ve selected? What technologies are needed to support this change? How would this change the way that information is provided, care is coordinated, families are supported?”. The scenarios constructed by the participant pairs allowed for exploration of how personas might interact with features of a future health system. This exploration of human-system interaction is termed “contextmapping” (29) and is a vital component of designing a healthcare innovation that is suitable for the environment into which it will be implemented (24). Within DigiComp Kids co-design, facilitators guided participants to define what would be different in the future state, which formed the basis of considerations for innovation design.

Step 5: Finally, participants re-convened in a large group for the Sharing Ideas sessions, where they each presented their persona scenario exercise in turn and spoke to the group about their experiences with the exercise. Facilitators and other group members used a process of appreciative inquiry to highlight the positive aspects of the persona scenario exercises, and to expand on and help to develop these ideas. Questions asked by facilitators and other group members during the audio-taped Sharing Ideas sessions helped presenting participants to highlight points of emphasis and importance, as well as areas of uncertainty encountered during the persona scenario exercise.

POST-DESIGN

Summary. The Post-Design phase of the Generative Co-Design Framework is comprised of Step 6, Data Analysis, and Step 7, Requirements Translation. During the Data Analysis phase, the research team sorts and transcribes data, organizes data by distilling themes, and engages in a process of checking in with co-design participants to ensure that the distilled themes match with participant views of relevant and important topics. The aim of data analysis is to capture the most pertinent and significant ideas, which will then be used to form the basis of the healthcare innovation.

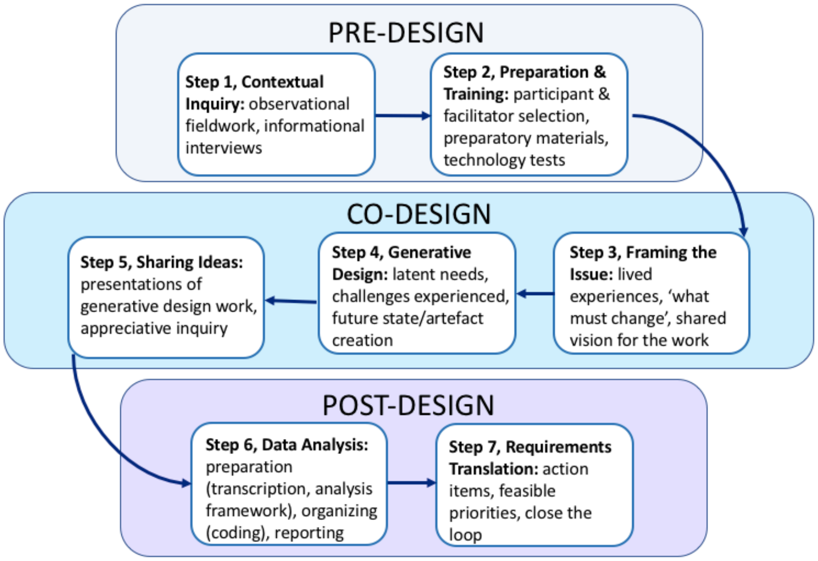
In the Requirements Translation phase, the research team uses the themes derived from co-design to decide on priorities for the innovation, plans the innovation based on what can reasonably be achieved, and finally closes the loop with co-design participants and stakeholders to identify plans for moving forward with the innovation. To accomplish this, the team starts by assigning action items to each theme and sub-theme from the co-design findings (i.e. actions that would be required to actualize the theme). For example, if co-design participants emphasized the need for an accessible source of personal health information, including current lab results and care plans, a secure patient portal, compatible with mobile devices, may be designed. Next, the research team reviews necessary action items to decide on innovation priorities by determining: which items already exist (and can be leveraged), which items are infeasible to develop, and which items should move forward to form the basis of the innovation (13). The final step in co-design is to circle back to co-design participants and stakeholders invested in co-design to inform them of the results of the design process, and the plan of action moving forward.

DigiComp Kids Operationalization: Post-Design

Step 6: Our team selected directed qualitative content analysis as our data analysis technique, and moved through three phases of preparation, organizing, and reporting results (32-34). The lead author (MB) collated and transcribed materials from large group co-design presentations, persona scenario audiotaped presentations and small group worksheets, as well as personal memos and reflections from the co-design process. Next, transcripts were read several times to facilitate a clear understanding of the data and emerging themes, and particular attention was paid to articulations of ‘what must change’ by participants. The lead author (MB) then developed an initial coding framework, based on the research question, which was to investigate the optimal processes, features, and workflows for a virtual care intervention (24). Definitions were developed for each of these categories, and the first ten pages of the transcript were coded independently by the lead author (MB) and a senior member of the research team with qualitative expertise (NC). These authors then met to compare and refine initial codes, after which time the lead author (MB) continued to code the rest of the transcript. Finally, codes were summarized under the categories of processes, features, and workflows, and themes and sub-themes were distilled from the data. These themes and sub-themes were collated into a summary document and shared with DigiComp Kids co-design participants through a process of member-checking. Participants were asked to reflect on the summarized content of co-design as to whether it ‘fit’ with their interpretation of the day, and to share edits, questions, or memos that came to mind as they read through the summary documents. These additions and edits were incorporated into the final summary co-design findings document.

Step 7: During DigiComp Kids Requirements Translation, the research team met to discuss the co-design findings and steps needed to realize each of the themes. Next, the research team communicated with leaders in the hospital, home care, and technology development sectors to identify if there existed tools or technologies that could be leveraged to meet any of the requirements for DigiComp Kids. With this new knowledge, the research team met several more times to design the processes, workflows, and features for DigiComp Kids, based on the requirements articulated by co-design participants and within the constraints of what was possible for the timeline, budget, and scope of work for the project. Co-design participants and healthcare leaders were once again thanked for their contributions to the design of this project, and the final project design was communicated in a news brief.

Figure 1: A Generative Co-Design Framework for Healthcare Innovation



Discussion

Healthcare innovation is essential for finding strategies to balance costs and quality of care in a climate of healthcare resource restriction juxtaposed against ongoing efforts to improve excellence in care delivery and quality of life for patients. While evidence of successful healthcare innovation programs exist, the majority of newly developed healthcare innovations are not routinely integrated into care. The term 'pilot-itis' was coined to represent the plethora of innovation attempts that begin and end with a pilot or beta model (35). To combat the pilot-itis that plagues the healthcare innovation sphere, incorporation of co-design methods may assist healthcare innovators, researchers, clinicians, and quality improvement specialists in developing useful, manageable, and sustainable healthcare innovations. The purpose of this work was to develop and apply A Generative Co-Design Framework for Healthcare Innovation in our project, DigiComp Kids.

Family Partners, who have been involved with the DigiComp Kids study since inception, were critical team members in ensuring the success of our co-design project. In being fully immersed in DigiComp Kids for over one year's time, both Family Partners used their expertise during co-design to support the overall goals of the DigiComp Kids project. For example, since the DigiComp Kids study seeks to design a virtual care program, one concern that our team had was that co-design participants would focus solely on the types of technology needed to implement this care model, as opposed to focusing on the necessary workflows, processes, and system requirements needed to support a technology-enabled care model. Knowing this, during our co-design day, our Family Partners were able to clearly articulate where they believed technology would help in caring for medically complex children at home, in addition to where other low-technology or technology-free options would be just as useful, and what would be needed to support these options. Because of this, the entire co-design team was able to focus on supporting system-level change as the focus of co-design, with technology acting as an enabler of care.

Based on our co-design experience, we encourage healthcare innovators and research teams to involve patient partners in projects from the earliest possible date to ensure immersion in the project, shared understanding between researchers and patient partners about the goals of the study, and full participation. In the DigiComp Kids study, our Family Partners worked with the research team to design the flow and activities of the co-design phase and reported satisfaction with the process. Additionally, although our Family Partners already encouraged other co-design team members to think of both technology-focused and low-technology solutions for care without our direction to do so, we could have asked that this be an explicit role of Family Partners during co-design. Healthcare Innovation teams may want to consider pre-assigning roles to individuals for co-design activities, for situations such as this, as we feel this would strengthen the implementation of the framework.

Strengths and Limitations of Our Framework

Situated in the conceptual areas of patient engagement frameworks and health innovation design, A Generative Co-Design Framework for Healthcare Innovation offers a method for research teams focused on engagement of end-users in creative innovation design work. One of the strengths of this framework is the emphasis on engagement of end-users, including patient partners and other stakeholders, as a vital component of designing relevant, acceptable, useable health innovations. Use of co-design strategies for healthcare innovation includes the lived experiences of end-users in research, generates ideas for patient-focused service improvements, empowers the included groups, and tailors interventions to end-user requirements thus increasing the likelihood of their adoption and integration (36-39). Successful examples of co-design have been demonstrated in existing literature (14, 15), wherein strategies such as patient journey-mapping, experience-based surveys, and workshops have been utilized to improve end-user adoption and integration of program services.

Another highlight of this framework is the emphasis on the incorporation of creative strategies for idea generation, while allowing for flexibility for research teams to customize these creative strategies to their needs. The ability to generate many alternative solutions to a problem, to approach problems with an open mind, and to tolerate ambiguity and persist in seeking novel solutions with merit are all attributes of individuals' creative personalities that strongly affect the likelihood of successful innovation (40). Thus, the central place of creative strategies within A Generative Co-

Design Framework for Healthcare Innovation is a key strength in its construction as a tool for health innovation.

Additionally, there are some limitations of the framework that must be considered. The first is that our framework relies on the in-depth participation of key end-users to shape the future state of care, which may result in an over-reliance on the perspectives of a dedicated group of few end-users, who may not be representative of the larger population of interest. In combating this limitation, healthcare innovation teams may want to consider selecting a diverse array of end-users to participate, including those working in diverse roles, from differing age, cultural, and gender identities, and with varying years of professional experience, in order to make the application of the framework more generalizable. While highly contextualized and intimate personal knowledge that comes from individual end-users is key to the creation of a useable healthcare innovation, these needs must be balanced against the creation of an innovation that will be applicable beyond a small group.

A second potential limitation of our Framework is that some end-users may have concerns about speaking up around personal challenges encountered in the current system. End-users are often highly entrenched in the system which they are being asked to critique during co-design, creating the potential for them to approach co-design in an overly cautious manner. In healthcare settings, fear of retaliation is a well-known barrier to speaking up with critiques of the healthcare system or context in which individuals work (41, 42). To confront this potential limitation, healthcare innovation teams are encouraged to invest time in establishing trusting relationships with participants and maintaining an environment of openness and acceptance during co-design. Some potential strategies to accomplish this are informal individual meetings with participants before co-design, as well as team building exercises such as those described under the 'Framing the Issue' step.

Finally, we acknowledge that the co-design process described within our framework is time- and labour-intensive. In the context of healthcare innovation, we appreciate that many innovation projects are undertaken by clinicians, quality improvement specialists, and researchers who are already pressed for time and resources. However, we have demonstrated that the actual co-design engagement from participants can be successfully undertaken in a single day, with the proper preparations being taken during the Pre-Design phase. This is in contrast to other methodologies such as Experience-Based Co-Design, in which engagement sessions are typically run over multiple days. Therefore, for teams in which engaging co-design participants over multiple sessions may be difficult, our framework may offer an advantageous alternative to others.

Conclusion

Co-design of healthcare innovations represents an opportunity to leverage the knowledge, experiences, and insights of end-users to achieve impactful innovations in healthcare contexts. For healthcare innovators seeking to expand their innovations beyond the pilot phase, A Generative Co-Design Framework for Healthcare Innovation provides guidance on incorporating end-user voices in innovation design. This Framework contributes to the literature in the patient engagement field by offering a new category of patient engagement frameworks focused on engaging end-users in the creative process of health innovation. Healthcare innovators, applied health science researchers, clinicians, and quality improvement specialists may wish to refer to the Framework and worked example presented here in order to elicit the viewpoints of end-users while distilling practical considerations for healthcare innovation and design.

List of Abbreviations

OTN: Ontario Telemedicine Network

Declarations

Ethics Approval and Consent to Participate

This research project was approved by the Hamilton Integrated Research Ethics Board (HiREB #8324). All participants signed informed consent to participate.

