A DESCRIPTIVE CORRELATIONAL STUDY OF RATE AND DETERMINANTS OF PARENTAL MHEALTH ADHERENCE TO SYMPTOM HOME MONITORING FOR INFANTS WITH CONGENITAL HEART DISEASE DURING THE SINGLE VENTRICLE INTERSTAGE PERIOD: THE DOMAIN STUDY

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by
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ABSTRACT

Single ventricle heart disease care in the ambulatory setting affects approximately 4,000 infants in the United States annually. Treatment typically involves a three-staged surgical strategy over the first three years of life with parental home monitoring of the infant during the interstage period, which is the time between the first two surgeries. Symptom home monitoring during the interstage period increasingly requires technology to maximize patient outcomes. Mobile health, or mHealth, transfers infant hemodynamic monitoring data captured by parents from the home to designated registered nurse coordinators who monitor the data remotely. Parental mHealth symptom home monitoring adherence is critical to improve morbidity and reduce mortality in infants during this high-risk period. However, rates and determinants of mHealth adherence have yet to be studied. The purpose of this research was to quantify the rate of parental mHealth adherence and to describe the relationship between patient-related, family-related, community-related, and healthcare system-related determinants of parental mHealth adherence for infants with congenital heart disease during the single ventricle interstage period. The pediatric self-management conceptual framework was used with a retrospective, descriptive, correlational research design. De-identified data from 312 infants treated at nine pediatric hospitals between March 2014-September 2019 were included from the Cardiac High Acuity Monitoring Program multi-site registry. This registry was developed in 2014 by Children's Mercy Kansas City and includes patient, family, and medical record data. SPSS AMOS software was used to refine a model to develop a theoretically identified, recursive structural equation model. The rate of parental mHealth adherence-data days was 75.54%. The overall model variance was 24.0%, with good local and global fit. A higher parental age ($p \leq .001$) and Medicaid insurance ($p = .009$) were positively associated with parental mHealth adherence. Higher rates of implementation of oxygen saturation symptom home monitoring were associated with lower clinic visits ($p \leq .001$) and increased education levels ($p = .001$). Adherence to mHealth video use was associated with increased healthcare team driven communications ($p = .047$). Future research areas proposed from these findings include determining mHealth adherence rates associated with optimized clinical outcomes and ways to reduce parental mHealth non-adherence.

APPROVAL PAGE

The faculty listed below, appointed by the Dean of the School of Nursing and Health Studies, have examined a dissertation titled "A Descriptive Correlational Study of Rate and Determinants of Parental mHealth Adherence to Symptom Home Monitoring for Infants with Congenital Heart Disease during the Single Ventricle Interstage Period: The DOMAIN Study," presented by Lori Anne Erickson, candidate for the Doctor of Philosophy degree, and certify that in their opinion it is worthy of acceptance.

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CHAPTER 1

INTRODUCTION

Congenital heart disease occurs in nearly 1% of live births, affecting about 40,000 neonates per year in the United States (Emelia et al., 2018; Hoffman & Kaplan, 2002). Approximately 25% of babies with congenital heart disease have critical congenital heart disease, heart defects requiring cardiac catheterization or surgical intervention within the first 31 days after birth (Oster et al., 2013). Of the infants with congenital heart disease, 1% have univentricular, or single ventricle congenital heart disease (Mozaffarian et al., 2016). Infants with single ventricle congenital heart disease routinely follow a three-staged surgical strategy over the first three years of life (Alsoufi et al., 2015). Parental home monitoring of the infant with single ventricle congenital heart disease occurs between the first two surgeries, the interstage period. Parental symptom home monitoring programs were developed in early the 2000s in response to the high incidence of infant mortality, up to 20%, in the interstage period (Ghanayem et al., 2012). Symptom home monitoring during the interstage requires the use of medical equipment of oxygen saturation monitors and infant weighing scales to evaluate oxygen saturations, heart rates, and weights. The National Institutes of Health (NIH) outlines mHealth as the ability to use mobile technology to manage, monitor, and treat illnesses from a distance to improve health outcomes, service, and research (Slaper & Conkol, 2014). Since 2012, mHealth is an additional technology tool available for symptom home monitoring for ease of data transfer from parents to the interstage healthcare team. Healthcare teams, primarily led by registered nurse coordinators, may be able to intervene early on signs of hemodynamic concerns by changes in oxygen saturations, heart rates, or infant weight. Some mHealth applications even have video options for use during the interstage period.

This chapter will include the description of single ventricle and interstage care with parental symptom home monitoring. The review of the use of mHealth in pediatrics, adherence, and the interstage period will set the groundwork for discussion of the significance of interstage care and mHealth technology. Lastly, an overview of clinical outcomes with parental symptom home monitoring will be presented with specific research aims and research questions related to parental mHealth adherence.

Description of the Problem

Single ventricle congenital heart disease is one of the most severe types of congenital defects due to near-certain mortality without surgical intervention (Pasquali, 2015). Single ventricle congenital heart disease is a life-long condition that can never fully be corrected. Surgical intervention has been termed *palliative* due to the inability of the surgeon to re-route the heart to its normal structure of all four chambers and four valves (Abernathy, 2018). However, with staged palliative surgeries, infants can achieve the maximization of oxygenated blood to the systemic circulation, which improves long term outcomes (Park, 2014). Heart and pulmonary function can also be enhanced through surgical procedures (Yuan & Jing, 2009). Care of an infant with a single ventricle begins with prenatal detection, then involves critical stages of surgeries-- stage one, stage two, and stage three, and potential heart transplant.

Stages of Care

Prenatal detection. Prenatal detection is the use of ultrasound echocardiography of fetal cardiac circulation to diagnose congenital heart disease before birth. Rates of prenatal detection for infants with single ventricle congenital heart disease can range from 59 to 85% (Lafranchi & Lincoln, 2015). The main reason that prenatal detection is important for infants born with single ventricle congenital heart disease is the timing of initiation of the critical medication, prostaglandin. Prostaglandin is required to maintain fetal circulation after birth for infants with single ventricle congenital heart disease and should be initiated in the first few hours of life to preserve infant hemodynamic stability through cardiac ductal circulation (Morris et al., 2014). Prenatal detection of congenital heart disease also allows the cardiology healthcare team to prepare families for the birth of an infant who will require palliative cardiac surgeries (Lafranchi & Lincoln, 2015). Families then have time to relocate closer to the tertiary pediatric cardiovascular surgery center, meet the healthcare team, and prepare financially and psychologically for their infant's long-term journey with congenital heart disease (Morris et al., 2014).

Stage one surgery. After birth, the first single ventricle surgery usually occurs in the first week of life. The type of stage one surgery depends on the infant's cardiac diagnosis and the need for increased blood flow to the lungs or systemically to the body (Park, 2014). Congenital heart defects that require stage one surgery include hypoplastic left heart syndrome, pulmonary atresia, tricuspid atresia, and unbalanced complete atrioventricular canal defects (Alsoufi et al., 2016). Congenital heart defects with decreased blood flow to the lungs primarily undergo a modified Blalock-Taussig or central shunt surgery to increase blood flow to the lungs (Dobrolet et al., 2011). Infants with low blood flow to the body as with aortic atresia, undergo a Norwood surgery (Lafranchi & Lincoln, 2015). The Norwood surgery, named after the pioneering surgeon Dr. William Norwood, was first performed in the early 1980s, and is a complicated pediatric cardiac surgery. Post-surgical outcomes for the Norwood surgery are used as an essential measure for infant mortality and morbidity (Anderson et al., 2016). There are two types of Norwood type surgeries, the Hybrid approach, with bilateral pulmonary artery bands and a patent ductus arteriosus stent, or a modified Blalock-Taussig or Sano shunt with an aortic reconstruction, atrial septectomy, and Damus-Kaye-Stansel anastomosis (Hanke et al., 2016; Ohye, Schranz, & D'Udekem, 2016).

The time between the stage one surgery and before stage two surgery is known as the interstage period, or between stages period, where the risk is highest for poor outcomes due to single ventricle physiology and imbalances of blood flow to the lungs and the body (Park, 2014). During the interstage period, the goal is for infant age-appropriate weight gain, 75 to 85% oxygen saturation levels, age appropriate heart rate, and healthcare provider in person or video assessment with stable hemodynamic parameters and respiratory exam (Nieves et al., 2017). Findings outside of the expected ranges for oxygen saturation and weight gain are the primary indicators of imbalances of blood flow to the infant's body or lungs (Shirali et al., 2016). The complex period of the interstage will be discussed extensively later in this chapter.

Stage two surgery. Stage two surgery is known as the Bidirectional Glenn surgery, where the superior vena cava is surgically connected to the pulmonary arteries, to provide blood flow to both lungs without first entering the heart (Yuan & Jing, 2009). All forms of single ventricle cardiac disease, no matter the type of stage one, undergo the Glenn surgery at approximately 6 to 9 months of age when pulmonary vascular resistance is lower than at birth (Colquitt et al., 2016). An infant who undergoes stage one Hybrid surgery will have a more extensive operation, the Comprehensive Stage two surgery, at the same age range as infants undergoing other Glenn surgeries (Park, 2014). Oxygen saturations are improved after the Glenn surgery to greater than 80% in most cases (Siehr et al., 2014). The risk of hemodynamic issues causing morbidity and mortality is much less after stage two surgery in comparison to stage one (Park, 2014).

Stage three surgery. The third surgery, stage three Fontan surgery, is completed around three years of age (Park, 2014). This surgical step provides fully oxygenated blood, typically greater than 92%, from the heart to the body and deoxygenated blood to the lungs in a surgically created circulation (Karamlou et al., 2018). These surgery techniques started in the 1980s, improved in the 1990s, and were refined in the 2000s. The oldest survivors have lived into their 40s, and long-term outcomes beyond that time are unknown.

Heart transplant. Currently, 67 to 80% of children with single ventricle survive to approximately 10 years of age without a heart transplant (Atz et al., 2017; Liu et al., 2018). A heart transplant is required when medical and surgical management has failed or when the disease has progressed to severe congestive heart failure. Transplant operations may occur between any stage of cardiac disease progression when medical and surgical interventions have failed. Higher risk of heart transplantation occurs in infants with hypoplastic left heart syndrome, higher rates of surgeries prior to a stage one Norwood surgery, and decreased pre-operative ventricular function (Ohye et al., 2010).

The three stages of surgery and potential heart transplant are critical time points in the life of an infant with single ventricle congenital heart disease. The period between the first two, the interstage period, is a complex period that requires interstage care from parental symptom monitoring, parenting in the interstage period, and interstage nursing care.

Interstage Care

Since the early 2000s, most cardiac surgery centers in the United States adopted the practice of parental symptom home monitoring for high-risk infants in the interstage period (Abernathy, 2018). A seminal symptom home monitoring study used a quasi-experimental design to evaluate daily parental home monitoring compared with in-person clinic visits with a cardiology provider. The study included 89 infants during the interstage period with single ventricle congenital heart disease and used pulse oximetry to assess oxygen saturation and infant scales to evaluate weight gain (Ghanayem et al., 2003). The symptom home monitoring group had no mortality (n= 0/24) while the in-person clinic visits only group had 15.8% mortality (n= 9/57) (p=.039). Despite the limitations of this study of small sample size, lack of randomization, and no masking of the intervention group, the implementation of parental symptom home monitoring programs has increased in pediatric cardiology over the last 15 years and is now the standard of care (Nieves et al., 2017). In a recent statement by the American Heart Association, parental symptom home monitoring programs for infants during the interstage period, with registered nurse coordinators as first responders, are recommended as a care model to combat the high rate of mortality and morbidity in this population (Marino et al., 2018).

Symptom home monitoring in mHealth is the continuous evaluation of symptoms of an illness or condition from home evaluated by the patient or family and transmitted to the healthcare team (Hamine, Gerth-Guyette, Faulx, & Green, 2015). Failure to manage or resolve symptoms of an illness or condition can lead to physical suffering, change in clinical status, or even death (Martin, Feig, Maksoudian, Wysong, & Faasse, 2018). Clinical management in the interstage period includes the symptom home monitoring of an infant's hemodynamic status through evaluation of heart failure, pulmonary congestion, or malnutrition. This evaluation identifies hemodynamic status through oxygen saturations, heart rates, and weight gain for infants with single ventricle cardiac disease (Abernathy, 2018). The parental symptom home monitoring steps included parents assessing their infant daily for four to six months for symptoms that indicated hemodynamic changes through measurement of oxygen saturation, heart rate, and infant weight. These data are gathered using oxygen saturation monitors and infant scales, which are provided to the parents by the hospital or durable medical equipment companies (Shirali et al., 2016). Data from home monitoring was documented on paper forms by parents and sent via email or verbally communicated (Shirali et al., 2016). Prior to the use of mHealth, symptom home monitoring systems required the parent to obtain the data, recognize deviations in symptoms, and then notify the healthcare team. Parents were taught to report an issue with the infant to the registered nurse coordinators by telephone, pager, email, or electronic message (Nieves et al., 2017). With the use of mHealth for interstage monitoring, parents now communicate their infant's symptom home monitoring data and video with interstage symptom home monitoring applications such as the Cardiac High Acuity Monitoring Program (CHAMP©) application.

Parenting in the Interstage Period

Parents are legal guardians who provide care for infants with single ventricle congenital heart disease at home during the interstage period. This may include mothers, fathers, grandparents, aunts, uncles, foster parents, and adult siblings. A grounded theory study of 53 parents and grandparents was conducted focusing on caregivers of children with hypoplastic left heart syndrome. The qualitative interviews found a primary theme of parenting under pressure (Rempel, Ravindran, Rogers, & Magill-Evans, 2013). The study presented four phases of parenting: "(1) realizing and adjusting to the inconceivable, (2) growing increasingly attached, (3) watching for and accommodating the unexpected, and (4) encountering new challenges" (Rempel et al., 2013, p. 619). Parenting infants with single ventricle heart disease like hypoplastic left heart syndrome has also been described as vigilant parenting, where at times this vigilance may be appropriate or potentially exaggerated in others parents through hypervigilance of symptom home monitoring (Meakins, Ray, Hegadoren, Rogers, & Rempel, 2015). Understanding the complexities of parenting an infant with single ventricle heart disease is key to evaluating symptom home monitoring and parental mHealth adherence.

Nursing Care in the Interstage Period

Interstage symptom home monitoring has traditionally involved multiple complex actions that required close collaboration between parents, registered nurse coordinators, and providers of the healthcare team. Interstage symptom home monitoring registered nurse coordinators are registered nurses with pediatric cardiology and cardiac surgery expertise developed through clinical experience. The registered nurse coordinators also have additional training through orientation and hospital-based courses regarding the risks of hemodynamic issues that can occur with each single ventricle heart disease (Nieves et al., 2017). Interstage symptom home monitoring training of parents involved in-person training provided in the hospital by registered nurse coordinators. Informational brochures and return demonstrations of infant home monitoring techniques were used to determine if parental home symptom monitoring training had been adequately achieved prior to discharge of the infant from the hospital.

The registered nurse coordinators, located at the hospital, provide outpatient nursing care through a review of weekly trends of infant weight gain, oxygen saturations, heart rates, video evaluation, and cardiac disease-specific hemodynamic changes (Shirali et al., 2016). Symptom home monitoring data was communicated by parents and then tracked, averaged, and charted by registered nurse coordinators. The registered nurse coordinators would escalate concerns as needed to providers of infant hemodynamic changes or possible instability were detected. Families were instructed by the registered nurse coordinators to call 24 hours a day for urgent changes in infant oxygen saturation, heart rate, breathing, feeding, or behavior that might indicate the need for immediate evaluation by the healthcare team. Additionally, registered nurse coordinators could use video enabled mHealth applications to review infant's color, neuro-behavior affect, breathing rate, work of breathing, and overall demeanor (Shirali et al., 2016).

Parental concerns were triaged by the registered nurse coordinator and escalated based on urgency to healthcare providers such as advanced practice nurses, pediatric cardiac fellow physicians, pediatric cardiologists, or emergency department physicians (Bingler et al., 2018). The specialized single ventricle healthcare providers evaluated infants in-person in the cardiology clinic usually monthly and as needed for parental home monitoring hemodynamic concerns, or red flags (Bingler et al., 2018). Registered nurse coordinators' that care for infants born with single ventricle congenital heart disease are integral in the system of communication and triaging in this high-risk population (Davis, Miller-Tate, & Texter, 2018; Shirali et al., 2016). Daily review of parent-entered mHealth data can provide more opportunities for proactive, timely interventions in this high-risk population (Bingler et al., 2018).

Interstage care is accomplished by parental symptom home monitoring, registered nursing coordinators triage, multi-disciplinary providers, and critical communication from home to the healthcare team. The addition of mHealth to interstage care has provided the opportunity for healthcare teams to receive data faster from parents at home but also the ability to see infants remotely through videos. The use of mHealth in expanded areas of pediatrics and the understanding of the concept of adherence will be discussed in the next sections to build to the significance of the research problem of parental mHealth adherence for infants with single ventricle congenital heart disease in the interstage period.

Use of mHealth Technology in the Care of Pediatric Patients

The World Health Organization classifies mHealth as a part of electronic health (eHealth) and as any "medical and public health practice supported by mobile devices, such as mobile phones, [as] patient monitoring devices" (2011, p. 6). Telemedicine, eHealth, and mHealth can address disparities in access to specialized care in areas like neonatology and pediatric cardiology (Sauers-Ford et al., 2019). In 2020, the recent issues with COVID-19 global pandemic and restrictions requiring social distancing has sped the need for telemedicine to aid in clinical decision support for fragile infants (Smith et al., 2020). Mobile technology can provide mobility, nearly instant access, and direct communication of healthcare needs to support families and healthcare systems (Marcolino et al., 2018).

Mobile technology. Mobile phones are ubiquitous across the world, with a higher number of cellular telephone lines in use than the world's population (International Telecommunication Union, 2018). In 2018, 80.9% of people had access to broadband internet to connect online in the United States (International Telecommunication Union, 2018). Although mHealth provides a communication tool for parental symptom home monitoring, the use of this tool requires the ability to connect from home through cellular or wireless internet service. Technology for parental symptom home monitoring with tablet-based or mobile telephone-based devices can offer a low-cost modality that improves access to care by increasing highly specialized provider availability for families (Nkoy et al., 2019). Technology through mHealth includes applications, secure messaging technology, and healthcare team dashboards where one-way and two-way communication between families and the home monitoring team can occur for patient monitoring, decision support, and treatment adherence (World Health Organization, 2011).

Outcomes using mHealth. Mobile applications for home monitoring allow the parent to "input patient-specific information and the use of formulae or processing algorithms, output and patient-specific result, diagnosis, or treatment recommendation to be used in clinical practice" (Barton, 2012, p. 2). The input of data by parents to the healthcare team through mHealth applications allows the review of data through a mHealth dashboard to enhance the ability to clinically care for complex pediatric patients at home (Barton, 2012). Since 2014, parental symptom home monitoring has become ingrained in the culture of healthy infant care and chronic complex pediatric disease through surveillance at home with mHealth technology and remote monitoring (Leaver, 2017). In complex pediatric disorders, the use of mHealth technology is correlated with improved parental management of complex pediatric conditions, better communication with providers, and improved decision-making with home monitoring (Slaper & Conkol, 2014).

The addition of mHealth into symptom home monitoring care models improves the registered nurse coordinator's ability to practice within the scope of practice for pediatric nursing. The American Nurses Association (2015) reported coordinated efforts for updated standards of practice for pediatric nurses. Ambulatory registered nurse coordinators working in a specialty pediatric clinic, such as a parental home monitoring program of infants during the interstage period, provide care coordination as a vital link between family and the healthcare team. Additionally, single ventricle registered nursing coordinators provide "accessible, comprehensive, continuous, and efficient" quality healthcare (American Nurses Association, 2015, p. 28).

Adherence

Adherence is the "extent to which a person's behavior […] corresponds with agreed recommendations from a health care provider" (Sabate, 2003, p. 3). Adherence is a proximal outcome that occurs before distal outcomes like mortality, morbidity, treatments, interventions, or access to healthcare (Modi et al., 2012). Compliance is the extent to which a parent's behavior conforms to healthcare professionals' advice for managing pediatric chronic illness (Nichol, Venturini, & Sung, 1999; Sabate, 2003). Older literature commonly reported compliance instead of adherence representing a paternalistic approach of following medical direction (Sabate, 2003). Concordance, another term that is sometimes used, emphasizes agreement between a family and the healthcare professional on a treatment plan (Dickinson, Wilkie, & Harris, 1999).

The antonyms of adherence--non-adherence, non-compliance, and non-concordance--are also related concepts that referred to discrepancies between a prescribed therapy and its execution (Sabate, 2003). Although there may be some variations, the most acceptable rate of adherence behavior is 80%, meaning 20% non-adherence to an intervention or treatment (Sabate, 2003). The comprehensive understanding of determinants for non-adherence is key to improving adherence. Non-adherence to long-term therapies has been described through patient-related, condition-related, therapy-related, socioeconomic-related, and health care team-related factors or determinants affecting the level of adherence (Sabate, 2003). Non-adherence can further be classified as intentional or non-intentional (Sabate, 2003).

Definition of parental mHealth adherence. The concept of mHealth adherence in pediatrics is the extent to which the parents' behaviors (transferring infant mHealth data from home monitoring to the healthcare team) agree with the healthcare provider's recommendations for parental home monitoring (Modi et al., 2012). A thematic analysis of research in parental mHealth symptom home monitoring use during the interstage period was used to develop a definition of parental mHealth adherence for infants with congenital heart disease during the single ventricle interstage period. This is the degree to which parents' transfer of their infant's mHealth data meet healthcare providers' recommendations for symptom home monitoring of oxygen saturation, heart rate, weight, and video evaluation. This definition and subsequent description are presented in Figure 1.1 as a conceptual analysis model.

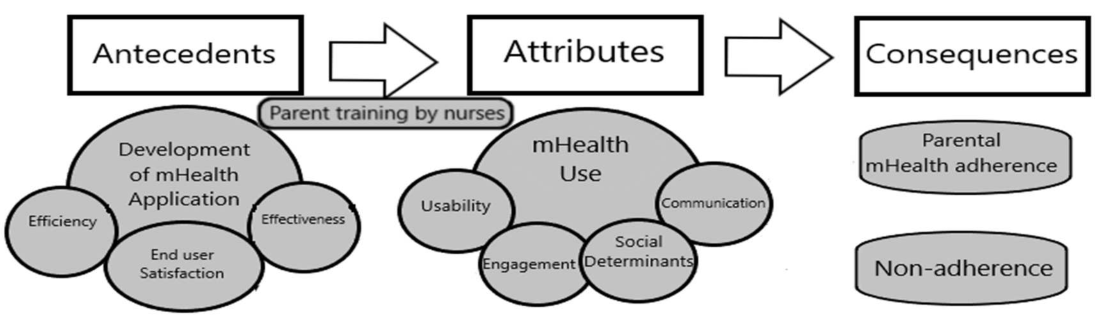

Figure 1.1. Parental mHealth adherence in the interstage conceptual analysis model

Using a definition of medication adherence which clarified initiation, implementation, and discontinuation (Vrijen et al., 2012), interstage mHealth literature was synthesized to develop definitions for initiation, implementation, and discontinuation for parental mHealth adherence (Black et al., 2014; Bingler et al., 2018; Cross, Steury, Randall, Fuska, & Sable, 2012; Shirali et al., 2016). The recommended frequency of hemodynamic data transfer is usually once daily for oxygen saturations, heart rates, weights, and videos (Shirali et al., 2016). *Initiation* in mHealth adherence refers to the first parental mHealth data transferred after the infant is discharged from the hospital, ideally on the same day of discharge as seen in Figure 1.2 (Black, Sadanala, Mascio, Hornung, & Keller, 2014). *Implementation* for parental mHealth adherence refers to the rate of data transferred for each symptom monitored and ideally transferred daily (Kumar et al., 2013). Symptom home monitoring is recommended to continue through the interstage period up until the day before the second surgery (Bingler et al., 2018). The measure of implementation adherence is a percentage calculated for each category of single ventricle symptom monitoring relevant to hemodynamic status, including of the infants' weights, heart rates, oxygen saturations, videos, and overall data days (Shaw et al., 2016), with perfect implementation adherence scoring 100%, and complete non-adherence scoring 0%. Partial adherence would score at 75% if data were transferred on 75 of every 100 non-hospitalized days during the interstage period, after the first hospital discharge and before the second stage surgery readmission. *Implementation data days* are the number of days in which parental mHealth data is transferred by the parents to the healthcare team (Bingler et al., 2018). The *data days transfer rate* is data days divided by the prescribed/expected number of days in which mHealth symptom home monitoring data is transferred by the parents to the health care team times 100. The adherence rate of data days ranged from 50.3 to 80% across pilot mHealth studies for parental home symptom monitoring for infants during the interstage period

(Black et al., 2014; Cross, Steury, Randall, Fuska, & Sable, 2012; Shirali et al., 2016). *Discontinuation* in parental mHealth adherence is the last day that data was transferred in the interstage period before the end of the interstage period.

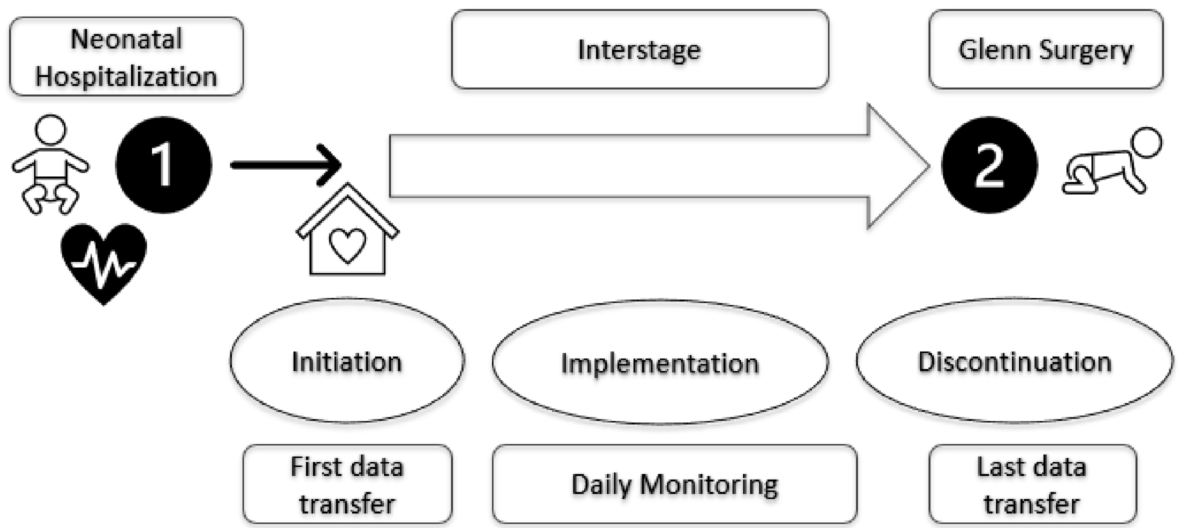

Figure 1.2. Interstage parental mHealth adherence outcome measures.

Other terms for mHealth adherence. Terms related to mHealth adherence may clarify the concept across disciplines and comparisons in nursing (McEwen & Wills, 2014). MHealth adherence may also be known as mAdherence, which is the adherence of patients and caregivers to chronic disease management (Hamine et al., 2015). Telehealth is the use of technology to bridge any distance in healthcare (Satou et al., 2017). Telemedicine is a specific technology of conducting provider care at a distance (Satou et al., 2017). EHealth is characterized by the World Health Organization as a cost-effective and secure use of information and communication technologies in support of health and health-related fields (World Health Organization, 2016). Telehealth, telemedicine, and eHealth are all related terms of mHealth connected to any transmission of health-related information compared with mHealth which is mobile health in the home setting (Niksch, 2015; Salisbury et al., 2016).

Prominent use of mHealth technologies exist for communication and disease management of adult cardiac disease, lung disease, transplantation, diabetes mellitus, and other chronic medical conditions (Devito Dabbs et al., 2009; Hamine et al., 2015; Shaw et al., 2016; Subhi, Bube, Rolskov Bojsen, Skou Thomsen, & Konge, 2015). In long-term therapies, factors related to the patient, medical condition, treatment, socioeconomic status, and health care team have all been associated with levels of adherence (Sabate, 2003).

Antecedents of mHealth adherence. Antecedents are phenomena that precede or provide preconditions for the concept (Rodgers, 1989). An important antecedent of parental adherence to mHealth for symptom monitoring is the development of adequate mHealth technology. The process of developing and evaluating tools for initial effectiveness, efficiency, and end-user satisfaction was highlighted as essential for appropriate home monitoring data transfer and to detect unintentional non-adherence due to technology or connectivity (Canter, Christofferson, Scialla, & Kazak, 2019).

Effectiveness referred to the accuracy and completeness of the specific goal to be reached through the mHealth technology; *efficiency* referred to the resources required to meet the objectives of the mHealth technology, and *satisfaction* was the acceptability of the mHealth technology for end-users (Health Information Management Systems Society, 2011). Evidence of the effectiveness of mHealth for parental monitoring of infants appeared in Shirali et al. (2016's) evaluation of CHAMP® mHealth technology. During the period studied, the use of a mHealth application was associated with a mortality rate of 0%, a significant improvement over the 17% mortality found with traditional monitoring alone

(Shirali et al., 2016). Black et al. addressed each of these issues in their pilot study with mHealth technology in the interstage, especially related to challenges with adherence for 18 infants with single ventricle heart disease in the interstage comparing outcomes of mortality with infants followed with traditional home monitoring. Effectiveness was decreased at a rate of only 66% of data transfer with data that was an attempt but incomplete; the concern for data transfer was mainly connectivity issues (Black et al., 2014). Cellular or wireless connectivity is required for the transfer of home monitoring data to the registered nurse coordinators for review. Sources found connectivity to be a principal reason for non-adherence (Marcolino et al., 2018).

