Clinical Pathway for the Fontan Patient to Standardize Care

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Abstract

The Fontan repair is the final stage of surgical palliation for the pediatric patient with a single ventricle heart. The post-operative medical management of this patient population can be variable and hospital length of stay prolonged. With the evidence-based practice movement, healthcare institutions have embraced clinical pathways as a means to standardize care and improve quality. The purpose of the retrospective quasi-experimental cohort project was to determine if the implementation of an evidenced-based clinical pathway for post-operative management of the Fontan patient at a large academic pediatric medical center in the Midwest would standardize care and decrease length of stay. Components of the clinical pathway include 1) supplemental oxygen until pleural drainage tubes are removed, 2) fluid restriction to 80% daily maintenance and a prescribed low-fat diet, 3) aggressive and standardized diuretic therapy while inpatient, and 4) central venous access. Charts were reviewed from consecutive immediate post-operative Fontan patients from 2014-2015, pre-pathway implementation, and 2017-2018, post-pathway implementation, with total sample size of 67 patients (37 pre-, 30 post-). Key outcomes measured were adherence to the pathway, length of stay, and readmissions for pleural effusion. Adherence to the pathway was nearly 100% with a statistically significant decrease in LOS from 12 to 9 days ($p = .007$) and no increase in readmissions ($p = 0.500$). Standardizing care can improve clinical outcomes for the Fontan patient population without negatively impacting quality of care, thus providing a positive benefit to the healthcare institution, industry, and patient.

Keywords: Fontan pathway, standardization of care, clinical pathway, length of stay

Implementation of a Clinical Pathway for the Fontan Patient

Since the 1990s, adult and pediatric cardiac surgery programs across the United States have developed clinical pathways for specific surgical repairs in order to standardize and streamline care (Allen & Davis, 1995; Miller et al., 2014; Uzark et al., 1998). Successful implementation of clinical pathways has been shown to yield high-quality, cost-effective care that promotes optimal patient outcomes (Kelly et al., 2000). The Heart Center at a Midwestern tertiary pediatric institution did not previously follow any available clinical surgical pathways nor had the program developed any of their own to guide patient care. A quality metric often used as a key benchmark for progress and efficiency in patient care is post-operative length of stay (LOS; Toledo et al., 2013). Historically, the average LOS after the Fontan repair at the study institution has been longer than the United States national reported average (Dean, Hillman, McHugh, & Gutgesell, 2011). The evidence-based practice (EBP) doctor of nursing (DNP) project therefore focused on the implementation of a post-operative clinical pathway for the Fontan patient to standardize care and potentially decrease LOS for this patient population.

Background and Significance

Hypoplastic left heart syndrome (HLHS) is a spectrum of abnormalities characterized by the underdevelopment of the left ventricular outflow tract with concomitant and variable degrees of hypoplasia of other left-sided heart structures (May, 2012). HLHS affects one in 5000 live births (Dean et al., 2011). The Fontan procedure, initially described in 1971 by Fontan and Baudet as a surgical treatment for tricuspid atresia (hypoplastic right heart), was adopted in the 1980s as the final stage in the surgical palliation of HLHS and other congenital heart defects with single ventricle anatomy (Dean et al., 2011; see Appendix A for Fontan diagram). Since this time, the Fontan procedure has undergone modifications in an attempt to improve post-operative

morbidity and mortality (Cava, Bevandic, Steltzer, & Tweddell, 2005; Sunstrom et al., 2015). The modified Fontan procedure consists of surgically placing an external tubular conduit or internal lateral tunnel to passively redirect systemic venous return via the inferior vena cava to the pulmonary arteries (May, 2012). The passive redirection of the venous system leaves the single ventricle only responsible for supplying blood to the body (May, 2012). While the 10-year survival rate after extracardiac conduit and lateral tunnel Fontan repair is excellent at 97%, significant morbidity continues to be an issue and can considerably affect hospital LOS (Cava et al., 2005; d'Udekem et al., 2014).

Economic

According to the Society of Thoracic Surgeons (STS) Congenital Heart Surgery database, over 1000 Fontan repairs are performed per year in the United States and Canada (Jacobs et al., 2016). The national median reported total charge from 1998 to 2007 for the Fontan procedure is $79,549 (Dean et al., 2011). Daily costs in 2007 for the Fontan were $3601 (with a charge of $8833/day), which extrapolated for a hospital stay of 14 days, the current national average, would make the actual cost $50,414 (Dean et al., 2011; Jacobs et al., 2016). Significant cost savings could be achieved if LOS was reduced for this patient population.

Local Issue

Management of patients after cardiac surgery at the study institution is often provider dependent with no surgery specific care guidelines. At the study institution, approximately 20 Fontan repairs are done annually and LOS has historically been longer than the national benchmark (Dean et al., 2011). Without a defined and clear standard approach to care, treatment can be variable, especially when complications arise. Patients who undergo the Fontan repair, in particular, are at a higher risk for developing complications related to continued pleural drainage,

thus prolonging their LOS (Cava et al., 2005; Gupta et al., 2004; Pike et al., 2015). It has been theorized that utilizing an evidence-based clinical pathway or protocol tailored specifically toward the unique physiology of Fontan patients may lead to a reduction in the incidence of pleural effusions, overall morbidity and LOS (Cava et al., 2005).

Problem and Purpose

The EBP project was selected because there was no standard of care for the post-operative Fontan patient at the study institution, and the institutional LOS for this patient population has historically been longer than the national benchmark, indicating a problem or area of potential improvement (Dean et al., 2011). Postoperative medical management for the Fontan patient varies widely among healthcare providers, which can contribute to the incidence of persistent pleural effusions, need for more aggressive and invasive therapies, and a prolonged LOS for this medically complex patient population (Cava et al., 2005; Gupta et al., 2004). The purpose of the retrospective quasi-experimental cohort project was to determine if the implementation of an evidenced-based clinical pathway for post-operative management of the Fontan patient at the study institution would standardize care and decrease LOS.

Facilitators and Barriers

The EBP project was supported, or facilitated by the following: the project site is a Lean institution, and therefore provides education and support for evidence-based, quality improvement (EBQI) initiatives; a small multidisciplinary team underwent QI training with this project in mind and then chose the student investigator as the lead for the project; and the Heart Center leadership (chiefs, inpatient director, inpatient APRNs) supported the project and has encouraged a culture of evidence-based practice (EBP). The overall economics of the project

was also a facilitating factor. The institution has the potential to achieve significant cost savings related to a decrease in LOS and reduced readmissions.

The main barriers to the implementation of the DNP project included physician resistance to standardizing care as they may believe it impedes their ability to use clinical expertise; staff and family anxiety related to the change in care as compared to what was done in the past and worry that the individual patients' needs or preferences may not be taken into account; and lastly the logistics of coordinating with other departments, namely interventional radiology (IR), for one of the interventions. To help obtain buy-in for the project, the use of Plan-Do-Study-Act (PDSA) cycles was essential. PDSA cycles allowed for each component of the pathway to be tested on a small scale prior to full implementation. By doing so, potential areas of concern were addressed or disproved, additional key stakeholders identified, support garnered, and the overall process streamlined.

A criticism of standardization of care is it can lead to dehumanization of work by stifling clinician creativity and a lack of customization of care to the patient (Mannion & Exworthy, 2017; Schrijvers, van Hoorn, & Huiskes, 2012). Implementing a clinical pathway based on the best available evidence and allowing for the use of professional judgement in the application of the protocol helped to create buy-in from healthcare providers and patients. Utilizing this approach also fits with the definition of EBP (Melnyk & Fineout-Overholt, 2015). Additionally, standardization of care can contradict family and patient-centered care models. Clinicians must take into account the risks and benefits of following the clinical pathway for the individual patient (Joint Commission International, 2016). Sustainability of the intervention during the project was promoted by allowing for provider individualization of care and use of shared-

decision making to ensure that the care preferences of the patient and family were considered (Joint Commission International, 2016).

Review of the Evidence

To provide evidential support for the DNP project, a synthesis of evidence was undertaken. The primary outcome of interest of the synthesis review was a reduction in LOS through the implementation of a post-operative clinical pathway. Studies in adults and surgical specialties other than cardiac were included in order to expand the available literature for review.

Inquiry

The project inquiry is, in the pediatric single ventricle patient who is status post Fontan procedure, does the implementation of an evidence-based clinical pathway in 2017-2018 versus care provided pre-pathway in 2014-2015 standardize care and decrease LOS at an academic tertiary pediatric institution?