Consent for Publication

Not Applicable.

Availability of Data and Materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing Interests

The authors declare that they have no competing interests.

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Author's Contributions

The author list for this manuscript includes a diverse array of investigators and end-users, including those involved in virtual care research (MB, MM, KL, CO, CW, NC), Family Partners on the DigiComp Kids Study (EMC, SVR), clinicians (JD, MG, AL, ANP), and experts in virtual healthcare service delivery (CJF, SM). MB led the study and conceptualized and drafted the manuscript. MM and NC provided strategic project guidance, and participated data analysis and manuscript revision. EC, JD, CF, MG, KL, AL, SM, CO, AP, SR, and CW participated in data generation during co-design, and critically revised the manuscript. All authors approved the final version of the manuscript for submission.

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Additional File 1
Table 1: Definitions of Terminology Used

Term	Definition
Healthcare innovation	Aims to develop new healthcare service and delivery methods, products, policies, technologies, or systems, with a view toward improving people's health (1).
End-user	Individuals who have a vested interest in the outcome of innovation design, development, and implementation.
Family members	Parents or caregivers responsible for caring for children with medical complexities; may or may not be biologically related.
Processes	The way that care is integrated and organized as a system, including the coordination of care between sectors.
Features	The components that make up the hardware and software of the intervention, as well as capabilities of the intervention for delivering virtual care.
Workflows	The way that individuals or families use the system to provide care, including the roles and responsibilities of the people involved.

1. World Health Organization. Promoting Health Through the Lifecourse. In: Group WHI, editor.

Additional File 2
GRIPP2 Long Form

Section and topic	**Item**	**Reported on page No**
Section 1: Abstract of paper		
1a: Aim	Report the aim of the study	2
1b: Methods	Describe the methods used by which patients and the public were involved	2
1c: Results	Report the impacts and outcomes of PPI in the study	2
1d: Conclusions	Summarise the main conclusions of the study	2
1e: Keywords	Include PPI, "patient and public involvement," or alternative terms as keywords	3
Section 2: Background to paper		
2a: Definition	Report the definition of PPI used in the study and how it links to comparable studies	3
2b: Theoretical underpinnings	Report the theoretical rationale and any theoretical influences relating to PPI in the study	7
2c: Concepts and theory development	Report any conceptual or theoretical models, or influences, used in the study	N/A
Section 3: Aims of paper		
3: Aim	Report the aim of the study	4
Section 4: Methods of paper		
4a: Design	Provide a clear description of methods by which patients and the public were involved	7-8
4b: People involved	Provide a description of patients, carers, and the public involved with the PPI activity in the study	7

Section and topic	Item	Reported on page No
4c: Stages of involvement	Report on how PPI is used at different stages of the study	7-8
4d: Level or nature of involvement	Report the level or nature of PPI used at various stages of the study	8
Section 5: Capture or measurement of PPI impact		
5a: Qualitative evidence of impact	If applicable, report the methods used to qualitatively explore the impact of PPI in the study	N/A
5b: Quantitative evidence of impact	If applicable, report the methods used to quantitatively measure or assess the impact of PPI	N/A
5c: Robustness of measure	If applicable, report the rigour of the method used to capture or measure the impact of PPI	N/A
Section 6: Economic assessment		
6: Economic assessment	If applicable, report the method used for an economic assessment of PPI	N/A
Section 7: Study results		
7a: Outcomes of PPI	Report the results of PPI in the study, including both positive and negative outcomes	11, 14, 17
7b: Impacts of PPI	Report the positive and negative impacts that PPI has had on the research, the individuals involved (including patients and researchers), and wider impacts	18-19
7c: Context of PPI	Report the influence of any contextual factors that enabled or hindered the process or impact of PPI	N/A
7d: Process of PPI	Report the influence of any process factors, that enabled or hindered the impact of PPI	N/A

Section and topic	**Item**	**Reported on page No**
7ei: Theory development	Report any conceptual or theoretical development in PPI that have emerged	N/A
7eii: Theory development	Report evaluation of theoretical models, if any	N/A
7f: Measurement	If applicable, report all aspects of instrument development and testing (eg, validity, reliability, feasibility, acceptability, responsiveness, interpretability, appropriateness, precision)	N/A
7 g: Economic assessment	Report any information on the costs or benefit of PPI	N/A
Section 8: Discussion and conclusions		
8a: Outcomes	Comment on how PPI influenced the study overall. Describe positive and negative effects	18-19
8b: Impacts	Comment on the different impacts of PPI identified in this study and how they contribute to new knowledge	21
8c: Definition	Comment on the definition of PPI used (reported in the Background section) and whether or not you would suggest any changes	N/A
8d: Theoretical underpinnings	Comment on any way your study adds to the theoretical development of PPI	N/A
8e: Context	Comment on how context factors influenced PPI in the study	N/A
8f: Process	Comment on how process factors influenced PPI in the study	20
8 g: Measurement and capture of PPI impact	If applicable, comment on how well PPI impact was evaluated or measured in the study	N/A

Section and topic	**Item**	**Reported on page No**
8 h: Economic assessment	If applicable, discuss any aspects of the economic cost or benefit of PPI, particularly any suggestions for future economic modelling.	N/A
8i: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so that others can learn from this study	19

PPI patient and public involvement

Additional File 3
Persona Development Worksheet

My name is:

____

I am _____ years old

I am a: Man Woman

My caregiver role:

Any other jobs that I have:

Other important caregivers/team members:

I typically provide ___ hours of care to a child with medical complexities in a
- Day
- Week

Important care tasks that I do are…

Typical assistive technologies that I interact with/use to provide care:

Wheelchair
Home oxygen
Tracheostomy
G/J tube feeds
Hearing aids
Dialysis
Non-invasive ventilation
Invasive ventilation
Long-term IV/port
CSF shunt
Other:
Other:

Highlights of my role…

Challenges/frustrations of my role…

My comfort level with technology:
- Not comfortable
- A little comfortable
- Mostly comfortable
- Very comfortable

The technology devices I use most often are:

Mobile phone
Land line
Desktop computer
Tablet
Remote monitor (e.g. Fitbit or vital signs monitor)
Webcam

Laptop computer Other:

I prefer to communicate with other caregivers/team members:

In person
On the phone
Over email
By video call

Other important details about me:

-
-

Chapter 4

A Novel Hospital-to-Home Virtual Health System for Children with Medical Complexities: Usability Testing Study

Bird, M., Carter, N., Kazmie, N., Lim, A., Fajardo, C., Reaume, S., & McGillion, M. A Novel Hospital-to-Home Virtual Health System for Children with Medical Complexities: Usability Testing Study. Submitted to Journal of Medical Internet Research (JMIR) Formative Research, November 1, 2021.

Overview

Chapter 4 in this dissertation presents the results of the usability testing process for the DigiComp Kids intervention. Using a combination of scenario-based and task-based usability testing, hospital-based clinicians, family members of CMC, and home-based clinicians engaged in a process of learning and testing the DigiComp Kids intervention via real-time virtual usability testing. Participant effectiveness, efficiency, and satisfaction metrics were collected, and user experience with the DigiComp Kids intervention was solicited via debrief interviews. Results from usability testing reveal high overall system usability, together with focused areas to improve upon, identified by participants. This study conveys the importance of formative testing in order to uncover challenges early and refine digital health interventions to suit the needs of end-users. Results from this study can be used to refine the DigiComp Kids intervention before implementation to tailor the intervention to meet the needs of hospital-based clinicians, family members, and home-based clinicians of CMC.

A Novel Hospital-to-Home Virtual Health System for Children with Medical Complexities: Usability Testing Study

Abstract

Background: Children with Medical Complexity (CMC) are a group of young people who have severe complex chronic conditions, substantial family-identified service needs, functional limitations, and high healthcare resource use. Technology-enabled hospital-to-home interventions designed to deliver comprehensive care in the home setting are needed to ease CMC family stress, provide proactive and comprehensive care to this fragile population, and avoid hospital admissions, where possible.

Objective: The objective of this usability testing study was to assess areas of strength and opportunity within the DigiComp Kids system— a hospital-to-home intervention for CMC, their families, and care providers.

Methods: Hospital-based clinicians, family members of medically complex children, and home-based clinicians participated in DigiComp Kids usability testing. Participants were virtually recorded and tasked to think aloud when completing usability testing tasks. Participants were scored on metrics of effectiveness, efficiency, and satisfaction, and a total usability score was calculated using the Single Usability Metric (SUM). Participants also provided insights into user experiences during post-usability testing interviews.

Results: A total of 15 participants (5 hospital-based clinicians, 6 family members, 4 home-based clinicians) participated in DigiComp Kids usability testing. Participants were able to complete all assigned tasks independently. Error-free rates for tasks ranged from 58 – 100%; average satisfaction rating across groups was 80% or higher, as measured by the Single Ease Question (SEQ). Task times of participants were variable as compared to task times of an expert DigiComp Kids user. SUM scores ranged from 80.5 – 89.5%. In qualitative interviews, participants stressed the need to find the right fit between user needs and the required effort to use the system. Interviews also revealed that the value of the DigiComp Kids system was in its ability to create a digital bridge between hospital and home, enabling participants to foster and maintain connections across boundaries.

Conclusions: Usability testing study revealed strong scores across groups. Insights gained include the importance of tailoring the implementation of the system to match individual user needs, streamlining key system features, and consideration of the meaning attached to system use by participants to allow for insight into system adoption and sustainment.

Introduction

Background

Children with medical complexities (CMC) live with significant disease burden, such as neurological impairment and organ dysfunction [1]. Medical advances have led to many CMC living longer than would previously have been possible with the added support of technologies such as ventilators and feeding tubes [2]. International epidemiological data indicate that CMC commonly constitute less than one percent of all children in a given population [1, 3, 4], yet Canadian data show that this fraction of the population account for up to one third of pediatric health-related expenditures [1]. With regard to these expenditures, many resources are expended on procedures to support technology-dependent CMC— a retrospective observational study from the United States estimated that CMC account for 73 to 92% of children undergoing resource-intensive technology placements in hospitals, such as gastrostomy feeding tubes, tracheostomies, and cerebrospinal fluid shunts [5]. Within the current care model, CMC have, on average, five or more inpatient hospital stays per year, a median of 38 days apart [6]. Once hospitalized, these patients typically spend eight times as many days in hospital as children without medical complexities [7]. Hospitalization and re-hospitalization drive the majority of healthcare spending for CMC, with thirty-day readmission to hospital rates in Ontario as high as 23.7% for children with multiple complex chronic conditions and technology dependence [1]. Fourteen percent of these thirty-day readmissions are due to preventable causes [1] such as blocked feeding tubes and aspiration pneumonia. In addition to the expertise of their acute care hospital teams and specialists, families of technology-dependent CMC often require specialized home-care nursing [8], however, health professional support for this population is fragmented in terms of home and specialist care, with considerable variation in the provision of these services by region. Many regions lack adequate numbers of specialized pediatric home care nurses trained to care for CMC, and specialist care is often episodic, separated geographically from hospital and home care, and lacks integration in terms of communication and documentation with other care systems [8, 9].

To reduce poor outcomes such as unmet healthcare needs as well as emergent and repeated hospitalizations of CMC, care models are needed that emphasize care coordination (organized care with a clear division of responsibility [6]), timely access to urgent care, and a focus on proactive, comprehensive care, as opposed to care that is reactive and episodic [10]. In other complex populations, hospital-to-home models of care using technology-enabled virtual care systems have successfully been used to decrease unmet health needs and unplanned hospitalizations. For example, a randomized trial of telephone care management and automated home symptom monitoring in patients with cancer showed improved scores in both pain (standardized effect size for between-group difference: 0.39 [95% CI, 0.01-0.77]), and depression (standardized effect size for between-group difference: 0.41 [95% CI, 0.08-0.72]) at one year of intervention, compared to a usual care group [11]. Additionally, a study examining care of older persons during periods of acute illness or functional decline via implementation of primary-care-to-home virtual case management showed a decrease in emergency department presentations (pre-intervention ED presentations median 1, IQR 0–2; post intervention: median 0, IQR 0–1; z=4.52, P<0.001) and unplanned hospital admissions, (pre-intervention unplanned admissions: median 1, IQR 0–1; post-intervention: median 0, IQR 0–0; z=4.79, P=0.001) [12].