Reduction of mHealth *efficiency* occurred when the information defined in the application programming for alerts, data values, and algorithms was not first reviewed by medical experts in the field, or the intervention delivered in the application was not supported by medical evidence (Subhi et al., 2015). Efficiency was an issue due to the set-up of the study design with concerns transferring to the research team prior to getting to the interstage registered nurse coordinators (Black et al., 2014). Black et al. (2014) reported in their feasibility study that satisfaction was low, with one family completely returning their mHealth home monitoring application prior to the stage two Glenn and 33% of parents had no initiation of the technology after hospital discharge due to unclear reasons. Efficiency cannot be achieved if the family does not have mobile equipment. Access to mobile devices is less of a concern with low-income families than it was five years ago, with close to three-fourths of the world's population having cellular connectivity, but access may remain an issue with in rural families' homes (DeKoekkoek et al., 2015). However, ongoing testing and evaluation of usability for mHealth technology including those applications that use video are vital for transfer of accurate symptom monitoring data as parents obtain new mobile health devices for use for symptom home monitoring (Shirali et al., 2016).

Another key antecedent to mHealth adherence was *parental training* in the use of the mHealth application, which was vital for achieving the rates for parental data transfer set by the healthcare team (Shirali et al., 2016). Registered nurse coordinators are key educators for parental use of mHealth. Thorough education, including the discussion of effectiveness (reasons mHealth is important) and efficiency (resources required at home including connectivity) (Alexander & Staggers, 2009), may be key to end-user satisfaction for both parents and registered nurse coordinators. Registered nurse coordinators often provide the training of parents for mHealth application use, so their initial instruction may influence the continued engagement and understanding of the mHealth application (Shirali et al., 2016). Parental anxiety may be reduced if they know there are regular communication and monitoring from the same nursing coordinators who provided their training (Shirali et al., 2016).

Attributes of parental mHealth symptom home monitoring adherence. Attributes of a concept are the behaviors and characteristics of the concept that define the phenomena within a specific population (Rodgers, 1989). Critical attributes of parental mHealth symptom home monitoring adherence include usability, communication, social determinants, and engagement (Black et al., 2014; Breitenstein, Brager, Ocampo, & Fogg, 2017; Hamine et al., 2015; Marmot et al., 2008; Modi et al., 2012). Each of these attributes will be described further in the next section.

Usability. Usability is the "extent to which a system, product, or service can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context" (International Organization for Standardization, 2018, p. 9241). In the literature on mHealth adherence, the usability of a health care product or technology was confirmed after multiple experiences in similar patient populations and following beta and pilot testing in a specified condition (Alexander & Staggers, 2009; Hamine et al., 2015). In the parental mHealth adherence research, processes of iterative communication and feedback from parents to healthcare information technology teams concerning issues with hardware or software were depicted as helping to improve the overall usability of mHealth tools (Shirali et al., 2016). A systematic review of mHealth remote monitoring reported barriers associated with mHealth usability, including technical malfunctions, short battery life, slow systems, lost or damaged devices, and changes in service plans (Simblett et al., 2018). Key facilitators for usability were precise, simple, and informative mHealth technology with a larger screen on the device (Simblett et al., 2018). Several sources indicated that parental mHealth adherence depended on technology that was consistent and usable for the intervention (Black et al., 2014; Shirali et al., 2016).

Communication. The definition of mHealth *communication* is parent-to-provider or provider-to-parent interactions conducted through dedicated applications, including patient portals, management systems, and other sophisticated communication software and platforms (Hamine et al., 2015). These interactions often comprised additional telephone and face-to-face visits to address concerns of parents while using mHealth technology. Rapid responsiveness to parent-initiated contact was a vital attribute of continued support from the healthcare and information technology teams (Black et al., 2014). Continuous, 24-hour-a-day support by a healthcare team knowledgeable in information technology was an integral part of parental mHealth adherence (Simblett et al., 2018). Difficulties or questions from parents about mHealth technology for home monitoring required prompt evaluation and intervention, especially if the difficulty was connectivity issues (Cross et al., 2012; Shirali et al., 2016).

Social determinants. Social determinants of mHealth for parents are "the immediate and structural conditions in which people are born, grow, live, work and age" that affected the use of mHealth by the parent for the infant's chronic disease management (Heiman & Artiga, 2015). Economic stability, neighborhood or community, education, food, and health care systems were all major social determinants that affect health outcomes (Heiman & Artiga, 2015). Social determinants have a significant impact on health outcomes such as mortality, morbidity, and health status, due in large part to access to health care (Heiman & Artiga, 2015). The cost and availability of mHealth technology equipment, availability of the health care intervention in the parent's primary language, educational and technological literacy of the parents, and availability for wireless or cellular connectivity in the parent's home community are all significant social determinants for mHealth use (Hamine et al., 2015; Shirali et al., 2016). Determinants of non-adherence are key to improving clinical care but also for future research study development, as the most non-adherent families may benefit the highest from mHealth technologies and equitable opportunities with mobile phones. A systematic review of 107 mHealth articles found that mHealth interventions were often implemented with high-risk, low socioeconomic populations, that otherwise may be difficult-to-reach patients (Hamine et al., 2015). Social barriers to adherence might be overcome with the use of mHealth that is tailored to the needs of the population with sufficient training by increasing opportunities for access to healthcare (Hamine et al., 2015).

Engagement. Engagement is "the level of activity within a program," including the rate of attrition of parents who returned or deleted the mHealth technology and the persistence of long-term use of the mHealth technology intervention (Donkin et al., 2013, p. e234). A randomized controlled trial of the ezPARENT program, a mHealth intervention for socioeconomically disadvantaged parents of young children, was focused on increasing parent training to deter maltreatment and abuse. Engagement was a central element of the study's success, with usage rates showing 82% completion of education modules and parents logging in on 77% of days in the three-month study period (Breitenstein et al., 2017). A recent systematic review of 33 mHealth remote monitoring studies focused on barriers and facilitators to patient engagement (Simblett et al., 2018). The review found barriers and facilitators to engagement included changes in health status (hospitalization days where home monitoring is not needed), usability (technical malfunctions or broken devices), convenience (forgetting to use mHealth or weak cellular coverage), perceived utility (financial costs and poor data reliability of home monitoring), and internal parental or external motivation from the healthcare team (Simblett et al., 2018).

Consequences of parental mHealth adherence. According to descriptions in the literature, consequences that followed from parental mHealth adherence included timely, accurate symptom home monitoring and communication with the healthcare team (Modi et al., 2012). Inversely, non-adherence led to delayed communication of symptom monitoring and associated morbidity (Black et al., 2014). Non-adherence often occurred with equipment failure (lack of efficiency) or end-user dissatisfaction (Cross et al., 2012).

Knowledge of the current rates of mHealth adherence is critical to understanding non-adherence. A three-group randomized controlled trial of 234 adolescents with asthma tested a mHealth intervention compared to standard care on medication adherence (Kosse, Bouvy, de Vries, & Koster, 2019). The ADAPT intervention was a mobile phone application that included weekly symptom monitoring of asthma, educational videos, medication reminders, and communication options with the healthcare team (Kosse et al., 2019). Limitations of the study include the risk of response bias of those participants willing and interested to use the mHealth intervention. There were 37.6% (n=88) of participants who were adherent starting the study, and while there may have been an additional benefit in only taking non-adherent participants, this baseline number does support that there were not only highly motivated or adherent participants enrolled. The adolescents with the lowest baseline adherence rates had the most substantial improvement in adherence but there was less improvement with adolescents who were already adherent to the medications (Kosse et al., 2019). Recognizing social determinants of non-adherence was cited as key to improving care and guiding future technology development, since the non-adherent families may benefit the most from mHealth technologies, especially the more equitable opportunities that widespread smartphone use allows.

In this section, an expanded definition of the phenomena of parental mHealth adherence to symptom home monitoring was thoroughly defined through a discussion of antecedents, attributes, and consequences. Through these concept discussions, the significance of parental mHealth adherence can be communicated through the multiple domains of patient-related, family-related, healthcare system-related, and community-related determinants.

Significance of the Problem

The significance of the problem of non-adherence to parental mHealth symptom home monitoring will be discussed in the next section through the incidence of births of infants with single ventricle congenital heart disease, the cost of interstage care, the cost of non-adherence, and post-operative and interstage outcomes. This research aims to support the National Institute of Nursing Research (NINR)'s expansion of research for chronic disease self-management and symptom management science to improve adherence to self-management interventions for populations including parents of high risk infants with single ventricle congenital heart disease (2016). These topics will develop the argument of the significance of parental mHealth adherence during the interstage period of infants with single ventricle congenital heart disease.

Incidence of Infants with Single Ventricle Congenital Heart Disease

In the United States, one in 110 infants is born each year with congenital heart disease (Lloyd-Jones et al., 2010). Single ventricle cardiac disease occurs in 5.9 out of 10,000 live births annually and include diagnoses such as hypoplastic left heart syndrome, hypoplastic right heart syndrome, and cardiac valve atresia of any kind (Lloyd-Jones et al., 2010; Reller, Strickland, Riehle-Colarusso, Mahle, & Correa, 2008). Approximately 4,000 infants are born each year with single ventricle congenital heart disease and are cared for across approximately 100 cardiac surgery centers in the United States, with the care occurring most often at the nearest tertiary hospital at birth (Czosek et al., 2013; Shirali et al., 2016). Over the past 15 years, the complexity of infants with hypoplastic left heart syndrome has increased with co-morbidities of associated genetic syndromes, non-cardiac anomalies, and secondary cardiac defects of total anomalous pulmonary venous return (Hamzah, Othman, Baloglu, & Aly, 2020). Single ventricle cardiac disease is a relatively small portion of the frequently occurring issue of congenital heart disease; but has an associated high cost for treatment and care.

Cost of Interstage Care

The incidence of infants born with single ventricle cardiac disease is relatively low. However, care of these infants is associated with high resource utilization and financial costs (Connor, Kline, Mott, Harris, & Jenkins, 2010; Dean, Hillman, McHugh, & Gutgesell, 2011; McHugh, Pasquali, Hall, & Scheurer, 2016; Petit, 2011). The initial neonatal stay for a stage one Norwood type surgery for hypoplastic left heart syndrome is often over $200,000 per patient for an average 25-day hospitalization (Anderson et al., 2016; Czosek et al., 2013; Dean et al., 2011). In 2009, the mean facility charge alone for inpatient hospitalization for cardiac surgery was $106,844, and this amount likely is much higher today (Chan, Kim, Minich, Pinto, & Waitzman, 2015). Using a quasi-experimental design, Shirali et al. (2016) compared traditional interstage monitoring with a newly implemented mHealth home monitoring technology for interstage communication from the family to the registered nurse coordinators to evaluate the interstage morbidity and associated charges. Unplanned readmission charges included parental interstage symptom home monitoring at an average of $249,000 per patient for interstage charges compared with patients utilizing a mHealth application interstage had $188,842 per patient (Shirali et al., 2016). The high-cost for healthcare during the interstage period may potentially be reduced with the use of interstage mHealth technology.

There are additional costs to the parents of infants with single ventricle congenital heart disease including constant *parenting under pressure* for parents of infants with hypoplastic left heart syndrome through the interstage (Rempel at al., 2013). The cost of interstage mortality is high and using interventions aimed at parents may help survival for the infants but also for survival for the parents themselves as they manage competing priorities of care (Rempel et al., 2013). A systematic review of 25 studies focused on the familial impact on families with infants with congenital heart disease and found that mothers had more anxiety than fathers (Jackson, Frydenberg, Liang, Higgins, & Murphy, 2015). There was more parental distress with parents during the interstage period compared with parents of infants with less critical congenital heart disease (Jackson et al., 2015). Additionally, families with fewer psychosocial resources and lower levels of support may be at risk of higher distress and lower well-being for both the parent and infant (Jackson et al., 2015).

Cost of Non-Adherence

In 2003, the reported rate of adherence to treatment in developed countries for chronically ill patients was between 50 to 60% for adults (Sabate, 2003). An estimated 50 to 80% of children and teens with chronic medical conditions have non-adherence with the treatment plan, which may lead to reduced beneficial health outcomes if they were otherwise adherent (McGrady et al., 2015). Additionally, non-adherence to medication regimens may account for up to $100 billion from medication-related hospitalizations and care in the United States (Anglada-Martinez et al., 2015). The use of healthcare resources through re-hospitalizations due to treatment failure and adverse health outcomes is an additional cost of non-adherence (Anglada-Martinez et al., 2015). The high price and high frequency of non-adherence is a significant issue for pediatric populations with chronic health issues, such as infant's with single ventricle congenital heart disease. However, the cost of non-adherence mHealth is not frequently reported. Decreased unplanned intensive care days and shorter delays in communication during the interstage period were found with utilization of a mHealth application compared with interstage monitoring (Bingler et al., 2018). Interventions aimed at reducing cost and reducing non-adherence, such as mHealth technology, should have a continued focus in mHealth adherence research.

Interstage Outcomes

For infants born with single ventricle congenital heart disease, the interstage period between stage one, after the initial neonatal hospitalization discharge, and stage two surgery has high infant mortality, ranging from 2 to 20% (Shirali et al., 2016). A large evaluation of 24,992 children from 333 hospitals was completed using the Kids' Inpatient Database from for mortality and complications evaluating interstage outcomes (Chan, Kim, Minich, Pinto, and Waitzman, 2015). The patients with the highest complexity, such as those undergoing the stage one Norwood surgery, were found to have an increased risk of 18.3 times for mortality (odds ratio [OR] 8.6-39.2 95% confidence interval (CI)) and a 4.6 times risk of in-hospital complication compared with infants with lower surgical complexities (OR 3.8; CI-5.7 95%) (Chan et al., 2015). A single site, 11-year, retrospective review of 486 infants with single ventricle congenital heart disease compared mortality outcomes between stage one Norwood surgery patients and shunt patients and found no significant difference in mortality between surgical types (11.1% vs. 6.8%; $p=0.17$) (Pizzuto et al., 2018). The current rates of interstage mortality after discharge home from the stage one surgery through to the stage two Glenn surgery for infants with single ventricle congenital heart disease is as low as 0% (Bingler et al., 2018) to 8% (Clauss et al., 2015). Morbidity events that can occur after the stage one surgery initial hospitalization into the interstage period include readmissions, prolonged hospital days, cardiac re-interventions, and malnutrition (Demianczyk et al., 2019; Hill et al., 2014).

Parental mHealth adherence for infants with congenital heart disease during the single ventricle interstage period is a significant research problem due to the high cost of non-adherence and associated mortality and morbidity. The ubiquitous rate of cellular and mobile devices provides an opportunity to provide mHealth technology to parents of infants in all areas of the United States. As seen in other pediatric chronic conditions, effective mHealth innovations are more likely to be sustainable with adequate proactive communication structures in programs that started with a robust home monitoring program and then add mHealth technology (Hamine et al., 2015). The discussion of mHealth technology that has been used in the interstage period and potential resulting research gaps will be reviewed in the next section.

Outcomes of Interstage mHealth Technology

Use of mHealth technology has demonstrated improved outcomes for infants during the interstage period. For example, one of the earliest pilot feasibility studies tested a mHealth home monitoring intervention to reduce mortality and morbidity (Cross et al., 2012). Using a quasi-experimental design with 49 infants with single ventricle congenital heart disease, the authors found a 9.1% interstage mortality for infants followed with mHealth (n=3 of 33 infants) compared with 7.1% (n=1 of 14) in infants with no mHealth monitoring (Cross et al., 2012). Another example is a quasi-experimental, pre-post design evaluating the Cardiac High Acuity Monitoring Program: CHAMP® mHealth application and its impact on parental home monitoring of 83 infants with single ventricle congenital heart disease found a reduced mortality from 17% to 0% during the period evaluated (Shirali et al., 2016).

Inversely, a single site, pre-post design, feasibility study comparing 18 infants with single ventricle congenital heart disease found increased infant mortality with mHealth parental home monitoring 22% compared to 11% with traditional home monitoring and the study was halted (Black et al., 2014). Technical mHealth issues, connectivity issues, and parental non-adherence that had both intentional and non-intentional reasons were reported. Non-adherence to mHealth monitoring was also a reason for an earlier stage two surgery for a high-risk infant during the study (Black et al., 2014). In addition to the importance of the finding of mHealth non-adherence and increased interstage mortality the study suggested that changes in adherence patterns away from the daily regimen may expose at-risk social situations prompting communication from the healthcare team (Black et al., 2014).

Interstage mHealth use has been evaluated in few experimental studies. For example, a randomized crossover study of 31 infants during the interstage period compared traditional home monitoring to a mHealth application intervention (Bingler et al., 2018). The mHealth intervention resulted in significantly fewer intensive care unit days, faster time to for recognition of red flags reducing interstage growth failure, and lower resource utilization during the unplanned readmissions (Bingler et al., 2018).

The outcomes of the use of mHealth in the interstage period for home monitoring have been mainly positive with reduced interstage mortality and lower resource utilization during readmissions (Bingler et al., 2018). Albeit a small sample size (n=9), it is vital to acknowledge the higher rate of interstage mortality with the mHealth technology in one case as the rate of non-adherence was a critical factor in the study and discussion (Black et al., 2014).

Rate of Parental mHealth Adherence

The specific frequency of adherence to parental home monitoring mHealth data transfer needed for improved infant outcomes in the interstage period is unknown. Researchers have demonstrated that weekly communication with the healthcare team improved outcomes and reduced adverse events in the home monitoring model of interstage nursing care (Ghanayem et al., 2012). Generally, the daily transfer of parental mHealth symptom home monitoring technology data is the recommended prescribed rate by the healthcare team (Shirali et al., 2016). Parental mHealth adherence has been previously evaluated primarily by data days, or the days where mHealth symptom home monitoring data is expected, is subsequently transferred by the parents to the healthcare team (Bingler et al., 2018; Black et al., 2014). Parental adherence to mHealth rate through data days was reported with a median rate of 80% (Bingler et al., 2018).

Determinants of mHealth adherence in pediatrics. The determinants of mHealth adherence for parental home monitoring includes multiple domains that influence the frequency of adherence. The processes and behaviors that affect the domains of patient-related, family-related, community-related, and healthcare system-related determinants, but all are a gap in current knowledge. The literature on patient-related determinants of parental mHealth adherence is lacking but there are numerous publications with increased interstage mortality and morbidity (Pasquali, 2015). Caregiver age, the total number of family members, and the number of children in the home have been reported as family-related determinants of adherence in mHealth publications outside of interstage care (Black et al., 2014; Modi et al., 2012; Moffett, Mattamal, Ocampo, & Petit, 2011). Community-related determinants include the neighborhood in which the family resides and the availability of health resources in their community (Modi et al., 2012). Healthcare system-related determinants of parental mHealth home monitoring adherence of infants with single ventricle congenital heart disease during the interstage period are the modifiable and nonmodifiable influences such as cardiology clinic availability, frequency of clinic visits, and patient and provider communication of interstage symptom monitoring and patient to provider two-way communication and frequency of clinic visits (Modi et al., 2012). Communication between parents and the healthcare team through mHealth technology provides increasing ways to increase access to the health system, which may improve distal outcomes through adherence to mHealth technology.

The multifaceted approach for the understanding and evaluation of parental mHealth adherence is key to strong research design and subsequent analysis. There is a dearth of research literature describing the rate and determinants of parental symptom home monitoring adherence during the interstage period of infants with single ventricle congenital heart disease. The review of parental mHealth adherence expanded beyond the single ventricle interstage period is critical for understanding mHealth adherence factors. Although the use of mHealth in pediatric cardiology is growing, the research is often at the pilot stages of evaluation despite the incidence and high-risk nature of infants with single ventricle heart disease.

Theoretical Frameworks

The theory of health behavior change (Fedele, Cushing, Fritz, Amaro, & Ortega, 2017; Marcolino et al., 2018; Parker, Dmitrieva, Frolov, & Gazmararian, 2012) and pediatric self-management conceptual framework (McGrady & Hommel, 2013; Naranjo, Mulvaney, McGrath, Garnero, & Hood, 2014) were some of the few conceptual or theoretical approaches used in research publications for parental home monitoring through mHealth technology in pediatrics. The pediatric self-management conceptual framework was used to guide this study through the primary concepts of self-management, adherence, and outcomes (Modi et al., 2012). The pediatric self-management conceptual framework provides a comprehensive pediatric model of self-management that is not disease-specific and considers complicated family, clinical, and developmental processes for children, parents, healthcare system, and community in separate domains, as seen in Figure 1.3 (Modi et al., 2012). The four domains of individual, family, community, and healthcare systems provide behaviors, processes, and influences that are both modifiable and non-modifiable and impact self-management through key cognitive, emotional, and social processes (see Figure 1.4). Consistent with the framework, in this study, parental influences will be the antecedent and adherence will be the mid-range outcome (Modi et al., 2012).

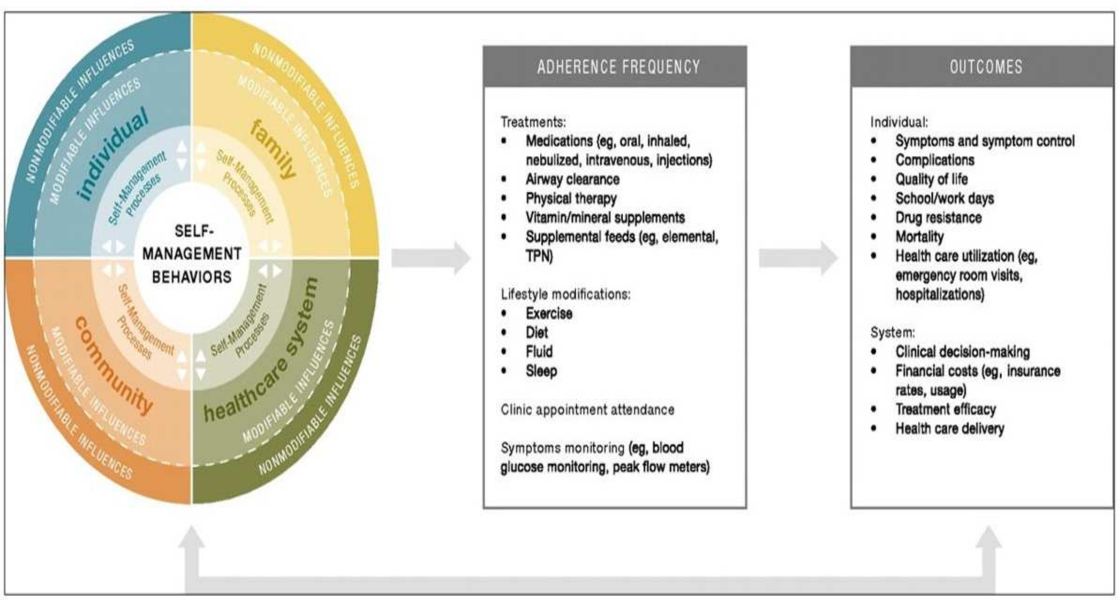

Figure 1.3. Pediatric Self-Management Model. Note. Reproduced with permission from *Pediatrics, Vol. 129,* Page e476, Copyright © 2012 by the American Academy of Pediatrics (AAP). Approval for use included in the Appendix.

Domains	Influences: Nonmodifiable[a]	Influences: Modifiable	Processes	Behaviors
Individual	• Age • Gender • Developmental level • Cognitive functioning (eg, IQ) • Sociocultural factors (eg, race/ethnicity, SES, religion)	• Disease and treatment knowledge • Child internalizing/ externalizing symptoms • Coping style • Health beliefs and perceptions (eg, self-efficacy, perceived stigma)	• Determining health care needs • Seeking disease- and treatment-related information • Communication with the medical team	• Taking medications or treatments • Attending clinic appointments • Refilling prescriptions • Self-monitoring of symptoms • Lifestyle modifications • Behavioral compliance with parental instructions and medical procedures • Self-care (eg, dressing changes) • Health care utilization
Family (eg, caregivers, siblings, extended family)	• Parent marital status • Family structure • Cognitive functioning (eg, IQ) • Insurance coverage • Income • Education • Sociocultural factors (eg, race/ethnicity, SES, religion)	• Disease and treatment knowledge • Family internalizing/externalizing symptoms • Family coping style • Health beliefs and perceptions • Family functioning • Relationship quality • Parental monitoring and supervision • Parental involvement	• Determining child's health care needs • Seeking disease- and treatment-related information • Allocation of treatment responsibility • Behavioral management (eg, reinforcement) • Management of stress, physical, and psychological functioning within the family • Communication with the medical team	• Giving medications or treatments • Attending clinic appointments • Refilling prescriptions • Monitoring of symptoms • Supporting lifestyle modifications • Parental support and supervision of treatments • Providing access to recommended therapies (eg, nutrition, physical activity) • Sibling/extended family support and behavioral compliance with parental requests • Respite care • Health care utilization
Community	• Neighborhood • Availability of health and wellness resources within communities and schools	• Peer support • Social stigma • School-based accommodations related to health • Availability of social networking	• Learning about patient's disease and treatments • Degree of social acceptability of disease • Provision of support for treatment regimens • Collective beliefs • School reintegration	• Provision of support for treatment regimens • Engagement in patient's disease-related activities (eg, camps) • Use of social networks • Community support
Health care system	• Availability of health care resources (eg, access, health insurance)	• Patient-provider communication • Frequency of clinic visits • Medical training models	• Modification of communication styles • Shared decision-making	• Patient advocacy • Legislation/health care reform • Health care provider training in sociocultural factors

[a] Nonmodifiable factors are defined as those that are not typically targeted in intervention but may be used to target subgroups for intervention or stratify intervention samples.

Figure 1.4. Pediatric Self-Management Domains, Influences, Processes, and Behaviors. *Note.* Reproduced with permission from *Pediatrics, Vol. 129,* Page e477, Copyright © 2012 by the American Academy of Pediatrics (AAP). Approval for use included in the Appendix.

Summary

Parents of infants with single ventricle heart disease care for their child on a journey through congenital heart disease treatment from the prenatal period through three surgeries, and potential heart transplant. The period between stage one and stage two surgery, the interstage, is a high-risk time for infant mortality and morbidity. Infants with single ventricle congenital heart disease are a high risk, low-frequency population who require parental symptom home monitoring supported by a highly specialized registered nurse coordinator during the interstage period. Parental symptom home monitoring adherence has been poorly studied due to the lack of access to data collected via paper documentation and phone communication. Parental mHealth symptom home monitoring of infants with single ventricle heart disease is improved through tracking data, assisted decision-making, and improved communication with the health care team (Slaper & Conkol, 2014). The use of mHealth to capture and relay parental symptom home monitoring data to the healthcare team provides an opportunity to explore the determinants of parental symptom home monitoring adherence without solely extrapolating distal clinical outcomes onto the proximal outcome of adherence to mHealth technology.

Mobile health technology removes the steps of the parent solely interpreting much of the symptom home monitoring data, provides the ability for videos of the infant to be reviewed from the healthcare team remotely, and allows the registered nurse coordinator to triage the data directly from secure healthcare team web portals. Despite reporting rates of overall data days and admissions during the interstage related to adherence, there are gaps of knowledge of rates of adherence, and a multifaceted approach to categories of determinants of parental mHealth adherence: patient-related, family-related, community-related, and healthcare system-related.

Specific Aim and Research Questions

The purpose of the DOMAIN (Determinants Of parental Mhealth Adherence to symptom home monitoring for INfants with congenital heart disease during the single ventricle interstage period) study is to determine the rate of parental mHealth symptom home monitoring adherence and to describe the relationship between patient-related, family-related, community-related, and healthcare system-related determinants of parental mHealth adherence for infants with single ventricle heart disease during the interstage period.

The specific aim of this study is to quantify the rate and to evaluate the relationship between patient-related, family-related, community-related, and healthcare system-related determinants of parental mHealth symptom home monitoring adherence of infants with single ventricle congenital heart disease during the interstage period. This DOMAIN study proposes the following research questions:

1. What is the rate of parental mHealth symptom home monitoring initiation, implementation, and discontinuation adherence of infants with congenital heart disease during the single ventricle interstage period?
2. What is the relationship between patient-related, family-related, community-related, and healthcare system-related determinants and parental mHealth symptom home monitoring adherence for infants with congenital heart disease during the single ventricle interstage period?

Mhealth technology provides the ability to transfer data to the healthcare team daily, changing the care paradigm to a proactive model of ambulatory nursing so continuous care can be provided with self-management support from parents at home. Improved clinical outcomes have been demonstrated with parental use of mHealth home monitoring of infants in the interstage period, but information about parental adherence to symptom home monitoring is lacking. The results of this proposed study may provide insight into the rate and determinants of parental mHealth symptom home monitoring adherence for this high-risk pediatric cardiology population. Chapter 2 contains an overview of the pediatric self-management conceptual framework, the status of current literature on pediatric use of mHealth, and a review of literature of parental use of mHealth technology for infants with single ventricle heart disease during the interstage period. This section will give more insight into the gaps in knowledge of the rate of parental home monitoring mHealth adherence and patient-related, family-related, healthcare system-related, and community-related determinants of mHealth adherence to parental to infants with congenital heart disease in the single ventricle interstage period.

CHAPTER 2

REVIEW OF LITERATURE

Chapter 2 examines the current body of literature pertaining to parental mHealth symptom home monitoring adherence of infants with single ventricle congenital heart disease during the interstage period. Initially, the proposed conceptual framework for this dissertation study will be presented for the organization of literature and understanding of the current state of the science. Secondarily, the background of literature expanded beyond the interstage period will be reported to provide an overview of mHealth, pediatrics, and pediatric cardiology outcomes that are patient-related, family-related, healthcare system-related, and community-related determinants of adherence and clinical outcomes. Although adherence is a proximal outcome, the understanding of the distal outcomes is also key if the literature is lacking reports of the rates and determinants of adherence. Lastly, a critical review of the pertinent literature from parental mHealth adherence for symptom home monitoring for infants in the single ventricle interstage period, including methods, results, discussion, strengths and limitations, and implications, will be presented. This critical review of the literature will provide gaps in the current knowledge and support for this dissertation.

Conceptual Framework

Pediatric self-management conceptual framework is the proposed theoretical framework for this research. The pediatric self-management conceptual framework was first described in pediatrics and health psychology literature by researchers at the Cincinnati Children's Center for Treatment Adherence and Self-management (Modi et al., 2012). The Center's research team has a fellowship that works with a range of pediatric chronic conditions, including diabetes, irritable bowel disease, and epilepsy (McGrady & Hommel, 2013; Pai & McGrady, 2014). The pediatric self-management conceptual framework provides a comprehensive pediatric model of self-management that is not disease-specific and considers complex family, clinical, and developmental processes for children, parents, healthcare system, and community in separate domains (see Figure 1.3) (Modi et al., 2012). The pediatric self-management model is conceptualized in Figure 1.3 with three interdependent areas: self-management, adherence frequency, and outcomes that flow from left to right (Modi et al., 2012). The four domains of individual, family, community, and healthcare systems provide influences that are both modifiable and non-modifiable and impact self-management through key cognitive, emotional, and social processes (Modi et al., 2012).