Search Strategies

The databases used for the literature search included Cochran, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Index Medicus (MEDLINE), and PubMed. The search engine of Google Scholar was also employed. Search terms utilized were the Fontan repair, standardization of care, clinical pathway, and length of stay. Linked similar articles identified by the databases and search engine, as well as articles referenced, were evaluated for possible inclusion. Only studies performed in the acute care setting in the last 10 years, unless historically important or specifically clinically relevant, were included. Studies not available in English or full-text were excluded.

Approximately 60 studies were identified by this search strategy and 22 studies met inclusion criteria and were therefore selected for critical appraisal (see Appendix B for Evidence

Table). Using Melnyk and Fineout-Overholt's *Rating System for the Hierarchy of Evidence for an Interventional Inquiry* (p. 11, 2015, adapted), the level of evidence of each article was rated according to study design (see Appendix C). One study is considered Level I evidence as it is a systematic review with meta-analysis. Three studies are systematic literature reviews of quantitative studies, or Level II evidence. One study is a prospective, non-randomized controlled trial, or Level III evidence. Fifteen studies are retrospective and/or prospective well-designed case-controlled or cohort studies, or Level IV evidence. One study is a prospective, longitudinal, observational mixed methods study, also Level IV evidence. One study is a literature review, classified as Level VII evidence.

Synthesis of Evidence

Standardization has gained much popularity in healthcare. A commonly accepted definition of standardization is the development and implementation of processes, methods, or practices with specific steps or criteria designed to increase consistency and improve quality and safety (Leotsakos et al., 2014, p. 111). The EBP movement promotes standardization in healthcare through the use of clinical practice guidelines, pathways, protocols, and checklists designed to improve quality and safety by reducing practice variations (Mannion & Exworthy, 2017). Key sub-topics regarding this subject as identified by the literature search include overall effectiveness of clinical pathways, improving efficiency via standardization, improving LOS and costs via clinical pathways, cardiac surgery clinical pathways in adults, pediatrics, and the Fontan procedure (see Appendix D for key terms).

Overall effectiveness of clinical pathways. When considering the implementation of a clinical pathway as a patient management strategy, it is important to evaluate the evidence regarding the overall effectiveness of use in healthcare. Three systematic reviews, one with a

meta-analysis, assessed the effects of using clinical pathways in the hospital setting and for surgery on key quality indicators and patient outcomes (Lemmens et al., 2008; Ronellenfitsch et al., 2008; Rotter et al., 2008). These reviews found that clinical pathways positively affect LOS and costs without compromising quality, as assessed by readmissions, and morbidity and mortality rates (Lemmens et al., 2008; Ronellenfitsch et al., 2008; Rotter et al., 2008). Through sub-group analysis, pathways used for invasive procedures had a stronger LOS reduction (WMD –2.5 versus -0.8 days; Rotter et al., 2008).

Improving efficiency via standardization. Efficiency is an important performance indicator in healthcare. The following studies sought to achieve improved efficiency by standardizing and streamlining key care processes. In the Netherlands, implementation of an improvement plan directed at discharge planning resulted in a 50% reduction of inappropriate hospital stay; with the average LOS decreasing from 10.4 days to 8.5 days (Niemeijer et al., 2010). By redesigning the discharge process at an academic hospital in Lebanon, inpatient and emergency department LOS improved from 3.4 to 3.1 days post-intervention ($p < .001$) and 6.9 to 5.9 hours ($p < .001$), respectively (El-Eid, Kaddoum, Tamim, & Hitti, 2015). Similarly, an academic hospital in Pennsylvania standardized the inpatient discharge workflow with the aid of a discharge checklist (Beck & Gosik, 2015). While median time of discharge order entry improved, actual discharge performance remained consistent (Beck & Gosik, 2015). Finally, operating room efficiency was improved at an academic hospital in Minnesota by minimizing variations, streamlining the preoperative process, reducing waste and redundancy, and promoting staff engagement (Cima et al., 2011). On-time starts improved ($p < .05$) and operations past 5 pm decreased ($p = .34$; Cima et al., 2011). None of these studies used a clinical pathway for

post-operative management, however, they did demonstrate that efficiency can be improved in a variety of settings by standardizing care and streamlining processes.

Improving LOS and costs via clinical pathways. A key indicator of quality in the acute care setting is LOS. Decreasing LOS can also have an impact on overall hospital costs. Multiple studies on clinical pathways with the outcome of interest of decreasing LOS have occurred in the setting of orthopedic surgery. In England, Ireland, and the Netherlands, clinical pathways were implemented for patients with hip fracture (McNamara et al., 2014; Niemeijer et al., 2013; Yousri, Khan, Chakrabarti, Fernandes, & Wahab, 2011). The studies in England and Ireland were based on the British Orthopedic Association's evidence-based guidelines (McNamara, 2014; Yousri et al., 2011). All three studies had a reduction in LOS, but only Niemeijer et al. (2013) found statistical significance (31% LOS reduction, p=.000), while Yousri et al. (2011) had significantly improved mortality (9.3%, p=.002).

Two additional cohort studies, one at a Veterans Affairs hospital in the United States and the other at a university medical center in Italy, and one systematic review focused on the implementation of clinical pathways for patients undergoing joint replacement of the hip and/or knee (Gayed, Black, Daggy & Munshi, 2013; Improta et al., 2015; Van Herck et al., 2010). For the cohort studies, LOS was significantly reduced (Gayed et al., 2013; Improta et al., 2015). The systematic review evaluated 34 publications and similarly found that LOS was significantly reduced in all 21 studies that included this specific outcome measure, aside from one study that found no difference (Van Herck et al., 2010).

Outside of orthopedics, an academic health center in North Carolina sought to decrease LOS and readmissions in post-liver transplant patients by enhancing communication and implementing a multidisciplinary clinical pathway (Toledo et al., 2013). Median LOS decreased

significantly ($p = < .05$) with no change in readmission rates or mortality (Toledo et al., 2013). The reduction in LOS brought the center's outcomes in accordance with the industry benchmark (Toledo et al., 2013).

Two key historic cohort studies examined the use of clinical pathways in the pediatric general surgery population – inguinal hernia repair (Kelly et al., 2000) and acute appendicitis (Warner et al., 1998). Costs were reduced significantly post-pathway implementation (Kelly et al., 2000; Warner et al., 1998). Kelly et al. (2000) found no significant differences in infection rates, readmissions, or emergency department visits, demonstrating that similar quality of care could be provided at a lower cost. Use of a clinical pathway by Warner et al. (1998) also significantly reduced LOS for both non-perforated (p=.014) and perforated appendicitis (p=.0001). As asserted by the systematic review with meta-analysis by Rotter and colleagues (2008), the evidence reviewed shows that LOS and costs are improved when clinical pathways are utilized for invasive, or surgical procedures.

Clinical pathways in cardiac surgery. The concept of standardizing care delivery for the post-operative cardiac patient emerged at the same time as other surgical services in the mid-1990s, with pediatric cardiology at the forefront of this movement (Allen & Davis, 1995). However, the literature available to review regarding the use of clinical pathways in adult and pediatric cardiovascular surgery is limited. The current evidence review emphasizes pathways used for the Fontan procedure as this is the focus of the DNP project.

Adults and pediatrics. In adult cardiac surgery, a recent study evaluated a high reliability organization's approach through goal-directed, evidence-based protocols to reduce LOS after cardiac surgery in 665 adult patients (Miller et al., 2014). Study outcomes included tracking adherence to the pathway via milestone scores, team compliance as demonstrated by the

proportion of critical behaviors observed, and CVICU and hospital LOS in number of days (Miller et al., 2014). While increased team compliance was positively associated with decreased ICU and hospital LOS (p = .08, p = .008), a statistically significant negative association was found with increased milestone scores and LOS (p <.001, p = .05; Miller et al., 2014).

As for pediatrics, in 1998 a pediatric academic tertiary institution developed clinical pathways for multiple cardiac lesions to promote effective and efficient care (Uzark et al.). In this prospective cohort study of 69 pre- and 173 post-pathway (78 atrial septal defects, 76 ventricular septal defects, 30 patent ductus arteriosus, 41 tetralogy of Fallot, and 17 arterial switch operations), hospital and ICU LOS were significantly reduced for atrial septal defects (p=.02, p<.01) and ventricular septal defects (p=.03, p<.05; Uzark et al., 1998). Costs were also significantly reduced for all lesions except the arterial switch operation (Uzark et al, 1998).

Both of these studies showed a reduction in LOS by standardizing care for cardiac surgery, but for different reasons (Miller et al., 2014; Uzark et al., 1998). The Uzark et al. (1998) study decreased LOS and costs because of the use of a clinical pathway. The Miller et al. (2014) study findings were due to improved teamwork and communication rather than greater adherence to the pathway.