While technology-enabled virtual care systems can theoretically help to bridge the gap between hospital and home and improve outcomes in CMC, this area remains largely underexplored for this population. Despite the relatively low number of studies in this area, what research has been done shows promise in easing the burden of care on CMC families and reducing poor outcomes such as reducing urgent and in-person healthcare delivery. Preliminary data from a virtual hospital-to-home intervention for CMC consisting of vital signs monitoring and virtual communications with a hospital-based clinical team showed a 42% reduction in emergency department visits per patient per month and a 26% reduction in inpatient admissions, with a 95% patient satisfaction rating [13]. Another virtual intervention program involving unrestricted access to a specialist healthcare team for parents of CMC via telephone, email, telemedicine, and in-person consultations demonstrated an increase in total health system encounters, but a decrease in in-person home and clinic care (average health system encounters 9.5 encounters per patient in Year 1 and 14.5 encounters per patient in Year 3; in-person care accounted for 43.8% of all care encounters in Year 1 and 33% by Year 3) [14]. These early studies demonstrate that virtual care models can indeed improve outcomes for CMC, yet, the lack of scalable, standardized virtual care models despite these promising results suggests a deeper exploration of factors influencing adoption, scalability, and spread is warranted.

Usability testing studies assist in understanding the interactions between people and technology in order to investigate the ease-of-use, learnability, and perceived benefits and challenges of novel systems, according to diverse end-user groups (those for whom a technology or product is ultimately designed) [15]. The granularity of these studies provides detailed usability information that informs larger concepts such as intervention adoption, scale, and spread. The concept of usability has roots in the field of human-computer interaction and is defined as the ease-of-use and effectiveness of a system when employed by end-users [16]. Metrics of effectiveness, efficiency, and satisfaction are widely accepted as important components in the composite concept of usability, and should be incorporated into usability measurement and reporting [17]. Using Principal Components Analysis, Sauro and Kinlund described the following relationship between usability components— a decrease in errors committed and time on task results in an increase in task completion and subjective participant task satisfaction [18]. Additionally, qualitative user experience data provides valuable insight into user behaviours, perspectives, needs, and desired outcomes from technology systems, helping to inform the relevance and acceptance of the technology by end-users

[19]. In this study, we aimed to investigate the usability of a virtual hospital-to-home health system for CMC and their families, called DigiComp Kids.

DigiComp Kids intervention

The DigiComp Kids intervention utilizes the Cloud DX Connected Health System and consists of a hospital clinician portal and a home-based kit, designed to communicate with one another. The hospital clinician portal is intended to enable hospital-based clinical teams to review biometric data and health information submitted by families and home-based clinicians, as well as to send health information to home-based kits in order to facilitate home-based care management decision making. Hospital-based clinicians receive personalized login information which allows them to access the portal from any internet browser. Hospital-based clinicians can review submitted patient vital signs measurements, photos, and survey responses; configure individual vital signs parameters and alerts for each patient; send and receive secure messages with family members and home-based clinicians; send health-related documents to families and home-based clinicians such as care plans or medication schedules; schedule and initiate video calls with families and home-based clinicians; and document patient care information directly within the hospital clinician portal. The home-based kit is intended for use by CMC family members and their home-based clinicians to transmit biometric data and health information to hospital-based clinical teams, as well as to receive health information sent by hospital-based clinical teams.

Components of the home-based kit include a Samsung tablet, Bluetooth-enabled pulse oximeter with heart rate monitoring capabilities, and dual tympanic-temporal infrared thermometer. Kit features allow CMC family members and home-based clinicians to connect Bluetooth devices to the tablet as well as manually enter data to be transmitted to their hospital-based clinicians. This data entry allows for remote monitoring of biophysical parameters such as body temperature, heart rate, oxygen saturation and respiratory rate (manual measurement); submission of responses to health-related monitoring questions; direct upload of photos to the cloud-based patient chart; real-time connection with hospital-based providers via video link and secure text messaging; and virtual appointment scheduling.

The DigiComp Kids system was designed with hospital-based clinicians, CMC families, and home-based clinicians to allow for comprehensive team-based care for CMC in the home setting. Details of the design methodology are available in detail in a previously published manuscript [20]. The aim of the DigiComp Kids system is to connect hospital-based clinical teams with CMC families and their home clinicians in order to proactively monitor CMC health needs and respond to them in a timely way. By better connecting families with home- and hospital-based clinicians, DigiComp Kids system has been designed to facilitate safe care at home for CMC.

Objectives

The objective of this usability testing study was to assess areas of strength and opportunity within the DigiComp Kids system, according to hospital-based clinicians, medically complex children and their family members, and home-based clinicians. During this early formative stage, results from this usability testing study will assist with making further improvements to the DigiComp Kids system during the pre-clinical implementation phase.

Methods

Ethics approval

This study was approved by the Hamilton Integrated Research Ethics Board (HiREB Project #8324). All participants provided informed consent prior to their engagement in usability testing.

Setting, recruitment, and participant groups

Usability testing took place entirely virtually, due to the need for physical distancing and research regulations in place during the COVID-19 pandemic. In usability testing studies, the engagement of four or more participants per group is typically sufficient to detect >80% usability problems [21], thus, we recruited six family members, four home-based clinicians, and five hospital-based clinicians, for a total of 15 usability testing participants.

Hospital-based and home-based clinicians were recruited via networks of various members of the study team (MB, NC, AL, MM, EC, SR). Emails were sent to distribution lists and individual contacts known to be working with CMC in either hospital settings or home settings. Included clinicians spoke and read English, had at least three months of experience caring for CMC in hospital or home settings, and provided informed consent to participate. Hospital-based clinicians included a System Navigator, a Complex Care Nurse Practitioner, and three Registered Nurses working with CMC populations. Home-based clinicians included Registered Nurses and a Registered Practical Nurse working directly with CMC in home settings, as well as a Clinical Nurse Specialist whose role it is to support the provision of home care by offering remote clinical support.

Family participants were recruited by a clinical member of the study team (AL) and CMC family partner on our study team (SR). Included family participants lived in the southern Ontario area, had a child that met the definition of medical complexity [22], spoke and read English, and provided informed consent for both themselves and their child to participate. In this study, all family members recruited were mothers of medically complex children.

Procedures

Our usability testing procedure incorporated both quantitative and qualitative measures via standardized usability testing and individual participant interviews to capture user effectiveness, efficiency, satisfaction, as well as user experience.

Training

All participants received DigiComp Kids intervention training using the Connected Health System via a dedicated virtual session. Before training, participants received either an at-home Connected Health System kit (family members, home-based clinicians), or access to the hospital Connected Health System clinician portal (hospital-based clinicians), as appropriate. All participants also received an electronic standardized training manual developed by the lead author of this paper (MB) to guide the training session. The purpose of training sessions was to orient participants to the DigiComp Kids program using the Connected Health System and its features, as well as to allow for participants to practice navigating the system and ask questions. Participants were given a general background on the project and the way that the home and hospital-based systems interact, before being specifically trained on the relevant components for their group, as detailed below.

Hospital-based clinicians

Hospital-based clinicians were trained on use of the hospital clinician portal. Training was guided by the standardized training manual which clinicians could refer to as needed throughout the training and testing sessions. Training topics included patient vital sign alerts management and configuration, communication with families and home-based clinicians via secure chat messages and video calls, patient home-based care scheduling including changes to care plans, medications, and required data entry from families or home-based clinicians, as well as direct documentation within the cloud-based platform. All tasks were demonstrated by the trainer (MB) via remote screen sharing, and participants were subsequently given the opportunity to practice tasks to solidify information retention and application.

Families and home-based clinicians

CMC family members and home-based clinicians were trained on the use of the at-home DigiComp Kids kit. Practice kits were delivered to family and home-based clinician participants prior to training taking place. Similar to the hospital-based clinician training, home-based training was guided by a standardized training manual, provided to participants for their use throughout the training and testing sessions. Topics for participant training included tablet login and set up, sending and receiving secure chat messages, viewing and undertaking scheduled vital signs assessments, photos, and surveys, as well as locating shared documentation such as care plans and medication orders. Participants were guided through tasks by the trainers (MB, NK) over video, and were encouraged to follow along and participate with their kits before the testing session took place.

Testing

Testing for all participants was scheduled either immediately following or as soon as possible after training sessions, within a few days. All testing sessions were audio-visual recorded using videoconferencing software to facilitate the review and scoring of usability testing sessions at a later time.

Hospital-based clinicians

Following the training session, hospital-based clinicians took part in an individual virtual testing session, facilitated by a Moderator (MB). Testing sessions began by reminding the participants that usability testing was intended to test the DigiComp Kids system and approach to usability training, and not their performance or abilities as clinicians. Participants were given an opportunity to ask questions and reminded that there would be a scheduled break during testing, but that they could request additional breaks at any time.

Next, participants were asked to “think aloud” during usability testing. Thinking aloud involves participants concurrently performing a task while verbalizing what comes to mind during the performance of that task [23]. The purpose of thinking aloud is for the Moderator to gather relevant data on specific issues of usability, such as system navigation issues, areas of frustration or obscurity, or confusion around workflow when using the system.

Hospital-based clinicians were asked to complete a series of usability testing tasks, guided by a standardized testing protocol. Tasks within the protocol represented the core competencies for the hospital clinician portal, including locating patient information, responding to changes in patient vital signs, and communication, documentation, and scheduling of patient tasks such as surveys and video calls. Usability testing tasks for hospital-based clinicians are listed in brief in Textbox 1, and in further detail in Multimedia Appendix 1.

To add realism to the usability test, the participant tasks were undertaken in the context of a simulated patient case. The fictional patient used for the case was a 2.5-year-old girl diagnosed with Spinal Muscular Atrophy Type 1, named Emma. Participants were introduced to Emma as their patient and given clinical information on her condition, such as her main clinical issues (generalized low muscular tone, respiratory impairment), as well as technology supports used (portable oxygen, suction machine) to maintain her wellbeing at home. At pre-specified time points, hospital-based clinicians were given new information about their patient case in order to indicate progression of the patient scenario, over time. Participants were asked to respond to information and updates on their patient given by the Moderator throughout the testing process by following the clinical protocols that were taught during their training session. Further details of the patient case are available in Multimedia Appendix 2.

Textbox 1: User testing tasks for hospital-based clinicians

Task 1: Verbalize vital signs readings and any generated alerts for last assessment

Task 2: Change Emma’s heart rate parameters from [0 (low) to 80 (high)] bpm, to [90 (low) to 130 (high)] bpm

Task 3: Request a video call with Emma's family

Task 4: Add a note to the oxygen saturation reading from this morning

Task 5: Add assessment to chart with actions taken

Task 6: Schedule a video call with Emma's family in 4 hours

Task 7: Change Emma's risk stratification to 'Medium'

Task 8: Change the 'Wellness Survey' from being sent once weekly to being sent every day for five days

Task 9: Send a chat message to Emma's family

Families and home-based clinicians

CMC family members and home-based clinicians each participated in an individual usability testing protocol, facilitated by a Moderator (MB or NK). Think aloud procedures were explained to participants as described above, and all participants were given the opportunity to ask questions before beginning their testing sessions. In contrast to the hospital-based clinician participants, usability testing sessions for family members and home-based clinicians did not take place within the context of a patient case, but rather focused on undertaking day-to-day tasks related to caring for CMC using the DigiComp Kids home-based technology kit. During these sessions, family members and home-based clinicians were invited to imagine using the home-based technology kit with a medically complex child that they provide care to. For realism, family members were also given the option of applying peripheral vital signs devices (e.g. pulse oximeter, thermometer) to their children, dependent on their comfort level. The content of home-based clinician and family member usability testing sessions focused on device set up and login, peripheral vital sign device application and use, submission of clinical information such as responses to survey questions and photos to a simulated hospital-based clinical team, location of information sent by a simulated hospital-based team, and determination of required daily tasks using the scheduling function. Usability testing tasks for home-based clinicians and family members are listed in brief in Textbox 2, and in further detail in Multimedia Appendix 3.