Historical Background

The formulation of the pediatric self-management conceptual model addressed the synthesis of complex behaviors and relationships in pediatrics (Modi et al., 2012). The parent theories of pediatric self-management, the health belief model, and ecological systems theory, provide numerous concepts that are central in nursing knowledge development including systems, interactions, outcomes, family-focused, person and environment interactions, and support for care (Fawcett & Desanto-Madeya, 2012). Modi and colleagues (2012) of the pediatric self-management conceptual framework for children with chronic health conditions for the following: (a) development of evidence-based interventions for self-management, (b) program development to reduce poor self-management, and (c) to inform healthcare policy for health and psychosocial outcomes.

Key Concepts

A metaparadigm is the most substantial subject matter or matters of interest to a specific discipline (McEwen & Wills, 2014). The content of the pediatric self-management conceptual model is comprehensive of interests of nursing research with all four nursing metaparadigm concepts addressed: nursing (healthcare team), person (children and family receiving care), environment (modifiable and non-modifiable influences), and health (adherence and outcomes) (Butts & Rich, 2015). The three key concepts in the pediatric self-management conceptual framework are self-management, adherence, and outcomes (Modi et al., 2012).

Self-management. Self-management is the interaction of health behaviors and processes that families engage in for the care of a chronic condition, which is similar to but is not recommended for interchangeable use with adherence (Modi et al., 2012). Pediatric self-management is not the same as adult self-management and should not be used interchangeably with adherence as self-management leads to adherence frequency (Modi et al., 2012). Management processes include treatment regimens with medications, dietary prescriptions, obtaining lab work, attending clinic visits, and communication with the healthcare team (Modi et al., 2012). Processes of self-management are influenced by health beliefs, or an individual's perception of the impact of behaviors on health. These perceptions are built through cognitive, emotional, and social processes (Modi et al., 2012). Self-management has been described since the 1950s (Lorig & Holman, 2003; Rapoport, 1957). The concepts of adherence and self-management have both been used frequently through nursing literature but have had more applications at the disease-specific level since 2012.

Adherence. Adherence is the degree a person's behavior coincides with medical or healthcare advice (Modi et al., 2012). Frequency of adherence to prescribed healthcare regimens for home monitoring, medication, diet, or healthcare treatment for infants with a medical condition is gauged by their parents' behaviors (Modi et al., 2012). Operationalization of adherence frequency outcomes occurs through the quantification of medication use, lifestyle modifications through diet and exercise, and clinic appointment attendance (Modi et al., 2012). Symptom home monitoring for chronic health conditions with mHealth devices at home is an adherence outcome used in both adult and pediatric literature (Whitehead & Seaton, 2016).

Outcomes. Pediatric self-management outcomes include individual and system outcomes. Individual results include symptoms and symptom control, complications, quality of life, school days, drug resistance, mortality, and health care and utilization (Modi et al., 2012). System outcomes include clinical decision-making, financial costs, treatment efficacy, and healthcare delivery (Modi et al., 2012).

Propositions

Self-management behaviors, processes, and influences are presented additionally in Figure 1.3 (Modi et al., 2012). Propositions are the assumptions that support the conceptual model to be true or false, based on the concepts within a framework (Risjord, 2009).

Relationship between concepts. The main propositions of the pediatric self-management conceptual framework involve the relationships between the concepts, such as the circular pattern of influence between the elements in each of the behaviors, processes, and influences in self-management (Modi et al., 2012). The direct relationship between adherence frequency and outcomes is also a fundamental proposition. Self-management behaviors affect adherence directly to varying degrees through the four domains of patient-related, family-related, healthcare system-related, and community-related determinants, and adherence in turn influences outcomes.

Outcomes without adherence frequency. Another proposition is that issues may be directly affected by changes in self-management behaviors irrespective of adherence frequency. The degree to which self-management behaviors affect adherence frequency and outcomes may result in possible interventions focused on self-management behaviors, processes, and influences (Modi et al., 2012).

Strengths of the Conceptual Framework

Strengths of the pediatric self-management conceptual framework include the clear presentation of concepts and robust description of the complex interrelationships between domains based on infants, their families, and their support networks. Although this is a relatively new model, pediatric self-management has been used to research multiple pediatric conditions and across inter-disciplinary teams including social work, physicians, and psychology (Barker & Quittner, 2016; K. A. Hommel, Greenley, Maddux, Gray, & Mackner, 2013; McGrady & Hommel, 2013). There are numerous applications for pediatric self-management in research on pediatric populations with chronic illness, including the framework that can be used to characterize the background or context for a variety of conditions (Hommel et al., 2017). Pediatric self-management conceptual framework can also inform the choice of variables and measures used to define and explore a problem, and the conceptual framework can be used as a basis for intervention design, and its propositions can inform the discussion of findings (Modi et al., 2012).

Challenges of the Conceptual Framework

A challenge of adapting the pediatric self-management conceptual framework to the parental mHealth symptom home monitoring adherence of infants with congenital heart disease during the interstage period is that it has not often been used either in nursing or with infants with cardiac disease. Additionally, the framework is designed for chronic illnesses, and the interstage is an acute period over six months but occurs with an associated life-long, chronic, congenital heart disease. After the second staged single ventricle surgery, the treatment regimen changes to a less risky and rigorous treatment regimen due to a change in the physiologic status of the infant (Shirali et al., 2016). Despite these challenges, pediatric self-management provides a solid theoretical foundation for parental mHealth home monitoring adherence of infants with single ventricle congenital heart disease during the interstage period.

Application of Pediatric Self-Management to Parental mHealth Home Monitoring Adherence of Infants with Single Ventricle Congenital Heart Disease during the Interstage

The pediatric self-management conceptual framework adequately describes the complex relationships that patients, families, their healthcare support team, including nurses and advanced practice nurses, and the community during the interstage period (Modi et al., 2012). In past retrospective research publications, unfavorable clinical outcomes have been hypothesized to be caused primarily by infants' specific types of congenital heart disease, like hypoplastic left heart syndrome, or family social contributors as non-modifiable determinants (Black et al., 2014; Pasquali, 2015; Shirali et al., 2016).

Although adherence goals and associations with outcomes in infants with single ventricle congenital heart disease during the interstage period have yet to be defined with data from parental mHealth home monitoring, there are opportunities with the CHAMP multi-site interstage registry. Parental symptom home monitoring of chronic pediatric conditions may be improved using mHealth applications (Slaper & Conkol, 2014). There have been a few pediatric cardiology and single ventricle pilot studies that incorporate facets of mHealth and thus many opportunities for future research to be informed by the pediatric self-management conceptual framework (Shirali et al., 2016). In the next section, pediatric adherence and pediatric cardiology clinical outcomes will provide a multiple-dimensional background guided by the pediatric self-management conceptual framework.

Background

Poorer levels of pediatric adherence are associated with more severe symptoms, and more complex and costly care regimens (Bosworth, Oddone, & Weinberger, 2006). The concepts of adherence and the behavior of non-adherence with mHealth technology may be understood more comprehensively through the evaluation of current literature in pediatrics, mHealth, and pediatric cardiology. The organization of the numerous types of determinants of adherence is presented through Modi et al.'s (2012) four multi-factorial domains of pediatric self-management influences of adherence frequency from the pediatric self-management conceptual framework through patient-related, family-related, healthcare system-related, and community-related determinants of parental mHealth adherence.

Patient-related Determinants of Adherence and Outcomes

Individual patient influences for infants include gender, cardiac disease, and secondary diagnoses, cardiac surgery, ventricular dysfunction, atrioventricular valve regurgitation, age at neonatal discharge, medications, genetic abnormalities, non-cardiac anomalies, and prenatal diagnosis (Modi et al., 2012). Research publications evaluating patient-related determinants of parental mHealth or traditional interstage adherence are sparse (Pasquali, 2015). Due to the lack of published evidence in interstage literature, patient-related determinants of distal clinical outcomes in pediatric cardiology or mHealth publications outside of the interstage will be used to understand possible correlations with proximal parental mHealth adherence.

Gender. Gender is the sex assigned to infants at birth based on congenital genitalia. There are no gender specific correlations with parental mHealth adherence. A retrospective review of a 27 site pediatric hospital database of inpatient admissions reviewed post-operative mortality risk and found an increased association with infant female gender and risk of mortality after cardiac surgery through a multivariable logistic regression (Seifert, Howard, Silber, & Jobes, 2007). A single site, retrospective review of ten years of interstage mortality with all types of single ventricle cardiac diagnoses found that of 486 patients, infant's with shunt or non-Norwood stage one were more likely to be female, have a genetic anomaly, and had a shorter neonatal hospital length of stay (Pizzuto et al., 2018).

Cardiac diagnosis and cardiac surgery type. Cardiac diagnosis is also known as the type of congenital heart disease and has associated cardiac surgery types that infants with congenital heart disease undergo as infants. There are no cardiac diagnosis or cardiac surgery type correlations with parental mHealth adherence. Infants with hypoplastic left heart syndrome and subsequent Norwood stage one surgery were evaluated with a retrospective database review and found to have no difference in interstage mortality compared with other types of single ventricle congenital heart disease (11.1% vs. 6.8%, $p=.17$) (Pizzuto et al., 2018). A systematic review of literature of 15 studies found a risk for interstage morbidity and mortality with increasing complexity in cardiac surgery type

(Tregay et al., 2015). Interstage symptom home monitoring began in response to the mortality of infants with hypoplastic left heart syndrome (Ghanayem et al., 2003), but with no differences in long-term interstage outcomes, all infants with single ventricle heart disease should be evaluated for correlation with parental mHealth adherence during the interstage (Pizzuto et al., 2018).

Secondary cardiac diagnosis. Secondary cardiac diagnoses are sub-categories or congenitally formed complications of single ventricle heart disease that include anomalous pulmonary venous return, aorta size of less than two millimeters, arrhythmia requiring therapy, endocardial fibroelastosis, intact atrial septum, and restrictive atrial septum. There are no secondary cardiac diagnosis correlations with parental mHealth adherence. Secondary cardiac diagnoses are tracked by the National Pediatric Cardiology Quality Improvement Collaborative (NPCQIC) due to early associations with interstage mortality (Kugler et al., 2009). A retrospective review the NPCQIC database found that after multivariable analysis, an independent risk factor of interstage mortality is infant post-operative arrhythmias (Taylor et al., 2016). A scientific statement from the American Heart Association about pediatric cardiac arrest reported that interstage mortality is increased with a secondary diagnosis of an abnormal pulmonary venous connection (Marino et al., 2018).

Prenatal detection rate. Prenatal detection prior to birth of single ventricle congenital heart disease has been associated with improved education from the healthcare team and improved coping by parents about their infants' congenital heart disease (Lafranchi & Lincoln, 2015). There are mixed reports of association with clinical outcomes with infants with prenatal detection of congenital heart disease. There are no correlations of prenatal detection of congenital heart disease with parental mHealth adherence. A systematic review of 15 studies focused on unexpected post-operative mortality and unplanned re-admissions found inconsistent associations with prenatal detection and mortality or unplanned readmissions for infants after cardiac surgery (Tregay et al., 2015). A review of the NPCQIC database evaluated the impact of prenatal detection on clinical outcomes of infants with hypoplastic left heart syndrome and found that clinical outcomes of interstage mortality and length of stay were not statistically different to infants who had not had prenatal detection (Brown et al., 2015).

Single ventricle dysfunction. Ventricular dysfunction is evaluated by echocardiograms and is rated as none, mild, moderate, or severe single ventricle dysfunction by pediatric cardiologists. There are no correlations reported for single ventricle dysfunction with levels of parental mHealth adherence. Associations of interstage infant mortality for infants undergoing stage one Norwood were evaluated in a single site retrospective review and found a higher risk of death reported with increasing single ventricle dysfunction (Simsic, Bradley, Stroud, & Atz, 2005). However, a systematic review of literature of 15 studies evaluating the risk for interstage morbidity and mortality; single ventricle dysfunction had inconsistent associations with interstage mortality and morbidity (Tregay et al., 2015).

Atrioventricular valve regurgitation. Atrioventricular valve regurgitation is the degree to which the atrioventricular valve blood flow inside the heart moves back to the previous chamber on evaluation by echocardiogram; this can be none, mild, moderate, or severe. There are no correlations reported for atrioventricular valve regurgitation with levels of parental mHealth adherence. A scientific statement about pediatric cardiac arrest from the American Heart Association reported an increased association with interstage death with higher degrees of atrioventricular valve regurgitation likely due to increased work on the heart (Marino et al., 2018). In a retrospective review over ten years of single ventricle interstage care, a higher degree of severity of atrioventricular valve regurgitation had an association with increased interstage mortality and morbidity with readmissions (Alsoufi et al., 2016).

Age in days at initial discharge. The length in days of the initial neonatal hospitalization may be an indication of the complexity or severity of an infant's congenital heart disease. There are no correlations reported for the infant age of initial discharge from the neonatal hospitalization with levels of parental mHealth adherence. A retrospective review of the multisite database, NPCQIC, focused on interstage events and found that after multivariable analysis, an independent risk factor of interstage mortality and morbidity is extended intensive care unit stays in the neonatal hospitalization (Taylor et al., 2016). Alternatively, a systematic review of literature of 15 studies evaluating the risk for interstage morbidity and mortality; longer initial hospital days have inconsistent associations with interstage risk (Tregay et al., 2015).

Number of medications. There have been limited studies on the use of medication in the interstage period. A metanalysis of adherence of 146 publications with 19,348 participants focused on medication adherence and found a direct inverse correlation with increased medication frequency and a lower rate of adherence (Conn, Enriquez, Ruppar, & Chan, 2016). The risk for non-adherence with complex regimens in the interstage, as with other chronic conditions, is possible with the single ventricle population with a potentially high rate of medication dosing (Moffett et al., 2011). In a systematic review of postoperative cardiac surgery morbidity and mortality outcomes, discharge recommendations that include higher rates of medication dosing and total medications are not a risk factors for increased interstage mortality or morbidity (Tregay et al., 2015).

Medication use in the interstage period usually includes four to five medications on a two or three times a day average with a range up to 18 times a day (Harahsheh et al., 2016; Moffett et al., 2011). A retrospective review was conducted on 395 infants with hypoplastic left heart syndrome found a median of five medications prescribed at discharge from the hospital (Ghelani, Spurney, Martin, & Cross, 2013). There were no specific number of medications associated with interstage mortality risk. However, an inverse relationship was found with a higher number of medications was associated with a lower weight for age Z-score through the interstage indicating potential weight gain issues ($r = -.19$, p.002) (Ghelani, Spurney, Martin, & Cross, 2013). Although the reason is unknown for this association, the rate of medications is a possible indicator of the complexity of care but also a possible competing factor for caregiver care at home with other care needs such as specialty feedings.

Number of interstage days. Adherence research outside of pediatric cardiology has found that a longer duration of treatment, such as symptom monitoring, is associated with poorer adherence (Bosworth et al., 2006). A retrospective review of 486 infants focused on interstage outcomes found that infants with non-Norwood or shunted types of single ventricle congenital heart disease surgery had a shorter length of stay after the neonatal surgery (Pizzuto et al., 2018). A shorter newborn hospital stay increases the exposure time at home during the interstage before stage two surgery (Pizzuto et al., 2018).

Major syndromes. Major syndromes include the genetic syndromes that occur congenitally along with congenital heart disease such as Down's Syndrome, Noonan's, CHARGE Syndrome, and other complex genetic syndromes. There are no correlations reported for major genetic syndromes with infants and levels of parental mHealth adherence. A systematic review of 15 publications focused on interstage morbidity and mortality outcomes and found that genetic differences or syndromes demonstrated a significant risk of unexpected post-cardiac surgery mortality for infants with congenital heart disease (Tregay et al., 2015).

Major anomalies of other organ systems. Major non-cardiac congenital anomalies add additional complexity to care in the hospital and at home and can include brain, respiratory, gastrointestinal, skeletal, and other complex combinations of anomalies. A single site retrospective review focused on interstage infant mortality after stage one Norwood and found a higher risk of death reported when infants had major non-cardiac anomalies of other organ systems (Simsic et al., 2005). Publications outside of pediatric cardiology report that with higher complexity of the diagnosis or treatment regimen, a more reduced rate of pediatric adherence occurs (Bosworth et al., 2006).

Proposed patient-related determinants of adherence or subsequent clinical outcomes include gender, cardiac diagnosis, cardiac surgery type, secondary cardiac diagnosis, prenatal detection rate, single ventricle dysfunction, atrioventricular valve regurgitation, number of medications, length of interstage days, length of neonatal hospitalization, major syndromes, and major anomalies of other organ systems. These patient-related determinants will be reviewed in the upcoming review of the literature with parental mHealth adherence for home symptom monitoring for infants with single ventricle congenital heart disease during the interstage period.

Family-related Determinants of Adherence and Outcomes

Family-related determinants are the parental, caregiver, sibling, and socioeconomic influences, both modifiable and non-modifiable, that affect mHealth adherence (Modi et al., 2012). Family-related determinants of distal clinical outcomes in pediatric cardiology or mHealth publications expanded beyond the interstage will be used to understand the background and possible correlations with proximal parental mHealth adherence rates during the single ventricle interstage period.

Age of primary caregiver. The age of the primary caregiver or parent at home is an important family-related determinant. In a retrospective review of the multisite database, NPCQIC, an independent risk factor of increased infant interstage mortality was having an adolescent mother (Taylor et al., 2016). In contrast, younger maternal age has been associated with increased mHealth adherence in studies outside of pediatric cardiology (Anderson-Lewis, Darville, Mercado, Howell, & Di Maggio, 2018).

Education level of primary caregiver. The influence of education level of the primary caregiver on adherence has shown mixed results. In a retrospective review of adherence after pediatric heart surgery, the lower number of education years of the primary caregiver was associated with reduced outpatient appointment adherence (Demianczyk et al., 2019). The level of parental education has been used as a proxy measure for socioeconomic status in preventive pediatric cardiology adherence research for adolescent self-management of metabolic risk factors (Santos et al., 2014). This study found that lower parental education level was associated with lower adherence to medically recommended outpatient preventive management (Santos et al., 2014). Another study evaluated a parental education level on mHealth intervention on adherence to a parental mHealth application, ezPARENT program, and did not find a relationship (Breitenstein et al., 2017).

Primary language at home. The primary language that is spoken at home, specifically families that are non-English speaking, may add increasing complexity for transition to home for families. Outpatient communication between the healthcare team and primary caregivers at home is also more difficult when the family's primary language is non-English. The language spoken at home is a determinant of mHealth adherence to medication regimens in chronically ill patients (Anglada-Martinez et al., 2015). A retrospective, correlational analysis of 219 children with congenital heart disease after cardiac surgery was conducted. The study found significantly worse adherence to cardiology care with non-English speaking families (Demianczyk et al., 2019).

Total family members at home. The total number of family members living at home can result in competing priorities for the primary caregiver of an infant with complex congenital heart disease. A positive correlation was found with larger home family size and morbidity (Karamlou et al., 2018). There are no studies examining the relationship between number of family members at home and parental mHealth adherence rate.

Family members below 18 years of age. A single adult caregiver providing care for an infant with single ventricle heart disease in the interstage period at home may increase the risk of interstage mortality. In a retrospective review of the multisite database, NPCQIC, an independent risk factor of increased infant interstage mortality was having single adult caregivers (Taylor et al., 2016). There are no studies examining the number of youths in the family at home and parental mHealth adherence.

Payer or insurance type. A systematic review of infants having undergone cardiac surgery defect repair, found insurance payer type, including self-pay, is a risk factor for morbidity and mortality (Tregay et al., 2015). A retrospective, correlational analysis of 219 children with congenital heart disease after cardiac surgery was conducted. The study found significantly worse adherence to cardiology outpatient clinic visits with Medicaid insurance (Demianczyk et al., 2019).

The family determinants of age of caregiver, total number of family members, number of children in the home, and insurance type have been reported as determinants of adherence. Additional determinants of mortality and morbidity include caregiver education level and language spoken at home. Family-related determinants of mHealth cover a wide range of socioeconomic, cultural, and financial influences.

Community-related Determinants of Adherence and Outcomes

Community-related determinants include the neighborhood where the family lives and the availability of community health resources (Modi et al., 2012). A retrospective, correlational analysis of 219 children with congenital heart disease after cardiac surgery was conducted focused on readmissions and adherence to outpatient cardiology clinic visits (Demianczyk et al., 2019). The study found significantly worse adherence to cardiology care with families whose homes were located at the federal poverty level, which may be found in far distances away from the tertiary pediatric cardiac care center (Demianczyk et al., 2019). A systematic review of readmissions for infants having undergone cardiac surgery, found mixed results when evaluating the distance where the family lived away from the tertiary center. There were two publications where distance was not a significant risk factor for interstage morbidity and mortality but one that reported distance was a significant risk factor (Tregay et al., 2015).

In addition to distance, socioeconomic status in communities may also be a determinant of adherence and outcomes for infants with single ventricle congenital heart disease. A secondary analysis of a multi-site registry for 525 infants with hypoplastic left heart syndrome was completed describing associations of socioeconomic factors with infant mortality (Bucholz, Sleeper, & Newburger, 2018). The authors found, in infants undergoing a stage one Norwood surgery, high neighborhood socioeconomic status was significantly associated with an improved survival to one year of age with a 38% lower risk of mortality or transplant. There was no difference in the 30-day survival based on socioeconomic demographics but this study did not specifically evaluate the interstage period (Bucholz et al., 2018).

Healthcare System-related Determinants of Adherence and Outcomes

Non-modifiable healthcare system-related influences include access to healthcare and communication with the healthcare team through the initiation of communication, number of communications, and clinic visits (Modi et al., 2012). Potentially modifiable healthcare system-related influences include the patient to provider communication and frequency of clinic visits (Modi et al., 2012).

Clinic visits. The outcome of increased clinic visits may be associated with lower rate of adherence to mHealth technology. For example, a review of literature of predictors of type 1 diabetes adherence in adolescents found that in-person social support may help with non-adherence for self-management (Naranjo et al., 2014). The frequency of clinic visits may need to increase when there is non-adherence, especially with younger patients and families (Naranjo et al., 2014).

Interstage communications. Before discharge from the hospital, parents receive anticipatory guidance and interstage training from registered nurse coordinators about when to call with clinical changes in their neonate and how to use the mHealth application (Hehir

& Ghanayem, 2013). The interstage red flag communications may be initiated by parents, the healthcare team, or the mHealth application. Interstage programs have similar red flags for communication, but the route and team member that triages the calls vary by the site. They can be nurses, advance practice nurses, fellows, and/or cardiologists (Clauss et al., 2015; Rudd et al., 2014). Interstage home monitoring programs led by advanced practice nurses have reported improved mortality outcomes and fewer high-risk readmissions (Siehr et al., 2014).

Communications using mHealth may also include proactive health messages and key symptom home monitoring guidance from the healthcare team. For example, a pilot study of a mHealth intervention, Text4baby, was evaluated for delivery of health promotion messages to parents to improve maternal and child health activities in the United States and Russia (Parker et al., 2012). The authors found enhanced communication with the healthcare team and adherence to health promotion activities.

Additionally, a qualitative, descriptive study of 13 caregivers through three focus groups was conducted to explore parental experiences with developing a mHealth monitoring tool for children with complex medical conditions (Nkoy et al., 2019). The researchers found that parents expected certain critical functionalities of the mHealth monitoring tool including infant symptom tracking, especially in times when symptoms were escalating indicating the possible need for an emergency room visit or hospital readmission. The key symptoms during the times of illness that would warrant inclusion in a mHealth application included low oxygen saturations, fevers, tachycardia, seizures, feeding intolerance, pain, and overall parental concern (Nkoy et al., 2019). Parents of the most fragile and medically complex children were more likely to adhere to mHealth technology (Nkoy et al., 2019).

Healthcare system-related determinants including number of clinic visits, number of interstage communications, and communications initiated from the healthcare team are associated with mHealth adherence. In the upcoming section, a focused review of literature on parental mHealth symptom home monitoring adherence of infants in the single ventricle interstage period will be completed. Adherence rate and patient-related, family-related, healthcare system-related, and community-related determinants will be examined.

Review of the Parental mHealth Adherence Literature during the Single Ventricle Interstage Period

A conceptual framework was found for organizing and evaluating pediatric self-management behaviors and processes that influence proximal adherence frequency and distal clinical outcomes. The four domains of self-management behaviors include (a) patient-related, (b) family-related, (c) community-related, and (d) healthcare system-related determinants (Modi et al., 2012). These four domains have been used extensively for research in treatment adherence and clinical outcomes in pediatric adherence research (K. Hommel et al., 2017; McGrady & Hommel, 2013). A review of the literature, including the search strategies, sample, data extraction, and results, will be presented to critically evaluate the literature from parental mHealth symptom home monitoring adherence of infants with single ventricle congenital heart disease during the interstage period.

Search Strategies

A comprehensive search was completed using multiple databases from 2000-2019. Publication searches included the following databases: The Cumulative Index of Nursing and Allied Health Literature (CINAHL), Pubmed, Medline, Psychinfo, Health Source: Nursing academic edition, Cochrane review, Google Scholar, and the University of Missouri-Kansas

City (UMKC) Libraries Summons 2.0 Advanced search. Keywords utilized in the search were *single ventricle*, *pediatric cardiology*, *nursing care*, *pediatrics mHealth*, *mobile health, home monitoring*, *parent*, *interstage*, *pediatric illness*, *complex congenital heart disease*, *adherence*, *compliance*, *non-adherence*, and combinations of these words and phrases. Reference lists from publications were also reviewed to identify other studies.

Sample

Published articles were included in the comprehensive review of literature if they met the following inclusion criteria:

1. The study sample included infants, less than one year of age, in the interstage period.
2. The study sample included infants requiring neonatal surgery for single ventricle congenital heart disease.
3. The study sample included infants who were in the interstage period.
4. The study evaluated parental mHealth symptom home monitoring interventions of infants with single ventricle congenital heart disease during the interstage period.

Exclusion criteria for this review of the literature included:

1. The study was not published or available in the English language.
2. The study was a dissertation or an unpublished manuscript.
3. The study included children over one year of age with single ventricle congenital heart disease.

Data Extraction

Data extraction from the selected studies included author, year, purpose, design, sample/setting, intervention, measures, outcomes, strengths, and limitations. A summary of the data extracted from the selected studies is found in Table 2.1.

Table 2.1

Summary of Data Extraction

Authors (Year)	Design	Sample/Setting	mHealth Intervention	Adherence results	Key Findings
Cross, R., Steury, R., Randall, A., Fuska, M., & Sable, C. (2012)	Quantitative, Cross-sectional, Feasibility Single-center	n=49 total, n=16 no monitoring n=33 monitored Washington DC, U.S.A.	Home-based telemedicine application with qualitative questions and quantitative hemodynamic data by parents Provider Web portal Device contracted from outside health system	9% mortality interstage; Data entered 50% of data days (1227/2437), 2/3 families utilized as instructed	APRN completed parent teaching; APRN's reviewed data proactively, systematically three times a week, instant alerts for triage from application to on-call cardiologists
Black, A., Sadanala, U., Mascio, C. E., Hornung, C. A., & Keller, B. (2014)	Quantitative Pre-post Pilot project Single center	n=20 total, n=11 pre intervention=9 post intervention Kentucky, U.S.A.	Web-based daily reporting of clinical data and 10-point questionnaire through cell or landline Data transfer and communications issues with feasibility pilot project Provider Web portal Device contracted from outside health system	Mortality with the intervention group (22%) Criteria for dis-enrollment- no data for >7 days not based on equipment malfunction (non-adherence) Average days to initiation from enrollment three days 57% of days with non-adherence all	Data outside range triaged through research team before clinical team Primary parent age was significantly younger in the intervention group

Table continues

Authors (Year)	Design	Sample/Setting	mHealth Intervention	Adherence results	Key Findings
				components of monitoring were missing	
Harahsheh, A., Hom, L., Clauss, S., Cross, R., Curtis, A., Steury, R... Martin, G. R. (2016)	Mixed methods Pre-Post design Parent and Cardiologist interviews Single-center	n=98 total, 42 pre and 56 post-intervention Washington, DC, U.S.A.	Telemedicine system for data transfer of hemodynamic data	5.4% mortality interstage	Weekly primary cardiology or pediatrician clinic visits Dedicated nurse practitioner improved communication with families.
Shirali, G., Erickson, L., Apperson, J., Goggin, K., Williams, D., Reid, K., . . . Stroup, R. (2016)	Quantitative Pre-Post design Single-center	n=83 total, n=53 pre intervention, n=30 post intervention Missouri, U.S.A.	Home-based mHealth application for hemodynamic data through cellular service Provider Web portal Mhealth device developed and maintained in an internal health system	Mortality reduction 17% to 0% with intervention "no issues with compliance" with data transfer from parents	Addition of video for interstage evaluation Nurse and APRN driven initial parental education and daily data review and proactive communication
Bingler, M., Erickson, L., Reid, K. Lee, B., O'Brien, J., Apperson, J., Goggin, K., & Shirali, G. (2018)	Randomized Crossover Design Single-center	n=31 infants Missouri, U.S.A.	Home-based mHealth application for hemodynamic data Provider Web portal Mhealth device developed and maintained in an internal health system	Mortality 0%, 75.8% data days (2237/2951)	Faster time to red flag communications with mHealth and team review with mHealth application compared with traditional monitoring

Results of Review of Literature

Of the 1,073,855 resulting publications, a total of 192 were downloaded into End-NoteX9 for further review after the removal of duplicates by review of titles and abstracts. An additional 26 articles were located by reviewing the reference lists of the articles, for a total of 218 publications. Seventy-two publications were removed that were non-English, not related to congenital heart disease, nor home monitoring in the interstage. The resulting 146 publications were evaluated for inclusion for further critical analysis by the screening of titles and abstracts. Subsequently, five publications were included in this review of the literature.