Fontan procedure. While little has been published regarding use of clinical pathways in pediatric cardiac surgery since the Uzark et al. study in 1998, there have been three studies regarding the implementation of a standardized plan of care for the management of the post-operative Fontan patient. The three institutions with published post-operative clinical protocols have lower LOS than the national average (Cava et al., 2005; Pike et al., 2015; Sunstrom et al., 2015). The Wisconsin protocol reduced mean hospital stay from 18 to 9 days (p = .001; Cava et al, 2005). The PORTLAND protocol improved LOS from 13 to 8 days (p = .001; Sunstrom et

al., 2014). Pike et al. (2015) utilized a modified Wisconsin Fontan protocol, reducing median hospital LOS from 8 to 6 days (p = .005).

In addition to a decrease in LOS, other key initial outcomes were improved through the use of a clinical pathway for the Fontan patient. Overall duration of chest tube days, amount of pleural drainage, and incidence of persistent pleural drainage decreased significantly (Pike et al., 2015; Sunstrom et al., 2015). While not statistically significant, the modified Wisconsin protocol demonstrated a clinically relevant 50% reduction in readmission rates (Pike et al., 2015). Estimated cost savings by using the Wisconsin pathway were 22% for overall costs and 29% for readmission costs (Pike et al., 2015). These protocols were well tolerated with no serious complications reported (Cava et al., 2005; Pike et al., 2015; Sunstrom et al., 2015). Further and more aggressive treatments historically used for continued pleural drainage were also avoided (Cava et al., 2005; Pike et al., 2015; Sunstrom et al., 2015). Moreover, the Pike et al. (2015) study was driven by advanced practice nurses (APNs).

Theory

The recent trend in healthcare has been to use the middle-range theory of Lean Six Sigma (LSS) – a synthesis of Lean and Six Sigma – to drive EBP and QI projects as they are complementary improvement methodologies (Nave, 2002; Young et al., 2004). The two major concepts of LSS are waste and variation. Waste is defined as anything not necessary to produce the product or service (Womack & Jones, 1990). Variation is what the customer sees and feels when they receive the product, or how far a given process deviates from perfection (General Electric, n.d.). Reducing waste improves efficiency, while reducing variation improves effectiveness (Lighter, 2014). The key concepts of LSS directly align with the key aims of the EBP project: reducing waste in order to decrease LOS, and reducing variation among healthcare

providers in order to standardize care for the Fontan patient. Additionally, LSS's structured method for process improvement through the steps of define, measure, analyze, improve and control (DMAIC) can be readily applied to the EBP project (Nave, 2002; see Appendix E for Theoretical and Conceptual Application of LSS to EBP Project). Operationally, waste or flow time was measured by tracking overall LOS for the Fontan patient. Variation was measured by tracking adherence to each component of the clinical pathway. Moreover, the literature supports the use of LSS to guide the implementation of clinical pathways as all four of the studies within the sub-topic of "Improving efficiency via standardization" (Beck & Gosik, 2015; Cima et al., 2011; El-Eid et al., 2015; Niemeijer et al., 2010), and six of the nine studies reviewed within the sub-topic of "Improving LOS and costs via clinical pathways" (Gayed et al., 2013; Improta et al., 2015; McNamara et al., 2014.; Niemeijer et al., 2013; Toledo et al., 2013; Yousri et al., 2011) had a theoretical basis of Lean or LSS.

Methods

The institutional review board (IRB) of the project was the study hospital, as was the site of the project. As the project is an EBQI initiative, it was categorized as non-human subjects research (see Appendix F for IRB Approval Letter). Individual informed consent was not obtained as it was not feasible nor appropriate for this project (O'Mathuna, 2015).

Ethical Considerations

The retrospective nature of the project minimized the harm or risk to the patient; however, there are other ethical aspects of the project that required consideration. The student investigator had no conflicts of interest. The ethical principle of justice was observed by the recruitment of subjects, as all undergoing the Fontan procedure were included, and by maintaining the privacy of the patient (Terry, 2018). The student investigator maintained

confidentiality of patient information gathered during the course of the project by removing the subject's names and by storing collected data on the hospital secured network with a password protected folder and access was only given to the study team members (Terry, 2018).

Funding

The estimated cost of the project was $69,224 (see Appendix G for Project Cost Table). Financial support for the cost of the project was provided by the Heart Center at study institution given this was a practice change by a current employee with support from departmental and hospital leadership. No other financial assistance was utilized.

Setting and Participants

The EBP project was implemented at an academic tertiary pediatric institution in the Midwest (see Appendix H for Logic Model). Study participants included all patients who underwent the extracardiac Fontan surgery and were discharged to home. Fontan revisions, additional surgeries – specifically permanent pacemaker placement, patients who were placed on palliative care, listed for transplant post-Fontan surgery, or who expired prior to initial hospital discharge were excluded. A convenience sample of two cohorts of consecutive immediate post-operative Fontan patients from 2014-2015, pre-pathway implementation, and 2017-2018, post-pathway implementation was utilized. Anticipated sample size was 80 subjects (40 pre- and 40 post-).

EBP Intervention

The post-operative Fontan clinical pathway was developed and approved for implementation by the Heart Center leadership in 2016. It was then trialed via PDSA cycles in 2016, fully implemented in 2017 and sustained in 2018 (see Appendix I for Project Timeline Flow Chart). As the project was a retrospective chart review, participants were not recruited.

The student investigator collected data on all patients undergoing extracardiac Fontan repair. The time period of the study included data that was collected on Fontan patients from 2014-2015 for pre-pathway and 2017-2018 for post-pathway.

Components of the clinical pathway for the post-operative management of the Fontan patient include 1) supplemental oxygen via nasal cannula until pleural drainage tubes are removed, 2) fluid restriction of 80% daily maintenance that is liberalized prior to discharge, a free water restriction, and a low-fat diet followed for two weeks after chest tube removal or six weeks if chylous drainage, 3) aggressive and standardized diuretic therapy while inpatient and a recommended minimal diuretic regimen for discharge, and 4) central access via placement of a peripherally inserted central catheter (PICC) in IR 24-72 hours post-operatively for patient ease and comfort related to need for frequent lab draws (see Appendix J for Intervention Flow Diagram).

Implementation in 2017 involved education of providers and nursing staff regarding the components of the pathway and tracking adherence. Educational sessions were held by the student investigator with the pediatric intensive care unit (PICU) and inpatient unit nurses at quarterly unit educational updates. A copy of the clinical pathway and a bedside checklist was provided to each unit. The student investigator sent electronic communication to the inpatient providers in the PICU and on the floor as each patient underwent the Fontan with the clinical pathway interventions and a bedside checklist included in the email as a reminder and resource (see Appendix K Educational Materials). An order set within the electronic medical record (EMR) was also developed to aid in the ordering of each component in the pathway. Inpatient APNs championed the implementation of the clinical pathway by encouraging its use and tracking adherence.

Change Process, EBP Model

Social science theories related to behavioral change have commonly been used as change models in healthcare, and have specifically been used to standardize care processes, and thus fits with the EBP project of standardizing care through the implementation of a clinical pathway for the post-operative management of the Fontan patient (Mork et al., 2017; Small et al., 2016). Kotter's Change Model incorporates eight steps for implementing change: 1) create urgency, 2) form a guiding coalition, 3) create a vision for change, 4) communicate the vision, 5) empower others, 6) create quick wins, 7) build on the change, and 8) institutionalize the change (Kotter, 2012). The Iowa model was used as the EBP model as its key stages fit with the current trajectory of the project (Gawlinkski & Rutledge, p. 296, Table 5). The key trigger for the project was the institution's LOS being higher than the national benchmark for post-operative Fontans, making it a priority for the Heart Center. A small team was therefore formed to gather and review the literature to determine if there was enough evidential support to develop a clinical pathway. The pathway was then piloted in 2016 and found to be feasible, with full implementation and continual monitoring of outcomes in 2017-2018.

The clinical pathway was implemented in 2017 with 2018 serving to solidify it as a sustainable practice change. The clinical pathway was slightly modified in 2018 to improve its ease of application and process of implementation. The updated pathway and nursing bedside checklist were then provided to the intensive care and inpatient units as well as made available for reference on the hospital's intranet. The inpatient APNs continued to be the champions of this change, ensuring the pathway was adhered to and any issues addressed in a consistent and timely fashion.

Study Design

The study design was a quasi-experimental single site retrospective chart review of a cohort of consecutive immediate post-operative Fontan patients. A cohort of Fontan patients from prior to the implementation of the standardized evidenced-based clinical pathway in 2014-2015 was compared to a cohort of Fontan patients from 2017-2018 after the implementation of the intervention. The study has a retrospective control group and it is quantitative in nature.