Textbox 2: User testing tasks for family members and home-based clinicians

Task 1: Set up and turn on the tablet

Task 2: Login to the tablet

Task 3: View and interpret pending measurements and surveys using red asterisk

Task 4: Complete/describe temperature measurement

Task 5: Complete/describe oxygen saturation measurement

Task 6: Complete and submit Wellness Survey

Task 7: Find and read out the up to date list of child’s medications

Task 8: Take and submit a photo using the tablet

Interviews

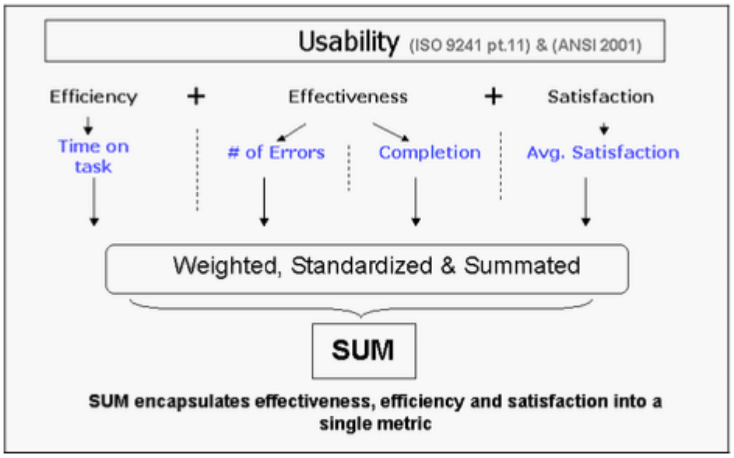
Immediately following individual testing sessions, each participant was interviewed about their experience participating in DigiComp Kids usability testing. The purpose of qualitative data collection in this study was to improve our understanding of the usability of *DigiComp Kids* by triangulating quantitative usability metrics with user experience data from interviews [24, 25]. A semi-structured interview guide was developed using constructs from the Holistic Framework to Improve the Uptake and Impact of eHealth Technologies [25]. Specifically, the constructs used to guide interview questions were those of 'technology'— the hardware and software comprising the DigiComp Kids system; 'people'— the participants themselves and other individuals specified by the participants; and context— the social, cultural, and physical environment in which the system is situated [25]. Across these categories, questions were designed to solicit areas of ease, frustration, and future improvement. Probing questions were used to encourage elaboration and clarification of participant responses where needed. Interview sessions were audio recorded using videoconferencing software. The interview guide can be found in Multimedia Appendix 4.

Measures

Usability is a composite measure comprised of task completion, error rate, task time, and satisfaction score metrics [18]. Each of these measures was collected for each task that a user attempted during DigiComp Kids usability testing, with the goal of combining these measures into a single usability metric or SUM score [26] (Figure 1).

Task completion, error rates, task times, and satisfaction were calculated and standardized following methods detailed by Sauro and Kindlund [18]. Task completion scores represented the ratio of successful task completion by participants to task attempts. Error rates were computed by dividing errors committed by the task error potential (number of participants multiplied by number of sub-tasks per task), to account for multiple possible errors being committed by the same participant on the same task. This value is was subtracted from one to calculate the error-free rate, enabling it to be combined with other usability metrics into a summative score [26]. Task times and satisfaction scores were standardized by computing them as Z scores. To do so, a specification limit was set, representing an acceptable score. The specification limit for task time was the time it took an expert user to complete the task, multiplied by 1.5 [27], and for satisfaction, the value of 5.6 was used on the 7 point Single Ease Question satisfaction scale [28, 29]. Detailed formulae for usability measures can be found in Multimedia Appendix 5.

Figure 1. SUM model* [18]



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Data management and analyses

Quantitative Analysis

Microsoft Excel v. 16.3 was used for all quantitative statistical analyses. Descriptive statistics were used to summarize participants' demographic data, child diagnostic information (family members), and professional work experience (clinicians) (Tables 1-3).

In addition to reporting usability metrics by user group and by task, Sauro and Kinlud [18] demonstrated that the constructs of efficiency, effectiveness, and satisfaction can be represented with a single, summated usability metric (SUM). By using SUM, usability as a construct is represented as a single score, making it intuitive to interpret without sacrificing the precision of using all four variables [18]. To construct the Single Usability Metric, standardized metrics (task completion, error rates, task satisfaction, and task times) are averaged together to create one single, summated score. This single score represents the overall usability of the DigiComp Kids system, equally weighted for metrics of task completion, error rates, satisfaction, and task times.

Qualitative Analysis

Audio-taped interviews were transcribed verbatim, and the lead author (MB) proofread the transcripts in order to ensure accuracy. A qualitative descriptive approach was taken to analyze data. Initially, three transcripts were read several times by three authors with qualitative training (MB, NK, NC), before meeting to develop a coding scheme. The coding scheme was developed deductively, using theoretical concepts from the Holistic Framework, including technology, people, and context [25]. This initial coding scheme was used to independently double-code four transcripts (MB and NK or MB and NC) using Dedoose data management software and thematic analysis techniques [32]. Team members met to discuss preliminary findings and refine the coding structure. The remainder of the transcripts were then coded by one author (MB or NK) and authors met to discuss emerging themes.

Multiple measures were used to maintain rigor during qualitative analysis. First, one author (NC) with qualitative expertise guided the qualitative data collection and analysis processes, approving methodological decisions before they were carried out.

Secondly, all authors involved in the qualitative portion of the project (MB, NK, NC) met weekly during the qualitative analysis process, and were in contact via email between meetings to review progress and discuss methodological issues. Process meetings were particularly helpful during times when major methodological milestones were encountered—for example, when defining and refining the code tree, or when developing emerging themes. The process of peer review and triangulation of ideas aided in establishing confirmability in decisions [33]. Finally, a detailed audit trail was kept throughout the analysis process, documenting reflexive memos, meeting notes, coding and thematic decisions, as well as methodological processes.

Results

Demographics

Hospital-based clinicians

Five hospital-based clinicians participated in usability testing. All participants were female, and the majority were employed on a fulltime basis and educated at a bachelor's or graduate degree level. One participant identified as a System Navigator, and the rest were Registered Nurses or Nurse Practitioners. The average length of clinical practice among participants was 12 years, with 5 years practicing with CMC populations. Hospital-based clinician demographic variables can be found in Table 1.

Table 1. Hospital-based clinician characteristics

Hospital-based clinicians (n=5)		
Gender, n (%)		
	Female	5 (100)
Ethnicity, n (%)		
	Asian	1 (20)
	Caucasian	3 (60)
	Unspecified	1 (20)
Role, n (%)		
	Registered nurse	3 (60)
	Nurse practitioner	1 (20)
	System navigator	1 (20)
Practice area, n		
	Pediatrics	2
	Complex care	3
Average length of clinical practice, years		
		12
Average length of clinical practice with complex populations, years		
		5

Family members and children

A total of six family members participated in usability testing. Four CMC participated in usability testing with their family members, and two family members simulated usability testing tasks due to their child not being available during testing time. All participating family members were female, and most were Caucasian and married. Most family members were educated at the university level and working full time or on leave. The experience level of family members using tablet technology was evenly distributed from 'somewhat experienced' to 'expert'. Medically complex children of family members in this study were mostly male and Caucasian, and between two and seven years old. CMC had four to six diagnosed chronic conditions and relied on a wide range of assistive technologies for support, as shown in Table 2.

Table 2. Family member and child characteristics

Family members (n=6)		
Gender, n (%)		
	Female	6 (100)
Ethnicity, n (%)		
	Asian	1 (17)
	Caucasian	5 (83)
Number of children, n (%)		

	1	1 (17)
	2	2 (33)
	3	1 (17)
	4	2 (33)
Highest level of formal education, n (%)		
	College diploma	1 (17)
	Bachelor's degree	3 (50)
	Professional degree	1 (17)
	Post graduate certificate	1 (17)
Employment status, n (%)		
	Unemployed	1 (17)
	Part time	1 (17)
	Full time	2 (33)
	On leave	2 (33)
Experience using tablet technology, n (%)		
	Somewhat experienced	2 (33)
	Very experienced	2 (33)
	Expert	2 (33)
Children (n=6)		

Gender, n (%)		
	Female	2 (33)
	Male	4 (66)
Ethnicity, n (%)		
	Asian	1 (17)
	Caucasian	5 (83)
Age in years, n (%)		
	2-4	3 (50)
	5-7	3 (50)
Number of chronic conditions		
	4	2 (33)
	5	2 (33)
	6+	2 (33)
Assistive technology, n		
	Enteral/parenteral feeding tube	5
	Home oxygen	5
	Mobility devices	3
	Non-invasive ventilation	3
	Invasive ventilation	2
	Tracheostomy	2

	Cerebrospinal fluid shunt	1
	Long term intravenous line/port	1
	Communication devices	1

Home-based clinicians

Four home-based clinicians participated in usability testing. All home-based clinicians were white females who were employed in contract or part-time positions by community agencies or by CMC families. The average length of clinical practice among participants was 14 years, with 12 years spent practicing with CMC populations. Demographic characteristics of home-based clinicians are found in Table 3.

Table 3. Home-based clinician characteristics

Home-based clinicians (n=4)		
Gender, n (%)		
	Female	4 (100)
Ethnicity, n (%)		
	Caucasian	4 (100)
Role, n (%)		
	Registered nurse	2 (50)
	Registered practical nurse	1 (25)

	Clinical nurse specialist	1 (25)
Practice area, n		
	Complex care	3
	Home/community care	3
	Emergency department	1
	Neonatal intensive care	1
Average length of clinical practice, years		
		14
Average length of clinical practice with complex populations, years		
		12

User performance

Scores for task completion, error-free task rates, task satisfaction, and task times are presented by end-user group in Tables 4-6. SUM scores are presented for each task as well as an overall score per user group.

Table 4: Hospital-based clinician performance

	Completion	Error-free rate	Satisfaction	Time	SUM Score
Task 1	1.00	0.80	0.9660	0.5675	0.8334
Task 2	1.00	0.85	0.9963	0.7549	0.9003
Task 3	1.00	1.00	0.9963	0.5199	0.8791

Task 4	1.00	0.97	0.9990	0.9878	0.9884
Task 5	1.00	0.93	0.8980	0.7580	0.8973
Task 6	1.00	0.92	0.8665	0.9798	0.9416
Task 7	1.00	1.00	0.9663	0.9999	0.9991
Task 8	1.00	0.70	0.3400	0.4350	0.6188
Task 9	1.00	1.00	0.9990	0.9994	0.9996
Mean score	**1.00**	**0.9078**	**0.8919**	**0.7780**	**0.8953**

Table 5: Family participant performance

	Completion	Error-free rate	Satisfaction	Time	SUM Score
Task 1	1.00	1.00	0.9987	0.6915	0.9226
Task 2	1.00	1.00	0.8577	0.3613	0.8048
Task 3	1.00	1.00	0.9987	0.9946	0.9983
Task 4	1.00	0.98	0.9222	0.8531	0.9392
Task 5	1.00	0.94	0.9987	0.9545	0.9744
Task 6	1.00	1.00	0.7734	0.6879	0.8653
Task 7	1.00	0.78	0.2327	0.3936	0.6010
Task 8	1.00	0.89	0.9806	0.4880	0.8394
Mean score	**1.00**	**0.9487**	**0.8453**	**0.6780**	**0.8681**

Table 6: Home-based clinician performance

	Completion	Error-free rate	Satisfaction	Time	SUM Score
Task 1	1.00	0.94	0.6879	0.2358	0.7153
Task 2	1.00	1.00	0.9893	0.9099	0.9748
Task 3	1.00	1.00	0.8159	0.2148	0.7577
Task 4	1.00	1.00	0.9990	0.8708	0.9675
Task 5	1.00	1.00	0.6664	0.7486	0.8538
Task 6	1.00	1.00	0.9990	0.5636	0.8909
Task 7	1.00	0.67	0.6844	0.3121	0.6658
Task 8	1.00	0.58	0.6554	0.2420	0.6202
Mean score	**1.00**	**0.8987**	**0.8058**	**0.5122**	**0.8057**

DigiComp Kids usability testing revealed strong usability across end-user groups with respect to task completion, errors, end-user satisfaction, and time on task. The average total SUM for hospital-based clinicians was 89.53%; family participants scored 86.81% across tasks, while home-based clinicians scored 80.57%. In terms of individual score components, participants in all groups achieved task completion scores of 100%. Error rates varied (range: 58 – 100% error-free), with participants achieving perfect scores across some tasks, while other tasks proved more complex and drew many errors. In general, participants committed more errors on tasks in which more steps were required to complete them (e.g. Task 8 for hospital-based clinicians). Participant satisfaction as measured by the SEQ was generally high; with all groups on average reporting satisfaction scores of 80% or higher. A direct positive correlation was observed between error-free rates and satisfaction scores. In general, simpler tasks (i.e. those with fewer error opportunities) were more likely to be completed error-free than more complicated tasks, and those tasks that were completed without errors by participants had higher satisfaction scores than those in which participants committed many errors. Task times varied across groups and were consistently the lowest score of the four usability measures.