Demographics

The five studies were published between 2012-2019 with sample sizes ranging from 20 (Black et al., 2014) to 83 participants (Shirali et al., 2016). The mHealth application studies were all conducted with samples from the United States and at single sites (Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). All the mHealth application studies were conducted with infants with single ventricle cardiac disease in the interstage period (n=5). Infant female gender was reported ranging from 41.9% (Bingler et al., 2018) to 50% (Harahsheh et al., 2016). The cardiac diagnosis of hypoplastic left heart syndrome ranged from 42% (Bingler et al., 2018) to 100% (Harahsheh et al., 2016). Major genetic syndromes were reported in 0% (Bingler et al., 2018) to 8.9% of infants (Harahsheh et al., 2016), and 7.1% were reported to have major non-cardiac anomalies (Harahsheh et al., 2016).

Parental demographics included a mean maternal age of 26 years, with a range of 17 to 37 (Black et al., 2014). Prenatal detection of congenital heart disease was reported in 78.6% of families (Harahsheh et al., 2016). English as the primary language was reported in

94% (Harahsheh et al., 2016) to 97% of participating families (Bingler et al., 2018). The education level of a bachelor's degree or above was reported in 37.5% of families (Harahsheh et al., 2016). No theoretical frameworks were reported in the five studies.

Study Designs

The five studies included one randomized crossover design (Bingler et al., 2018) and four pilot or feasibility studies (Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). There were no randomized controlled trials, systematic reviews, or meta-analyses evaluating parental mHealth home monitoring adherence of infants with single ventricle congenital heart disease during the interstage period. All five publications about mHealth in the interstage are a level five for research evidence, providing a low to moderate level of evidence ranking below randomized controlled trials but above case reports and editorials (Ingram-Broomfield, 2016).

Interstage mHealth Symptom Home Monitoring Equipment

Equipment was provided to the parents by the home monitoring team or insurance companies in all five studies. This included oxygen saturation monitors to check oxygen saturations and heart rates, and infant scales to weigh their child (Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). Two studies reported the use of 15-second videos to be transferred from the parents to the home monitoring team (Bingler et al., 2018; Shirali et al., 2016). The estimated cost of the application for use by each parent, not including the healthcare team staffing cost, was $540 per day for each interstage period, which averaged four to five months in length (Shirali et al., 2016). Specific training methods were not reported in any of the five publications other than that training was completed prior to discharge home or first use of the mHealth.

Technology systems to support parental mHealth symptom home monitoring data transfer included using a tablet or stand-alone mobile device in all studies. Two studies utilized a cellular communication system (Bingler et al., 2018; Shirali et al., 2016), one study utilized two options, analog telephone line or internet modem (Black et al., 2014), and one study used all three options (Cross et al., 2012). One study used mobile oxygen saturation devices that transferred data to the healthcare team but did not clarify which technology system was used for the transfer (Harahsheh et al., 2016). Three studies provided a no-cost tablet device to the family that was not already part of the parents' personal cellular phone (Bingler et al., 2018; Cross et al., 2012; Shirali et al., 2016).

Interstage mHealth Parental Symptom Home Monitoring

The parents documented hemodynamic assessment data using mHealth technology of an application in all five studies. Parental symptom monitoring included assessment by the parents of their infant for hemodynamic changes through measurement of oxygen saturations, heart rates, and weights data using oxygen saturation monitors and scales at a frequency of daily for four to six months (Shirali et al., 2016). Symptom home monitoring training of the parents involved in-person training by single ventricle registered nurse coordinators using informational handouts and return demonstration techniques. Data found to be outside of set parameters, or red flags, for oxygen saturation, heart rate, weight gain, video changes, and infant behavior concerns are taught by registered nurse coordinators to parents to be communicated as soon as possible to the home monitoring team (Shirali et al., 2016).

One study reported eight minutes per day on average for families to use the mHealth application for data transfer (Black et al., 2014). Bingler et al. (2018) and Shirali et al. (2016) both had an additional feature of mHealth technology for daily 15-second videos taken by parents for evaluation of symptoms of cyanosis, respiratory rate, respiratory effort, edema, infection, and overall demeanor of the infant with single ventricle congenital heart disease.

Results of Parental mHealth Symptom Home Monitoring

Reduction in the mortality rate was the primary outcome in all the studies of parental mHealth symptom home monitoring of infants during the interstage period. Mortality in the interstage period ranged from 0% in two studies (Bingler et al., 2018; Shirali et al., 2016) to 22% in one study (Black et al., 2014). Unplanned infant readmissions from parental mHealth symptom home monitoring of infants during the interstage period ranged from 36.4% (Cross et al., 2012) to 56% (Bingler et al., 2018) at a cost of $188,842 per patient (Shirali et al., 2016). The frequency of infant cardiology clinic visits with parental mHealth symptom home monitoring of infants during the total interstage period ranged from a mean of 4.8 (Black et al., 2014) to 6 (Bingler et al., 2018). Three studies followed guidelines for monthly cardiology clinic visits (Bingler et al., 2018; Cross et al., 2012; Shirali et al., 2016). The total number of intensive care unit days with parental mHealth symptom home monitoring of infants during the interstage period compared to symptom home monitoring was significantly reduced to 54 days from 173 days ($p<.0001$) (Bingler et al., 2018). All five publications also analyzed mHealth acceptability, adherence, and non-adherence, along with clinical outcomes. These outcomes will be reviewed in the next section.

Acceptability of parental mHealth symptom home monitoring. The qualitative and quantitative feedback from parents on exit interviews have been positive regarding parental mHealth symptom home monitoring of infants during the interstage period (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016). One study reported that 87.1% of families selected the mHealth option over home monitoring after having exposure to both methods of parental mHealth symptom home monitoring (Bingler et al., 2018).

Only one study had a parent self-report survey. A 40 question, five-point Likert survey was presented to 50 families after their use of telemedicine in the interstage and found a low (n=16, 32%) response rate (Harahsheh et al., 2016). From the families that did respond, the overall summary score for parental approval of items 1-37 (α= .97) was 4.34 $\pm$ .62 (95% CI, 4.01-4.67) with no differences in acceptability across parental education level, primary language, or prenatal diagnosis of congenital heart disease (Harahsheh et al., 2016). Qualitative themes derived from responses to open-ended questions indicated gratitude from the parents, improved family-centered care, and adequate communication from the healthcare team (Harahsheh et al., 2016). Another improvement noted by the parents conducting mHealth symptom home monitoring of infants during the interstage period included better support systems during off-hours and weekends (Harahsheh et al., 2016).

Parental mHealth symptom home monitoring adherence. No studies compared mHealth adherence versus other types of parental symptom home monitoring adherence for infants during the interstage period as the primary outcome measure. A qualitative report of adherence from one study of 30 families with mHealth interstage technology “did not have any problems with families’ compliance” (Shirali et al., 2016, p. 7). Cross et al. (2012) reported difficulty with mHealth adherence from families with the recommended daily data transfer, but the rate of adherence improved when the recommended data transfer rate was reduced to three times a week for hemodynamic data to be transferred from parents to the home monitoring team for evaluation. The final adherence rate was two-thirds, or 12 of 20 families, transferred data from parental mHealth symptom home monitoring of infants during the interstage as recommended (Cross et al., 2012). Adherence by parents to mHealth symptom home monitoring is measured in various objective and subjective ways, with no studies reporting reliability or validity of the measures but reports of the initiation, discontinuation, and implementation of data transfer through the interstage period.

Initiation. Only one study reported initiation, or the first parental mHealth symptom home monitoring received through data transfer after infant discharge. This was found to be a mean of three days after discharge to home (Black et al. 2014). Parents who were enrolled later in the study and were using home monitoring before mHealth had a longer rate of initiation (Black et al., 2014). No other studies reported the rate of initiation.

Implementation. Symptom home monitoring is recommended to continue to be implemented through the interstage period up until the day before the second surgery (Bingler et al., 2018). None of the five publications reported the rate of individual data points of oxygen saturation, heart rate, or videos. One study reported parental non-adherence behavior to the recommended daily data transfer occurred 58% of interstage days but did not list which symptom home monitoring measures were not reported (Black et al., 2014).

Data days were the number of non-hospitalized days in which any parental mHealth data was transferred by the parents to the healthcare team during the interstage period (Bingler et al., 2018). The data days were calculated by the expected number of days in which mHealth symptom home monitoring data was transferred by the parents to the health care team times 100, or 1227-2237 data days, divided by 2437-2951 days where the infant was not in the hospitalized (Bingler et al., 2018; Cross et al., 2012). Shirali et al. (2016)

reported a rate of 80% implementation of data days, while Cross et al. (2012) reported a lower rate of 50.3%.

Discontinuation. None of the five publications reported discontinuation or the last use of data transfer during the interstage period.

Parental mHealth symptom home monitoring non-adherence. The reported parental mHealth non-adherence of 50% by Cross et al. is difficult to evaluate since, during the study, at an unclear time, reduced the recommended rate of daily transfer from daily to three times a week (2012). Black et al. (2014) reported that 11% of parents were removed from the study due to non-adherence of a minimum of weekly data transfer requirements during the interstage which is less than the recommended daily rate of data transfer. Reasons for non-adherence included intentional and non-intentional reasons: parents forgot to report the data, the family was traveling, the family was busy, the family had scheduling conflicts, or the family had difficulty with cell phone transmission (Black et al., 2014). This study was stopped early due to higher than anticipated mortality in the study group (n= 2, 22%) compared with the pre-study baseline (n=1, 11%) and earlier than the expected age of staged palliative surgeries. Both of these negative outcomes were postulated to be due, in part, to parental mHealth non-adherence (Black et al., 2014).

Patient-related Determinants of mHealth Adherence

None of the five publications analyzed patient-related determinants for associations with mHealth adherence outcomes (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). All of the publications were evaluated for report of the demographics of gender, cardiac diagnosis, cardiac surgery type, secondary cardiac diagnosis, prenatal detection, single ventricle dysfunction, atrioventricular valve regurgitation, age in days at initial discharge, number of medications, length of the interstage period, major syndromes, and major non-cardiac anomalies.

Gender. The occurrence of female gender was reported in two of five interstage publications ranging from 41.9% (Bingler et al., 2018) to 50% (Harahsheh et al., 2016). Gender was not reported in the other three publications.

Cardiac diagnosis. All the mHealth application studies were conducted with infants with single ventricle cardiac disease in the interstage period (n=5) and reported the cardiac diagnosis of hypoplastic left heart syndrome ranged from 42% of the sample (Bingler et al., 2018) to all infants with hypoplastic left heart syndrome in the study sample (Harahsheh et al., 2016).

Cardiac surgery type. All of the mHealth application studies were conducted with infants that followed the single ventricle palliative cardiac surgeries through the interstage period (n=5) and reported the cardiac surgery type of Norwood ranging from 42% of the sample (Bingler et al., 2018) to all infants undergoing a stage one Norwood surgery (Harahsheh et al., 2016). Cardiac surgery type is a non-modifiable influence on parental mHealth adherence but should be assessed due to the risk of interstage mortality and morbidity (Modi et al., 2012).

Secondary cardiac diagnosis. None of the five interstage publications reported the occurrence of secondary cardiac diagnoses.

Prenatal detection rate. Prenatal detection of congenital heart disease was reported in two publications at a rate of 78.6% of families (Harahsheh et al., 2016) to 80.6% (Bingler et al., 2018), but was not reported in the other three publications.

Single ventricle dysfunction. None of the five interstage publications reported the degree of single ventricular dysfunction found on echocardiogram.

Atrioventricular valve regurgitation. None of the five interstage publications reported the degree of atrioventricular valve regurgitation found on echocardiogram.

Age in days at initial discharge. Of the five publications of mHealth in the interstage, the reported age to start the interstage period at neonatal discharge was published as a median of 36 days (Shirali et al., 2016) to a mean of 49.9 days (Harahsheh et al., 2016).

Number of medications. None of the five interstage publications included the number of medications prescribed at discharge or used during the interstage period.

Number of interstage days. The rate of interstage days of the five reviewed interstage mHealth publications reports a mean number of interstage days per infant ranging from 109 (Harahsheh et al., 2016) to 143 days (Shirali et al., 2016). The range of age of the infant at the end of the interstage period was reported from 159.8 (Harahsheh et al., 2016) to 175 days (Shirali et al., 2016). Shirali et al. (2016) reported a quasi-experimental study on the use of mHealth application in the interstage period compared with home monitoring and found a significant reduction in the number of interstage days from a median of 7.23 months (home monitoring) to 5.85 months (mHealth). Each day less of this high-risk interstage period reduces the risk of mortality and morbidity in the single ventricle population (Shirali et al., 2016).

Major syndromes. Major genetic syndromes are less common to occur for infants born with single ventricle congenital heart disease but were reported to be in 0% (Bingler et al., 2018), ranging up to 8.9% of infants (Harahsheh et al., 2016).

Major anomalies of other organ systems. Major non-cardiac anomalies were reported in 7.1% of the infants in one interstage mHealth intervention study (Harahsheh et al., 2016). Of note, there was a report of lack of initial parental agreement for enrollment to a mHealth application study with the infants with higher medical co-morbidities due to concerns of adding increased complexity at home, potentially biasing the studied sample (Black et al., 2014). Although gastrostomy feeding tubes are not a congenital anomaly, the use is a non-cardiac complexity and was reported to be used in 48.4% of patients in one study (Bingler et al., 2018).

Many patient-related determinants of mHealth adherence were presented in the five publications but not in all. Non-modifiable influences on parental mHealth adherence include gender, cardiac diagnosis, cardiac surgery type, secondary cardiac diagnoses, prenatal detection of congenital heart disease, single ventricle dysfunction, atrioventricular valve regurgitation, major genetic syndromes, and major non-cardiac anomalies. Although non-modifiable, these determinants are important for research for correlation of proximal and distal outcomes for parental mHealth adherence for infants during the single ventricle interstage period (Modi et al., 2012). Potentially modifiable influences on parental mHealth adherence include the age in days at initial discharge, number of medications at discharge, and number of interstage days (Modi et al., 2012).

Family-related Determinants of mHealth Adherence

Family-related determinants are the parental, caregiver, sibling, and socioeconomic influences, both modifiable and non-modifiable, that affect mHealth adherence (Modi et al., 2012). All five publications reported at least one occurrence of family-related influences of mHealth adherence (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016).

Age of primary caregiver. Parental demographics reported in one mHealth interstage publication included a mean maternal age of 26 years, with a range of 17 to 37 (Black et al., 2014). Younger maternal age was found to be significantly different in the mHealth intervention group compared to the traditional monitoring group ($p=0.02$) (Black et al., 2014). Non-adherence to the mHealth application was difficult to evaluate but was possibly due to younger parental age. The other four publications did not report primary caregiver age.

Education level of primary caregiver. The education level of a bachelor's degree or above was reported in 37.5% of families (Harahsheh et al., 2016) but was not reported in the other four publications.

Primary language at home. English as the primary language was reported in 94% (Harahsheh et al., 2016) to 97% of participating families for publications of mHealth use in the interstage (Bingler et al., 2018).

Total family members at home. There are no interstage publications about family size, but Black et al. (2014) in a pilot study for mHealth technology application for the interstage, found that families reported an extra eight minutes of added time daily for symptom home monitoring for their infant (2014). However, they did not extrapolate this additional care time for associations with the number of siblings or family members in the home.

Family members below 18 years of age. There were none of the five publications that were reviewed that reported the number of siblings or the number of family members less than 18 years of age other than the patient in the home.

Payer or insurance type. None of the five publications that were reviewed reported insurance or payer type.

Community-related Determinants of mHealth Adherence

None of the five publications reported occurrences of community distance but Bingler et al. (2018) utilized the community distance from the hospital to home as a characteristic for analysis of high-resource utilization readmissions compared with low resource utilization readmissions. There were no significant differences in the distance from the hospital that the infants and parents lived in the two types of readmissions during the interstage period (Bingler et al., 2018). However, Black et al. (2014) discussed that data was more consistently transferred where land-lines or full cellular coverage was available in urban settings.

Healthcare System-related Determinants of mHealth Adherence

Potentially-modifiable influences will be evaluated in the review of literature for healthcare system-related determinants of mHealth adherence through the number of clinic visits, the total number of interstage red flag communications initiated by the mHealth application, parents, or initiated from the healthcare team, communications from the registered nurse coordinator, nurse practitioner, fellow, or attending cardiologist.

Clinic visits. A mean rate of all types of cardiology clinic visits, including planned and unplanned, was 5.5 visits during the interstage (Bingler et al., 2018). The recommended rate of cardiology clinic visits is usually monthly, barring no concerns of red flag changes from families or the healthcare team (Harahsheh et al., 2016). Before the initiation of mHealth, some interstage programs would see patients weekly for a clinic visit. In one study, this frequency was reduced when using the mHealth application lead to close monitoring at home through transfer of data each day by the parents to the healthcare team (Shirali et al., 2016).

Communication of mHealth red flag alerts. All five studies documented alerts that triggered a page or email to the healthcare team if clinical risk values were outside of an established threshold (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). Studies varied in how alerts were triaged. Black et al. (2014) reported alerts were triaged through the research team first, while the four other studies triaged them directly to the clinical healthcare team of nurses, advanced practice nurses, and cardiologists (Bingler et al., 2018; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). One study used two levels of alerts based on data thresholds. The first, more critical alert, sent a page to a cardiologist at any time during the day or night when critical data such as infant weight loss or infant low oxygen saturations were obtained. The second alert automatically emailed the home monitoring nursing team for follow-up with less urgent findings such as an increased respiratory rate or signs of dehydration or infection in the infant (Cross et al., 2012). Shirali et al. (2016) reported 91 instant alerts with 295 alerts initiated by the parent or healthcare team for the 30 infants who were monitored. Over 90% of infants had at least one red flag alert from data entered by parents via mHealth symptom home monitoring for infants during the interstage period (Shirali et al., 2016).

Communications between parents and the healthcare team. A minimum communication frequency between the healthcare team and families of at least weekly were reported with all five of the mHealth application studies even with no red flags or concerning findings, were reported (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). Frequency of proactive mHealth data review included daily data review by nurses or advanced practice nurses (Bingler et al., 2018; Shirali et al., 2016) and three times a week by advanced practice nurses (Cross et al., 2012). Four of the mHealth applications reported a web portal system for review of data transferred from home to the health care team (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Shirali et al., 2016). The registered nurse coordinators logged-in every morning to the mHealth web portal and initiated proactive communication with the family to discuss concerns noted through data trends, video evaluation, or other red flags of hemodynamic instability (Shirali et al., 2016).

Communications can be initiated from families at home, the healthcare team, or the mHealth application alerting to data outside the set parameters, but the rate of these communications associated with levels of adherence and ideal clinical outcomes are unknown. The time to recognition of a red flag concern before readmission and communication with a family was significantly reduced, nearly 30 minutes, with the use of mHealth technology was improved compared with home monitoring (Bingler et al., 2018). Interstage communications are a potentially modifiable influence on parental mHealth adherence and should be assessed for association with parental mHealth adherence with support provided by the healthcare team (Modi et al., 2012).

Strengths and Limitations

Determining the strengths and limitations of publications assist in understanding the current research findings to present key gaps in knowledge of parental mHealth adherence. Guidelines for research presentation and evaluation, such as the CONSORT statement

(Schulz, Altman, Moher, & the Consort Group, 2010), can guide a brief review of mHealth publications through specific discussion of the use of theory, design, sample, setting, instruments, procedures, and data analysis. A strength of all five primary publications for interstage symptom home monitoring were published in peer-reviewed journals and three of the five were published in the past four years following contemporary research trends (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016).

All five publications had thorough backgrounds presented of the outcomes and status of the single ventricle interstage period for pilot testing of mHealth interventions, but none of the studies reported theoretical underpinnings of the design (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). The publications were primarily (4 out of 5 [80%]) quasi-experimental with no comparison of contemporary participants other than the randomized cross-over design from Bingler et al. (2018).

The four feasibility pilot studies had samples ranging from n=20-83, which are appropriate for the sample size for that study design (Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). A limitation for the sample size for Bingler et al. (2018) was the goal size of 50 patients by an a-`priori power analysis was not reached before the study was halted. The reporting of the reasons for the deviation of research procedures was a strength, but the low sample for a randomized intervention study reduces generalizability (K. Schulz, Altman, & Moher, 2010). The settings were all relevant for the representative population at homes with parental symptom home monitoring of infants with single ventricle congenital heart disease.

Harahsheh et al. (2016) was the only publication that used an instrument. The survey's internal reliability for all measures of the 40 questions was assessed by the research team and reported as "adequate" through Cronbach's alpha, but the value was not reported in the publication (Harahsheh et al., 2016). All five of the publications reported the equipment used for measuring hemodynamic data and type of equipment for mHealth (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). Providing this information is vital for replication for future researchers, especially when most publications were feasibility or pilot designs.

Research and mHealth technology procedures were reported for all five publications (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). Interventions that utilize mHealth have an increased responsibility to detail program and interface functions along with research procedures. Agarwal et al. (2016) published guidelines for the reporting of mHealth interventions evidence reporting and assessment (mERA) checklist that can be used along with CONSORT guidelines for reporting and interpreting future mHealth publications (Schulz et al., 2010).

Data analysis plans were clearly in the methods, reported in the results, and reviewed in the discussion for all studies. The primary outcome of all five studies was for the reduction in interstage mortality (Bingler et al., 2018; Black et al., 2014; Cross et al., 2012; Harahsheh et al., 2016; Shirali et al., 2016). Four out of the five studies had an improvement in infant interstage mortality with parental mHealth symptom home monitoring of infants with single ventricle congenital heart disease during the interstage period. Three of the publications reported mHealth adherence through the rate of data days (Bingler et al., 2018; Cross et al., 2012; Shirali et al., 2016). Although there was increased mortality reported by

Black et al. (2014) in the mHealth intervention group, the study provided a novel evaluation of parental mHealth non-adherence. The review of strengths and limitations in publications of mHealth technology in the interstage period offers insights into areas of future research for parental mHealth adherence for infants in the single ventricle interstage period.

Gaps in Literature

Current findings from this review of the literature suggest a gap in knowledge regarding the determinants of mHealth adherence by parents of infants with single ventricle cardiac disease in the interstage period. Health outcomes cannot be adequately assessed if only measured by mortality and morbidity as the outcomes of mHealth interventions without the rate of adherence (Sabate, 2003). Adherence is a proximal outcome that occurs before the distal outcome of mortality and morbidity in the single ventricle interstage, but the reactive model with home monitoring left the optimal rate of adherence widely unknown (Modi et al., 2012).

Reducing gaps in data communication during the high-risk interstage time can be supplemented by mHealth technology integration with symptom home monitoring for hemodynamic symptom monitoring (Bingler et al., 2018; Shirali et al., 2016). The implementation data days is a primary indicator of mHealth adherence, but areas of proposed expansion for reflective indicators of mHealth adherence are additional observable measures of initiation (first use), implementation of interstage data (data days, weight, oxygen saturation, heart rate, and videos), and discontinuation (last use) (Kumar et al., 2013; Vrijens et al., 2012).

Patient-related Determinants

Unfortunately, many studies did not evaluate the determinants of parental mHealth adherence. The level of evidence of retrospective studies, even at a multi-site level, is lower at level four with one systematic review of mortality and morbidity outcomes, which is a level three of evidence (Ingram-Broomfield, 2016). The number of medications as associated with a complex regimen for care at home did have an association with adherence beyond the five publications reviewed. The number of interstage days, age at initial discharge, cardiac diagnosis, surgery type, and prenatal detection have an association with mHealth adherence. Additional determinants that are not reported with the proximal outcome of adherence but should be evaluated due to associations with the distal outcomes of mortality and morbidity include gender, secondary cardiac diagnoses, atrioventricular valve regurgitation, ventricular dysfunction, major syndromes, and major anomalies of organ systems (Alsoufi et al., 2015; Brown et al., 2015; Colquitt et al., 2016; dUdekem et al., 2012). These determinants are similar to Modi's pediatrics self-management domains and influences on mHealth adherence but have the expansion for evaluation and understanding with determinants from pediatric adherence, mHealth, and pediatric cardiology literature (2012).

Family-related Determinants

The age of caregiver, the total number of family members, the number of children in the home, and insurance have reported determinants of family-related determinants of adherence (Modi et al., 2012). All six family-related determinants are non-modifiable influences on parental mHealth adherence but should be evaluated for correlation with parental mHealth adherence based on previously reported proximal and distal outcomes beyond the five interstage publications reviewed (Anderson-Lewis et al., 2018; Demianczyk et al., 2019).

Community-related Determinants

The distance from the tertiary center is a non-modifiable influence on parental mHealth adherence (Modi et al., 2012). Although this is non-modifiable, the determinant should be assessed for association with parental mHealth adherence due to concern for increased morbidity outcomes in background literature beyond the five reviewed interstage publications (Tregay et al., 2015).

Healthcare System-related Determinants

All healthcare system-related determinants are potentially modifiable expect parental initiated red flag communications (Modi et al., 2012). The rate of clinic visits may be assessed for association with non-adherence with mHealth. The communication patterns of initiation of concerns from parents, healthcare team, or mHealth application and the subsequent triaging of calls by a registered nurse coordinator, nurse practitioner, pediatric fellow, or cardiology attending physician is a gap in evaluation in the interstage literature.

Five studies with mHealth in the interstage period were selected to review for determinants of mHealth adherence. Due to the scarcity of publications directly focused on the proximal outcome of parental mHealth adherence, determinants of mortality, and morbidity events as distal outcomes in infants requiring cardiac surgery should also be evaluated in future research. Further expansion into mHealth adherence literature outside of the interstage into pediatric cardiology, mHealth technology, and mHealth adherence led to possible determinants of parental mHealth adherence. There is a need for correlative research that includes theory and possible associations of patient-related, family-related, healthcare system-related, and community-related determinants of parental mHealth adherence.

Summary

Chapter 2 discussed a proposed conceptual framework, background of pediatric adherence and pediatric cardiology outcomes, and a critical review of the literature for parental mHealth adherence for infants during the single ventricle interstage period. Themes of parental mHealth adherence in the interstage were presented through parental mHealth adherence rate of initiation, implementation, and discontinuation. Additionally, the pediatric self-management conceptual framework's four domains: patient-related, family-related, healthcare system-related, and community-related determinants formed the critical literature review and subsequent gaps in current knowledge. Chapter 3 will outline the methodology and study design used to evaluate the rate of adherence and to describe the relationships between patient-related, family-related, community-related, and healthcare system-related determinants of parental mHealth adherence for infants with single ventricle heart disease during the interstage period.

CHAPTER 3

METHODOLOGY

Chapter 3 presents the study design, setting, sample, measures, and procedure. The data analysis plan using structural equation modeling (SEM) is also delineated. The purpose of the DOMAIN study was to describe the rate of parental mHealth symptom home monitoring adherence and the relationship between patient-related, family-related, community-related, and healthcare system-related determinants of parental mHealth symptom home monitoring adherence of infants with single ventricle congenital heart disease during the interstage period.

Research Design

The study utilized a cross-sectional, correlational design to investigate the rate of parental mHealth adherence and the relationship between patient-related, family-related, community-related, and healthcare system-related determinants of parental mHealth symptom home monitoring adherence of infants with single ventricle congenital heart disease during the interstage period. The pediatric self-management conceptual framework was used to guide the study. Study data were obtained after institutional review board approval for non-human subjects' research. The de-identified data set was obtained from the CHAMP (CHAMP®) multi-site registry housed at Children's Mercy Kansas City in Kansas City, Missouri. The independent variables were patient-related, family-related, healthcare system-related, and community-related determinants of mHealth adherence. The dependent variable was the parental mHealth symptom home monitoring adherence. A proposed structural equation model was fitted to the data (see Figure 3.1). Structural equation modeling is a form of multiple regression that can be used for theory testing through the utilization of empirically analyzed variables within a structural or measurement model (Kline, 2016). Structural regression uses covariances to evaluate strengths of parameter correlations and hypothesized directionality of determinant and outcome variables.

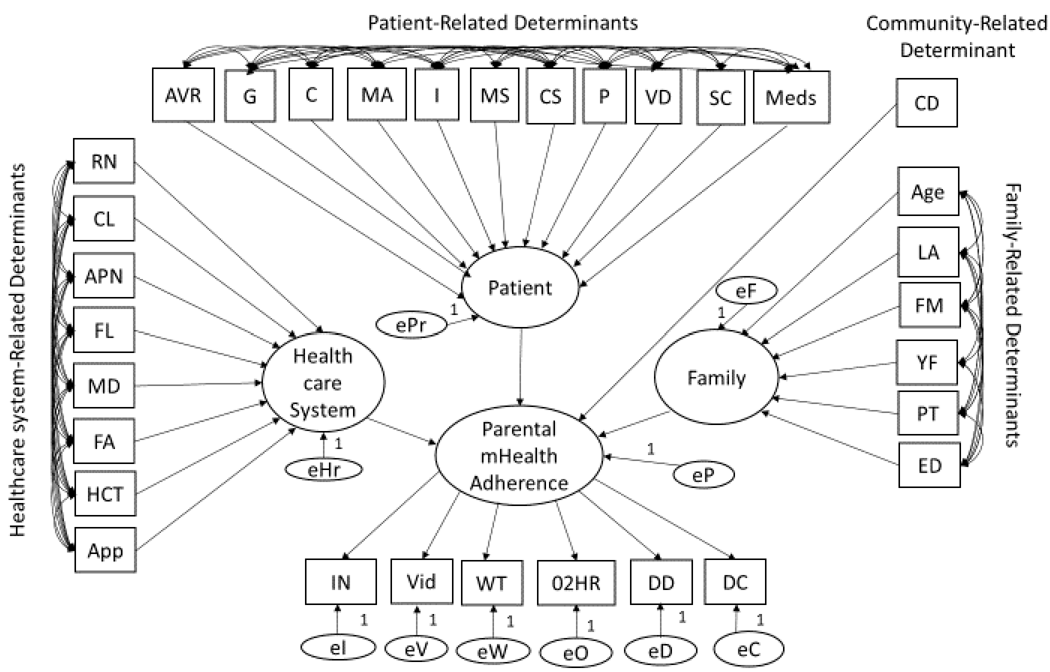

Figure 3.1. Proposed model for parental mHealth adherence for infants with single ventricle interstage congenital heart disease.

Sample

The study sample included infants born with single ventricle congenital heart disease. Inclusion criteria, listed in the enrollment form from the CHAMP database, were to include children: (a) less than 1 year of age before their first cardiac surgery; (b) with single ventricle congenital heart disease; (c) followed by the healthcare team with the CHAMP mHealth application beginning in March 2014; (d) during the interstage period after neonatal discharge from the hospital; (e) included in the CHAMP multi-site registry database; and (f) with parents or legal guardians who speak English, Spanish, Chinese, Korean, Vietnamese, Arabic, German, or French languages.