Validity

The quasi-experimental retrospective cohort study design is a threat to the internal validity of the EBP project. This design makes it difficult to establish a causal relationship between the intervention of implementing a clinical pathway for the post-operative management of the Fontan patient and the measured outcomes given the lack of control of other variables. By comparing key demographic data regarding the two cohorts to detect any differences and tracking adherence to each component of the pathway, the internal validity of the project was strengthened. With a single study center some components of the clinical pathway are site specific, and with a relatively small sample size, the generalizability or external validity of the findings are limited. By using the three published Fontan clinical pathways as a guide for the evidence-based intervention, having a clearly defined patient population, and utilizing similar outcome measures as other studies, external validity is enhanced.

Outcome Measures

Data collected on Fontan patients from 2014-2015 pre-pathway and 2017-2018 post-pathway was compared to assess any differences in outcomes as a result of utilizing evidence-based and standardized care. Primary outcome measures include the percent adherence to the pathway and LOS in number of days. Secondary outcomes measures include development of

chylous effusions, PICC line infections and/or thrombi, and number of patients readmitted within the first 30 days of discharge for treatment of reoccurrence of pleural effusions (morbidity), as well as number of lab draws per patient and an overall cost analysis. In addition to collecting data with regards to the primary and secondary outcomes, the following patient demographic information was also obtained: age, fenestration, and use of Coumadin for anticoagulation therapy.

Measurement Instruments

Data was collected via a retrospective chart review of the EMR. LOS, morbidity and mortality rates, readmissions and costs are commonly published outcomes measures for studies on the use of clinical pathways for invasive procedures and therefore data obtained from the EMR can be considered a reliable and valid method of measurement. Percent adherence to a clinical pathway is not reported as often in the literature and therefore has limitations with regards to its reliability and validity as a measure.

Quality of Data

As the anticipated sample size of the EBP project was 80, a power analysis was calculated based on medium effect d = 0.5, power of 0.8, and alpha of 0.5. Outcome measures selected to compare pre- and post-clinical pathway care have been frequently used in the literature for similar studies. The data collected was directly compared to current published data regarding post-operative clinical pathways in general (LOS), and use of a pathway for the Fontan patient specifically (LOS, readmissions; Cava et al., 2005; Pike et al., 2015; Sunstrom et al., 2015). LOS data was compared to the national benchmark data for the Fontan patient population (Dean et al., 2011; Jacobs et al., 2016). Potential threats to the quality of the project data include possible bias of the student investigator being responsible for the collection of data as well as

missing data or errors in collection related to the nature of a retrospective chart review. To counter these threats to the quality of the data, all data was rigorously collected and placed in a pre-formatted Excel spreadsheet by only the student investigator, providing for consistency in its collection, and key data collected related to demographics and outcomes was independently verified by another small group member co-investigator (Appendix L Data Collection Template).

Analysis Plan

The Statistical Package for the Social Sciences (SPPS) was used to perform the data analysis for the EBP project (Appendix M Statistical Analysis Table Template). Descriptive statistics were used for both primary and secondary outcomes. A t-test was used to compare the groups on age and Wilcoxon Rank Sum tests were used for LOS and total lab draws as those variables were fairly skewed. Chi-square and Fisher's Exact tests were used for comparing the groups on the categorical variables of readmissions, fenestration, use of Coumadin, presence of chylous effusion, PICC line, and PICC line complications of thrombus and/or infection. Percent adherence was reported descriptively as it is only a post-pathway measure. The cost analysis is an estimation based on benchmark national data and the projected cost of the EBP project and therefore is not specific to each patient's Fontan hospitalization encounter at the institution.

Results

Settings & Participants

The EBP project was implemented at a Midwestern academic tertiary pediatric institution from 2014-2018. Participants were all patients who underwent initial Fontan surgical palliation and were discharged to home. Patients were excluded if they were undergoing a Fontan revision, required an additional unplanned surgical intervention – specifically placement of a permanent pacemaker, were placed on palliative care, listed for transplant, or expired prior to initial hospital

discharge. After exclusions, the total sample size for the project was 67 participants, with 37 pre-pathway and 30 post-pathway. As for patient demographics, there was a statistically significant difference for age with mean age of 5.84 vs 3.73 years old ($p < .001$) of pre- versus post-pathway. The number of patients who had a fenestrated Fontan was similar (29.7% pre- versus 23.3% post-pathway; $p = .557$), but those who were started on Coumadin for anticoagulation were statistically different with 32.4% pre- and 3.3% post- ($p = .003$) due to changes in surgeons and their anticoagulation preferences of Coumadin versus aspirin for fenestrated Fontans.

Intervention Course, Actual

The clinical pathway was developed from 2015-2016. Components of the clinical pathway were 1) a minimum of 0.5 L of supplemental oxygen provided via nasal cannula until pleural drainage tubes are removed, 2) fluid restriction of 80% daily maintenance with liberalization to 100% prior to discharge, a free water restriction, and a low-fat diet (total number of grams of fat per day limited based on patient weight as calculated by a registered dietician) for two weeks after chest tube removal or six weeks if chylous drainage, 3) aggressive and standardized diuretic therapy while inpatient and a recommended minimal diuretic regimen for discharge, and 4) central access via placement of a PICC line in IR 24-72 hours post-operatively for patient ease and comfort related to need for frequent lab draws. Each of the four components of the pathway were trialed via PDSA cycles on three patients each during 2016. The post-operative clinical pathway for the Fontan patient was fully implemented in 2017 and sustained in 2018. Pre-pathway data was collected on all Fontan patients from 2014 and 2015 (44 patients) and post-pathway data was collected on the all Fontan patients from 2017 and 2018 (36 patients). Exclusion criteria was applied after all data was obtained.

Outcome Data

Primary outcomes for the project were LOS and percent adherence to the clinical pathway. The pathway had nearly 100% adherence as calculated by whether each patient followed each component of the pathway. LOS was significantly shorter post-pathway with median LOS of 9 days versus pre-pathway of 12 days ($p = .007$; see Appendix M for Statistical Results Tables & Graphs).

Secondary outcomes included incidence of chylous effusions, readmissions for pleural effusions, PICC line associated thrombi and/or infections, and number of lab draws. Incidence of chylous effusions (3, 8.1% pre- vs. 2, 6.7%; $p = 1.00$), readmissions (4, 10.8% pre- vs. 5, 16.7%; $p = .500$) and number of lab draws were similar (28 pre- and post-; $p = .837$). The number of Fontan patients who had a PICC line placed was significantly higher (13, 35.1% vs 22, 73.3%; $p = .002$) as this was one of the components of the pathway. Unfortunately, line-associated complications were also greater ($p = .006$).

No data was missing. Two patients post-pathway were ready for discharge from a post-operative standpoint, but had longer stays related to the need for further social work evaluation and inpatient rehabilitation. LOS was therefore calculated from when they met discharge criteria post-surgery. The number of lab draws for hospitalization and any complications past that LOS for these two patients were not included in the outcomes data calculations.

Discussion

Both of the primary outcomes of the project were successfully met. Previously care varied widely from attending provider to provider, particularly with regards to management of nutrition, fluids and diuretics in the post-operative Fontan patient. After implementing the post-operative clinical pathway, care was successfully standardized. Additionally, there was a

statistically significant decrease in LOS without an increase in morbidity as evidenced by similar readmission rates and incidence of chylous effusions.

Study Strengths

The EBP intervention of implementation a post-operative clinical pathway for a specific subset of pediatric cardiac surgery patients was well supported by the organizational culture of the study institution, cardiology department, and provider and nursing staff in the intensive care unit and the inpatient cardiology ward. The project hospital is a Lean institution and encourages EBQI projects by providing training and support to its employees. The Heart Center is also one of the leading pediatric cardiac surgery programs and is always striving to meet or exceed the national benchmarks with regards to overall surgical outcomes. The providers and nursing staff also recognized that the Fontan patient population is uniquely challenging and could benefit from a standardized approach in care.

As anticipated, performing PDSA cycles prior to fully implementing the clinical pathway allowed for the identification and ability to address potential barriers as well as promoted buy-in for the project from key stakeholders. Adherence during PDSA cycles was 100% for each component of the pathway except for fluid restriction, with only one out of three patients adhering to the 80% fluid restriction. More education was therefore provided to the physicians, APNs, and nurses regarding goal fluid status for each patient. It was also recommended that suspension of the fluid restriction and/or restarting intravenous fluids only be made if there were clinical signs or symptoms of dehydration and with the approval of the attending or on-call cardiologist. Once fully implemented, adherence to the clinical pathway, including the fluid restriction component, was nearly 100%, demonstrating that the project was a success with regards to standardizing the care provided to this patient population.