Qualitative Findings

Thematic analysis of qualitative interview data generated five themes, as follows: Fostering and maintaining team connections across boundaries; Finding the right fit between user needs and required effort; Improving system efficiencies and eliminating redundancies; Making the system work in daily life; Reflecting on current and future technology needs.

Fostering and maintaining connections across boundaries

An important value highlighted in the co-design process for DigiComp Kids was that the system should aim to foster a sense of cohesion and connection between hospital-based clinicians, families, and home-based clinicians. During qualitative interviews, this aspect of the DigiComp Kids system was touched on by twelve of fifteen participants, highlighting its importance. For example, one parent participant relayed:

> *Like, we were going to have an NG tube and we were going to come home with it and like having someone to walk us through, like doing those kinds of things that freak me out right now. I don't want to do that… I don't have the confidence of me to be listening to see if it went in. But if that [video call] was a possibility that would like totally ease my stress, like if she pulled out an NG tube that it would, um that somebody would be there to walk me through it.* [Parent 002]

For this participant, the possibility of remotely connecting with a clinician meant easing her stress in performing a procedure for her child at home. Similarly, hospital-based clinicians agreed that connecting with families at home would enable them to play a more supportive role for the child and family:

> *I think that this also provides reassurance to families when they're calling clinicians or emailing clinicians and they're unsure of when they're going to get a response. It might make families feel better. Even when it's an initial discharge say from the NICU and a technology dependent kid and there's a lot of anxiety on whether they'll be able to reach clinicians or whether they live really far away geographically. They'll have this one-on-one support depending on the hours.* [Hospital 012]

For families and care teams situated in different geographic areas, having access to a communication channel via a remote system can help to break down boundaries and facilitate team cohesion and support.

Finding the right fit between user needs and required effort

Family members and hospital-based clinicians spoke to the need for the DigiComp Kids system to be implemented using flexible protocols that allow for users to titrate their use of the system up or down as needed. Family members commented that CMC have labile medical conditions, resulting in a continuum of disease severity and subsequent health needs depending on manifestation of their conditions. Participants commented that the right fit between the user and system would need to be struck in order to balance daily user requirements with self-identified user needs. One family member shared the importance of making the tool worthwhile to use:

> *Adding in another thing as another day-to-day task, that kind of seems like a bit much. If it was a point of time where we were trying to track something or a point where we were trying to wean him off the vent and we really wanted to zoom in on something, some numbers, I could see it being a daily thing… I'm trying to think of how it would be used as more tool rather than another chore, task to do with a complex kid.* [Parent 001]

Similarly, another family member spoke to the need for system use to add value to their lives as motivation to adopt the system:

> *But having the unit open and on every day, unless it's for a specific reason, it sounds really selfish but I feel like we would just open and use it if we needed something dealt with, not just so the team could find information of how normal our day is going. If that makes sense?* [Parent 002]

The fit or balance of required effort versus user needs was touched on by most participants as being an important factor in whether they could envision adopting the DigiComp Kids system as part of their daily care routine.

Improving system efficiencies and eliminating redundancies

In terms of improving system efficiencies and eliminating redundancies, five participants spoke to the potential for the DigiComp Kids system to streamline and accelerate the timing of communication between clinicians. Using DigiComp Kids to enable multiple clinicians to view real-time patient data and communicate necessary changes in a timely fashion was seen as an important care improvement, for example one home care clinician said:

> *Because* [the hospital-based clinicians] *are able to end up getting changes right away … rather than, for families what they would do is they would call the hospital, that they would page someone and then depending on how busy the person,* [or] *the team is, sometimes it takes a bit longer to answer that call or get back.* [Homecare 007]

The DigiComp Kids system was seen as a strategy to accelerate necessary changes to care plans by allowing families, home-based clinicians, and hospital-based clinicians to view data in real time, as patient changes are taking place. Other important factors for streamlining communication that arose in interviews were ease of access to information and system interoperability, as detailed by the following participant:

> *I think this is so great. Honestly if everyone could just use this and have access to this, everyone's life would be so much easier. Nurses, specialists, complex care teams, homecare, like I do not understand why we we're are on so many different platforms for one patient.* [Homecare 009]

Finally, participants also pointed out areas for improvement in the DigiComp Kids system that would further improve its usefulness with regard to streamlining team communication and work processes, for example:

> *When you have interdisciplinary groups, you're like well I need this person to be able to address this issue and they might not be present at the time. I think that's always the challenge in team communication, trying to get messages to people and you know in hospital, it's like flagging charts and paging. So, if there was some way to flag people, that we need their attention, that would be really useful.* [Hospital 011]

Participants contributed important insights with respect to the context in which the DigiComp Kids system would be implemented and made suggestions as to how the system could be further optimized to enable efficiency and eliminate redundancies.

Making the system work in daily life

The fourth theme generated from participant interviews was "Making the system work in daily life". Facets of this theme include envisioning how the DigiComp Kids system would fit into the daily workflows for families and clinicians, as well as the practicalities of using the system in real life. For example, parents spoke to the advantage of using the DigiComp Kids system to be able to provide a thorough report and history of the child to different care providers:

> *And the more I kind of say it, the more excited I get about the idea of having it on my phone. Because even just pulling up, you know going to an appointment or*

> *having to go to the hospital or even just in a complex care appointment, being like, this is what he's currently doing. This is our history, our results history. Or I've taken subsequent pictures, check out this camera roll of all of the things I've documented for you.* [Parent 003]

This parent envisioned using the system as a "one-stop" documentation hub that would accessible from their phone to share with different healthcare providers. Similarly, hospital-based clinicians spoke of envisioned positive changes to their workflows while using the system:

> *I think the live feature of chats, of getting notified when things are happening in the home is fantastic in comparison to our regular phone call where a message is left or an email where a message is left. And you only get to it at the end of the day. Whether clinicians get notified during these events that are occurring. I think it's great.* [Hospital 012]

Streamlining workflows to enable families and clinicians to easily access information and engage in real time with each other was viewed as a potential advantage of the DigiComp Kids system. These real-time connections were discussed as having the potential to facilitate proactive patient care and earlier intervention in case of patient deterioration. Finally, participants again assisted in contextualizing proposed workflows for the intervention and identifying necessary backups and safeguards in case of unforeseen issues:

> *The other thing would be a power failure, if you like potentially were working in an environment like, you'd have to have a back-up. Like if it did work for your routine documentation, you'd have to have a protocol for all your back-up um, documentation. But I guess just if you don't have working power or working internet or data, I guess through the iPad then it may not function properly.* [Homecare 008]

Reflecting on current and future technology needs

The fifth and final theme generated from interview data was participant reflections on how DigiComp Kids might fit with their current and future technology needs. One homecare nurse highlighted how the DigiComp Kids system may enable families and clinicians to have a clear understanding of disease progression to enable proactive care planning:

> *I think the result dashboard probably would be helpful so that we can see changes over time. I'm thinking like specifically if they have some sort of progressive disease or something that affects let's say their breathing and their respiratory system. I*

> *think it would be helpful to those numbers over time and allow people to make decisions based on those numbers.* [Homecare 010]

The DigiComp Kids system tracks and trends patient disease progress over time, enabling families and care providers to have an accurate understanding of current needs and forecast anticipated future needs. Importantly, the system is able to do this without adding additional charting for families who are already busy taking care of medically complex children. One parent commented:

> *I do a really bad job of tracking things. And so, having something that kind of does it for me and keeps it all together in one spot. We're one of the few families that choose not to have nursing, so I don't even have nursing charts. So, if somebody were to ask me…I can tell you what his normal oxygen levels are, and his normal heart rate is because I see it every night. But I have no idea what his blood pressure is or anything, not a clue. Because we don't have nursing and I just don't keep track.* [Parent 005]

Ongoing tracking of disease progression was deemed an important part of providing anticipatory and proactive care, ultimately benefitting medically complex children, their families, and healthcare providers alike.

Discussion

Principal Findings

This study was conducted to assess the usability of the DigiComp Kids intervention using the Cloud DX Connected Health System. By conducting usability testing, areas of strength and opportunity may be identified in virtual health innovations prior to large-scale clinical implementation.

The DigiComp Kids intervention using the Connected Health System attained high usability scores across groups, with SUM scores achieved by hospital-based clinicians, family participants, and home-based clinicians placing them in the 97th, 93rd, and 80th percentile, respectively, in relation to SUM scores across all technology industries [34]. In addition, consistent with Sauro and Kinlund's definition of usability [18] we noted a direct positive correlation between task error-free rates and task satisfaction.

Qualitative participant feedback highlighted favourable aspects of the DigiComp Kids system such as its ability to connect home-based and hospital-based clinicians across geographic boundaries, to eliminate inefficiencies in care processes, and to encourage more proactive tracking of disease progress and planning for future needs. In addition, participants assisted with contextualizing the intervention with regard to their daily lives and workflows, highlighting areas where the system could be further refined to improve the fit between user needs and system requirements.

Interpretation

The DigiComp Kids intervention out-ranked the majority of reported intervention SUM scores across technology industries. We hypothesize that part of our high usability scores stems from the DigiComp Kids intervention having been co-designed alongside hospital-based clinicians, family members of CMC, and home-based clinicians. By intentionally building the system with the needs of our end-users in mind, the co-design process may have contributed to the intervention achieving high SUM scores across end-user groups. Of particular interest is one component of total SUM scores, the task completion score, which was 100% across all usability participants. This score is well-above the average task completion rate for technologies from the usability literature which is 78% [35]. It is possible that our task completion rates were falsely inflated due to a user belief bias, whereby participants believed that the task they were being asked to complete in the simulated testing environment was indeed achievable, and therefore tried harder to complete the assigned task than they might have in a real-life scenario [36]. Though we cannot know whether user belief bias influenced our task completion scores, they should be interpreted with caution.

Qualitative interview data yielded insights beyond reflections on the immediate usability testing procedures. As participants were questioned on what the value of using the DigiComp Kids intervention would be in their daily lives, many responded by transcending their immediate circumstances, reflecting on what meaning the intervention would hold for them in the short and long term. For example, some family participants were able to envision DigiComp Kids as part of their future daily lives, with their child in worse health than they were presently. The meaning of the system to these parents seemed to lie in its ability to create a digital bridge between hospital and home for families in need of support, either now or in the future. Evaluating the utility of a system by envisioning the role of technology in one's future circumstances is a view supported by the literature on digital technology adoption, in that users may change their perceptions of technology value and meaning over time, as their circumstances change [37]. These findings highlight the need for those responsible for implementing technological innovations such as the DigiComp Kids system to interpret user feedback in context, paying particular attention to the meaning that participants place on technology in their present and future lives. Consideration of these user perspectives allows for insight into factors that affect technology adoption, abandonment, or sustainment [38].

Comparisons with Prior Work

Results from DigiComp Kids usability testing using the Connected Health System build on previous usability studies by highlighting the critical roles of multi-method data collection in usability testing, consideration of the critical role of human factors, and the role of virtual health systems in connecting patients, families, and clinicians across traditional geographic barriers, as detailed below.