Exclusion criteria, listed in the enrollment form from the CHAMP database, excluded children: (a) who had not reached an interstage period endpoint of stage two surgery (Glenn) or who had withdrawn during the interstage period by September 13, 2019; and (b) who had stage two surgery that ended in bi-ventricular cardiac anatomy due to lower risk of mortality and morbidity.

A power analysis was conducted to determine the sample size for the study, which was estimated at 300 infants. The power analysis was completed using the statistical program, STATISTICA, for the recursive, theoretically identified, structural equation model with degrees of freedom (d*f*) of 492, 104 parameters, and 595 sample moments (Statsoft, 2016). A one-tailed evaluation was planned with an alpha level .05, population root mean square error of approximation (RMSEA or R) of .08, and null hypothesized RMSEA (R0) .01 as an indicator of model fit. The null hypothesis was $R \leq R0$ with a power level of 1.0. The power for H0 $R \geq R0$ was found to be .116. This provided a 100% probability of detecting a RMSEA less than 0.01 if it existed as a fit for the population (Kline, 2016). There were an expected 34 observed variables to participants with an 8.82:1 ratio (Kyriazos, 2018).

Setting

Data for this study was obtained from an existing registry, CHAMP database. Data in the CHAMP registry contains symptom home monitoring, demographic, and clinical data. The CHAMP application was placed on a cellular enabled electronic tablet set in kiosk mode as a mobile health application. This mHealth application is designed for the transfer of parental symptom home monitoring data from infants with single ventricle congenital heart disease during the interstage period. The mHealth technology application was designed and implemented at Children's Mercy Hospital in Kansas City, Missouri, in 2014 with subsequent expansion to eight other pediatric cardiac surgery centers (Files et al., 2019). The primary coordinating site is Children's Mercy Hospital in Kansas City, Missouri. The additional participating locations are Seattle Children's Hospital (Seattle, Washington), Primary Children's Hospital (Salt Lake City, Utah), Cincinnati Children's Hospital (Cincinnati, Ohio), Nationwide Children's Hospital (Columbus, Ohio), Arkansas Children's Hospital (Little Rock, Arkansas), West Virginia University (Morgantown, West Virginia), Cook Children's Medical Center (Fort Worth, Texas), and Children's National Health System (Washington, District of Columbia).

Operational Definitions

Operational definitions are provided for the predictors of patient-related, family-related, healthcare system-related, and community-related determinants of parental mHealth adherence and the outcome of parental mHealth symptom home monitoring adherence. For clarity, each of the measures in the structural equation model will include the variable name in the model throughout the remainder of Chapters 3 and 4. For example, parental mHealth adherence initiation will be abbreviated as IN, discontinuation as DC, and implementation-data days as DD.

Parental mHealth symptom home monitoring adherence. Parental mHealth symptom home monitoring adherence was defined as the degree to which parents' transfer of mHealth data for their infant met health care providers' recommendations for symptom home monitoring behavior. Parental mHealth symptom home monitoring adherence, the continuous outcome or endogenous variable in structural equation modeling (SEM), was measured as a latent variable with observed measurable indicators (Kline, 2016). For this study, reflective indicators of the latent endogenous variable of parental mHealth symptom home monitoring adherence were used to operationalize this variable. The observed variables included initiation (IN) of first parental symptom home monitoring data after discharge, implementation of data days and each hemodynamic data transferred through the mHealth technology (implementation- data days (DD), implementation- weight (WT), implementation- oxygen saturation (02), implementation- heart rate (HR), and implementation- video (Vid)), and discontinuation (DC) of the mHealth technology through the interstage period (see Table 3.1) (Bingler et al., 2018; Breitenstein et al., 2017; Helmy et al., 2017; Shaw et al., 2016).

Table 3.1

List of Variables Included in the Proposed Structural Equation Model (SEM)

Latent Variable Construct	Observed Measure	Measurement Scales	Observed or calculated data
Parental mHealth adherence (Endogenous)	Implementation- Data days (DD)	Ratio	Number of days in which any type of data points divided by non-hospitalized days at home interstage
	Initiation (IN)	Ratio	Number of days after discharge data first entered
	Implementation- Weight (WT)	Ratio	Number of days in which weight data received daily up to 8 kilograms divided by days at home interstage
	Implementation-Oxygen saturation (O2)	Ratio	Number of days in which oxygen saturation data received divided by days at home interstage
	Implementation- Heart Rate (HR)	Ratio	Number of days heart rate data received divided by days at home interstage
	Implementation- Oxygen Saturation/Heart Rate (02HR)	Ratio	Number of days in which oxygen saturation/heart rate data received divided by days at home interstage
	Implementation- Video (Vid)	Ratio	Number of days in which video individual data points divided by days at home interstage
	Discontinuation (DC)	Ratio	Total number of days from the last data transfer to the end of the interstage
Patient-Related Determinants (Exogenous)	Gender (G)	Dichotomous Nominal	Observed from CHAMP data
	Cardiac diagnosis (C)	Nominal	Observed from CHAMP data
	Secondary diagnosis (SC)	Nominal	Observed from CHAMP data
	Cardiac surgery type (CS)	Dichotomous Nominal	Observed from CHAMP data
	Prenatal diagnosis (P)	Ordinal	Observed from CHAMP data
	Single ventricle cardiac dysfunction (VD)	Ordinal	Observed from CHAMP data

Table continues

Latent Variable Construct	Observed Measure	Measurement Scales	Observed or calculated data
	Atrioventricular valve regurgitation (AVR)	Ordinal	Observed from CHAMP data
	Age in days at initial discharge (AD)	Ratio	Observed from CHAMP data; Day of birth from day of first discharge
	Number of interstage days (I)	Ratio	Observed from CHAMP data; Calculated from date of initial discharge to date of endpoint in study in total days
	Major syndromes (MS)	Nominal	Observed from CHAMP data
	Major anomalies of other organ systems (MA)	Nominal	Observed from CHAMP data
	Medications (Meds)	Ratio	Observed from CHAMP data; Number of medications prescribed at neonatal discharge
Family-related Determinants (Exogenous)	Age of primary caregiver (Age)	Ratio	Observed from CHAMP data
	Education level of primary caregiver (ED)	Ordinal	Observed from CHAMP data
	Primary language at home (LA)	Nominal	Observed from CHAMP data
	Total family members in home (FM)	Ratio	Observed from CHAMP data
	Family members below 18 years of age (YF)	Ratio	Observed from CHAMP data
	Payer type (PT)	Nominal	Observed from CHAMP data

Table continues

Latent Variable Construct	Observed Measure	Measurement Scales	Observed or calculated data
Healthcare system-related Determinants (Exogenous)	Communications App (APP)	Ratio	Number of Instant alert red flags
	Communications Family (FA)	Ratio	Number of family initiated red flags
	Communications Team (HCT)	Ratio	Number of healthcare team initiated red flags
	Communications first communicator nurse (RN)	Ratio	Number of nurse (RN) first communicator red flags
	Communications first advanced practice nurse (APN)	Ratio	Number of advanced practice nurse (APN) first communicator red flags
	Communications first Fellow (FL)	Ratio	Number of Fellow physician first communicator red flags
	Communications first cardiologist (MD)	Ratio	Number of cardiologist first communicator red flags
	Clinic visits (CL)	Ratio	Observed from CHAMP data
Community-related Determinant (Exogenous)	Distance from the tertiary center where the family resides in miles (CD)	Interval	Observed from CHAMP data

Initiation of parental mHealth symptom home monitoring. Initiation (IN), for the purposes of this study, was defined as the first parental mHealth data transferred after the infant was discharged from the hospital. The recommended timing of initiation (IN) is on the first date of hospital discharge from the neonatal hospitalization at the beginning of the interstage period. Initiation (IN), as a continuous measure, was calculated by the number of days by subtracting the date that the first data was transferred from the parents to the healthcare team and the date of initial hospital discharge.

Implementation of parental mHealth symptom home monitoring. Implementation for this study was defined as the rate of days parental mHealth adherence data transferred for each symptom monitored including weight (WT), oxygen saturation (02), heart rate (HR), video (Vid), and data days (DD). Implementation symptom monitoring is recommended to continue through the interstage period up until the day before the second surgery (Bingler et al., 2018). The measure of implementation adherence was a percentage calculated from each category of single ventricle symptom monitoring relevant to hemodynamic status, including of the infants' weights, heart rates, oxygen saturations, videos, and overall data days with perfect implementation adherence scoring 100%, partial implementation adherence between 1 and 99%, and complete non-adherence scoring 0%.

Implementation- Data days (DD) were defined as the number of days in which parental mHealth data was transferred by the parents to the healthcare team (Bingler et al., 2018). The data days transfer rate was the number of days that any data was received divided by the prescribed/expected number of days in which any mHealth symptom home monitoring data was transferred by the parents to the health care team times 100. Weight was dropped as an outcome because there was incomplete data on many infants. This was due to the fact that the scales that were used to measure the infant weight could not capture weights greater than 8 kg and many of the infants exceeded this weight. Heart rate and oxygen saturation fields on the mHealth application were required to be entered together by parents when using the CHAMP application. This led to the formation of an additional variable of combined implementation- oxygen saturation/heart rate (O2HR). The rate of implementation for each outcome of data days, weight, oxygen saturation/heart rate, and video were calculated as the number of days of data submitted for each outcome category divided by the prescribed/expected number of days in which data for each outcome was transferred by the parents to the health care team times 100.

Discontinuation of parental mHealth symptom home monitoring. For this study, discontinuation (DC) of parental mHealth symptom home monitoring was defined as the last day that data was transferred before the end of the interstage period, ideally the last day before the second stage surgery.

Measures

Demographic variables. The following demographic variables were extracted from the CHAMP registry: infant gender (1= male, 2= female), infant race (1= white, 2= black/African American, 3= American Indian/Alaska native, 4= Asian, 5= Native Hawaiian/Pacific islander, 6=other), infant ethnicity (1= non-Hispanic, 2= Hispanic), infant birth weight, infant gestational age at birth, infant cardiac diagnosis (0= double inlet left ventricle, 1= double outlet right ventricle with left sided stenosis, 2=double outlet right ventricle with pulmonary outflow obstruction, 3= hypoplastic left heart syndrome with mitral and aortic atresia, 4= hypoplastic left heart syndrome with mitral and aortic stenosis, 5= hypoplastic left heart syndrome with mitral stenosis and aortic atresia, 6= hypoplastic left heart syndrome with mitral atresia and aortic stenosis, 7= pulmonary atresia with intact ventricular septum, 8= single ventricle not otherwise specified, 9= tricuspid atresia, 10= unbalanced complete atrioventricular canal), infant secondary cardiac risk factors (1= none, 2= anomalous pulmonary venous drainage, 3= aorta <2mm, 4= arrhythmia requiring therapy, 5= endocardiofibroelastosis (EFE), 6= intact atrial septum (IAS), 7= moderate to severe atrioventricular valve regurgitation, 8= moderate to severe ventricular dysfunction, 9= restrictive atrial septum, 10= other, 11-21= combinations of above, infant major genetic syndromes (0= none, 1= 22q11 deletion-Digeorge, 2= CHARGE syndrome, 3= Dextrocardia, 4= Dextrocardia with Heterotaxy, 5= Down syndrome, 6= Heterotaxy with Down Syndrome, 7= Heterotaxy syndrome, 8= VATER syndrome, 9= Other), infant major anomalies of other organ systems (0= none, 1= brain, 2= gastrointestinal, 3= renal, 4= ear nose and throat, 5= lung, 6= spine, 7-17= combinations of others), prenatal detection of congenital heart disease (0= not prenatally detected, 1= prenatal detection), parental age, parental education level, and primary language spoken at home by parents (1=English, 2= Spanish, 3= Arabic, 4= Chinese, 5= French, 6= Other).

Predictor variables. Predictor variables of parental mHealth symptom home monitoring adherence in infants with single ventricle congenital heart disease during the interstage period included patient-related, family-related, healthcare system-related, and community-related factors. These predictor variables were selected because they are known determinants for adherence, morbidity, or mortality with single ventricle congenital heart disease during the interstage period (Clauss et al., 2015). Additionally, the pediatric self-management conceptual framework established these as key self-management concepts (Modi et al., 2012). Twenty-seven variables in total were selected for inclusion from the

CHAMP registry (see Table 3.1). These variables included: (a) twelve patient-related; (b) six family-related; (c) eight healthcare system-related; and (d) one community-related determinants. Three variables were operationalized as latent variables through observed variables from the CHAMP registry. The three new latent variables, named patient-related determinants, family-related determinants, and healthcare system-related determinants, were abstracted from pediatric self-management conceptual framework domains (see Figure 1.3). Other than the community-related determinant, which had a single variable, each of the other determinants had more than two observed variables for the same construct meeting minimum criteria for structural equation latent formative variables (Kline, 2016).

Patient-related variables. Patient-related determinants of parental mHealth symptom home monitoring adherence of infants with single ventricle congenital heart disease during the interstage period included: gender (G); cardiac diagnosis (C); secondary cardiac diagnosis (SC); cardiac surgery type (CS); prenatal detection (P); single ventricular dysfunction (VD); atrioventricular valve regurgitation (AVR); age in days at initial discharge (AD); number of interstage days (I); major genetic syndromes (MS); number of medications at neonatal discharge (Meds); and major differences of other organ systems (MA) (Modi et al., 2012). There was a mix of continuous and categorical variables with dichotomous, ratio, ordinal, and nominal levels of measurement (Kline, 2016).

Family-related variables. Family-related determinants of parental mHealth symptom home monitoring adherence in infants with single ventricle congenital heart disease during the interstage period included: total family members in the home (FM); children in the home not counting the infant with congenital heart disease (YF); language spoken at home (LA); age of primary caregiver (Age); payer type (PT); and education level of primary caregiver

(ED) (Modi et al., 2012). There was a mix of continuous and categorical variables with ratio and nominal levels of measurement (Kline, 2016).

Healthcare system-related variables. Healthcare system-related determinants of parental mHealth symptom home monitoring adherence in infants with single ventricle congenital heart disease during the interstage period included: frequency of cardiology clinic visits (CL); route of red flag communication through mHealth application (APP), route of red flag communication through healthcare team (HCT); route of red flag communication through family (FA); initial communication through nurse (RN), initial communication through advanced practice nurse (APN), initial communication through cardiology fellow (FL), initial communication through cardiologist (MD) (Modi et al., 2012). There was a mix of continuous and categorical variables with ratio and nominal levels of measurement (Kline, 2016).

Community-related variable. The community-related determinant of parental mHealth symptom home monitoring adherence in infants with single ventricle congenital heart disease during the interstage period included the distance the family was living on first discharge from the tertiary care center (Modi et al., 2012). Distance from the tertiary center was a single-indicator measure and a categorical variable with a nominal level of measurement (Kline, 2016).

Outcome variables. Parental mHealth symptom home monitoring adherence as a latent variable was the primary outcome variable evaluated in the structural equation model. Five types of implementation were used as indicators of adherence: (a) implementation-weight (WT), (b) implementation- oxygen saturation (O2), (c) implementation- heart rate (HR), and (d) implementation- videos (Vid), (e) implementation- data days (DD).

Procedures

The Principal Investigator (PI) is the CHAMP clinical program manager, passed her comprehensive exam as part of a Ph.D. program in nursing, and is a Master's prepared advanced practice registered nurse at Children's Mercy Hospital. The PI submitted this study to CMH's Institutional Review Board (IRB) for review. Study data were obtained after IRB approval for non-human subjects research from both the Children's Mercy Hospital and at the University of Missouri-Kansas City IRB (Project # 2017743). The de-identified data set was obtained from the CHAMP multi-site registry housed at Children's Mercy Kansas City in Kansas City, Missouri. Children's Mercy Heart Center CHAMP research team software specialist accessed the secure, online, encrypted multi-site registry in October 2019 to pull the approved subjects and associated measures for inclusion in the de-identified data set and provided this data in a Microsoft Excel CSV file via secure email to the PI in November 2019.

Only data were included in the study from parents who provided informed consent for using their infant's data. Informed consent for participation in the multi-site retrospective registry was obtained through each participating site after the consent form was approved by Children's Mercy Hospital's IRB. The informed consent forms included a description of the registry and the plan for collaborative research among the participating sites for future secondary research projects.

To ensure registry data integrity, each participating site data collector completed a one-day on-site training with the central site on the clinical use of the mHealth application and the provider web portal. The CHAMP web portal includes data entry forms for the registry of enrollment, neonatal surgery, neonatal hospital discharge, clinic visits, red flags, readmissions, stage two Glenn surgery, and exit form if needed. There are data quality ranges on the data entry forms for continuous variables but have no safeguards for required fields or non-sequential dates of data entry. The registry can only be accessed after IRB approval, so individual sites maintain the reliability of their data with downloadable electronic reports. Quarterly web calls for each participating site are set and have a 75% required attendance for engagement and updates for the registry.

Human subjects protection. There was no interaction with human participants in this retrospective review of the CHAMP registry. The CHAMP registry is Health Insurance Portability and Accountability Act (HIPAA) compliant and stored in a secure, encrypted Microsoft Azure platform (Shirali et al., 2016). All data variables were de-identified, and there were no direct benefits to the infants or parents for participating in this study. Inclusion in the registry was provided at no cost, and there was no payment given to parents for participation. There was no perceived risk to infants beyond the risk of lack of confidentiality with the need to access data by the Heart Center CHAMP information technology staff in the encrypted registry. No protected health information was used for this analysis, but the registry included videos and protected health information. The PI did not access the encrypted registry.

Data Analysis

Descriptive statistics, model evaluation, confirmatory factor analyses, and model revision was completed by the PI using AMOS through SPSS (AMOS Development Corporation, 2017). Descriptive statistics were used to describe the sample characteristics, including demographics with percent, means with standard deviations for continuous variables, medians and ranges for outcome variables, frequency and percentage for categorical variables, normality (skewness and kurtosis), and missing data for all variables. The indicators of adherence must be continuous and have a multivariate normal distribution in structural equation modeling. The Two-step approach to achieve normality of continuous variables was used for the achievement of normality for outcome variable measures (Templeton, 2011). Data found to be missing at random (MAR) and missing completely at random (MCAR) was imputed using the expectation-maximization (EM) algorithm to form a complete data set, and non-normal outcome variable data was transformed using SPSS software (Dong & Peng, 2013; IBM, 2013). Empirical evidence of the occurrence of data missing completely at random (MCAR) and the theoretical arguments of the causes of missing data were provided (Kline, 2016).

Nominal variables were transformed using rank cases transformation in SPSS. A fully saturated structural model of all outcome variables was evaluated in AMOS for correlations and covariances. A measurement model was evaluated through principal component analysis factor loadings with no rotation using SPSS to evaluate each of the patient-related, family-related, and healthcare system-related domains. A score of greater than or equal to .4 was used as the factor loading cut-off for determination for retaining variables (Matsunaga, 2010). Findings for each of the patient-related, family-related, and healthcare system-related determinants were reported for factor analysis testing of Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy and Bartlett's Test of Sphericity (Williams, Onsman, & Ted Brown, 2010). A value of KMO above .5 is recommended for suitability for factor analysis and is recommended as a specific index when the variable ratio is less than 1:5. Variables were evaluated for extreme collinearity. Secondary analysis in the measurement model was completed for implementation- oxygen saturation (02HR) with an

ANOVA evaluation of comparing mean rate of adherence by hospital site when the cohort was found to have a significantly high rate of adherence.

Patient-related, family-related, healthcare system-related, and parental mHealth adherence were used as latent variables represented by observed measures of the specific variables from the CHAMP registry with assumed associations and directionality as seen in the proposed model in Figure 3.1. The goal was to generate an explanatory model based on the theoretical framework of pediatric self-management.

The goodness of fit was evaluated by absolute, incremental, modification, and parsimony adjusted indices (Kline, 2016). An outcome only model and a full structural exploratory analysis of the causes of parental mHealth adherence without prespecified covariances or latent variables was completed. The exact-fit hypothesis chi-square statistic test, including degrees of freedom, root mean square error of approximation (RMSEA), standardized root mean square residual (SRMR), and p-value, were used to evaluate if the null hypothesis supported or rejects the model (Kline, 2016). Standardized root mean square residual (SRMR) was reported as an absolute fit index and root mean square error of approximation (RMSEA) and the 90% confidence interval as a parsimony index (Kline, 2016). For standardized root mean square residual (SRMR), values less than .06 indicate good fit (Hu & Bentler, 1999). For root mean square error of approximation (RMSEA), values less than .08 indicate adequate fit, and less than .05 indicate good fit with perfect = 0 (Hu & Bentler, 1999; Kline, 2016; MacCallum, Browne, & Sugawara, 1995). The comparative fit index (CFI) for incremental fit was evaluated as an index of covariance structure analysis. Values greater than .95 indicate a good fit between the proposed model and actual data (Hu & Bentler, 1999). Type II error is possible if the p-value is not considerably greater than .05 in structural equation modeling (Kline, 2016).

Model parameters were reported through standardized regression weights and significant findings to parental mHealth adherence with covariances (Kline, 2016). Unstandardized and standardized estimates were reported for all estimated parameters and statistical significance as applicable. A correlation matrix for the analyses was reported with Pearson product-moment correlations between continuous variables, polychoric correlations between ordinal variables, and polyserial correlations between ordinal and continuous variables. Standardized regression weights were evaluated for any value over two, indicating poor local fit (Kline, 2016). Using Cohen (1988) guidelines, a correlation < .3 was considered "low", .3-.6 "moderate", and >.6 "high", and >.7 very large (Rosenthal, 1996). Model variances were reported with the correlation of determination (R^2). Bootstrapping through maximum likelihood and Bollen-stine bootstrap were completed to provide nonparametric estimates of categorical variables with four or fewer levels. The estimations were completed using SPSS and AMOS software (AMOS DevelopmentCorporation, 2017; IBM, 2013). Alternative models, including a full exploratory model with no prespecified covariances, were tested for comparison with model fit and the final model. Suggested modification indices for direct weight regression and covariances were added if theoretically sound for the final model.

Summary

Chapter 3 presented the DOMAIN study design, setting, sample, operational definitions, measures, and procedures. The data analysis results and evaluation using structural equation modeling were also delineated. Chapter 4 will present the results of the

DOMAIN study of the parental mHealth adherence rate and the relationships between patient-related, family-related, community-related, and healthcare system-related determinants of parental mHealth symptom home monitoring adherence of infants with single ventricle congenital heart disease during the interstage period.

CHAPTER 4

RESULTS

Chapter 4 includes the results of the DOMAIN study; a cross-sectional, correlational study completed on data obtained from the CHAMP multi-site database. The proposed structural equation model was exploratory including outcome modeling, and re-specification was completed after the primary model was rejected. Preliminary statistics, data analysis, model assessment, and model comparison is reported for the proposed structural equation model using journal article reporting standards for structural equation modeling (Appelbaum et al., 2018).

Preliminary Statistics

Normality

Exogenous predictor variables were assumed to be measure error-free. Estimation was assessed for all variables for multivariate normality, including kurtosis |10| and skewness |3| (Sterne et al., 2009). On the case screening for outliers, kurtosis, and skewness, 14 variables were non-normally distributed. Nine variables were found to have both skewness and kurtosis, one variable with skewness, and 11 variables with kurtosis alone. Endogenous continuous outcome variables of (a) initiation (IN), (b) implementation- weight (WT), (c) implementation- oxygen saturation (O2), (d) implementation- heart rate (HR), and (e) implementation- videos (Vid) were transformed using the Two-step approach using SPSS to maintain multivariate normality to follow structural equation modeling guidelines (IBM, 2013; Kline, 2016). The Two-step approach to achieve normality of continuous variables uses fractional rank and then imputation through observed mean and standard deviation of the original sample (Templeton, 2011).

Distribution for normality is a key part of data preparation required prior to the evaluation of continuous endogenous outcome variables in structural equation modeling (Kline, 2016). Maximum likelihood estimation in structural equation modeling assumes multivariate normality for the continuous outcome variables through univariate evaluation of all other variables (Kline, 2016). The Two-step approach for transformation provides four benefits of validity towards data analysis, including the statistical conclusion, internal, and construct validity(Templeton, 2011). Statistical conclusion validity may be more accurate after transformation to mitigate outliers. Although other transformation methods may change the order of values, this order does not change in the Two-step approach so inferences using parameters like p-values remain valid (Templeton, 2011). Internal validity can be improved with the retaining and bounding of extreme values with the Two-step approach. Construct validity can be enhanced through the operationalization of theory-relevant terms in the same distributional shape, so the coefficient results are non-biased (Templeton, 2011). Non-normal distributions for outcome measures may cause heteroscedasticity in regression analysis and potential bias in analysis and structural equation modeling is highly sensitive to skewed or kurtotic variables (Qureshi & Compeau, 2009). The Two-step approach for data preparation for normality has important impacts on the validity and analysis of structural equation modeling. In addition to distribution, missing data evaluation is a key step in data preparation for structural equation modeling.

Missing Data

Data were evaluated for missing data values from 33 variables using SPSS missing value analysis and multiple imputation analysis for patterns. Of the 11,394 possible data points, 150 (1.3%) were missing, which allowed 208 complete cases with nine variables having any missing data. The majority of missing data appeared to be missing completely at random (MCAR) with the majority of cases missing less than 5% of variables except for the primary caregiver age (Age) which was missing at random with no correlation with other missing variables (Kline, 2016). Two individual variables used in the model had higher rates of missing variables which included education level of primary caregiver (ED) at 93 cases (29.8%) and primary caregiver age (Age) at 16 cases (5.1%) with no patterns of missing data by individual hospitals (Dong & Peng, 2013).

Expectation-maximization (EM) algorithm was used in SPSS for multiple imputation of the missing data variables (Dong & Peng, 2013). Expectation-maximization is a principled method used to handle missing data by evaluating other observed data to estimate population parameters and potentially the mechanism for missing data. The use of a principled method to statistically assess missing data provides benefits over other methods to handle missing data such as replacement of missing data with the variable mean, listwise deletion, or pairwise deletion due to the risk of the bias of inefficient estimates with these methods (Dong & Peng, 2013). The initial separate variance t test's found significant ($p < .05$) missing variable patterns for the pairs of primary caregiver age (Age) with the total number of family members (FM) and children in the home (YF) and with education level of caregivers (ED) with family members (FM) and children in the home (CY). The family-related determinant variables correlate within each other indicating missing at random (MAR) (Kline, 2016). However, the EM means provided through Little's missing completely at random (MCAR) test were non-significant for the variables with missing data, so the missing data patterns did not hold on this second evaluation (Chi-Square=88.720, *df*=108, p=.912). This finding supports the use of the EM algorithm method for missing data

(Dong & Peng, 2013). The subsequent single imputation dataset was used for model analysis in AMOS (IBM Corporation, 2017).

Results

The sample description was reported in Table 4.1 and Table 4.2 of the 312 infants from the nine hospitals that contributed to CHAMP multi-site registry during the interstage period from March 2014 through September 2019. Prior to data imputation for distribution or missing data issues, the original patient cohort was found to be primarily white (n= 255, 81.7%), non-Hispanic (n= 270, 86.5%), born at term gestation (38.2 $\pm$ 1.67 weeks), and male (n=195, 62.5%) infants. Survival through the interstage period to the second stage Glenn surgery was 97.1% (n= 303) with a mean age of 183 $\pm$ 162 days. The majority of infants' congenital heart disease was prenatally detected (n=258, 82.7%) with the primary cardiac diagnosis being hypoplastic left heart syndrome (n=114, 36.6%) with no secondary diagnoses (n=234, 75.0%) with over half the cohort receiving a Stage I Norwood surgical palliation (n=166, 53.2%). Many infants had no major genetic syndrome (n=256, 82.1%) nor major non-cardiac anomalies (n=274, 87.8%). The mean initial neonatal discharge age was 45 days, with infants prescribed a mean of 3.45 $\pm$ 2.2 medications. Evaluation by echocardiogram revealed many infants had no single ventricular dysfunction (VD) (n=288, 92.3%) with about half of infants' having no atrioventricular valve regurgitation (AVR) (n=154, 49.4%).