Results Compared to Evidence in Literature

The literature demonstrated that clinical pathways are effective as they can reduce LOS and decrease costs without compromising quality of care as assessed by readmissions, morbidity and mortality. This project had similar findings as LOS was reduced by three days with associated cost savings, and no increase in readmissions or the incidence of chylous effusions. For the 2014-2018 reporting period to STS, the project hospital had 0% mortality in the Fontan patient population (O'Brien, 2019).

When the project was initially started, the national benchmark for LOS for post-operative Fontans' was 11 days (Dean et al., 2011) whereas the study institution's LOS was 14 days for this patient population without applying the exclusion criteria used for the project. From 2011 to 2014, STS tracked 4161 Fontan surgical outcomes and found the aggregate average LOS to be 13.4 with a median of 14 days (Jacobs et al., 2016). The implementation of the post-operative clinical pathway at the study institution resulted in a decrease in median LOS from 12 days to 9 days, with exclusion criteria applied, which exceeds the current national benchmark. This is similar to the other three pediatric institutions with published post-operative clinical protocols who also have lower LOS than the national benchmark (Cava et al., 2005; Pike et al., 2015; Sunstrom et al., 2015). With the Wisconsin protocol, mean hospital stay was reduced from 18 to 9 days (p = .001; Cava et al, 2005). The PORTLAND protocol improved LOS from 13 to 8 days (p = .001; Sunstrom et al., 2014). Pike et al. (2015) utilized a modified Wisconsin Fontan protocol, reducing median hospital LOS from 8 to 6 days (p = .005).

Limitations

Internal Validity Effects

Confounding factors, bias, imprecision in EBP intervention processes and the collection of data can affect the internal validity of study outcomes. A possible confounding factor for this project includes a change in the surgeons who were operating during the study period and subsequently a change in practice due to surgeon preference of using aspirin versus Coumadin for anticoagulation on fenestrated Fontans. Achieving appropriate Coumadin dosing for adequate anticoagulation can increase LOS, therefore a decrease in the use of Coumadin post-pathway could also be contributing to the decrease in LOS. The exclusion criteria used could introduce bias into the study, however it was consistently applied to pre- and post-pathway patients. The tracking of adherence to each component of the EBP intervention introduces bias as well as this is a more subjective measure. Only the student investigator tracked adherence, therefore this limits the variability in determining whether the pathway was followed or not.

External Validity Effects

Factors such as participant and setting characteristics can affect generalizability. Being a single site study and focusing on a very specific patient population limits the external validity of the findings of the project. However, all patients undergoing the Fontan procedure were included, regardless of underlying cardiac anatomy or comorbidities. Exclusion criteria for participants was also clearly defined and applied. There was a significant difference between the pre- and post-pathway cohorts with regards to age. Napolene and colleagues (2010), however, found that age at the time of Fontan surgery is not a factor in post-operative outcomes. The study institution is considered a high-volume center for pediatric cardiac surgeries, including those performed for the single ventricle patient (O'Brien, 2019). Both of these factors enhance the transferability of the intervention in achieving the intended results at other similarly sized pediatric hospitals with robust cardiac surgery programs.

Sustainability of Effects

After the implementation of a practice change, there is the potential for observed gains to weaken over time, therefore it is important to have a plan in place for maintaining the improvement. The success of the clinical pathway in standardizing care and decreasing LOS in a historically complex patient population has contributed to its embracement as a change in practice by the physicians, APNs, and nurses at the study institution. Only 20 Fontan surgeries occur a year out of a total of approximately 1400 cardiac surgeries at the study institution (O'Brien, 2019). With the rotating schedule of physicians who care for the patients in the ICU and cardiology ward, each provider cares for a relatively low number of post-operative Fontan patients in a year. The clinical pathway is therefore appreciated by providers as it outlines a specific standard of care that can be followed or adjusted as needed. To sustain the project, the Heart Center APNs will continue to educate nursing, residents, and providers regarding the components of the clinical pathway and encourage its use.

Efforts to Minimize Study Limitations

In order to minimize the effect of a single site study, the post-operative Fontan clinical pathway was developed using components of the published clinical pathways or protocols used at other pediatric institutions (Cava et al., 2005; Pike et al., 2015; Sunstrom et al., 2015) that were based on evidence and physiology (Gupta et al., 2004). Key demographic data and other process measures between the pre- and post-pathway cohorts were obtained in order to show similarities between the groups, or that the differences between groups likely did not contribute to a change in LOS. Obtaining this data diminishes the inherent limitation of a retrospective study of drawing inferences between the intervention and outcomes due to lack of control of variables.

Interpretation

Expected & Actual Outcomes

A decrease in LOS and standardization of care were the expected and actual outcomes of implementing the Fontan clinical pathway. A secondary aim was a reduction in readmissions, but this was not realized. Readmissions for re-accumulation of pleural effusions were similar between the pre- and post-cohorts. The expected outcome of obtaining a PICC line in the post-operative Fontan patient was for patient and family satisfaction related to need for frequent blood draws and stable access for intravenous medications. Historically, the use of PICC lines in Fontans has been a benign intervention, with only one out of 47 patients (2%) over a four-year period (2014-2017) having a line-associated complication of a thrombus. Unfortunately, in 2018 there was a significant increase in thombi and infections of PICC lines in the Fontan patient population and across the study institution as a whole, necessitating this component of the pathway be suspended as inclusion as a component in the pathway reassessed.

Intervention Effectiveness

The Fontan clinical pathway standardized care and during the post-pathway period, LOS was significantly reduced. The study was appropriated powered. While there are limitations, which have been discussed, a similar clinical pathway could be implemented for post-operative Fontans at other pediatric hospitals with cardiac surgery programs. Institutions that are focused on improving quality and outcomes, and have support from a leadership and system standpoint to do so, will be more successful in implementing this change in practice. In the U.S. and Canada alone, over 1000 Fontan procedures are performed in a year (Jacobs et al., 2016). If other pediatric institutions used evidence-based standardized pathways for post-operative Fontans, overall LOS as tracked by STS, incidence of complications related to prolonged hospitalization, and associated-costs could be reduced.

Intervention Revision & Opportunities

Even though the intervention was successful in achieving the primary outcomes of decreasing LOS and standardizing care, there are several revisions that should be considered. The use of PICC lines was initially proposed and included as a component of the clinical pathway as a way to increase satisfaction and diminish harm and stress to Fontan patients and their families. Given the decrease of LOS and the increase in line-associated complications, the component of obtaining central venous access post-operatively did not need to be included in the pathway and could have continued to be considered on a case-by-case basis. Additionally, given that most Fontans post-pathway were discharged home on multiple diuretics in order to decrease incidence of pleural effusions, a basic guideline on how to manage outpatient weaning of the diuretics would have been helpful for providers. This could have possibly decreased the readmission rates for re-accumulation of pleural effusions post-pathway. Providing more education to parents/families pre-operatively regarding the dietary and fluid restrictions, as well as guidance on how to get the toddler/pre-school aged child to take multiple diuretics/medications at home, also could have led to fewer readmissions related to effusions due to lack of medication compliance.

Expected & Actual Impact to Health System, Costs

One of the secondary expected outcomes of the use of a clinical pathway for post-operative Fontan patients was an overall savings in cost to the healthcare institution and system. A cost analysis was performed based on the national reported average daily cost of a post-operative Fontan patient (Dean et al., 2011) as compared to the overall cost of implementing the post-operative clinical pathway. With a decrease in LOS of three days, a cost savings of $10,803 per patient for 30 patients post-pathway equals a savings of over $300,000 for the study

institution during the post-pathway period. With an average of 20 patients per year, the study institution could continue to see savings of over $200,000 a year related to the reduction in LOS for post-operative Fontans. The cost of implementing the pathway was estimated at just under $70,000 (Appendix G). The Fontan clinical pathway financially benefited the institution as the total costs saved exceeded those spent to implement this practice change. The cost to continue to use the pathway is minimal, especially since the cost of obtaining a PICC line in IR and the cost of the DNP student's time were the bulk of the expense of implementing the pathway – both of which will not factor into the cost of its continued use.