DigiComp Kids usability testing resulted in relatively high SUM scores across end-user groups. Despite this, interview findings gathered from end-users in our study assisted in identifying areas for improvement in the DigiComp Kids intervention. As was emphasized by DigiComp Kids study participants, the process of implementing virtual health interventions requires attention to be paid to the subjective needs of end-users, together with the goals of the intervention and system requirements. These subjective needs are often best gathered using qualitative techniques, which help to distil user experience data essential to assessing end-user acceptance. This finding aligns with the literature in which subjective user needs gathered via qualitative techniques illuminate distinct and important insights into end-user acceptance. For example, in a study of the comparative effectiveness of three virtual health media for communicating health information to parents, authors found no significant differences in knowledge retention or efficiency of parents using each of the three tools, yet, subjective feedback revealed a strong preference of one tool over the other two. Similar to qualitative results generated by family members in DigiComp Kids, parents in this study desired a tool that was simple, trustworthy, efficient, and gives practical information on condition management [39]. These qualities were important to parents in this study, and were found to influence parents' perceptions of usability of different media, separate from quantitative metrics of usability that were collected [39]. This study highlights the importance of gathering both quantitative and qualitative information from end-users, as each may offer different insights into end-user preference and overall usability. In our study, gathering qualitative experience data helped to contextualize the intervention and raise issues for system improvement that otherwise may not have been uncovered until full scale implementation.

A second important finding of DigiComp Kids usability testing was the critical role of human factors in virtual health system usability. Human factors, or the ways that people interact with technology, have a critical impact on the success of virtual innovations [40]. In our study participants engaged in two tasks wherein icons or functions that they were required to access were hidden, either within another icon on the tablet or in a different section of the clinician portal. For instance, in Task 7 for family and home-based clinicians (find and up-to-date medication list), the folder that participants were required to locate was hidden within another folder. Conversely, all other icons that participants were asked to find were accessible through paths from the main screen. Similarly, when hospital-based clinicians undertook Task 8 (change the schedule of Wellness Surveys to be sent to participants), they needed to navigate out of the individual patient profile to the main hospital clinician portal before being able to access the survey scheduling function, while all other clinician tasks were accessible through the individual patient profile. These two tasks resulted in high error rates and low satisfaction ratings were corroborated by frustration voiced by participants in qualitative interviews for these tasks. Other usability studies have found similar results. For example, in a study in which authors tested the usability of patient portals for parents of children with chronic disease (i.e., cystic fibrosis, diabetes, arthritis) using scenario-based usability testing and think-aloud protocols, high error rates and low completion scores resulted when information was located in a different place than participants expected [41]. This direct relationship between system ease of use and participant task performance speaks to the importance of understanding human factors within formative usability testing procedures when innovating in the virtual health sphere [38].

Finally, of particular importance to DigiComp Kids participants was the ability to connect with remote clinicians in differing geographic locations. In a similar usability study, McGillion and colleagues examined usability of a postoperative hospital-to-home remote automated monitoring intervention, and found that being able to connect remotely with care team members was invaluable, particularly for patients experiencing acute recovery [42]. As was the case in our study, patient participants expressed a sense of security in knowing that a clinician would be able to monitor their postoperative progress and was reachable, should it be required [42]. This theme reinforces the important role that virtual health technologies can have in transcending traditional barriers to providing and receiving healthcare, such as physical location, while offering patients and families additional support in their home environments. This point may be particularly important for patient and families with frequent or intensive healthcare requirements, such as those with complex chronic conditions.

Limitations

One potential limitation of this study was the lack of diversity in participant samples. All participants in this study were English-speaking females, and the majority were Caucasian. While prevalent groups included in this study (i.e. primary caregivers for children, nurses) have historically been predominantly female, inclusion of male participants may have yielded different results. Inclusion of non-English-speaking participants was not possible at the time of this study, due to limitations of the study team. Additionally, family participants were well-educated and at least “somewhat experienced” using tablet technology, thus, our results may not be reflective of family members with lower education or less experience with tablet computing. Although the objective of a usability testing study is not to generalize results to a broad population, but to uncover areas of usability strength and opportunity to make refinements, it is possible that the inclusion of a more diverse group of participants would have yielded different results and perspectives.

Another potential limitation of this study is that collection of data related to the SUM metric and its component parts may have missed information that other scales capture. Our choice to collect data on effectiveness, efficiency, and satisfaction was guided by accepted usability standards [17], which are well-captured in the SUM. However, other scales, such as the Net Promoter score [43] and the Standardized User Experience Percentile Rank Questionnaire (SUPRQ) [44] capture data that we did not, such as participant ratings of trust and credibility of the intervention. We are confident that some of these data came through in our qualitative interviews, however, we did not collect quantitative data related to them.

Finally, task completion rates across all groups were 100%, as shown in Tables 4-6. This may represent a user belief bias in our results such that participants may be more likely to believe that the task they are being asked to complete is indeed achievable in a simulated testing scenario. Alternatively, because participants were trained in DigiComp Kids system use immediately prior to usability testing, perfect task completion scores may simply represent increased training material retention by participants due to the short interval between training and testing times.

Conclusions

Implementation of virtual health system solutions for children with medical complexities and their families is an important initiative in providing comprehensive care in the home setting. This usability testing study offered valuable insights in the pre-clinical implementation phase for the DigiComp Kids intervention using the Connected Health System. Examples of such insights include the importance of tailoring the implementation of the system to match individual user needs, streamlining system features in key areas to allow for intuitive system use with the fewest steps possible needed to complete tasks, and investigation and consideration of the meaning attached to system use by participants to allow for insight into system adoption and sustainment. Taken together, these findings emphasize the importance of formative virtual health system testing in order to uncover challenges early and refine the intervention to suit the needs of end-users.

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Chapter 5: Discussion and Conclusion

The challenges that face CMC, their families, and clinicians related to iatrogenic harms and unmet care needs are difficult to address using conventional, in-person care models (Berry, 2015; Bradford et al., 2014; Cheshire et al., 2010; Srivastava et al., 2005). As such, the aim of this sandwich thesis was to develop and user test a digital health-enabled intervention to provide hospital-to-home care for CMC. This thesis has three main components, including a scoping review (Bird et al., 2019), a description of the DigiComp Kids co-design framework (Bird et al., 2021), and a report of the usability testing process and results for DigiComp Kids (Bird et al., 2022).

The objective of the scoping review was to summarize the current body of literature concerning the use of synchronous digital technologies to deliver care to medically complex children at home (Bird et al., 2019). A total of 38 articles were included, spanning feasibility studies, studies that aimed to directly deliver care to CMC via digital health, and studies that aimed to support parents to care for CMC at home (Bird et al., 2019). Results of the scoping review emphasized the need to include end-users in the design of digital health interventions in order to promote the development of digital heath systems that meet end-user needs (Bird et al., 2019).

In the next phase of this sandwich thesis, scoping review results were used to inform co-design of the DigiComp Kids intervention. In this phase, the needs of end-users, including hospital- and home-based clinicians, as well as parents of medically complex children receiving care at McMaster Children's Hospital, were solicited in relation to requirements for the provision of safe at-home care for CMC (Bird et al., 2021). Through the development and application of a co-design framework, generative techniques for channeling creativity resulted in actionable steps to customize the Connected Health Kit from Cloud DX to meet the needs of local end-users.

Finally, the usability testing process for DigiComp Kids identified areas of strength and opportunity within the system with the aim of optimizing system processes and features before large-scale deployment (Bird et al., 2022). The DigiComp Kids system attained usability scores in the 80th percentile and above according to hospital- and home-based clinicians and family members of CMC (Bird et al., 2022). In addition, areas of opportunity for optimizing the system were identified during user testing, such as highlighting the necessity of safeguards and detailed alternative workflows in case of power failures (Bird et al., 2022).

The results of these studies contribute to the growing body of evidence related to caring for medically complex populations using digital health technologies. The aims of this chapter are to: (1) synthesize the results of the previous three chapters that comprise this thesis and summarize the lessons learned across studies, and (2) make recommendations as they apply to nursing practice, education, research, and policy, in relation to using digital health technologies to enhance care for medically complex populations. Finally, strengths and limitations of this thesis will be discussed, and conclusions will be drawn.

Synthesis of Findings and Recommendations

Select findings from the scoping review, co-design process, and usability testing of the DigiComp Kids intervention are summarized below, framed by the concepts of technological, human, and contextual factors drawn from the eHealth Holistic Framework used throughout this thesis (van Gemert-Pijnen et al., 2011). The eHealth Holistic Framework highlights the existing gap in literature between the postulated benefits of digital health technologies and the actual outcomes of these technologies when deployed in practice, which often fall short of their predicted benefits (van Gemert-Pijnen et al., 2011). These digital health technologies are often developed by research teams without adequate attention paid to human factors, such as involvement of end-users in the design of interventions, resulting in a lack of adoption, scale, and spread (van Gemert-Pijnen et al., 2011). Based on a critical appraisal of existing eHealth frameworks, empirical research, and discussions with researchers in digital health, the eHealth Holistic Framework was chosen to guide this thesis because it brings together elements that impact the design, implementation, and sustainability of digital health interventions, such as the complex interactions between technologies, humans, and the contextual environment that must be accounted for when developing, implementing, and evaluating digital health interventions (van Gemert-Pijnen et al., 2011). The complexity of both the technologies used in digital health interventions, as well as the context of healthcare in which they are implemented, results in interdependent technological, human, and contextual factors that all affect the outcomes of digital health implementation (van Gemert-Pijnen et al., 2011). Simply put, digital health technologies are developed to be used by real people within their real environments, such that it is impossible to develop effective technologies without consideration of factors that will influence them in the real world.

In this context, facets of the category 'technological factors' include hardware and software components of digital health interventions, availability and function of supporting features such as Bluetooth services and broadband Internet, as well as related concepts such as data transfer and information privacy and security. Human factors refer to characteristics of the human-technology interface such as individuals' preferences, routines, and habits when using technology. Finally, contextual factors refer to the environment, including its physical, social, and political characteristics and the resources available that affect the development, implementation, adoption, and sustainability of digital health innovations. In what follows, select results from the three studies comprising this thesis will be discussed in relation to salient technological, human, and contextual factors that surfaced within them, with the aim to inform recommendations for the design of digital health interventions for complex care populations.

Technological factors: Synthesis. Results from the scoping review, co-design process, and usability testing undertaken in this sandwich thesis support that technological factors associated with digital health innovations have important impact on system acceptability, usability, and opportunities for scale and spread. For example, within studies included in the scoping review, authors reported systemic disparities in patients' opportunities to engage with digital health due primarily to a lack of access to high speed Internet services required to participate in digital health interventions (Gur et al., 2017; Ludikhuize et al., 2016). In one included study from the Netherlands, the limited availability of Internet services with sufficient bandwidth to provide a reliable video connection proved to be an implementation barrier to providing video consultations for coagulation factor replacement to families of children with hemophilia (Ludikhuize et al., 2016). Because the target time for coagulation factor replacement therapy in hemophilia patients experiencing bleeding episodes is less than 120 minutes, authors reported that a lack of availability of reliable video connections could delay home- or hospital-administered treatment (Ludikhuize et al., 2016). Those families living without access to reliable video connections are therefore more susceptible to negative clinical outcomes resulting from delays in treatment (Ludikhuize et al., 2016).

In another study included in the scoping review from Israel, authors found that cystic fibrosis patients living in rural areas tended to have more technical difficulties using digital health to connect with specialists, which limited their ability to build meaningful clinician-patient relationships (Gur et al., 2017). Positive clinician-patient relationships are critical to effective treatment in children with cystic fibrosis as treatment plans are lifelong and notoriously demanding— often requiring over two hours per day for treatment activities, including the administration of multiple medications and physical therapy sessions in addition to dietary and lifestyle modifications (Sawicki et al., 2009). For these reasons, treatment adherence is often problematic— in one study, mean medication adherence in cystic fibrosis patients was estimated at 48% (Quittner et al., 2014). A known facilitator of treatment adherence is positive patient-clinician relationships, thus, if patients living in rural areas are disadvantaged in their ability to participate in digital health interventions that facilitate positive clinician-patient relationships, patient clinical outcomes are likely to be negatively affected (Drotar, 2009; Gur et al., 2017). These studies demonstrate the relative disadvantage that is experienced by medically complex populations, highlighting the crucial importance of reliable connection infrastructure to facilitate timely interactions when using digital health intervention approaches.