Table 4.1

Demographics

	Frequency (%)
Institution	
A	124 (39.7)
B	48 (15.4)
C	52 (16.7)
D	8 (2.6)
E	38 (12.2)
F	25 (8.0)
G	9 (2.9)
H	6 (1.9)
I	2 (0.6)
Race	
White	255 (81.7)
Black/African American	30 (9.6)
American Indian/Alaska Native/Native Hawaii/Pacific Islander	4 (1.3)
Asian	7 (2.2)
Other	16 (5.1)
Hispanic	42 (13.5)
Exit status	
Stage 2 Glenn Surgery	303 (97.1)
Death	9 (2.9)
Birthweight kg (Mean ±SD)	3.14 ±.53
Gestational Age (Weeks) (Mean ±SD)	38.2 ±1.67
Hospital readmission stay during the interstage (days)	12.44 ±21.57
Age at exit (days)	183.33 ±162.0

Note. n=312

Table 4.2

Descriptive Statistics

Patient-related	Frequency (%)	Min	Max	Mean	SD	95% CI
Female Gender (G)	117 (37.5)	1	2	1.38	.49	[1.32, 1.43]
Prenatally Detected (P)	258 (82.7)	0	1	0.83	.38	[.72, .83]
Cardiac Diagnosis (C)		0	10	5.2	3.21	[5.0, 5.9]
DILV	20 (6.4)					
DORV/Left sided-stenosis	28 (9.0)					
DORV/PS	24 (7.7)					
HLHS with MA/AA	44 (14.1)					
HLHS with MS/AS	33 (10.6)					
HLHS with MS/AA	29 (9.3)					
HLHS with AS/MA	8 (2.6)					
PA/IVS	20 (6.4)					
Single Ventricle (NOS)	38 (12.2)					
Tricuspid atresia	33 (10.6)					
Unbalanced CAVC	35 (11.2)					
Secondary Diagnoses (SC)	234 (75.0)	1	21	3	4.45	[2.5, 3.8]
None	11 (3.5)					
TAPVR/PAPVR	10 (3.2)					
Arrhythmia requiring Therapy	3 (1.0)					
EFE	12 (3.8)					
Moderate to Severe AVR	1 (.3)					
Moderate to Severe VD	19 (6.1)					
Restrictive Atrial Septum	3 (1.0)					
Other	19 (6.1)					
Combinations of Above						
Age at Initial Discharge in days (AD)		0	384	45.06	38.96	[40.2, 48.9]

Table continues

Patient-related	Frequency (%)	Min	Max	Mean	SD	95% CI
Cardiac Surgery Type (CS)		0	7	3.38	2.10	[3.3, 3.9]
Norwood with BT	55 (17.6)					
Shunt	92 (29.5)					
Norwood with Sano Shunt	7 (2.2)					
DKS with Shunt	12 (3.8)					
Hybrid Norwood	68 (21.8)					
BT/Central Shunt	32 (10.3)					
Pulmonary Artery Band	8 (2.6)					
Other Surgery for stage I	38 (12.2)					
No Stage I surgery						
Single Ventricular function (VD)		0	3	0.08	.33	[.04, .12]
None	288 (92.3)					
Mild	18 (5.8)					
Moderate	2 (.6)					
Severe	1 (.3)					
Atrioventricular valve regurgitation (AVR)		0	3	.66	.78	[.54, .75]
None	154 (49.4)					
Mild	90 (28.8)					
Moderate	49 (15.7)					
Severe	2 (.6)					
Major Syndrome (MS)		0	9	1.14	2.66	[.89, 1.7]
None	256 (82.1)					
DiGeorge Syndrome	1 (.3)					
CHARGE	2 (.6)					
Dextrocardia	3 (1.0)					
Dextrocardia with Heterotaxy	8 (2.6)					
Down Syndrome	1 (.3)					
Down Syndrome with Heterotaxy	1 (.3)					
Heterotaxy Syndrome	22 (7.1)					
Other	16 (5.1)					

Table continues

Patient-related	Frequency (%)	Min	Max	Mean	SD	95% CI
Major Non-Cardiac Anomalies (MA)		0	17	0.61	2.14	[.39, 1.02]
None	274 (87.8)					
Brain	3 (1.0)					
GI	12 (3.8)					
Renal	6 (1.9)					
ENT	2 (.6)					
Lung	1 (.3)					
Spine	1 (.3)					
Other	6 (1.9)					
Combinations of Above	7 (2.2)					
Medications at neonatal discharge (Meds)		0	11	3.45	2.20	[3.21, 3.71]
None	26 (8.3)					
1	28 (9.0)					
2	52 (16.7)					
3	76 (24.4)					
4	47 (15.1)					
5	33 (10.6)					
6	17 (5.4)					
7	16 (5.1)					
8	7 (2.2)					
9	7 (2.2)					
10	2 (.6)					
11	1 (.3)					
Interstage days		9	582	126.01	71.1	[118, 135]

Family-related		Min	Max	Mean	SD	95% CI
Age of Primary Caregiver (Age)		15	52	28.2	6.11	[27.4, 29.0]
Education level of Primary caregiver (ED)		2	17	13.28	2.27	[12.97, 13.6]
Language Spoken (LA)		1	6	1.11	.56	[1.03, 1.19]
English	294 (94.2)					
Spanish	13 (4.2)					
Arabic	1 (.3)					
Chinese	1 (.3)					Table continues
Other	3 (1.0)					

Family-related	Frequency (%)	Min	Max	Mean	SD	95% CI
Total Family Members (FM)		1	11	3.50	1.51	[3.33, 3.66]
1	6 (1.9)					
2	80 (25.6)					
3	98 (31.4)					
4	52 (16.7)					
5	37 (11.9)					
6	20 (6.4)					
7	8 (2.6)					
8	3 (1.0)					
9	1 (.3)					
11	1 (.3)					
Children in the Home (YF)		0	9	1.32	1.37	[1.17, 1.48]
0	102 (32.7)					
1	93 (29.8)					
2	56 (17.9)					
3	29 (9.3)					
4	18 (5.8)					
5	5 (1.6)					
6	1 (.3)					
9	1 (.3)					
Payer Type (PT)		1	4	1.53	.66	[1.38, 1.54]
Medicaid/State Insurance	168 (53.8)					
Private Insurance	133 (42.6)					
Self-Pay	2 (.6)					
Other	9 (2.9)					

Table continues

Community-related %	Frequency	Min	Max	Mean	SD	95% CI
Distance home located from Tertiary Care Center (CD)		0	4	2.68	1.42	[2.43, 2.83]
0-10 miles	36 (11.5)					
11-20 miles	40 (12.8)					
21-50 miles	40 (12.8)					
51-100 miles	65 (20.8)					
Greater than 100 miles	130 (41.7)					

Healthcare system-related	Frequency (%)	Min	Max	Mean	SD	95% CI
Clinic Visits (CL)		0	17	5.61	3.13	[5.26, 5.95]
Route of red flag communication- mHealth application (APP)		0	69	2.21	6.55	[1.48, 2.94]
Route of red flag communication through parent (FA)		0	19	2.49	3.55	[2.09, 2.88]
Route of red flag communication through healthcare team (HCT)		0	10	1.1	1.64	[.92, 1.28]
Initial Contact Attending (MD)		0	5	.09	.44	[.04, .14]
Initial Contact Fellow (FL)		0	65	.50	3.77	[.08, .92]
Initial Contact Advanced practice nurse (APN)		0	50	3.13	5.75	[2.49, 3.77]
Initial Contact Nurse (RN)		0	28	2.07	3.4	[1.69, 2.45]

Note. n = 312. AA= Aortic atresia, AS= Aortic stenosis, AVR= Atrioventricular valve regurgitation, BT= Blalock Taussig, CAVC= complete atrioventricular canal, CI=confidence interval, DKS= Damus-Kaye-Stansel, DILV= Double inlet left ventricle, DORV= Double outlet right ventricle, EFE= Endocardial fibroelastosis, ENT= Ear, nose, and throat, GI= Gastrointestinal, HLHS= Hypoplastic left heart syndrome, IVS= Intact ventricular septum, Mitral atresia= MA, MS= Mitral stenosis, NOS= Not otherwise specified, PA= pulmonary atresia, PAPVR= Partial anomalous pulmonary venous return, PS= Pulmonary stenosis, SD= Standard deviation, TAPVR= Total anomalous pulmonary venous return, VD= Ventricular dysfunction.

Family-related factors found in Table 4.2 include a pre-imputation cohort of infants primarily cared for by English speaking (n=294, 94.2%) mothers (n=300, 96.2%) with a mean age of 28.2 $\pm$ 6.11 years, and 53.8% (n=168) having Medicaid/State insurance. The primary caregiver was reported as having a mean year of education at 13.4 $\pm$ 2.4 years which extrapolated to 55.4% (118/213 families) had some college education or above. Family size was a mean of 3.5 members, and, in the home, there were a mean of 1.32 children in addition to the infant with congenital heart disease. Over a third of patients lived with their parents (n=130, 41.7%), more than 100 miles from the tertiary care center during the interstage period.

Healthcare system-related factors included clinic visits, communications, and initial contact with nurses, advanced practice nurses, fellows, and attending physicians. Infants had a mean frequency of 5.61 clinic visits. The three routes of red flag communications had a mean occurrence rate per patient through the mHealth application (APP) at 2.21 $\pm$ 6.55, parents (FA) at 2.49 $\pm$ 3.55, and the healthcare team (HCT) at 1.1 $\pm$ 1.64. The communications were initially reported through nurses (RN) at a mean rate of 2.07 $\pm$ 3.04, advanced practice nurses (APN) at 3.13 $\pm$ 5.75, cardiology fellows (FL) at .5 $\pm$ 3.77, or attending physician cardiologists (MD) at .09 $\pm$ .44 occurrences per patient.

Data Summary

Analysis with structural equation modeling requires a step-wise approach to determine the validity of acquired data to answer research questions. This is evaluated through the volume of subjects for power analysis, missing data, normality, and characteristics of variables. This cohort had n=312 infants which is sufficient for the power analysis which was completed with 300 infants and goal was over 200. The range of contribution to the data set per hospital ranged from n=2 (0.6%) to n= 124 (39.7%). The nine hospitals were not nested individually by groups for this initial overall cohort analysis. Beyond the comparisons of the mean rate of implementation- oxygen saturation/heart rate (O2HR) adherence, no hospital site nested comparisons were evaluated in this analysis. There was a relatively low rate of missing or non-normalized data in the original cohort. The data was missing at random (MAR) or missing completely at random (MCAR) and was transformed through single imputation processes. The initial data set with n=189 infants with parental education level reported had a mean level of 13.11 + 2.31 compared to the mean in the imputed set in Table 4.2 There was a moderate rate of variables that were non normally distributed but only the final outcome variables requiring two-step transformation for normality to be used in the structural equation model. Each of the descriptive statistics for the patient-related, family-related, and healthcare system-related determinant categories for evaluation of validity.

Patient-related determinants. Descriptive statistics related to patient-related variables should be evaluated prior to interpretation of structural modeling to ensure adequate fit for the sample being explored. Patient-related variables found in the DOMAIN study are similar to large studies of infants with congenital heart disease from the American Heart Association Heart Disease and Stroke Statistics 2016 update (Mozaffarian et al., 2016) and through the NPCQIC (Hurst, Oster, Smith, & Clabby, 2015). The DOMAIN study patient-related characteristics are also similar to the findings from a contemporary cohort from Hamzah et al. (2020)'s evaluation of a large hospital database of 11,470 infants with hypoplastic left heart syndrome from 2006-2014. The findings of the evaluation by Hamzah et al. (2020) concluded that the contemporary cohort of patients had an increasing incidence of more complex anomalies, smaller birth weight, and earlier gestational age compared with the care of infants with single ventricle heart disease in the 1990s-early 2000s.

Although the majority of findings were similar to other studies, there were a few patient-related determinants that were different from previous research, including length in days of the interstage period and degree of atrioventricular valve regurgitation (AVR) on echocardiogram. The longer length in days of the interstage period has been discussed as a risk factor for interstage mortality but longer length of the interstage and higher mortality was not seen in the DOMAIN study (Bates et al., 2018). The DOMAIN study findings on single ventricular dysfunction (VD) of moderate or greater (n=3, .9%) on discharge was similar to other studies (Bates et al., 2018). However, the DOMAIN study had a higher rate of moderate atrioventricular valve regurgitation (AVR) compared with others (Bates et al., 2018). This may be due to the heterogeneity of the type of cardiac surgeries that patients had undergone beyond the Norwood palliative surgery as from (Bates et al., 2018). Overall, the patient-related determinants had consistent findings with previous research for infants with congenital heart disease but family-related and healthcare system-related determinants should also be compared for external validity.

Family-related determinants. As with patient-related variables, the majority of family-related variables are similar to other large studies of congenital heart disease. Table 4.2 findings are similar to other publications about caregivers of infants with congenital heart disease-related to language, mothers as primary caregivers, age of primary caregivers, family size, and case mix of insurance status (Demianczyk et al., 2019; Taylor et al., 2016). The number of family members in the home (FM) and children in the home (YF) had a very large correlation (r= .872) which has concerning findings for discriminant validity between these two variables (Kline, 2016). These measures were assessed similarly by the total family members (FM), except the patient, and just those in the family under 18 years of age (YF), so the two variables similar linearity is explained. The education years of the primary caregiver of the DOMAIN study was consistent with other studies (Taylor et al., 2016) but the amount of single imputation needed for the DOMAIN study cohort was high for this variable at nearly 30% so findings with this variable should be interpreted with caution. As with patient-related variables, the majority of family-related variables were consistent with other comparable studies but one variable that had different findings was community distance (CD) from the tertiary hospital during the interstage period.

Community distance (CD) in the DOMAIN study found that over half of the patients lived more than 40 miles from the tertiary care center which was a farther distance than comparable publications (Taylor et al., 2016). This may be due to the locations of CHAMP multi-site hospitals and the treatment of families in in neighboring states and the ability of mHealth to help monitor families farther from the tertiary centers. A restriction in the CHAMP multi-site registry for the community distance measure is no reports of families moving during the interstage period, so the distance is calculated on the first discharge home. Additionally, individual zip codes were not available to have further evaluation of neighborhood resources or socioeconomic evaluation into the community-related determinants of parental mHealth adherence as recommended in the pediatric self-management conceptual framework (Modi et al., 2012).

Healthcare system-related determinants. Lastly, most of the healthcare system-related variables are new measures in pediatric cardiology and are only available due to mHealth technology so there are not as many opportunities to compare descriptive findings from the DOMAIN study The mean rate of clinic visits in the DOMAIN study is consistent with comparable to the frequency of interstage infant clinic visits with parental mHealth home monitoring (Bingler et al., 2018; Black et al., 2014). There is potential decreased internal validity for the rate of red flag communications with the total reported communications from the multi-site data resulting only from one care center at a rate of 73.9% (n=1336) of the 1808 communications initiated from all routes. Although the majority are from one center, the high rate of occurrence of these communications provides a depth of opportunity to understand patterns and potential correlations.

The data summary findings for missing data, normality, and external validity supported the advancement of the interpretation of findings to the specification of the research questions one and two (Appelbaum et al., 2018). There is some risk of non-independence occurring between centers having some sites with lower ranges of data contribution but the overall consistent demographics with other studies in interstage single ventricle congenital heart disease, the DOMAIN study findings support the external validity of the research questions potential rates and relationships.

Parental mHealth Adherence Outcome

Research question one is: "What is the rate of parental mHealth symptom home monitoring initiation (IN), implementation (WT, 02/HR, DD, Vid), and discontinuation (DC), of infants with single ventricle heart disease during the interstage period? The results for research question one is shown in Table 4.3. All 312 infants had initiation (IN) of any symptom home monitoring data. The mean initiation (IN) for the first use of the mHealth application was 5.28$\pm$ 15.03 days after discharge. The range of initiation (IN) was the day of discharge, 0 days to 104 days with a median of 0 days. There were 71.2% (n=222/312) of primary caregivers who entered data on the day of discharge. This number increased to 82.3% (n=257/312) within 24 hours of discharge. Discontinuation (DC) of use of the mHealth application was found to be a mean of 15.56$\pm$ 27.42 days prior to the end of the interstage period. As with initiation (IN), the range of discontinuation (DC) days was wide at 0-167 days prior to the end of the interstage period. The median discontinuation (DC) was four days with 66.0% (206/312 infants) having discontinuation (DC) in the last week prior to the end of the interstage.

Table 4.3

Adherence Statistics

	Min	Max	Med	Mean	SD	95% CI
Initiation (IN)	0	104	0	5.28	15.0	[3.7, 7.1]
Implementation Data Points	3	5832	497.0	793.45	855.7	[698, 890.2]
Implementation-WT	.36	533.33	62.5	64.81	42.0	[59.4, 71.6]
Implementation-O2 Sat (02)	1.68	1313.9	86.22	103.01	114.4	[95.5, 123.0]
Implementation-Heart (HR)	1.68	1313.9	86.22	103.01	114.4	[95.5, 123.0]
Implementation-Videos (Vid)	0	500	43.5	52.86	47.3	[51.6, 65.5]
Implementation- DD	1.68	100	92.7	75.54	30.2	[72.21, 79.0]
Discontinuation (DC)	0	167	4	15.56	27.4	[12.5, 18.6]

Note. n= 312. CI=confidence interval, DD= Data days, Med= Median, Min= Minimum, 02 Sat= Oxygen saturation, SD= standard deviation, WT=Weight.

The mean number of data points transferred by each parent of symptom home monitoring data was 793.45± 855.7 data points. The lowest rate of implementation adherence by percentage was found to be implementation- videos (Vid) on non-hospitalized interstage days at 52.86± 47.3%. Implementation-weight (WT) was found to be 64.81± 42.0% adherence. Implementation- data days (DD) was found to be 75.54± 30.22% with a wide range of 1.68-100% but a 95% confidence interval of 72.21 and 79.0. The highest rate of adherence was found for the implementation-oxygen saturation/heart rate (02HR) at 103%-114.44%.

Measurement Model

To answer Research question two, findings for each of the patient-related, family-related, and healthcare system-related determinants were reported in Table 4.4. The KMO output was below .5 for healthcare system-related determinants, as seen in Table 4.4, but the ratio of cases to variables is more than 1:5 so all variables were retained in that domain (Williams et al., 2010). Variables that loaded at a value less than .4 were gender (G), cardiac diagnosis (C), major non-cardiac anomalies (MA), atrioventricular valve regurgitation (AVR), age at neonatal discharge (AD), and interstage days (I) in the patient-related variables. All other variables loaded above the goal of .4 so were retained. Community-related variable of distance was evaluated with family-related determinants and loaded appropriately above .4 within family-related determinants.

Table 4.4

Principal Component Analysis

	KMO	Bartlett's Test of Sphericity			Extraction
		Chi-Square	*df*	Sig	
Gender (G)	.602	276.97	66	p<.0001	.356
Cardiac Diagnosis (C)					.383
Secondary Cardiac diagnosis (SC)					.458
Cardiac surgery (CS)					.687
Major genetic syndromes (MS)					.534
Multiple non-cardiac anomalies (MA)					.392
Prenatal diagnosis (P)					.647
Medications (Meds)					.693
Ventricular dysfunction (VD)					.527
Age at discharge (AD)					.391
Atrioventricular valve regurgitation (AVR)					.360
Interstage days (I)					.396
Community distance (CD)	.533	668.40	21	p<0.0001	.551
Total family members (FM)					.899
Children in home (YF)					.925
Age of caregiver (Age)					.713
Education level of caregiver (ED)					.683
Payer type (PT)					.614
Language (LA)					.548
Clinic visits (CL)	.202	2006.6	28	p<0.0001	.429
mHealth application initiated communications (APP)					.868
Family initiated Communications (FA)					.709
Healthcare team initiated communications (HCT)					.556
Initial contact cardiology attending (MD)					.724
Initial contact cardiology fellow (FL)					.853
Initial contact APN (APN)					.847
Initial contact RN (RN)					.760

Table continues

	KMO	Bartlett's Test of Sphericity			Extraction
		Chi-Square	*df*	Sig	
Implementation oxygen saturation/heart rate (02HR)	.773	773.76	15	p<.0001	.543
Implementation weight (WT)					.780
Implementation data days (DD)					.796
Implementation videos (Vid)					.548
Initiation (IN)					.140
Discontinuation (DC)					.309

Note. Cut-off for extraction was $\leq .4$ for factor analysis. Bartlett's Test of Sphericity was found to be significant at $p < .05$. All initial communalities were 1.000. Abbreviations include *df*= Degrees of Freedom, KMO= Kaiser-Meyer-Olkin Measure of Sampling Adequacy, Sig= Significance.

Outcome measurement model. A measurement component analysis of the reflective portion of the model with the latent variable of parental mHealth adherence was completed. Covariances and correlations were evaluated between initiation (IN), implementation- weight (WT), implementation- oxygen saturation/heart rate (02HR), implementation- data days (DD), implementation-video (Vid), and discontinuation (DC). All factors were significant p>.01 except the relationship between initiation (IN) and discontinuation (p= .338) as seen in Table 4.5. There was one very large correlation with implementation- data days (DD) and implementation- weight (WT) of .736 (p<.001). There were four positive correlations and one negative large correlation above .5 and one medium correlation above .3 (Cohen, 1988).

Table 4.5

Outcome Variables, Variances, Correlations, and Covariances Matrix

Outcome Variables Correlations[b] and Covariances[a]								
	σ^2	SE	IN	DD	WT	Vid	02HR	DC
IN	126.82	10.17		-.75.3	-129.4	-114.6	-168.1	16.8
DD	910.44	73.01	-.222‡		881.3	642.8	1677.3	-465.3
WT	8375.24	671.63	-.289‡	.736‡		959.3	2243.0	-396.0
Vid	1598.18	128.16	-.255‡	.533‡	.604‡		1544.6	-297.4
02HR	8375.23	671.63	-.163†	.607‡	.617‡	.422‡		-445.0
DC	749.45	60.10	.054	-.563‡	-.364‡	-.272‡	-.178†	

Note. All variances were significant at the p<.001 level. Covariance estimates were indicated as significant at the ‡$p \leq .001$ level †$p \leq .01$. *$p \leq .05$. σ^2 =variance. All variances were significant at p<.001. DC= Discontinuation, DD= Data days, IN= Initiation, 02HR= Oxygen saturation/heart rate, Vid= Video
a. Covariances are located in the upper echelon.
b. Correlations are located in the lower echelon.

Principal component analysis (PCA) factor loadings were completed using SPSS to evaluate major factor loading of reflective variables of parental mHealth adherence. Factors that loaded at a value less than .4 were initiation (IN) and discontinuation (DC) of adherence, as seen in Table 4.4. Due to a concern of extreme collinearity, the observed variables of implementation- heart rate (HR) and implementation- oxygen saturation (02) adherence were combined into a new variable implementation- oxygen saturation/heart rate (02HR). The mHealth application requires entry of oxygen saturation with heart rate data transfer and vice versa by parents so the combination and findings of extreme collinearity were justified. All other variables were found to load above the goal of .4 without concerns of extreme collinearity.

This theoretically identified recursive model was run with the four observed reflective indicator variables for the latent variable of parental mHealth adherence and was found to have a good fit with p=.124, chi-square=4.175, *df*=2, CFI=.996, RMSEA=.059 [0.00, .140] (Hu & Bentler, 1999). There were no standardized regression weights over two, and no modification indices suggested. These findings indicate good local and global fit (Kline, 2016). Implementation- weight (WT) had the highest variance at 79.5%, then implementation- data days (DD) at 69.0%, followed by implementation- oxygen saturation and heart rate (02HR) at 48.9%, and implementation- video (Vid) at 43.1% as seen in Figure 4.1.

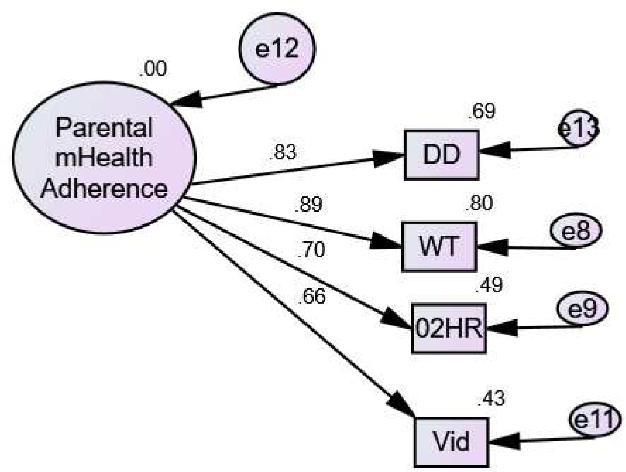

Figure 4.1. Parental mHealth adherence outcome model for infants with single ventricle interstage congenital heart disease.

Specification

The DOMAIN study is an application of data from a multi-site registry to an exploratory structural equation model of the pediatric self-management conceptual framework. To reach the final model in Figure 4.3, a measurement model, structural exploratory model, model trimming and building, and re-specification were completed.

Measurement model. The parental mHealth adherence outcome portion of the model from Figure 3.1 was used for a measurement component analysis of the reflective latent outcome variable. The measurement model is a theoretically identified model with more than two indicators for the latent factor, and the factors were set to scale with a recursive adherence model (Kline, 2016). Additionally, supporting theoretical identifiability was the finding of degrees of freedom greater than zero and no correlated errors or cross-loadings (Kline, 2016). The measurement model evaluated the four observed reflective indicator variables of adherence for the latent variable of parental mHealth adherence and was found to have good local and global fit (Kline, 2016).

Implementation- data days (DD) was a fixed parameter at one due to the known rates of data days percentage in other studies in the single ventricle interstage period and to fulfil the requirements of one variable in a latent model needing to be set at a fixed level. Implementation- weight (WT) had the highest explained variance at 79.5%, then implantation- data days (DD) at 69.0%, followed by implementation- oxygen saturation/heart rate (02HR) at 48.9%, and the lowest of implementation- video (Vid) at 43.1% with all variances being a medium or large effect size (Cheung, 2018). The previously completed principal component analysis and the measurement component analysis for the outcome latent variable provided support for the continuation of the measurement model onto a structural exploratory model.

Structural Exploratory Model

A full exploratory analysis of the 27 possible variables with correlations on parental mHealth adherence without prespecified covariances or latent variables was completed. This model resulted in a chi-square= 3509.5, *df*=434, probability level p<0.001, SRMR=.1331, CFI=.172, RMSEA=.151 [.146, .156], and multiple modification indices. Although this model was overall ill-fitting from the manifested variables as demonstrated from the outputs above, the squared multiple correlations was a medium effect variance of 45.6% for an explanation of overall parental mHealth adherence (Cheung, 2018). Reflective indicators of parental mHealth adherence continued to have high variance for implementation- weight (WT) at 80.1%, then implementation- data days (DD) at 74.1%, followed by implementation- oxygen saturation and heart rate (02HR) at 55.7%, and implementation- video (Vid) at 49.8%.

Next, the hypothesized model with four latent variables was attempted to be analyzed but was met with identification issues. Despite attempts at correlating the disturbances of patient-related, family-related, healthcare system-related, and community-related factors with themselves, no admissible solution was found. The hypothesized model was acting as a multiple indicator-multiple causes (MIMIC) model, and the lack of parsimony in the formative models was likely leading to the analysis difficulties (Lee, Cadogan, & Chamberlain, 2013). The original hypothesized model with multiple latent variables was then rejected. The final retained model was a structural exploratory model with one latent outcome variable of parental mHealth adherence with the previous three latent variables trimmed (see Figure 4.3). The original covariances for patient-related, family-related, and healthcare system-related in the hypothesized model were retained for analysis after the model trimming of the formative latent variables.

Modification Indices

After preliminary evaluation of the structural model (see Figure 4.2), additional modification indices greater than four were evaluated which included covariances and direct regression weights. Theoretically sensible covariances were added, which included clinic visits (CL) and route of and red flag communication through the healthcare team (HCT) with community distance (CD); primary caregiver age (Age) with major syndromes (MS); prenatal detection (P) with insurance payer type (PT); and secondary cardiac diagnoses (SC)with clinic visits (CL) for model building. Additional added covariances included single ventricular dysfunction (VD), with the route of red flag communication through the mHealth application (APP), route of red flag communication through the healthcare team (HCT), route of red flag communication through the parent (FA), initial contact with fellows (FL), initial contact with advanced practice nurses (APN), and initial contact with nurses (RN). The final added covariances included medications (Meds) with the route of red flag communication through the mHealth application (APP), initial contact with fellows (FL), and initial contact with advanced practice nurses (APN).

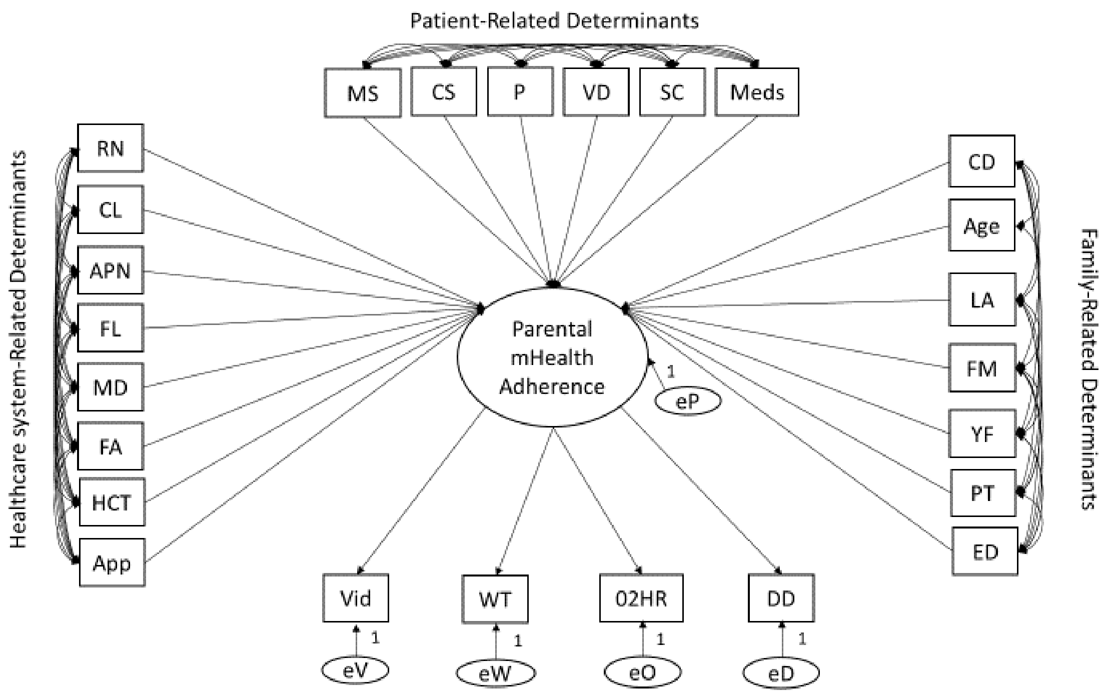

Figure 4.2. Structural exploratory model for parental mHealth adherence for infants with single ventricle interstage congenital heart disease.

Direct regression weights with modification indices greater than four were placed with model building between implementation- oxygen saturation/heart rate (O2HR) from parental education level (ED), route of red flag communication through the parents (FA), clinic visits (CL), initial contact with attending cardiologist (MD), and insurance (PT). Implementation- weight (WT) had direct regression weights added from major syndromes (MS), route of red flag communication through the mHealth application (APP), route of red flag communication through the healthcare team (HCT), route of red flag communication through the parents (FA), initial contact with advance practice nurses (APN), and initial contact with nurses (RN). Additionally, regression weights modification indices were added via direct effect from clinic visits (CL), secondary cardiac diagnosis (SC), and major genetic syndromes (MS) to implementation- data days (DD). Major syndromes (MS), route of red flag communication through the healthcare team (HCT), route of red flag communication through the parents (FA), and initial contact with fellows (FL) to implementation- video (Vid).

Correlation Matrixes

A correlation matrix with associated variances and covariances were presented for all patient-related, family-related, and healthcare system-related determinants in Tables 4.6-4.8 with areas of significance at the 0.01, 0.05, and <0.001 probability levels. Tables 4.6-4.8 provides the variances, standard errors, covariance matrix with significance testing, and correlation matrix for the retained bootstrapped categorical and continuous exogenous variables in a sufficient summary of statistics for readers to complete secondary analysis as recommended for structural equation modeling reporting standards (Appelbaum et al., 2018). There were no findings of extreme collinearity between the 21 retained variables. Fifty-two significant coefficient pairs from the matrix were found using cut-off values for correlations of small (.1), medium (.3), and large (.5) from Cohen (1988) and additionally very large (.7) from Rosenthal (1996).