Conclusion

Clinical pathways should be utilized for the post-operative management of certain patient populations, including the Fontan patient, as a means to standardize care and improve initial outcomes. The aim of the project was to standardize care for Fontan patient population and ultimately reduce LOS to meet or exceed the national benchmark, and resulting in quantitative benefits to the institution and qualitative benefits to the patient and family. There is a need for multi-center prospective randomized controlled studies to provide a higher level of evidential support for the use of clinical pathways. For the three published Fontan clinical pathways, a meta-analysis of findings could also be undertaken to strengthen the scientific support for this intervention. Published guidelines on how to wean diuretics as an outpatient after hospital discharge in order to prevent re-accumulation of pleural effusions and associated readmissions are non-existent for the Fontan patient. The weaning of post-discharge diuretics is therefore a planned next step to investigate in order to develop recommendations.

Findings from the EBP project were presented at the Heart Center QI meeting, the study institution's annual EBQI poster session in October 2017, 21st Annual Update on Pediatric &

Congenital Cardiovascular Disease hosted by Children's Hospital of Philadelphia in February 2018, and the 26th Evidence-Based Practice Conference in April 2019. The poster was also submitted to Share@Children's Mercy, a website for scholarly health, academic and research exchange, and findings posted to the SharePoint through the Pediatric Acute Care Cardiology Collaborative. A manuscript was also submitted to *Clinical Nurse Specialist* for potential journal publication. This EBP project will add to the limited body of evidence available concerning the implementation of a clinical pathway for the post-operative Fontan patient, and it is likely the first study on this topic with a theoretical basis.

References

Allen, H. D., & Davis, J. T. (1995). Standardizing care delivery for infants and children with common congenital cardiac lesions. *Current Opinion in Pediatrics, 7*(5), 601-605.

Beck, M. J., & Gosik, K. (2015). Redesigning an inpatient pediatric service using Lean to improve throughput efficiency. *Journal of Hospital Medicine, 10*(4), 220-227. doi:10.1002/jhm.2300

Cava, J. R., Bevandic, S. M., Steltzer, M. M., & Tweddell, J. S. (2005). A medical strategy to reduce persistent chest tube drainage after the Fontan operation. *American Journal of Cardiology, 96,* 130-133. doi:10.1016/j.amjcard.2005.03.034

Children's Mercy Kansas City. (2015). *2015 Equity and Diversity Report*. Retrieved from https://www.childrensmercy.org/library/uploadedFiles/childrensmercyorg/Utility_Pages/Sidebars/2015EquityDiversityAnnRpt.pdf

Cima, R. R., Brown, M. J., Hebl, J. R., Moore, R., Rogers, J. C., Kollengode, A., . . . Deschamps, C. (2011). Use of Lean and Six Sigma methodology to improve operating room efficiency in a high-volume tertiary-care academic medical center. *Journal of American College of Surgeons, 213*(1), 83-92. doi:10.1016/j.jamcollsurg.2011.02.009

Dean, P. N., Hillman, D. G., McHugh, K. E., & Gutgesell, H. P. (2011). Inpatient costs and charges for surgical treatment of hypoplastic left heart syndrome. *Pediatrics, 128*(5), e1181-e1186. doi:10.1542/peds.2010-3742

d'Udekem, Y., Iyengar, A. J., Galati, J. C., Forsdick, V., Weintraub, R. G., Wheaton, G. R., . . . Winlaw, D. S. (2014). Redefining expectations of long-term survival after the Fontan procedure: Twenty-five years of follow-up from entire population of Australia and New Zealand. *Circulation, 130*(11 Suppl 1), S32-S38. doi:10.1161/CIRCULATIONAHA.113.007764

El-Eid, G. R., Kaddoum, R., Tamim, H., & Hitti, E. A. (2015). Improving hospital discharge time: A successful implementation of Six Sigma methodology. *Medicine, 94*(12), e633. doi:10.1097/MD.0000000000000633

Gawlinksi, A. & Rutledge, D. (2008). Selecting a model for evidence-based practice changes: A practical approach. *AACN Advanced Critical Care, 19*(3), 291-300.

Gayed, B., Black, S., Daggy, J., & Munshi, I. A. (2013). Redesigning a joint replacement program using Lean Six Sigma in a Veterans Affairs hospital. *Journal of American Medical Association, 148*(11), 1050-1056. doi:10.1001/jamasurg.2013.3598

General Electric. (n.d.). *What is Six Sigma? The roadmap to customer impact.* Retrieved from https://www.ge.com/sixsigma/SixSigma.pdf.

Gupta, A., Daggett, C., Behera, S., Ferraro, M., Wells, W., & Starnes, V. (2004). Risk factors for persistent pleural effusions after the extracardiac Fontan procedure. *The Journal of Thoracic and Cardiovascular Surgery, 127*, 1664-1669. doi:10.1016/j.jtcvs.2003.09.011

Improta, G., Balato, G., Romano, M., Carpentieri, F., Bifulco, P., Russo, A., . . . Cesarelli, M. (2015). Lean Six Sigma: A new approach to the management of patients undergoing prosthetic hip replacement surgery. *Journal of Evaluation in Clinical Practice, 21*(4), 662-672. doi:10.1111/jep.12361

Jacobs, J. P., O'Brien, S. M., Pasquali, S. K., Jacobs, M. L., Lacour-Gayet, F. G., Tchervenkov, C. I., . . . Mavroudis, C. (2011). Variation in outcomes for benchmark operations: An analysis of the Society of Thoracic Surgeons Congenital Heart Surgery database. *The Annals of Thoracic Surgery, 92*, 2184-2192. doi:10.1016/j.athoracsur.2011.06.008

Jacobs, J. P., Shahaian, D. M., Prager, R. L., Edwards, F. H., Mcdonald, D., . . . Bavaria, J. E. The Society of Thoracic Surgeons National Database 2016 Annual Report. (2016). *The Society of Thoracic Surgeons, 102*, 1790-1797.

Joint Commission International. (2016). Clinical practice guidelines: Closing the gap between theory and practice. Retrieved from https://www.elsevier.com/__data/assets/pdf_file/0007/190177/JCI-Whitepaper_cpgs-closing-the-gap.pdf

Kelly Jr, R. E., Wenger, A., Horton Jr, C., Nuss, D., Croitoru, D. P., & Pestian, J. P. (2000). The effects of a pediatric unilateral inguinal hernia clinical pathway on quality and cost. *Journal of Pediatric Surgery, 35*(7), 1045-1048. doi:10.1053/js.2000.7768

Kotter, J. P. (2012). *Leading change.* Boston, MA: Harvard Business Review Press.

Lemmens, L., van Zelm, R., Vanhaecht, K., & Kerkkamp, H. (2008). Systematic review: Indicators to evaluate effectiveness of clinical pathways for gastrointestinal surgery. *Journal of Evaluation in Clinical Practice, 14*, 880-887. doi:10.1111/j.1365-2753.2008.01079.x

Leotsakos, A., Zheng, H., Croteau, R., Loeb, J. M., Sherman, H., Hoffman, C., . . . Munier, B. (2014). Standardization in patient safety: The WHO High 5S project. *International Journal for Quality in Health Care, 26*(2), 109-116. doi:10.1093/intqhc/mzu010

Lighter, D. E. (2014). The application of Lean Six Sigma to provide high-quality, reliable pediatric care. *International Journal of Pediatrics and Adolescent Medicine, 1*, 8-10. doi:10.1016/j.ijpam.2014.09.009

Mannion, R. & Exworthy, M. (2017). (Re) Making the procrustean bed? Standardization and customization as competing logics in healthcare. *International Journal of Health Policy and Management, 6*(6), 301-304. doi:10.15171/ijhpm.2017.35

May, L. E. (2012). *Pediatric heart surgery: A ready reference for professionals* (5th ed.). Milwaukee, WI: maxiSHARE.

McNamara, R., Butler, A., Baker, C., Mullen, J., Lenehan, B., Grimes, S., . . . Condon, F. (2014). Use of Lean principals to improve flow of patients with fractured neck of femur – the HOPE study. *Irish Medical Journal, 107*(3), 70-72. Retrieved from https://www.imo.ie/news-media/publications/March-2014-IMJ-hr.pdf

Melnyk, B. M., & Fineout-Overholt, E. (2015). *Evidence-based practice in nursing and healthcare: A guide to best practice* (3rd ed.). Philadelphia: Wolters Kluwer. The levels of evidence adapted by Lindholm, L. (2017) from Melnyk & Fineout-Overholt, Rating System for the Hierarchy for Intervention/Treatment Questions (p. 11).