The DigiComp Kids intervention provides families with a Samsung tablet, Bluetooth-enabled pulse oximeter with heart rate monitoring capabilities, and dual tympanic-temporal infrared thermometer, which wirelessly transmit data to a cloud-based portal accessed by hospital teams. Though remote monitoring devices used Bluetooth connections to enable short-range data transfer to the Samsung tablet, uploading these data to the cloud-based portal uses an Internet connection as a backup to cellular communications. Though tablets in the DigiComp Kids user testing process had cellular communications enabled, some technical difficulties using this feature occurred during testing, such as difficulties uploading biometric data from a tablet to the clinician-facing portal. Though these instances were rare, they required a switch from a cellular to an Internet connection when they occurred. For future large-scale roll-out, patients living in rural or remote areas may be disadvantaged in their inability to access some features of the DigiComp Kids program if they are without access to high-speed Internet connections. Consideration should therefore be given to strategies to improve the health equity of these groups, such as the provision of temporary access to high-speed Internet services or alternatively, use of highly reliable cellular packages to bypass the need for wireless Internet connections.

Technological factors: Recommendations. Barriers to accessing broadband Internet influence digital health innovations' impact on health equity. Health equity, or the absence of systemic disparities in health between groups of differing social advantage or class (Braveman & Gruskin, 2003), is closely related to the opportunities that social groups have to participate in health-promoting initiatives, such as digital health interventions. Over time, relative divergence in health equity between those with social advantage and those without can contribute to the 'Digital Divide'—a phenomenon whereby opportunities to access digital information and communication services are more limited for socially disadvantaged individuals, such as those from lower socioeconomic backgrounds (Crawford & Serhal, 2020; Ramsetty & Adams, 2020). As a lack of access for some groups to digital health information persists, digital health technologies amplify disparities in health between groups, allowing socially advantaged groups the ability to access and act on reliable health information, as well as to participate in digital health promoting initiatives, while socially disadvantaged groups are not afforded those opportunities (Makri, 2019). On the other hand, increasing access to digital health innovations for all can support a shift toward a more equitable society, and thus, **digital health innovations have the ability to help curb or exacerbate the 'Digital Divide'** (Sieck et al., 2021).

The design of digital health innovations and related implementation programs must work toward minimizing the 'Digital Divide' by providing opportunities for inclusion in digital health to those who may not have the personal resources to do so. For nurse researchers and innovators who design, implement, and evaluate digital health innovations, an important aspect of ensuring the equity of these innovations is providing participants with all necessary hardware and software to engage with the innovation, regardless of social or economic factors. Some researchers are already taking steps toward this goal. For example, to mitigate potential inequities, some studies included in the scoping review delivered digital health interventions to families via loaned equipment and temporary access to high-speed Internet (Bradford et al., 2010; Katalinic et al., 2013; Looman et al., 2015; Looman et al., 2018; Ludikhuize et al., 2016; McCrossan et al., 2012; McCrossan et al., 2008). In the Canadian context, investigators in recent trials have also begun to provide digital healthcare using bundled interventions, whereby the technology and cellular interface are provided to patients as an 'all-in-one' solution, diminishing the 'Digital Divide'. For example, in a recently published interim analysis of a virtual clinical management program for medically complex ventilated children and adults, investigators provided patients with a tablet and

SIM card with which to conduct virtual visits, so as enhance connectivity and neutralize patient-incurred costs (Amin et al., 2021). In a second recent study, investigators in the PVC-RAM-1 trial provided patients with Bluetooth-enabled wireless remote monitoring devices which were paired with a preprogrammed, cellular modem–enabled Samsung tablet computer (McGillion et al., 2021). In both of the aforementioned studies, patients were loaned hardware interfaces such as tablet computers with which they accessed the intervention (Amin et al., 2021; McGillion et al., 2021). This model highlights the important role that private industry may play in curbing the 'Digital Divide' by contributing loaner equipment to digital health intervention studies that can then be provided to patients at little to no cost for pre-defined durations. Support for such private-public payment models for digital health initiatives has been articulated by organizations such as the United Nations and World Health Organization who endorse the incorporation of private health technologies into public health initiatives, in an effort to curb the 'Digital Divide' (Varghese, 2016).

The aforementioned initiatives highlight efforts to curb inequities in opportunities to participate in digital health interventions due to access issues including rurality and limited availability of Internet technologies. Though Canada is a high-income country, these efforts are still necessary— Canadian literature cites inequitable access to digital services as a critical barrier to increasing the uptake of digital healthcare (Bhatia & Falk, 2018). Specifically, of Canadians living in rural areas (<1,000 people), 37% reported that they had access to digital healthcare in 2020, while 54% of respondents living in urban areas (1 million+ people) reported access to digital healthcare (Canada Health Infoway & Leger, 2020). Similarly, Canadians with low digital health literacy scores reported less access to digital healthcare (34%) than those with higher digital health literacy scores (57%) (Canada Health Infoway & Leger, 2020). These statistics indicate that systemic barriers such as inequitable access to digital services limit some individuals' opportunities for effective engagement with digital health, disproportionately affecting those experiencing poverty, a lack of stable housing, or living in rural or remote locations, who tend to have fewer material resources available to participate in digital healthcare (Crawford & Serhal, 2020). As such, equitable access to digital healthcare and impact of digital health interventions on the health equity of individuals and communities are important concepts to consider for those who design, develop, and implement digital health innovations. Efforts to diminish the 'Digital Divide' by supplying complex care populations with the necessary hardware and software components with which to participate in digital health initiatives are underway in Canada, but further advancements are needed in this area to ensure equitable access for all. Going forward, solutions to enable consistent reliability of cellular connections within the DigiComp Kids intervention will be sought with product vendors in an effort to improve the health equity-promoting ability of the intervention before future large-scale testing.

Human factors: Synthesis. Consideration of human factors—the ways in which people interact with technology—is critical to understanding why digital health innovations succeed or fail, and should be taken into account in the design of digital health innovations for complex populations (Huckvale et al., 2019; van Gemert-Pijnen et al., 2011). Examples of human factors which influence the success of digital health technologies include the attitudes and preferences of end-users with regard to digital management of their healthcare, real or imagined barriers to digital health innovation use, and end-user habits, rituals, and routines that affect the implementation and uptake of digital healthcare. In general, disregard of human factors when designing and implementing digital health innovations results in technologies with low impact in healthcare settings, because the resulting technologies do not correspond with the needs, habits, and rituals of end-users (van Gemert-Pijnen et al., 2011). To combat this effect, consideration of the needs, desires, and habits of end-users is vital to creating high-impact, usable digital health innovations.

In both the scoping review and usability testing phases of this dissertation, human factors had significant influence on digital health intervention outcomes. Results from the scoping review indicate that participants were generally open to learning and implementing digital health technologies that positively influenced their lives and work practices. For example, in one study examining administration of digital health interventions via the Intel Health Guide and Apple iPad in Australia, clinicians and patients were likely to adopt digital health interventions that were perceived as timesaving and less likely to adopt ones that perceived as cumbersome or error-prone, which impeded their work practices (Katalinic et al., 2013). In another study utilizing digital health to deliver services to patients with cerebral palsy, clinicians perceived barriers to utilizing digital healthcare in their practices; for example, physiotherapists indicated that video and audio quality at times impaired their ability to provide therapy, and social workers felt that using digital health versus in-person counseling impaired their ability to develop a personal connection with patients (Edirippulige et al., 2016). The end-user perceptions of interventions reflected in these studies significantly influenced the uptake of digital health use and highlights the need for end-user involvement when designing digital health innovations as well as detailed usability testing to uncover problems before large scale clinical implementation.

Commensurate with findings from the broader literature, the concept of gaining a “return-on-investment” in exchange for learning a new system and changing one’s practices to adopt digital health innovations was voiced by a majority of participants in DigiComp Kids usability qualitative interviews (Bird et al., 2022). Participants emphasized that they could envision incorporating the DigiComp Kids intervention into their lives *if* the intervention was felt to be making a positive and tangible impact on their lives (Bird et al., 2022). For example, family participants commented that they would scale their use of the system based on the needs of their child at the time. One family participant felt that they might use the intervention daily if there was an acute change in medical status taking place (for example, weaning from the ventilator), but cautioned that they would not want use of the system to be another task or chore added to their already full lives (Bird et al., 2022). This notion of willingness to put energy and effort into learning and using the DigiComp Kids system as long as it is perceived to be of benefit to participants underscores the importance of designing digital health innovations alongside end-users, so that their needs can be incorporated into innovation design.

A recent, relevant example from the literature of successful digital health innovation co-design for complex pediatric populations comes from researchers undertaking a participatory design process with nurses, pediatricians, and parents to develop a hospital-to-home transition platform for families discharged from a neonatal intensive care unit in Sweden (Strand et al., 2021). In this study, parents and clinicians contributed technical requirements for the digital health solution and iteratively provided verbal and written feedback on solution prototypes, with the resulting solution providing a means for replacing some in-person visits in a way that made both clinicians and parents feel safe and comfortable (Strand et al., 2021). By continually consulting end-users throughout the requirements generation and prototyping process, researchers in this study successfully created a system that was of value to both parents and clinicians, creating ‘buy-in’ for continual system use and eventual program sustainability.

Human Factors: Recommendations. In the field of digital health, there exists a well-known discrepancy between the hypothesized benefits of digital health interventions and the actual results of such interventions when deployed in practice, which often fall short of their aims. In order to realize the full benefits of digital health interventions, **digital health innovations must be designed and implemented to meet the needs of end-users.** The shift toward co-designing digital health innovations represents a movement from an institution-centred or researcher-centred view to an end-user-centred view toward health system innovation (Sanders & Stappers, 2008). In a digital health design paradigm where end-user views are central considerations, nurse researchers and innovators must pay careful attention to end-user workflows related to new technologies, as well as personnel and resource requirements for successful implementation (Imison et al., 2016). Moving forward, explicit use of co-design methodologies is recommended for design of digital health innovations for complex populations, in order to better understand end-user needs and tailor innovations to meet those needs from the outset of the innovation process.

Several examples of co-designing digital health innovations with end-users exist in recent literature. In one recent example, researchers aimed to engage caregivers of functionally-impaired older people in the design and prototyping of a website designed to support caregivers' help-seeking needs (Tremblay et al., 2021). Similar to the DigiComp Kids project, end-user engagement in this study was undertaken via co-design and user testing processes, wherein caregivers provided formative feedback for a web-based digital health solution (Tremblay et al., 2021). During usability testing, human factors concerns were raised that had the potential to affect the implementation success and sustainability of the innovation, such as participants having problems with efficiently identifying region-specific resources to support their caregiving needs (Tremblay et al., 2021). This example highlights the utility of co-design and usability testing studies in uncovering end-user needs prior to large-scale clinical implementation, thereby positively affecting the uptake and sustainability of digital health interventions. Lack of attention to incorporating formative end-user feedback before large-scale digital health innovation deployment may explain some of the discrepancy between the predicted benefits and actual outcomes of digital health innovations when deployed in practice (Harsha, 2019). The inclusion of the necessary knowledge concerning the complex needs and life contexts of end-users is only accessible through the inclusion of end-users in digital health design, and thus, moving forward, end-user engagement in this phase of digital health innovation is of critical importance.

Contextual Factors: Synthesis. Finally, an understanding of contextual factors, or the complex and interconnected network of settings and conditions into which a digital health intervention is implemented, is intrinsic to evaluating the outcomes of digital health implementation projects. Contextual factors refer to the physical environment as well as sociopolitical factors that may influence how an intervention is perceived, adopted, and/or sustained in practice (van Gemert-Pijnen et al., 2011). Digital health interventions are often implemented in order to solve complex and challenging problems related to clinical practice, patient care, and population health management.