All variances were significant at the $p<.001$ level. Patient-related correlations and covariances are presented in Table 4.6. There was one medium effect found between medications (Meds) and the cardiac surgery type (CS) (.420, $p \leq .001$) and four small effect correlations for patient-related variable pairs between .1 and .299. All significant patient-related covariances were relationships that were accounted for in the final retained model.

Table 4.6

Variables, Variances, Correlation [and] Covariances [b] Matrix

Patient-related Correlations and Covariances								
	σ^2	SE	Meds	VD	SC	CS	P	MS
1	4.84	.388		.085	.06	-.42	.136	.050
2	.106	.008	.061		.20	-.17	-.07	-.03
3	11.52	.924	-.388	-.054	.001	.14	-.008	.04
4	9.76	.783	-.178	-.082	-.13	.09	-.001	-.03
5	32.94	2.64	-1.12	-.001	.02	.071	-.06	.13
6	14.17	1.14	.273	-.022	-.03	-.10	.05	-.04
7	.193	.015	.096	-.004	-.04	-.07	.04	-.07
8	12.56	1.01	-.358	-.033	.05	.023	-.02	.09
9	2.69	.216	-.272	-.020	.01	.10	.028	.08
10	42.77	3.43	-.322	-.054	-.04	.04	-.02	.03
11	2.30	.184	-.192	-.013	-.02	.01	-.11	-.005
12	36.08	2.89	.534	-.093	-.02	.01	-.01	.13
13	1.844	.148	-.115	-.016	.03	.03	-.10	.01
14	5.16	.413	.169	-.012	-.01	-.03	.06	-.03
15	.313	.025	-.067	-.016	.005	.09	-.004	-.008
16	.435	.035	.032	-.020	-.10	.03	.12	-.03
17	19.77	1.59	.601	.288‡		-.02	-.02	.031
18	4.38	.351	-1.92‡	-.117†	-.15		-.003	.24
19	.143	.011	.113*	-.009	-.03	-.002		.05
20	2.00	.161	-.270	.005	-.27	.25	-.01	.05
21	7.03	.564	.297	-.028	.365	1.35‡	.05	

Note. All variances were significant at the p<.001 level. Covariance estimates were indicated as significant at the ‡p≤.001 level † $p \leq .01$. *$p \leq .05$. σ^2 =variance. Variable labels for this table include 1 = Secondary cardiac diagnosis (SC). 2 = Gender (G). 3 = Cardiac Surgery (CS). 4= Ventricular dysfunction (VD). 5 =Atrioventricular valve regurgitation (AVR). 6 = Age at Discharge (AD). 7 = Medications (Meds). 8 = Initial contact RN (RN). 9= Clinic visits (CL). 10= Initial Contact APN (APN). 11= Initial contact Fellow (FL). 12= Initial contact MD. 13= Communications Parent (FA). 14= Communications Healthcare team (HCT). 15= Communications Application (APP). 16= Family members in the home (FM). 17= Primary caregiver age (Age). 18= Children in the home (YF). 19= Insurance (PT). 20= Education level of caregiver (ED). 21= Language in the home (LA). 22= Prenatal detection (P). 23= Community distance from hospital (CD). 24= Major syndromes (MS). 25= Major non-cardiac anomalies (MA).

a. Correlations are located in the upper echelon.

b. Covariances are located in the lower echelon.

Family-related correlations and covariances are presented in Table 4.7. The number of family members (FM) in the home and children in the home (YF) were found to have a very large correlation (.872, $p \leq .001$), which had concerning findings for discriminant validity between the two variables (Kline, 2016; Rosenthal, 1996). Three correlations were found with medium effect sizes and included primary caregiver age (Age) and the number of children in the home (YF) (.300, $p \leq .001$), primary caregiver age (Age) and primary caregiver education level (ED) (.364, $p \leq .001$), and payer type (PT) and primary caregiver education level (ED) (.368, $p \leq .001$). The ten other significant family-related variable correlations were found to have a small effect size. All family-related covariances were accounted for with relationships between variables in the final retained model.

Table 4.7

Variables, Correlation and Covariances b Matrix for Family-related Determinants

Family-Related Correlations and Covariances							
	FM	Age	YF	ED	LA	PT	CD
1	-.06	.040	-.038	.034	-.054	.022	-.08
2	-.03	-.048	-.035	-.017	-.047	-.09	.01
3	.07	.058	.061	.016	-.019	-.03	-.05
4	.06	.091	.010	.011	.007	.06	-.16
5	.05	.119	.044	.084	-.045	-.09	.00
6	.11	.054	.128	.024	-.024	.003	.024
7	.06	-.045	-.007	-.138	-.027	.053	.10
8	.02	-.003	.001	-.039	-.039	-.11	-.006
9	.03	.065	.013	-.027	-.060	-.01	.14
10	.15	.158	.149	.114	-.028	-.02	-.03
11		.183	.872	-.171	.085	-.18	-.006
12	1.66†		.300	.364	.151	.187	-.12
13	1.79‡	2.42‡		-.094	.027	-.16	.003
14	-.587†	4.96‡	-.289		-.042	.368	-.06
15	.072	.507†	.021	-.054		-.12	-.07
16	-.179†	.739‡	-.139†	.552‡	-.043*		.08
17	-.111	-.460	.172	-.097	.012	-.30	-.04
18	.021	.150	.080	-.150	.105	.05	.083
19	-.060	-.030	-.052	.047	-.001	.03*	-.03
20	-.013	-1.06*	.006	-.190	-.053	.073	
21	-.021	2.05*	.046	-.169	-.012	-.05	.17

Note. Covariance estimates were indicated as significant at the ‡$p \leq .001$ level † $p \leq .01$. *$p \leq .05$. Variable labels for this table include 1 = Medications (Meds). 2 = Ventricular dysfunction (VD). 3= Initial contact RN (RN). 4= Clinic visits (CL). 5= Initial Contact APN (APN). 6= Initial contact Fellow (FL). 7= Initial contact Attending (MD). 8 = Communications Parent (FA). 9= Communications Healthcare team (HCT). 10= Communications mHealth Application (APP). 11= Family members in the home (FM). 12= Primary caregiver age (Age). 13= Children in the home (YF). 14= Education level of caregiver (ED). 15= Language in the home (LA). 16= Insurance (PT). 17= Secondary cardiac diagnosis (SC). 18= Cardiac Surgery (CS). 19= Prenatal detection (P). 20= Community distance from hospital (CD). 21= Major syndromes (MS).
a. Correlations are located in the upper echelon.
b. Covariances are located in the lower echelon.

The healthcare system-related variable correlation and covariance matrix is presented in Table 4.8. Two correlations were found to have a very large effect size and included the variables of initial contact with nurse (RN) and route of red flag communication through mHealth application (APP) (.718, $p \leq .001$) and initial contact with advanced practice nurse (APN) and route of red flag communication through parent (FA) (.738, $p \leq .001$). The relationship between the variables of route of red flag communication through parents (FA) and initial communication with advanced practice nurses (APN) and with the initial communications with nurses (APN) support the description as CHAMP as a registered nurse coordinator led mHealth program. Four additional significant variable pair were found to have large effect sizes. These four pairs included initial contact with nurse (RN) and initial contact with advanced practice nurse (APN) (.578, $p \leq .001$), initial contact with nurse (RN) and route of red flag communication with parent (FA) (.648, $p \leq .001$), initial contact with advanced practice nurse (APN) and route of red flag communication through mHealth application (APP) (.619, $p \leq .001$), and the last pair of initial contact with fellow (FL) and route of red flag communication with mHealth application (APP) (.571, $p \leq .001$). Unfortunately, the CHAMP de-identified dataset did not report what time of day the red flag communications occurred through the mHealth application, but with the correlations occurring with the advanced practice nurses and fellows, this finding is likely due to the after-hours call systems in which advanced practice nurses and fellows answer communications overnight from families. This positive association with mHealth application and communications with the healthcare team could potentially be from use of the mHealth application, in a feedback loop format. Primary caregivers may have an increased perceived importance of adherence after using the mHealth application and having communication with their interstage healthcare team provider, promoting then increased use of symptom home monitoring.

Five pairs of healthcare system-related variables had significant correlations with medium effect sizes. The five pairs included the initial contact with a nurse (RN) and clinic visits (CL) (.30, $p \leq .001$); route of red flag communications through parents (FA) with both the route of red flag communications through the healthcare team (HCT) (.397, $p \leq .001$) and the route of red flag communications through the mHealth application (APP) (.415, $p \leq .001$); and route of red flag communications through the healthcare team (HCT) with both initial contact with nurses (RN) (.450, $p \leq .001$) and with initial contact with an advanced practice nurse (APN) (.495, $p \leq .001$). These correlations would follow the finding that front-line registered nurse coordinators monitor and triage data that has been transferred from the mHealth application and parent calls to advance the concerns to the advanced practice nurse on the healthcare team. The subsequent exogenous variable pairs were found to have a small effect size between 0.1 and 0.29, as noted in Table 4.8 (Cohen, 1988).

There were eleven other significant correlations found between the healthcare system-related, family-related, or patient-related variables in the covariance matrix. All retained variables were evaluated for significant covariance relationships. The patient-related variable of secondary cardiac diagnosis (SC) and was covaried with clinic visits (CL) and retained in the final model. Family-related variables of community distance (CD with cardiac surgery (CS) and route of red flag initiation through the health care team (HCT) were covaried in the final retained model. There were eight additional significant correlations that were found in the covariance matrix but did not occur in the final retained model.

Table 4.8

Variables, Correlation [a] and Covariances [b] Matrix for Healthcare System-related Determinants

Healthcare System-Related Correlations and Covariances								
	RN	CL	APN	FL	MD	FA	HCT	APP
1	-.052	-.026	-.088	.033	.099	-.046	-.075	-.022
2	-.049	-.081	.000	-.018	-.030	-.029	-.037	-.025
3		.299	.578	.236	.099	.648	.450	.718
4	3.17‡		.156	.172	.143	.214	.205	.237
5	11.26‡	2.80†		-.069	.001	.738	.495	.619
6	3.02‡	2.02†	-1.49		.086	.126	.019	.571
7	.147	.197*	.004	.142		.064	.116	.108
8	7.80‡	2.37‡	15.0‡	1.68*	.099		.397	.415
9	2.51‡	1.05‡	4.66‡	.117	.084*	2.31‡		.219
10	15.95‡	4.84‡	23.2‡	14.07‡	.311	9.61‡	2.35‡	
11	.370	.267	.466	.631	.040	.104	.074	1.44*
12	1.19	1.70	4.11*	1.22	-.120	-.057	.645	6.2†
13	.282	.042	.344	.654*	-.004	.007	.030	1.32†
14	.126	.075	1.09	.208	-.137*	-.316	-.101	1.69*
15	-.036	.013	-.146	-.050	-.007	-.077	-.055	-.102
16	-.069	.124	-.330	.008	.015	-.256	-.014	-.081
17	.009	-1.78*	.496	-.530	-.074	.822	.077	-1.04
18	1.022*	.590	.857	-.759	-.064	.173	.351	.534
19	-.010	-.001	-.121	.071	.006	-.021	.017	-.038
20	-.254	-.69†	-.001	.129	.062	-.028	.316*	-.291
21	.317	-.280	1.94*	-.432	-.081	.827	.341	.582

Note. Covariance estimates were indicated as significant at the ‡$p \leq .001$ level † $p \leq .01$. *$p \leq .05$. Variable labels for this table include 1 = Medications (Meds). 2 = Ventricular dysfunction (VD). 3= Initial contact RN (RN). 4= Clinic visits (CL). 5= Initial Contact APN (APN). 6= Initial contact Fellow (FL). 7= Initial contact Attending (MD). 8 = Communications Parent (FA). 9= Communications Healthcare team (HCT). 10= Communications mHealth Application (APP). 11= Family members in the home (FM). 12= Primary caregiver age (Age). 13= Children in the home (YF). 14= Education level of caregiver (ED). 15= Language in the home (LA). 16= Insurance (PT). 17= Secondary cardiac diagnosis (SC). 18= Cardiac Surgery (CS). 19= Prenatal detection (P). 20= Community distance from hospital (CD). 21= Major syndromes (MS).
a. Correlations are located in the upper echelon.
b. Covariances are located in the lower echelon.

Model Assessment

Maximum likelihood (ML) estimation procedure was used for this analysis in AMOS (IBM Corporation, 2017). The final model with 143 distinct parameters (see Figure 4.3) was found to have a chi-square χ^2 = 200.25, degrees of freedom (*df*) =182, and p=.168. The p value was a non-significant result so the model assessment would retain the null hypothesis. The chi-square fit index can assess the magnitude of discrepancy between the sample and the fitted covariance matrices (Awang, Wan Afthanorhan, & Asri, 2015). The model's fit indices include a CFI=.995, RMSEA= .018 [0.00, 0.032], and SRMR=.0430. CFI compares the sample covariance matrix and the null model with the assumption of uncorrelated variables (Awang et al., 2015). RMSEA is the root mean square estimation area, which is sensitive to the number of estimated model parameters and prefers a parsimonious model (Awang et al., 2015). Overall there is good global and local fit with low SRMR, high CFI, and the overall, low, and high 95% CI of RMSEA in range (Hu & Bentler, 1999).

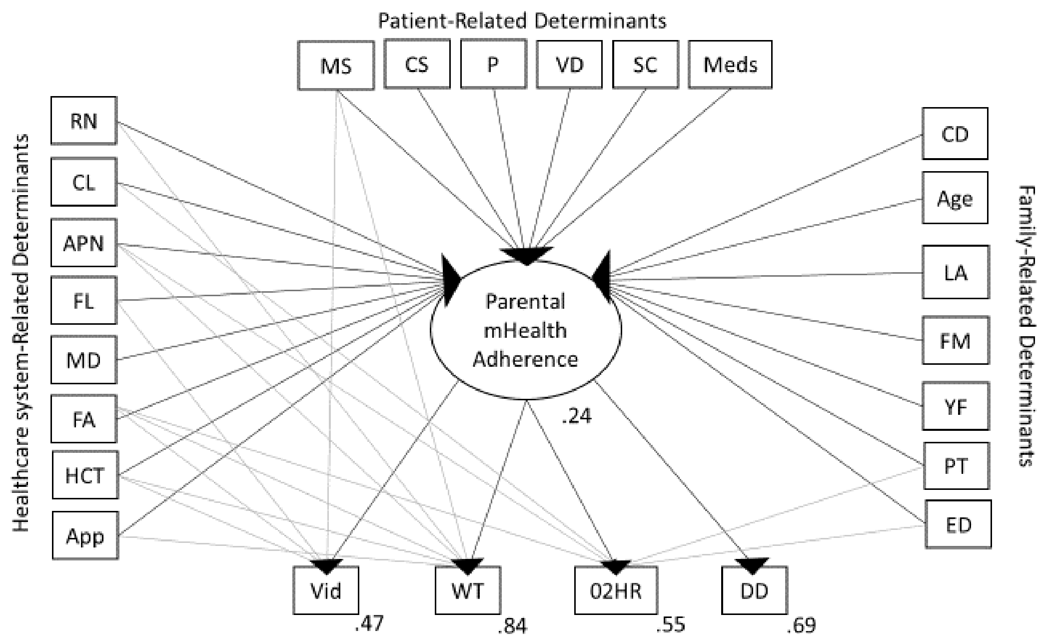

Figure 4.3. Final model for parental mHealth adherence for infants with single ventricle interstage congenital heart disease.

Note. Variances are labeled to the right lower corner of outcome variables. Added 15 direct weight regression modification indices are in grey. All outcome variables errors and covariances were removed for ease of review of structural equation model.

Due to the categorical variables of prenatal detection (P), ventricular dysfunction (VD), and insurance (PT) with four or fewer levels, bootstrapping maximum likelihood (ML) and bootstrapping Bollen-stine bootstrap were completed for this analysis. Bootstrapping provides a nonparametric estimate of effects through a reference distribution with result confidence intervals at 95% and a statistical significance test. Using AMOS, 1000 bootstrap resamples were conducted for the model analysis (Kline, 2016). This analysis helped to test the null hypothesis and the interval validity of the sample ($p=.513$). Additionally, the Bollen-stine bootstrap of 1000 bootstrap distributions, was found to have a mean of 246.49 and a standard error of 3.044. The ML bootstrapped sample variance (R^2) was found to be .243 [0,

.279], p= .267. This bootstrapped variance finding was the same as the observed data overall variance at .243 for parental mHealth adherence supporting the categorical variables effectiveness in the model.

Standardized Residual Covariances

There were nine standardized residual covariances |2| indicating some issues with the local fit of data (Kline, 2016). The nine covariances were added to evaluate improved fit, but there were continued standardized residual covariances |2| so the covariances were removed in the final retained model.

Parameter Estimates

Table 4.9 denotes standardized and unstandardized parameter estimates with path coefficients, variances, correlation of determination (R^2), standard errors (SE), and *p*- values. All variances were significant for $p \leq .001$. The four variables that reflected parental mHealth adherence implementation were all significant with large effect sizes in the model analysis (Cheung, 2018). These findings are similar to the factor loading that was completed prior to the addition of the exogenous variables into the full model. Implementation- data days (DD) was set as a parameter of one for comparison of the other three variables in the model and was found to have a very large effect size of .829. Observed variables of implementation- video (Vid), implementation- weight (WT), and implementation- oxygen saturation/heart rate (02HR) all had a significant direct correlation on the formed variable of parental mHealth adherence. In the latent variable model, these findings would reliability translate a correlation between the observed variables and the newly formed latent variable of parental mHealth adherence (Kline, 2016).

Four positive direct correlations were found between exogenous determinants and endogenous outcome variables, all with small effect sizes. Age of the primary caregiver (Age) (.24, $p < .001$) had a direct positive correlation with parental mHealth adherence. Payer type (PT) also had a direct positive correlation with parental mHealth adherence (.167, p=.009). Implementation- oxygen saturation/heart rate (O2HR) adherence had a direct positive correlation from education level of caregivers (ED) (.146, p=.001). The number of healthcare team initiated communications (HCT) had a significant direct positive correlation with implementation- video (Vid) adherence (.101, p=.047).

Four direct negative correlations were found with three indictors of adherence and all with a small effect size. The number of clinic visits (CL) was found to have a negative correlation on implementation-oxygen saturation/heart rate (02HR) with a small effect (-.167, $p \leq .001$). Additionally, payer type (PT) also had a direct negative correlation with implementation-oxygen saturation/heart rate (02HR) (-.115, p=.012). There was a direct negative correlation on implementation- video (Vid) with the major genetic syndromes (MS) a small effect (-.108, p=.004). Finally, a direct negative correlation was found between implementation- weight (WT) with the major genetic syndromes (MS) with a small effect (-.110, p=.004).

Table 4.9

Parameter Estimates of the Final Model

Direct path coefficients			Direct path (Continued)		
Path	Unstand. (*SE*)	Stand	Path	Unstand.(*SE*)	Stand
ADH ← CL	-794 (.473)	-.100	02HR← PT	-.133 (.053)*	-.115
ADH ←APN	-.543 (2.09)	-.124	02HR← ED	5.83 (1.83)‡	.146
ADH ← FL	-1.03 (2.02)	-.155	02HR← ADH	2.41 (.192)‡	.665
ADH ← MD	-.905 (3.74)	-.016	02HR← FA	-.323 (1.74)	-.013
ADH ← FA	1.75 (2.24)	.247	02HR← CL	-4.83 (1.22)‡	-.167
ADH ← HCT	1.80 (2.34)	.116	02HR← APN	1.89 (1.07)	.120
ADH ← APP	1.66 (2.00)	.434	Variances		
ADH ← PT	.053 (.020)†	.167	Variable	Unstand.(*SE*)	
ADH ← YF	-1.71 (2.16)	-.093	Meds	4.816(.385)‡	
ADH ← FM	.472 (1.88)	.029	VD	1736.5(139)‡	
ADH ← LA	-1.79 (2.51)	-.040	RN	11.51(.923)‡	
ADH ← ED	.981 (.714)	.089	CL	9.837(.791)‡	
ADH ← SC	.039 (.714)	.107	APN	32.89(2.64)‡	
ADH ← CS	-.004 (.018)	-.013	FL	14.17(1.14)‡	
ADH ← P	.006 (.023)	.014	MD	.193(.015)‡	
ADH ← VD	.033 (.033)	.055	FA	12.55(1.01)‡	
ADH ← MS	.008 (.026)	.019	HCT	2.66(.212)‡	
ADH ← Meds	-1.06 (.692)	-.092	APP	42.82(3.43)‡	
ADH ←CD	.032 (.017)	.109	FM	2.30(.184)‡	
ADH ← Age	1.04 (.281)‡	.249	ED	5.16(.413)‡	
ADH ←RN	-2.43 (2.21)	-.329	YF	1.84(.148)‡	
DD← ADH	1.00	.829	Age	36.25(2.90) ‡	
Video← ADH	1.05 (.084)‡	.655	LA	.313(.025)‡	
Video← MS	-.072 (.031)*	-.108	CS	7741.5(621)‡	
Video← HCT	2.47 (1.24)*	.101	SC	4668(373)‡	
Video← FL	.806 (.498)	.076	P	3482.5(279)‡	
Video← FA	.080 (.598)	.007	MS	3621(289)‡	
Weight← ADH	1.48 (.088)‡	.931	PT	6175(491)‡	
Weight← FA	-1.24 (.799)	-.111	CD	7370(587) ‡	

Table continues

Direct path coefficients				Direct path (Continued)		
Weight← APN	-.157 (.530)	-.023		Variable	Unstand (SE)	R^2
Weight← HCT	-1.47 (1.16)	-.060		eADH	474.8 (57.1)‡	.243
Weight← APP	-.559 (.414)	-.092		eO2HR	3713(338.8)‡	.550
Weight← RN	.917 (.820)	.078		eWT	259.5(53.5)‡	.836
Weight← MS	-.073 (.025)†	-.110		eDD	284.4(33.0)‡	.688
				eVid	852.5(75.0)‡	.466

Note. n = 312. Significance levels were indicated by ‡$p \leq .001$ level † $p \leq .01$. *$p \leq .05$. Variable labels for this table include AD= Age at discharge. ADH= Adherence. Age = Primary caregiver age. APN= Initial Contact APN. APP= mHealth application communications. AVR= Atrioventricular valve regurgitation. CD= Community distance from hospital. CL= Clinic visits. CS= Cardiac Surgery. DD= Data days. ED= Education level of caregiver. FA= Parent communications. FL= Initial contact Fellow. FM= Family members in the home. G= Gender. HCT= Healthcare team communications. LA= Language in the home. MA= Major non-cardiac anomalies. MD= Initial contact MD. Meds= Medications. MS= Major syndromes. O2HR= Oxygen saturation and heart rate. P= Prenatal detection. PT= Insurance. RN= Initial contact RN. SC= Secondary cardiac diagnosis. VD= Ventricular dysfunction. YF= Children in the home.

Model Variances

The overall model correlation of determination (R^2) for parental mHealth adherence was R^2=.243. This would mean that with controlling through the decomposition of other variables, there is a 24.3% explanation of variability of the data around the mean with a small effect size (Rutledge & Loh, 2004). Effect size for the correlation of determination that is used in similar behavioral research is used as the small effect of .10-.29, medium effect .3 to .49, and large .5 or above (Rutledge & Loh, 2004). Figure 4.3 denotes the correlation of determination (R^2) for implementation- video (Vid) adherence, which was found to be .466 or 46.6% explained variance which is a medium effect size. Finally, large effect sizes were found with implementation oxygen saturation/heart rate (O2HR) adherence at .550 or 55.0% explained variance, implementation- weight (WT) adherence at .836 or 83.6% explained variance, and implementation- data days (DD) adherence at .688 or 68.8% explained variance (Rutledge & Loh, 2004).

Model Comparison

An alternative model was evaluated with the same structural portion of the model but with an alternative path for measurement with the addition of all theoretically reasonable modification indices added from the exploratory model. Multiple modification indices with values over four were presented in the output for the exploratory model. Recommended modification indices that had a theoretical basis were added to the exploratory model. All 27 variables along with planned patient-related, family-related, and healthcare-team related covariances.

Covariances were added between interstage days (I) with all other patient-related and healthcare system-related variables. Additional covariances were added due to modification indices from patient-related variables that included major syndromes (MS) with primary caregiver age (Age) and initial contact with an advanced practice nurse (APN); cardiac diagnosis (C) with family members in the home (FM), children in the home (YF), initial contact with an advanced practice nurse (APN), and route of red flag communication by the healthcare team (HCT); atrioventricular valve regurgitation (AVR) with caregiver education level (ED); prenatal detection (P) with insurance (I); cardiac surgery (CS) with initial contact with a nurse (RN); major anomalies (MA) with initial contact with a fellow (FL).

Additional family-related covariances were added between primary caregiver age with initial contact with an advanced practice nurse (APN), route of red flag communication by the mHealth application (APP), and community- distance from site (CD); education level of the caregiver (ED) with initial contact with attending physician (MD) and route of red flag communication by the mHealth application (APP); the number of family members in the home (FM) with children in the home (YF) and route of red flag communication by the mHealth application (APP); and the number of children in the home (YF) with initial contact with the cardiology fellow (FL) and route of red flag communication by the mHealth application (APP).

Healthcare system-related variables included modification indices with clinic visits (CL) with secondary cardiac diagnosis (SC) and community-distance from surgery site (CD); initial contact a nurse (RN) with medications (Meds) and major non-cardiac anomalies (MA); route of red flag communication by the healthcare team (HCT) with medications (Meds) and community- distance from site (CD); initial contact with an advanced practice nurse (APN) with medications (Meds) and major non-cardiac anomalies (MA); initial contact with a fellow (FL) with medications (Meds); and route of red flag communication by the mHealth application (APP) with medications (Meds).

The alternative model did not reveal any new significant direct effects and an overall model variance of 0.359. The global fit was weaker in this alternative model with a larger chi-square, significant p value, lower CFI, and higher RMSEA (X^2= 1241.74, d*f* =330, $p<0.001$; CFI=.755; RMSEA = .094 [.089, .100]). This would indicate in the chi-square test to reject the null hypothesis. RMSEA is not adequate in this local fit of data. The standardized residual covariances had nine covariances greater than or equal to two, indicating areas where the relationships between variables need further explored. Based on these findings, the exploratory model in Figure 4.3 with hypothesized patient-related, family-related, and healthcare system-related factors would be retained as the model with a stronger theoretical and overall fit.

Summary

Chapter 4 presented the results of the DOMAIN study. The results presented the rate and relationships between patient-related, family-related, community-related, and healthcare system-related determinants of parental mHealth symptom home monitoring adherence of infants with congenital heart disease during the single ventricle interstage period. Prior to confirmation of the final retained model, a structural exploratory model was completed. An exploratory analysis without pre-specified covariances within or between the patient-related, family-related, or healthcare system-related determinants or any latent variable errors was completed to evaluate associations of parental mHealth adherence. The alternative exploratory model with no prespecified covariances for patient-related, healthcare system-related, or family-related determinants had poor global and local fit. This finding supported the process of model building through the addition of the latent variables and determinant related covariances. Once the four latent variables were added, the model became non-parsimonious, and structural equation modeling identification issues related to the multiple indicators-multiple causes (MIMIC) model were found. Other researchers in computer modeling of MIMIC modeling have found that empirical testing is difficult with models that have both formative and reflective indicators (Lee et al., 2013). The rate of parental mHealth adherence-data days (DD) was 75.54%. The final accepted model variance was 24.0%, with good local and global fit for the model. Higher parental age (.249, $p \leq .001$) and Medicaid insurance (.167, $p = .009$) were positively associated with parental mHealth adherence through direct weight regression. Higher rates of implementation of oxygen saturation/heart rate (02HR) symptom home monitoring was associated with lower clinic visits (-.167, $p \leq .001$ and increased parental education levels (.146, $p = .001$). Adherence to mHealth video use was associated with increased healthcare team driven communications (.101, p=.047). Chapter 5 will include the discussion of the study results of the research questions of the DOMAIN study.

CHAPTER 5
DISCUSSION

Chapter 5 will present the discussion of a descriptive, correlational research study completed using structural equation modeling. The purpose of the DOMAIN study was to understand the rate of parental mHealth symptom home monitoring adherence and to describe the relationship between patient-related, family-related, community-related, and healthcare system-related determinants of parental mHealth symptom home monitoring adherence for infants with congenital heart disease during the single ventricle interstage period. Chapter 5 will be organized by research questions followed by strengths, limitations, implications, future research, and conclusions.

Interpretation of Findings

Rate of Parental mHealth Symptom Home Monitoring Adherence

Research question one focused on the rate of parental mHealth symptom home monitoring adherence through six measures: initiation, implementation- video, implementation- weight, implementation- oxygen saturation/heart rate, implementation- data days, and discontinuation. Each of these contributed to the overall description and understanding of parental mHealth symptom home monitoring adherence for infants with congenital heart disease during the single ventricle interstage period. To this author's knowledge, this is the first study to evaluate parental mHealth home monitoring initiation, implementation, and discontinuation adherence for infants with single ventricle congenital heart disease in the interstage period. This section discusses the rate of parental mHealth initiation, implementation-video, implementation-weight, implementation-oxygen saturation/heart rate, implementation-data days, and discontinuation adherence.

Initiation (IN). Initiation of parental mHealth symptom home monitoring adherence was measured as the first day after hospital discharge that data was transferred to the healthcare team through the mHealth application. The recommended time for parents to initiate mHealth symptom home monitoring is immediately upon arriving home from the hospital. The median initiation was zero days after the neonatal hospital discharge. Parents in this study were more adherent than the initiation adherence of 3 days (median) found in comparable literature (Black et al., 2014). This is likely due to the feasibility study having some technological issues with a small sample size (Black et al., 2014) compared with a large multi-site sample with over 300 neonates.

If the mean of five days for initiation is considered, it provides an opportunity for further evaluation of possible reasons for this delay. Intentional initiation non-adherence may be influenced by parental health beliefs of the mHealth app or stress with transition home (Simblett et al., 2018). On the other hand, non-intentional initiation non-adherence may be influenced by perceived utility (poor data reliability of home monitoring) or technology issues (Simblett et al., 2018).