Miller, A., Wagner, C. E., Song, Y., Burns, K., Ahmad, R., Parmley, C. E., & Weinger, M. B. (2014). Implementing goal-directed protocols reduces length of stay after cardiac surgery. *Journal of Cardiothoracic and Vascular Anesthesia, 28*(3), 441-447. doi.org/10.1053/j.jvca.2014.01.010

Mork, A., Krupp, A., Hankwitz, J., Malec, A. (2017). Using Kotter's Change Framework to implement and sustain multiple complementary ICU initiatives. *Journal of Nursing Care Quality, 00*(00), 1-8. doi:10.1097/NCQ.0000000000000263

Napolene, C. P., Oppido, G., Angeli, E., Giardini, A., Resciniti, E., & Gargiulo, G. (2010). Results of the modified Fontan procedure are not related to age at operative. *European Journal of Cardio-Thoracic Surgery, 37,* 645-650. doi:10.1016/j.ejcts.2009.09.003

Nave, D. (2002). How to compare Six Sigma, Lean and the Theory of Constraints. *Quality Progress, 35*(3), 73-78.

Niemeijer, G. C., Flikweert, E., Trip, A., Does, R. J. M. M., Ahaus, K. T. B., Boot, A. F., & Wendt, K. W. (2013). The usefulness of Lean Six Sigma to the development of a clinical pathway for hip fractures. *Journal of Evaluation in Clinical Practice, 19*(5), 909-914. doi:10.1111/j.1365-2753.2012.01875.x

Niemeijer, G. C., Trip, A., Ahaus, K. T. B., Does, R. J. M. M., & Wendt, K. W. (2010). Quality in trauma care: Improving the discharge procedure of patients by means of Lean Six Sigma. *The Journal of TRAUMA Injury, Infection, and Critical Care, 69*(3), 614-619. doi:10.1097/TA.0b013e3181e70f90

O'Brien, James. (2019). Surgical outcomes and dashboards: 2014-2018. Results From the Society of Thoracic Surgeons Congenital Heart Surgery Database [PowerPoint presentation].

O'Mathuna, D. P. (2015). Ethical considerations for evidence implementation and evidence generation. In B. M. Melnyk & E. Fineout-Overholt (Eds.), *Evidence-based Practice in Nursing & Healthcare: A Guide to Best Practice* (3rd ed.) (pp. 515-530). Philadelphia: Wolters Kluwer Health.

Pike, N. A., Okuhara, C. A., Toyoma, J., Gross, B. P., Wells, W. J., & Starnes, V. A. (2015). Reduced pleural drainage, length of stay, and readmissions using a modified Fontan management protocol. *The Journal of Thoracic and Cardiovascular Surgery, 150*(3), 481-487. doi:10.1016/j.jtcvs.2015.06.042

Ronellenfitsch, U., Rossner, E., Jakob, J., Post, S., Hohenberger, P., & Schwarzbach, M. (2008). Clinical pathways in surgery—should we introduce them into clinical routine? A review article. *Langenbachs Archives of Surgery, 393*, 449-457. doi:10.1007/s00423-008-0303-9

Rotter, T., Kugler, J., Koch, R., Gothe, H., Twork, S., van Oostrum, J. M., & Steyerberg, E. W. (2008). A systematic review and meta-analysis of the effects of clinical pathways on length of stay, hospital costs and patient outcomes. *BMC Health Services Research, 8*(265). doi:10.1186/1472-6963/8/265

Schrijvers, G., van Hoorn, A., & Huiskes, N. (2012). The care pathway: Concepts and theories: An introduction. *International Journal of Integrated Care, 12*. doi:10-1-113788/ijic2012-192

Small, A., Souza, D., Magny-Normilus, C., & David, D. (2016). Using Kotter's Change Model for implementing bedside handoff: A quality improvement project. *Journal of Nursing Care Quality, 31*(4), 304-309. doi:10.1097/NCQ.0000000000000212

Sunstrom, R. E., Muralidaran, A., Gerrah, R., Reed, R. D., Good, M. K., Armsby, L. R., . . . Langley, S. M. (2015). A defined management strategy improves early outcomes after the Fontan procedure: The Portland Protocol. *The Society of Thoracic Surgeons, 99*, 148-155. doi:10.1016/j.athoracsur.2014.06.121

Terry, A. J. (2018). *Clinical research for the doctor of nursing practice* (3rd ed.). Burlington, MA: Jones & Bartlett Learning.

Toledo, A. H., Carroll, T., Arnold, E., Tulu, Z., Caffey, T., Kearns, L. E. & Gerber, D. A. (2013). Reducing liver transplant length of stay: A Lean Six Sigma approach. *Progress in Transplantation, 23*(4), 350-364. doi:10.7182/pit2013226

Uzark, K., Frederick, C., Lamberti, J. J., Worthen, H. M., Ogino, M. T., Mainwaring, R. D., & Moore, J. W. (1998). Changing practice patterns for children with heart disease: A clinical pathway approach. *American Journal of Critical Care, 7*(2), 101-105.

Van Herck, P., Vanhaecht, K., Deneckere, S., Bellemans, J., Panella, M., Barbieri, A., & Sermeus, W. (2008). Key interventions and outcome in joint arthroplasty clinical pathways: A systematic review. *Journal of Evaluation in Clinical Practice, 16*, 39-49. doi:10.1111/j.1365-2753.2008.01111.x

Warner, B. W., Kulick, R. M., Stoops, M. M., Mehta, S., Stephan, M., & Kotagal, U. R. (1998). An evidence-based clinical pathway for acute appendicitis decreases hospital duration and cost. *Journal of Pediatric Surgery, 33*(9), 1371-1375.

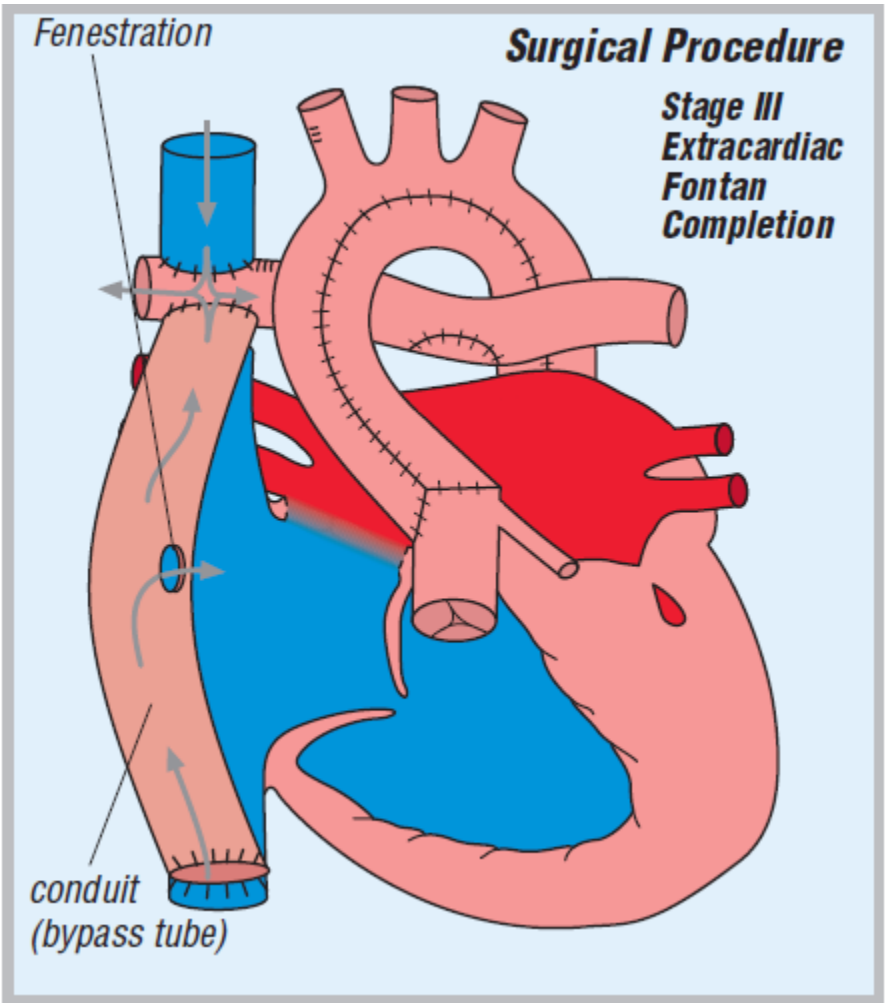
Womack, J. P., Jones, D. T., & Roos, D. (1990). *The machine that changed the world*: *The story of Lean production.* New York, NY: Rawson Associates.