As such, it is not enough for evaluations of these interventions to focus solely on the intervention itself and its associated clinical endpoints, as the contextual environment can carry unexpected influences that significantly alter how the intervention is implemented and used (Bird & Strachan, 2020; Greenhalgh & Papoutsi, 2018). Thus, an understanding of context can be useful to help explain the impact of digital health interventions (i.e. what works, for whom, and why?). This examination of context is often best garnered through the application of various research methodologies (e.g. quantitative, qualitative, and mixed or multiple methods) during digital health intervention evaluation to assist in developing a full understanding of the influence of contextual factors on intervention outcomes (van Gemert-Pijnen et al., 2011).

Across studies embedded in this thesis, the influence of context was apparent in several ways. First, some studies included in the scoping review cited contextual factors as having an impact on the outcomes of interventions. For example, Jury and colleagues noted the significant effect that complex billing procedures for physician consultations via digital health had in their study— 36% of booked telehealth appointments were not billed to Medicare, which led to an underrepresentation of intervention implementation (Jury & Kornberg, 2014). In other studies, results reported no difference or inconsistent differences between treatment groups, wherein contextual factors may have played an undefined but mediating role in the treatment effects seen. For example, Garbutt and colleagues (2010) studied the impact of a telephone-delivered asthma coaching program on the number of urgent care events and quality of life for pediatric asthma patients and their parents. Authors reported that the intervention had a significant impact on parents' quality of life as measured by the Pediatric Asthma Caregiver's Quality of Life Questionnaire, but not on children's quality of life or urgent asthma-related events (Garbutt et al., 2010). Further, parents' perceived quality of life improved with more coaching phone calls, but more phone calls were not necessarily related to further improvement in clinical outcomes or children's quality of life (Garbutt et al., 2010). Results of this study indicate that other, perhaps contextual, factors were at play which influenced parents' quality of life outcomes without being captured or reported in this study. A deeper examination of parents' quality of life, for example, perhaps using qualitative interviews, may have helped to illuminate mechanisms behind the dose-response effect shown between the number of asthma coaching phone calls and parental quality of life.

The influence of contextual variables was also highlighted in usability testing for DigiComp Kids. During the usability testing process, participants were asked to speak to contextual variables that may have affected their experience with the system. For example, participants were asked about elements of their physical environment that affected their use of the system, as well as the fit of the system with their usual care routines and workflows. Using these prompts, participants shared information that bears significant weight on the future implementation of DigiComp Kids, such as hardware requirements for system use at home, including a preference for longer charging cords for the tablet so as to facilitate ease of use when the device is plugged in, as well as appreciation of devices with long battery lives to enable them to be useful when traveling away from the home to clinic appointments and other services (Bird et al., 2022). As well, family participants described some overlap of the DigiComp Kids monitoring parameters with usual workflows for home care nurses, noting that homecare protocols for some children already specify collection of vital signs parameters such as pulse oximetry and heart rate (Bird et al., 2022). Participants additionally specified areas where DigiComp Kids might expand to in the future, such as continuous streaming of ventilator and oximetry data (Bird et al., 2022). Knowing this, negotiation of monitoring and documentation requirements with homecare agencies is an important step to undertake before implementation of DigiComp Kids to ensure that DigiComp Kids compliments usual care pathways for children with medical complexities, rather than conflicting with them (Bird et al., 2022). By calling out these contextual variables as important to system implementation, and by using various methods such as co-design activities and interviews to illuminate them, the complexities of the setting into which DigiComp Kids will be embedded may be better attended to during implementation.

More recent literature has further highlighted the importance of understanding contextual variables and their effects on digital health implementation and sustainability. For example, lessons learned from a longitudinal evaluation of a £37 million national digital health program in the United Kingdom revealed important contextual factors that affected the ability of the health system to support and promote the digital health program (Lennon et al., 2017). Within the “Delivering Assisted Living Lifestyles at Scale” (dallas) program, a wide range of digital health products targeting various demographic groups were developed and implemented at a population level with the aims of promoting general wellness, self-management, and independent living (Lennon et al., 2017). Longitudinal program evaluation revealed contextual variables that influenced program adoption. For example, interoperability and the ability for patients to share information collected through digital health products and services to clinicians responsible for patient care proved to be key factors in the success of the dallas program (Lennon et al., 2017). Despite efforts by program implementers to improve product interoperability, some commercial companies engaged in the project perceived interoperability as a threat to their market share and business model (Lennon et al., 2017). This study highlights the importance of understanding contextual factors, such as the sociopolitical environment in which digital health programs are being implemented, as these unique variables often have influence on the outcomes of digital health deployment. Examples of these important sociopolitical factors include stakeholder buy-in and resistance, which have the ability to significantly affect the probability of successful program implementation (Tappen et al., 2017). During implementation, scale, and spread of the dallas program, the resistance of for-profit companies to cooperate with the aim to develop interoperable products proved to be a barrier to the progress and adoption of the larger dallas program (Lennon et al., 2017).

Contextual Factors: Recommendations. Attending to contextual factors enables those responsible for the design, program implementation, and evaluation of digital health innovations to be better informed as to the mediating influences at play between end-users and the innovation being implemented. Contextual factors which influence the design and implementation of digital health innovations are considered essential to account for when engaging in digital health evaluation by scholars who view evaluation as ‘social practice’— that is, evaluation as socially constructed and enacted by individuals (Greenhalgh & Russell, 2010). This view of evaluation considers aspects of the contextual environment such as values, perspectives, relationships, and trust, as integral components of digital health innovations to be assessed (Greenhalgh & Russell, 2010).

Understanding that an appreciation of contextual factors is crucial, success in digital health implementation and evaluation is often realized with well-thought-through usage of mixed methodologies. Knowing this, a lesson to carry forward is that **digital health innovations may benefit from evaluation designs that capture contextual variables, in addition to defined outcomes**. By employing a full range of quantitative, qualitative, and mixed methods evaluation designs for digital health programs, valuable information may be captured that can assist in understanding the full range of innovation impacts and mediating factors at play, as contextual factors may not easily be accounted for using evaluation methods that focus solely on linear cause and effect relationships (Greenhalgh & Russell, 2010). Due to the influence of contextual variables, multiple methods may be required to evaluate digital health innovations as they are implemented in real-world environments.

Recent advancements in thinking around digital health evaluation design approaches have surfaced in response to calls for innovation in this field. For example, Guo and colleagues (2020) have suggested that cluster randomization trials and micro-randomization trials may provide solutions for researchers seeking digital health evaluation approaches that maximize the cost-effectiveness and timeliness of evaluations while maintaining robust data outputs. In cluster randomized trials, groups of patients are randomly allocated to receive a new intervention or standard care, allowing researchers to account for the specifics of the contexts in which interventions are evaluated, and the influence of various contextual variables on intervention results (Hurley, 2020). For example, if researchers were to evaluate the deployment of a digital health intervention based on rosters of patients in various clinical practices (i.e., the ‘clusters’), investigation of the characteristics of the practice that influence the uptake of the intervention in addition to the effects of the digital health intervention would be possible (Hurley, 2020). However, one caution to note with cluster randomized trials is that differences in intervention uptake or effects between various clusters require careful interpretation to distinguish between the role of the context and the role of other factors, such as the types of patients enrolled in each cluster, on effects shown (Hurley, 2020).

In micro-randomization trials, researchers evaluate the effects of individual components of interventions by delivering them to patients multiple times in a given period, with each delivery designed to impact a proximal outcome that will in turn affect a long-term outcome. For example, an mHealth intervention might be designed to increase an individual’s physical activity in the 30 minutes following the delivery of an activity suggestion to their phone (proximal outcome), with a goal of increasing individuals’ overall moderate intensity physical activity (long-term outcome) (Walton et al., 2018). Researchers using micro-randomized trial designs can randomize individuals to various treatment options each time a treatment component may be delivered, allowing for hundreds or thousands of randomizations during a single study. In so doing, researchers may make inferences about the causal effect of treatment components as well as the sequencing or combination of these components that produce the best effect (Walton et al., 2018). Moving forward, use of innovative evaluation methodologies that allow for investigation of intervention effects as well as mediating contextual variables are recommended to fully capture the relationship between variables at play in digital health innovations. Based on these recommendations, future effectiveness trials of DigiComp Kids should incorporate methodologies that allow for careful consideration of both interventional and contextual effects, such as cluster- or micro-randomized trials.

Strengths and Limitations

Strengths of this sandwich thesis include the purposeful, sequential approach to intervention development and testing, the incorporation of a robust theoretical framework throughout all studies, and the deep engagement of end-users in this work. Using a step-wise approach to intervention development allowed for results of the scoping review to inform the process of co-design and intervention development, including building on lessons learned from other studies. The use of the eHealth Holistic Framework as theoretical scaffolding throughout all three phases of this thesis allowed for conceptual continuity, such as the identification and analysis of technological, human, and contextual factors in each phase. Finally, the deep engagement of end-users in various roles in this work—as co-authors, steering committee members, and research participants—allowed for continual attention to the needs of family members and clinicians of CMC for digital healthcare innovation. The robust understanding of these needs informed all phases of this work and were crucial to the creation of the DigiComp Kids intervention as a usable, acceptable intervention.

There are also several limitations to this work. First, though the scoping review considered international literature, the co-design work and usability testing of DigiComp Kids occurred in Hamilton, Ontario, and therefore the results and lessons learned may not apply to those in other geographical locations or with substantially differing cultural and socioeconomic backgrounds. Next, though recruitment for co-design work as well as usability testing was open to participants of all sexes and gender identities, clinicians and family members who chose to participate were largely female. While a predominantly female sample for both co-design and usability testing may well be an accurate representation of end-users, as caregiving roles such as nursing and parenting are indeed gendered in nature (Revenson et al., 2016), the voices of male participants such as fathers were not captured in this study. This is an important limitation as fathers' needs, perspectives, and experiences of using digital health to care for CMC may differ significantly from those of mothers. In addition, due to the small number of participants included in usability testing, the sample of children in this study is not representative of the full span of ages, medical conditions, and level of medical/social complexity or acuity that would typically be included in a pediatric complex care population. Next, the perspectives of CMC themselves in co-design and usability testing were captured indirectly by their parents, as proxies, for children who were non-verbal, as well as by observing the children's body language while usability testing the DigiComp Kids system, and not as direct verbal messages from children themselves. While some CMC have verbal communication abilities, many do not, and this study was limited in its resources to be able to gather direct perspectives as to the needs and experiences of CMC themselves. A closer and more in-depth exploration with CMC related to the benefits and challenges of the DigiComp Kids system may yield different perspectives than the ones captured in this study. Finally, usability testing in this thesis was conducted with a single enabling technology provided by a sole vendor, Cloud DX. For future scalability of the DigiComp Kids intervention, technologies may be supplied by additional vendors, and would require a similar granular examination of usability as was conducted in this thesis.

Conclusions

This study is the first of its kind to co-design and usability test a digital health innovation to provide comprehensive hospital-to-home care for CMC, their families, and clinicians. Using a theoretically informed approach, the influence of technological, human, and contextual factors was repeatedly highlighted throughout this work, representing the need to attend to these factors during the design, development, and implementation of digital health technologies. Several overarching lessons were learned, including optimizing the potential of digital health innovations for reducing the 'Digital Divide', the need to include the perspectives of end-users when designing digital health innovations, and the importance of using the full spectrum of evaluation methods available for assessing the impact of digital health innovations in complex, real-world contexts. This work also found that the incorporation of co-design principles allowed for the innovation of a digital health intervention that was useable and acceptable by a group of its target end-users.

Building on these lessons learned, the immediate next step for the DigiComp Kids intervention is to further refine the system according to feedback gathered from end-users during usability testing. A careful examination of health equity principles in relation to the DigiComp Kids system is also warranted to ensure that it has been optimized to reduce the ‘Digital Divide’ to the fullest extent possible. Finally, in planning for an effectiveness trial of the DigiComp Kids intervention, consideration will be given to selecting a trial methodology that allows for a robust examination of the impact of both the intervention itself, as well as surrounding contextual factors.

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