Implementation- video (Vid). The implementation-video adherence rate, non-hospitalized days where videos were received by the healthcare team, had the lowest mean rate of implementation adherence at about 50%. This frequency would equate to a video begin sent to the team about every other day compared with the recommended daily rate. Only two of the five previous interstage mHealth publications reported the use of videos as a measure of symptom home monitoring with no reported adherence rates to video monitoring (Bingler et al., 2018; Shirali et al., 2016).

Registered nurse coordinators triage videos transferred by parents for evaluation of the infants' color, breathing, and neurologic behavior. Video evaluation is an expanded scope of practice for registered nurse coordinators and advanced practice nurses in the interstage. In complex pediatric chronic disease management, pediatric self-management and decision making for the healthcare team can be improved with mHealth technology (Canter et al., 2019). Healthcare teams that have used mHealth for a longer period may be more comfortable recommending daily videos to parents during initial parent training on the use of mHealth technology. The external motivation from the healthcare team would then be passed onto parents to improve parental mHealth video implementation adherence (Simblett et al., 2018). The experienced registered nurse coordinators are more likely to have the daily video review integrated into their daily clinical decision making for symptom home monitoring measures providing optimized use of mHealth in the interstage (Canter et al., 2018). The use of videos is not available in all mHealth applications for the interstage period and could be considered as an additional feature for proactive interstage nursing interventions.

Implementation- weight (WT). Daily implementation-weight adherence was over 60%. Most parents understand the importance of measuring weight during the interstage period (Hurst et al., 2015). Intentional non-adherence for weight monitoring may be because parents do not believe in the usefulness of this measure (Simblett et al., 2018). This may occur if their child's weight is stable and the child does not have supplemental nutrition needs through extra calorie formula or feeding tubes for interstage weight gain.

Implementation- oxygen saturation/heart rate (O2HR). There was over 100% (mean rate) implementation of parental mHealth symptom home monitoring of oxygen saturation/heart rate during non-hospitalized days. Further examination of this high adherence rate found that one of the nine centers recommending twice a day symptom home oxygen saturation monitoring. A secondary analysis was conducted to check interval validity through a comparison of normalized mean rates of implementation oxygen saturation/heart rate per hospital site. This analysis found the hospital that recommended the rate of twice-daily monitoring was similar to many of the other hospital's implementation-oxygen saturation/heart rate rates, when the percentage would have been expected to be much higher. Parents from five of nine centers provided oxygen saturation data more frequently than the recommended daily reporting. The mean implementation oxygen saturation/heart rate adherence for all hospitals was found to have a wide range of 26.6% to 182.3%. An ANOVA comparison did find a significant difference between all nine groups in the post hoc analysis (p=0.003) likely due to this wide range. This finding indicates that there should be a standardization of recommended implementation oxygen saturation symptom home monitoring across all interstage programs.

The higher than recommended rate of oxygen saturation/heart rate symptom home monitoring reporting appears similar to other patterns of vigilance reported by parents of infants with single ventricle heart disease (Meakins et al., 2015). There are many possible reasons for this increased reporting including continuous monitoring of oxygen saturation and heart rates during hospitalizations (health status), ease of use of the oxygen saturation monitor (convenience), and parental health beliefs for the importance of this symptom home monitoring measure for their child (internal motivation) (Simblett at al., 2018; Modi et al., 2012). Inversely, intentional non-adherence may be due to parental stress and fear about this symptom home monitoring measure and need for cardiac interventions if the finding is outside of the recommend range of 75-85%. Conversely, non-intentional non-adherence for oxygen saturation and heart rate monitoring could be from usability issues with oxygen saturation monitor (Simblett et al., 2018).

Implementation- data days (DD). Implementation- data days, or any non-hospitalized interstage day where any type of symptom home monitoring data was received, was 75% (mean rate). This implementation rate was the only adherence outcome that had been previously reported in mHealth publications and was found to be within the range (50.3 to 80.0%) of other mHealth studies for interstage infants (Black et al., 2014; Cross et al., 2012; Shirali et al., 2016). Though not clearly linked to clinical outcomes in most diseases, the most widely used adherence rate for many behaviors is 80% (Sabate, 2003). The finding of 80% daily adherence to any type of data transfer as an adherence goal is consistent with other adherence literature, but as interstage outcomes are linked with adherence, this rate may change.

Discontinuation (DC). Discontinuation, or last date of data transfer during the interstage, was found to be just over two weeks (mean) before the end of the interstage period. This finding indicates a decrease in data entry by parents toward the end of the interstage period. However, it is reassuring that the median discontinuation of four days was closer to the recommendation from the healthcare team. The length of the interstage period of over four months and the required persistence through a high-risk period with daily recommendations for symptom home monitoring may have been a factor. None of the five publications of parental mHealth adherence for symptom home monitoring during the interstage period included discontinuation adherence rates. As with initiation, discontinuation may be better addressed with a time to event analysis (Vrijens et al., 2012).

Unfortunately, the calculation of discontinuation adherence did not address if there were readmissions at the end of the interstage. If readmissions occurred or families relocated to the tertiary hospital during this time, the non-intentional non-adherence rate would increase. Intentional non-adherence to discontinue monitoring earlier than recommended could be due to changes in parental health belief, perceived lack of utility of monitoring, or parental stress-related factors nearing the second stage surgery (Simblett et al., 2018).

Rate of parental mHealth adherence. Overall understanding of the rate of parental mHealth symptom monitoring adherence includes frequencies but also correlations between initiation, implementation, and discontinuation. Of all six types, initiation and discontinuation were the only two that were not significantly correlated with each other. The interstage period is a relatively short period over four to six months but with high acuity recommendations for symptom home monitoring. The lack of correlation of between initiation and discontinuation may be due to differences of the length of the interstage period. As seen with other mHealth adherence literature, parental engagement in monitoring may dwindle as the months of required monitoring lengthen (Donkin et al., 2013; Simblett et al., 2018). Additionally, there may be other social determinants that impacted parental ability to measure and record symptom home monitoring data that were not measured in this model such as family income, employment, housing, and community support (Heiman & Artiga, 2015).

Intriguingly, initiation and discontinuation were individually negatively correlated with all other implementation adherence variables: implementation-weight, implementation-oxygen saturation/heart rate, implementation- video, and implementation- data days. Lower initiation adherence was associated with higher rates of implementation adherence through the interstage. Additionally, lower discontinuation adherence was also associated with higher rates of implementation adherence. Each of the four types of implementation adherence were all significantly positively correlated with each other with medium to large effect sizes. This finding may be due to the method in which parents are trained where registered nurse coordinators spend focused time with parents over multiple meetings prior to neonatal discharge. During this training parents engage in education about their child's cardiac diagnosis, reasons for interstage monitoring, and equipment training all focused on single ventricle interstage care.

In the previous section, the findings of research question one, "What is the rate of parental mHealth symptom home monitoring adherence for initiation, implementation, and discontinuation adherence of infants with congenital heart disease during the single ventricle interstage period?" were discussed. Parental mHealth adherence was presented in this data set by four indicator variables of implementation- data days, implementation- videos, implementation- weight, and implementation- oxygen saturation/heart rate. The rate of mHealth adherence was highest in oxygen saturation/heart rate and lowest in videos. All variables of implementation were highly correlated with each other and individually with initiation and discontinuation of parental mHealth adherence. The second research question will help to further evaluate the relationships between the multi-dimensional variables chosen for the structural equation model.

Relationships between Patient-related, Family-related, Community-related, and Healthcare System-related Determinants of Parental mHealth Symptom Home Monitoring Adherence

Research question two evaluated the relationship between patient-related, family-related, community-related, and healthcare system-related determinants and parental mHealth symptom home monitoring adherence. Structural equation modeling revealed discussion areas of variance for correlation of determination of the model, areas of improved parental mHealth adherence, and areas of reduced parental mHealth adherence. Through this discussion, strengths, limitations, future research, and conclusions are offered.

Model variance for adherence. Structural equation modeling is an estimation method that is based on covariances and correlations. Variances of structural equation modeling are the quantity of the outcome variables explained by each of the relationships and the determinant variables (Kline, 2016). Implementation- weight was the most well-explained adherence variable with over 80% of the variance explained through the structural equation model. The overall variance of explanation of the final model was 24.3% with a small effect size. This lower variance indicates the possibility that there may be variables left out of the model that could aid in the explanation of parental mHealth adherence. Potential future variables include the route of feedings and formula concentration specifically for implementation-weight. Pediatric self-management conceptual model includes parental health belief related to adherence which may also impact parental mHealth adherence (Modi et al., 2012).

Modification indices of direct regression weights and covariances were offered by the computer modeling to improve model outcome variance. The final retained parental mHealth adherence model was built through model trimming off of the three latent variables and model additions. Although adding modification indices may suggest a risk of fitting to local data, the suggested indices added seemed to be clinically and theoretically sensible. Some of these modifications included variables that crossed from patient-related to family-related, family-related to healthcare system-related, and patient-related to healthcare system-related.

Factors Associated with Increased Adherence

In the final model, there were four determinants significantly associated with increased adherence when accounting for all other defined covariances and directed relationships. Parental age, payer type, and parental education level were significant variables from family-related determinants. Healthcare team initiated communications were the only healthcare system-related determinant variable found to have association with increased adherence. There were no patient-related determinants individually associated with adherence outcomes. Parental age and payer type were found to have associations with parental mHealth adherence. Individual parental mHealth adherence outcome variables of implementation- oxygen saturation/heart rate and implementation- video had associations with parental education level and healthcare team initiated communications. Parental age, payer type, primary caregiver education level, and healthcare team initiated communication will be discussed individually in this upcoming section.

Parental age. The overall latent variable of parental mHealth adherence was found to have a significant positive association from a higher primary caregiver age, meaning older parents had higher adherence. A higher mean age of caregivers at 28 years was found compared with 26 years with other mHealth interstage studies (Black et al., 2014). Inversely, parental age has been negatively associated with mHealth adherence to applications outside of pediatric cardiology (Anderson-Lewis et al., 2018). The use of mobile phones has been pervasive in the past twenty years and younger parents have grown up with mobile phones. Older parents may be more likely to use a separate mHealth tablet compared with a mHealth application on a mobile phone (Simblett et al., 2018). Older mothers may perceive the additional tablet as less cumbersome and may be more likely to have health belief of symptom home monitoring.

Payer type. Payer type, another family-related determinant, was associated with increased parental mHealth adherence. When parents had Medicaid/state insurance payer type, they were more adherent to symptom home monitoring. Conversely, previous pediatric cardiology literature has found decreased adherence with Medicaid/state insurance (Demianczyk et al., 2019) and increased risk of mortality and morbidity events with Medicaid/state insurance (Tregay et al., 2015). Neither of these studies evaluated mHealth specifically so the use of mHealth has the potential to bridge a socioeconomic gap in outpatient care in this patient population. Additionally, Medicaid may be added as a secondary insurance in some states and the CHAMP database does not provide more than one insurance for each infant. Although parental age and payer type are non-modifiable influences, evaluation of these determinants' impact on interstage care may be important to understanding and potentially improving parental mHealth adherence.

Primary caregiver education level. The mean rate of primary caregiver years of education was 13.4 years with a wide range of 2-17 years. Higher education level was found to have a direct positive association with higher implementation- oxygen saturation/heart rate symptom home monitoring. All families are provided an oxygen saturation monitor for use at home from the healthcare team or from insurance depending on the individual hospital's program preference. This finding is consistent with reduced outpatient adherence after pediatric heart surgery with lower parental education levels (Demianczyk et al. 2019; Santos et al., 2014).

Parental education level has been used as a proxy for socioeconomic status in previous pediatric cardiology publications focused on adherence (Santos et al., 2014). Social determinants impact adherence for parents from often unseen forces. Along with overall socioeconomic factors, parental education levels impact potential learning and engagement with the hospital discharge process. A significant amount of training is provided by registered nurse coordinators to parents prior to discharge home from the neonatal hospitalization. Parents with a higher education level may also have an improved ability to absorb and demonstrate back to the healthcare team the utility of oxygen saturation monitoring (Bucholz, Sleeper, & Newburger, 2018).

Healthcare team initiated communications. The healthcare system-related determinant, route of healthcare team red flag communications was found to positively influence the frequency of implementation- video adherence, albeit at a small effect size. The variance for this outcome variable was nearly 50% with a medium effect, indicating a good portion of the variables chosen to evaluate potential correlations were correctly included in the structural equation model.

The reviews of parent provided mHealth videos by the healthcare team provide an opportunity for proactive communication that is potentially modifiable. Interstage registered nurse coordinators that proactively communicate with families about videos may be influencing the rate of adherence to video monitoring. The final model had imposed directionality from healthcare initiated communications impacting implementation of video adherence. Parents that understanding the importance of videos may improve engagement but also having communication back from the healthcare team after video review is a key for continued parental mHealth video adherence.

These four determinants of parental age, payer type, primary caregiver education, and healthcare team initiated communication were found to have a direct positive significant relationship with parental mHealth adherence, implementation-oxygen saturation/heart rate, and implementation-videos. Variables that may influence decreased adherence frequency are also important for a comprehensive understanding of adherence. These variables will be addressed in the next section.

Factors Associated with Decreased Adherence

There were three determinants that had a significant direct negative association with parental mHealth adherence in the final model evaluation. All associations were found with individual types of implementation outcomes. The patient-related determinant of major syndromes, the family-related determinant of payer type, and the healthcare related determinant of clinic visits were all found to have lower rates of implementation adherence for weight, video, or oxygen saturation/heart rate. Each of these determinants will now be discussed.

Major syndromes. Implementation- video and implementation- weight adherence both had lower rates of adherence frequency by parents of infants with no major genetic syndromes. Eighty two percent of infants had no major syndromes. The reported major genetic abnormalities include DiGeorge Syndrome, CHARGE syndrome, Heterotaxy syndrome, Down Syndrome, and other complex syndromes. This study found a higher incidence of major syndromes at nearly 18% compared with other mHealth interstage publications at 8.9% (Harahsheh et al., 2016). Additionally, in 2014-15, the CHAMP database was the data source for Bingler et al.'s (2018) publication with mHealth use in the interstage and reported a 0% incidence of infants with major syndromes. The finding of 18%

is much higher and potentially indicates more complex infants are surviving to discharge home or can be discharged home with the additional aid of mHealth for symptom home monitoring over the last four years.

Parents of infants with major syndromes were more adherent to weight and video symptom home monitoring. Reduced rates of adherence have been reported with children with a complex diagnosis and treatment regimens (Bosworth et al., 2006). However, this report was before mHealth was used to improve outpatient medical care in high risk infants so the reduced adherence may be improved with the aid of current mHealth technology. In a recent review of mHealth use by parents' of medically complex children, parents of the most fragile children were more likely to adhere to use mHealth technology for monitoring symptoms in their infant (Nkoy et al., 2019).

Major syndromes may increase the rate of non-cardiac conditions and medical complexities resulting in a negative impact on the parent's ability to visually evaluate their child, including evaluating their respiratory function. Although the health care team recommends submitting videos of the infant each day even with no concerns, videos may be more likely to be transmitted if parents are concerned about their infants' color, behavior, or breathing. A connection to their child's major genetic syndrome may give caregivers more reasons to monitor weight or transmit videos. Additionally, weight gain with infants with major syndromes and single ventricle congenital heart disease require close monitoring and complex care by parents. The use of mHealth for home weight gain and nutrition would be a convenient method for symptom home monitoring. The direct visual of weight gain changes may provide internal parental motivation for infant growth. Conversely, parents of infants without major syndromes and no major non-cardiac conditions, may not see the utility in the additional measures of weight and videos for mHealth symptom home monitoring for their child (Simblett et al., 2018).

Payer type. Family-related determinant of payer type was found to have a direct negative correlation with the reflective variable of implementation-oxygen saturation/heart rate for parental mHealth adherence. Primary caregivers of infants with Medicaid/state insurance would have a lower rate of data transfer of oxygen saturation/heart rate. This finding is similar to previous findings of outpatient adherence in pediatric cardiology (Demianczyk et al., 2019). Obtaining oxygen saturation and heart rate is a time-consuming symptom home monitoring activity that requires use of the pulse oximeter monitor to measure oxygen saturations over a few minutes and then entry into the mHealth application. The time burden of multiple steps required for data transfer may be one factor in reducing parental adherence to data transfer. Increased primary caregiver educational level was associated with a higher frequency of oxygen saturation/heart rate data transfer. Parents with less educational opportunities may be more likely to have Medicaid insurance with a lower socioeconomic status.

Clinic visits. The mean rate of 5.6 cardiology clinic found in this study was similar to findings of 4.8 to 6 cardiology clinic visits during the interstage period (Black et al., 2014; Bingler et al., 2018). The healthcare system-related determinant of increased clinic visits was associated with a lower frequency of parental submitted oxygen saturation and heart rate data. Likewise, increased clinic visits are associated with non-adherence in the general population (Naranjo et al., 2014). An explanation of this association could be a healthcare team’s directive for infants to have weekly clinic appointments during the interstage period. Consequently, parents may be less likely to perceive the benefit of transferring data since their infants are evaluated in person during the clinic appointments. The next section will describe the strengths of this study.

Strengths

This is the first study to evaluate multi-level determinants and their relationship to a comprehensive conceptualization of mHealth adherence, specifically initiation, implementation, and discontinuation. The study had adequate sample size, exceeding the sample size recommended by the power analysis. Determinant variables had comparable univariate descriptive characteristics with literature for infants with single ventricle congenital heart disease thus increasing the external validity of the findings. Most variables loaded well on the principal component analysis and seemed to reflect the potential latent variables of patient-related, family-related, and healthcare system-related determinants. The covariance and correlation matrices helped to further understand significant correlations, and there were numerous findings with medium to very large effect sizes between variables. The variances, standard errors, covariances, and correlation matrices are provided for reviewers for ease of understanding and for interest in replication of findings.

Each of the three domain areas of patient-related, family-related, and healthcare system-related had significant direct weight regressions that were improved by modification indices. These additional model covariances were added between patient-related with healthcare system-related and family-related with healthcare system-related determinants of mHealth. The final retained model accounted for cross-domain interactions while maintaining theoretical foundations from the pediatric self-management conceptual framework (Modi et al., 2012). This is a strength because the pediatric self-management conceptual framework suggests that interventions that cross multiple domains may have a greater impact on adherence (Modi et al., 2012). Although there were many strengths, there were weaknesses found with this study and will be subsequently reviewed below.

Limitations

This study has several limitations. The first limitation was the use of a de-identified, retrospective data set. The de-identified data set did not contain dates of patient encounters. Consequently, there was no way to correlate patterns of reduced adherence and patient related events such as clinic visits and readmissions. The second limitation included data outliers and missing data that required imputation for the variable's primary caregiver education level. As such, this outcome should be interpreted with caution. Most of the variables were continuous however some categorical variables required additional steps for imputation. A third limitation is the unavailability of some data that could assist in explaining parental mHealth adherence. For example, the study did not include information regarding infant weight that could shed additional light on the adherence findings such as if the infant was orally fed, if any extra fortified feeds were provided, use of feeding tubes, and/or adherence to the recommended feeding volumes and routes.

The last limitation was the finding of a MIMIC model and the inability to identify and analyze the proposed model due to complexity. However, from the onset, this study's proposed model was an exploratory model, not a confirmatory one, with planned re-specification for outcome modeling which allows for transformation as needed with theoretical testing. SEM provides the ability of researchers to provide theoretical assumptions of directionality and covariances between measures and obtain fit of the data. The findings of this study will need to be repeated in a confirmatory SEM to prove any causal assumptions as the current findings are now more plausible but not proven.

Implications

Results of this study have implications for nursing practice, policy, and theory in pediatric cardiology, interstage care, and parental mHealth adherence. Evaluation of this study can lead to numerous areas of future research.

Nursing practice. Numerous implications for nursing clinical practice are found from this study that include mHealth video use, clinic visits guidelines, family centered care for infants without major syndromes, standardization of parental training on mHealth use, and equity of care with addition of a mobile version of the mHealth application. A modifiable area of interstage nursing care is the use of mHealth symptom home monitoring via videos by the parents of infants with congenital heart disease during the single ventricle interstage period. The ability for nurses and advanced practice nurses to proactively review videos supports an innovative area of ambulatory nursing beyond phone calls and clinic evaluations. Pediatric cardiology centers that have been using mHealth for longer periods of time may be more comfortable in recommending a rigorous daily schedule for symptom home monitoring that include measures beyond home monitoring without mHealth, such as video monitoring. Maximizing the healthcare team's use of mHealth and improving comfort with proactive review of data may improve clinical outcomes with earlier interventions with infant hemodynamic changes.

Clinic visits during the interstage were associated with lower oxygen saturation/heart rate adherence. Registered nurse coordinators that work in the interstage period bridge the transition from hospital to patient home and back to ambulatory care in clinic. Home monitoring program healthcare providers that care for families during weekly clinic appointments may change their adherence recommendations to increase symptom home monitoring of oxygen saturations when mHealth is added as another tool for interstage care.

Parents of infants with no major genetic syndromes were found to be a non-modifiable patient-related determinant that had associations of decreased rates of adherence of video and weight symptom home monitoring. This finding could indicate that parents of infants without major syndromes were more likely less adherent, possibly due to decreased complexity. Infants without major syndromes may be in the hospital a shorter time with less exposure to specialty teams consequently having less exposure to the interstage team for education. Registered nurse coordinators may consider adding more interstage education to parents of infants without major syndromes with a focus on teach back prior to discharge home. Weight outcomes had a high percent of explained variance indicating the variables of the model explained the outcome well; however, the use of feeding tubes, specialized nutrition, and adherence to feeding regimens were not included in this analysis and may impact nursing clinical care and adherence. Parents of infants without major syndromes may need time to facilitate parental engagement of videos and weight symptom home monitoring.

CHAMP pediatric cardiology clinical sites utilize their own guidelines for care including parental mHealth training. Interstage clinical care begins after surgery and not just at the hospital discharge and there are numerous educational activities that are completed prior to discharge (Nieves et al., 2017). Registered nursing care could potentially improve parental mHealth adherence through standardization of parental training on the mHealth application.

Additionally, the findings of this study support the continued equity of care across all socioeconomic backgrounds for families. Parental age and parental education level impacted parental mHealth adherence and may be proxies for socioeconomic status. Registered nurse coordinators should work closely with the interstage social work team for a comprehensive understanding of the parental background that may impact parental mHealth adherence prior to discharge home from the neonatal hospitalization. An example of improving nursing policy and equity for all families is the transition to a mobile version downloadable onto parental phones. CHAMP is available in nine language which supports diversity, but parents reported that the tablet version was an impeding factor for parental mHealth adherence. Since younger parental age was associated with reduced overall parental mHealth adherence, providing a mobile phone version may increase younger parents' mHealth adherence.

Nursing policy. Implications for nursing policy include non-modifiable family-related influences of parental age, payer type, and parental education level. Nurses may be advocates at the state and federal level for improved access and coverage of Medicaid state insurance with the finding of improved parental mHealth adherence for caregivers of infants with Medicaid payer type. The CHAMP database did not contain any data from infants that had secondary Medicaid as their insurance, so it is unclear if some infants had Medicaid due to their complexity or only their socioeconomic status. Reimbursement for remote monitoring via telemedicine like CHAMP has only been possible for the last few years. Nurses can advocate for the importance of telemedicine and mHealth, especially in the age of COVID-19 pandemic changing the face of ambulatory care in 2020.

Nursing theory. The pediatric self-management conceptual framework was supported by the findings on this study. For example, parental health belief is a family-related determinant reported in the pediatric self-management framework that may impact numerous areas of modifiable and non-modifiable processes that impact adherence. There are also opportunities to modify the study outcomes using pediatric self-management conceptual framework. For example, since clinic appointment frequency was also an area that Modi et al. (2012) conceptualized as a mid-range adherence outcome and there were important findings within this study, adherence to clinic visits could also be focused on with the same conceptual framework. The pediatric self-management conceptual model could support the next research study where exploration of the association between adherence and clinical outcomes are explored. Future research could include a further understanding of correlation of ideal frequency of weight gain monitoring and improved clinical outcomes. Additionally, interventions to improve adherence may be sustained longer if they interact with more than one domain (patient, family, healthcare system, and community) in the pediatric self-management conceptual framework (Modi et al., 2012).

Future Research

The findings of this research study led to many ideas for future research in parental mHealth adherence. A primary research focus would be exploring the extent of parental mHealth adherence required for improved infant clinical outcomes. These findings could guide pediatric cardiology healthcare team recommendations for care in this fragile infant population. Another research focus would be further understanding of the reasons for the association between lower parental mHealth adherence and clinic appointment visits. It is unclear if non-adherence by parents to symptom home monitoring results in higher rates of clinic appointment visits or if it is because the higher rates of clinic appointment visits results in non-adherence by parents to symptom home monitoring. There is potential for future opportunities for evaluation of patterns of clinic visits for association with periods of implementation- oxygen saturation/heart rate with correlation of modifiable influences on parental mHealth adherence.

There are opportunities to further evaluate mHealth initiation and discontinuation adherence. Both initiation and discontinuation could be evaluated with a time to event Kaplan-Meier curve analysis. In addition, correlations between morbidity and early and late initiation and discontinuation could be evaluated. The association between discontinuation adherence could be explored including frequency of clinic visits toward the end of the interstage period, type of neonatal cardiac surgery, complexity of cardiac diagnosis, and hospital readmission days before the end of the interstage period with a stage two surgery. Future research could explore parental health beliefs and initiation, implementation, and discontinuation adherence.

Using different types of structural equation analyses could be used in future research to further understand parental mHealth adherence. Future research could use only continuous variables for the model instead of categorical variables which could reduce the need for imputation and data transformation, thus making the analysis more robust. Additionally, adding model variables may improve the explained variance of parental mHealth adherence. These may include patient-related nutrition information and socioeconomic information from zip codes to expand the area of community-related determinants.

Oxygen saturation symptom home monitoring adherence was the only type of adherence where parents exceed the 100% adherence goal. Future research could focus on parental health beliefs and this hypervigilance of data reporting. In addition, research could explore the associations between patterns of oxygen saturation and outcomes so the appropriate monitoring recommendations could be made by the healthcare team. Also, oxygen saturation/heart rate and weight implementation adherence had a large effect size and were highly correlated, which provides an area of research to evaluate the parental use of routines and time of day for symptom home monitoring as these values would take the most time to complete.

Finally, an improved understanding of the interpretation and use of mHealth videos from the healthcare team perspective may provide future research areas to improve parental mHealth adherence and subsequent clinical outcomes. The healthcare team's comfort with video evaluation may be a part of the reduced use by parents for data transfer. A tool for standardizing video evaluation by healthcare providers is under development (Aly et al., 2019). Video review is the newest addition to mHealth use in the interstage period as part of the hemodynamic assessment along with oxygen saturation, heart rates, and growth. Although video adherence had the lowest rate of all the types of implementation, there is an opportunity to further understand this relationship and provide intervention for future research studies to improve clinical care maximized by the pediatric self-management theoretical framework.

Conclusions

A review of literature found a lack of evidence regarding the rate of parental mHealth adherence to symptom monitoring of infants with congenital heart disease during the single ventricle interstage period. Additionally, there was no evidence about individual patient-related, family-related, community-related, and healthcare team-related determinants of parental mHealth adherence to symptom home monitoring of infants with single ventricle congenital heart disease during the interstage period. Using the pediatric self-management model, this study sought to close this knowledge gap. The findings of the DOMAIN study inform the science of interstage symptom home monitoring and contribute to the growing knowledge of parental mHealth adherence. The theoretically identified, recursive model had a good global and local fit with an adequate sample size for structural equation modeling. There was a range of findings of variances for the outcome variables in the model with medium to large effects with an overall good statistical fit for the variables chosen for the model.

Improved rates of parental mHealth symptom home monitoring adherence were found with both higher parental education levels and Medicaid payer type. Improved adherence to mHealth video use was found with patients that had more red flag communications that were initiated by the healthcare team. Improved adherence to oxygen saturation data entry into the mHealth application was found with higher parental education level. Lower entries of infant weight and videos were found with primary caregivers of infants without major genetic syndromes. Lower rates of oxygen saturation and heart rate monitoring data transferred were found with a higher rate of clinic visits. These findings lead to areas of nursing practice, policy, theory, and research. These areas include the determinants of parental age, education level, payer type, major syndromes, and healthcare team initiated red flag communications and associations with parental mHealth initiation, implementation, and discontinuation adherence.

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VITA

Lori Anne Erickson was born on March 22, 1982, in Lawrence, Kansas. She was educated in public schools in Kansas and graduated from Salina High School South in 2000. She graduated cum laude in 2006 with a Bachelor of Arts in Chemistry and a Bachelor of Science in Nursing. After working as a nurse in a pediatric intensive care unit for three years, Ms. Erickson additionally obtained a degree of a Master of Science in Nursing, all from the University of Missouri-Kansas City.

Over the last 13 years as an Advanced Practice Nurse, Ms. Erickson has obtained nearly $65,000 in grants and funding for clinical and research endeavors. Ms. Erickson was a co-editor in a book chapter for pediatric cardiology in 2015, with a 9th revision of this chapter under review for publication in 2019. Additionally, she has been the first author twice and the second author on two recent publications about the Cardiac High Acuity Monitoring Program: CHAMP Application. Overall, Ms. Erickson has been involved and presented 26 referred poster presentations, 11 invited lectures, and 20 invited educational presentations, and has maintained authorship on 10 published abstracts. The research and clinical work with CHAMP and the Ward Family Heart Center team was honored by receiving numerous awards including the Top Research Award at Cardiology 2019: CHOP Pediatric Cardiology Conference, Top 8 Oral finalists for Nursing research in 2019, 2016 ANCC Magnet Prize, and the Society of Pediatric Nursing Excellence in Advanced Practice yearly award in 2017. Ms. Erickson was the recipient of the 2016 Nurse Scientist Award at CHOP's yearly Cardiology conference.

In the Summer of 2016, Ms. Erickson began coursework for her Doctor of Philosophy degree in Nursing at the University of Missouri-Kansas City. She passed her comprehensive exams in September 2019. Upon completion of her degree requirements, Ms. Erickson plans to continue her career as an advanced practice nurse with an emphasis on research and outcomes.

Ms. Erickson is a member of the American College of Cardiology, the Society of Pediatric Nurses, the American Nurse Foundation, Phi Kappa Phi National Honor Society, and the Lambda Phi Chapter of Sigma Theta Tau International.