Young, T., Brailsford, S., Connell, C., Davies, R., Harper, P., & Klein, J. H. (2004). Using industrial processes to improve patient care. *British Medical Journal, 328*(7432), 162-164. doi:10.1136/bmj.328.7432.162

Yousri, T. A., Khan, Z., Chakrabarti, D., Fernandes, R., & Wahab, K. (2011). Lean thinking: Can it improve the outcome of fracture neck of femur patients in a district general hospital? *Injury, 42*(11), 1234-1237. doi:10.1016/j.injury.2010.11.02

Figure A

Extracardiac Fontan Repair with Fenestration



An external tubular conduit is surgically connected to the inferior vena cava and to a branch pulmonary artery (branch pulmonary artery was previously connected to the superior vena cava in stage II repair) to complete the passive redirection of the systemic venous return.

Appendix B

Definition of Terms

Adherence: The act of following the set standard or rules.

Clinical pathway: An evidence-based, structured, multi-disciplinary management tool used for a specific group of patients with a predictable clinical course by which different interventions involved in patient care are clearly defined and sequenced in an effort to improve quality of care.

Extracardiac Fontan Procedure: An external tubular conduit is surgically connected to the inferior vena cava and to a branch pulmonary artery (branch pulmonary artery was previously connected to the superior vena cava in stage II repair) to complete the passive redirection of the systemic venous return.

Length of stay: Duration of a single hospitalization as calculated from day of admission to day of discharge in total number of days.

Standardization: The development and implementation of processes, methods, or practices with specific steps or criteria designed to increase consistency and improve quality and safety (Leotsakos et al., 2014, p. 111).

Appendix C

Synthesis of Evidence Table

In the pediatric single ventricle patient who is status post Fontan procedure, does the implementation of an evidence-based clinical pathway in 2017-2018 versus the non-standardized care approach in 2014-2015 standardize care and decrease length of stay at an academic tertiary pediatric institution?

Author, Year, Title, Journal	**Purpose, Theory Used**	**Design, Evidence Level[1]**	**Sample, Setting**	**Study Variables**	**Measures & Reliability**	**Results & Analysis Used**	**Limitations & Usefulness**
Fontan							
Pike *et al.* (2015). Reduced pleural drainage, length of stay, and readmissions using a modified Fontan management protocol. *The Journal of Thoracic and Cardiovascular Surgery*	To determine if implementation of a clinical protocol for the post-operative Fontan patient can improve immediate outcomes and decrease overall costs Atheoretical	Retrospective cohort quantitative study Level IV	60 pre and 60 post, excluded deaths or Fontan conversion Academic tertiary pediatric institution (Children's Hospital of Los Angeles)	Standard protocol Duration of pleural tube drainage, NPO + TPN, LOS, re-admissions, hospital costs	LOS - day of admission to day of d/c. Readmissions - recurrence of pleural effusion w/in 30 days of hospital d/c. Hospital cost savings	Decreased LOS ($p = .005$); persistent drainage ($p = .001$). Reduced readmits 50% ($p = .1$); no NPO/TPN ($p = .06$). Saved 22%; readmits 29%. Mann Whitney *U*, Chi-squared, Fisher's	(-)Adherence not tracked (-)CI for all results not provided (-)Design limits ability to correlate (+)Same population, similar protocol (+)Significant & clinically relevant results (+)APN driven
Sunstrom *et al.* (2015). A defined management strategy improves early outcomes after the Fontan procedure: The Portland Protocol, *The*	Determine efficacy of institution's Fontan management protocol in reducing chest tube drainage & LOS Atheoretical	Retrospective cohort quantitative study Level IV	28 pre and 14 post protocol Academic tertiary pediatric institution (Doern-becher	Defined surgical strategy and strict post-operative manage-ment plan CT drainage, LOS,	Median CT drainage days & total drainage, ICU & hospital LOS, mortality in-hospital & 30-day, stroke, readmissions for pleural	CT days ($p < .001$), total drained ($p < .001$). ICU ($p = .004$), LOS ($p = .001$). Mann-Whitney, Chi-squared, multiple linear regression, Kaplan-Meier	(-)All patients fenestrated - controversial (-/+)Evolved pathway to improve adherence (+)Surgical technique also standardized (+)Reported morbidities similar for pre & post-protocol

[1] Levels of Evidence, see Appendix E (Melnyk & Fineout-Overholt, 2015, adapted)

Society of Thoracic Surgeons			Children's Hospital)	M&M, re-admissions	effusions, required PPM. P values 2-sided, statistical significance = 0.05, CI 95%	curve, Cox proportional hazards & negative binomial regression	
Cava *et al*. (2005). A medical strategy to reduce persistent chest tube drainage after the Fontan operation, *The American Journal of Cardiology*	Does a more standard approach to post-operative Fontan care reduce prolonged pleural drainage & LOS, reduce further interventions Atheoretical	Retrospective cohort quantitative study Level IV	N=25 Historical controls, N=33 random patients Academic tertiary pediatric institution (Children's Hospital of Wisconsin)	Standard protocol Duration of pleural chest tube drainage, LOS, need for NPO/TPN and/or pleural sclerosis	Postoperative day CT removed, LOS s/p Fontan, # made NPO, # utilized TPN, # underwent sclerosis	Decreased CT days (*p = .003*); decreased LOS (*p = .001*); 0 NPO/TPN or sclerosis (*p = .002*) CT days, LOS – 1-way analysis of variance; NPO/TPN, sclerosis – Fisher's 2-way exact test	(-)Adherence not discussed (-)Historical controls selected at random (+)Historical medical management discussed, non-standard (+)Protocol well tolerated, no complications or readmissions for effusions
CV surgery							
Miller *et al.* (2014). Implementing goal-directed protocols reduces length of stay after cardiac surgery. *Journal of Cardiothoracic and Vascular Anesthesia*	Evaluate high reliability organization (HRO) approach through goal-directed, evidence-based protocols to reduce LOS s/p cardiac surgery High reliability	Prospective, longitudinal observational study – mixed methods Level IV	665 adult cardiac surgery pts, CVICU care team (100 RNs, 16 providers) Academic medical center - Vanderbilt	Use of pathway – milestone scores; team compliance score – critical behaviors observed CVICU & hospital LOS	Team compliance = proportion SREBP-related team behaviors exhibited during rounds; milestone score diff between actual and expected; CVICU & hospital LOS (days)	Increased team compliance = decreased ICU & hospital LOS (*p=0.08, p=0.008*). Increased mile-stone scores, ICU & hospital LOS increased (*p<0.001, p=0.05*). Regression analysis	(-)135 missing data (-)Stat. significant neg association w/ milestones met & LOS (+)Evaluated teamwork (+)Early identification of deviations, decrease adverse events?

Uzark *et al.* (1998). Changing practice patterns for children with heart disease: A clinical pathway approach. *American Journal of Critical Care*	Developed clinical pathways to promote effective and efficient care of children with heart disease Atheoretical	Prospective cohort quantitative study Level IV	69 pre and 173 post; no exclusions 78 ASD, 76 VSD, 30 PDA, 41 TOF, 17 ASO Pediatric academic (Children's Hospital of San Diego)	Clinical pathways for cardiac surgeries Hospital & ICU LOS, time to extubation, blood tests, hospital costs, variances, re-admissions	Hospital LOS (days), ICU LOS (days), duration of mechanical ventilation (hrs), lab (blood) tests (#), hospital costs, variance, readmissions, correlations Statistically significant = *p<.05*	Hospital & ICU LOS reduced (ASD *p=.02, p <.01*; VSD *p=.03, p<.05*). Costs & resources used reduced. Mann-Whitney *U*, unpaired two-tailed *t* tests, median, Pearson correlation coefficients	(-)Re-admissions tracked for only 2 weeks (-)No Fontan pathway (-)20 yrs old (+)Tracked deviations from pathway and estimated cost savings (+)Multiple CV surgery pediatric pathways evaluated with significant findings
Allen & Davis (1995). Standardizing care delivery for infants and children with common congenital cardiac lesions. *Current Opinion in Pediatrics*	Literature review of care guidelines & care pathways for pediatric cardiac surgery to standardize care, improve quality, reduce costs Atheoretical	Literature review Level VII	N/A Pediatric cardiology	N/A	Care guidelines or clinical pathways Impact on cost, outcomes such as LOS, re-admissions, M&M	Cardiac cath, exercise testing, activity/sports recs, listing of donor hearts, specific lesion algorithms CV surgery – decrease LOS, hospital charges w/no adverse effects outcomes or quality	(-)20+ yrs old (-)Low level of evidence (+)Provides historical context for standardization of care movement (+)Pediatric cardiology specific
LOS and Costs							
Improta *et al.* (2015). Lean Six Sigma: A new approach to the management of patients	Demonstrate that Lean Six Sigma appropriate method to develop clinical pathway for hip	Retrospective and prospective cohort quantitative study Level IV	82 pre and 48 post, prosthetic hip replace-ment (3	Implement-tation of post-operative clinical pathway	LOS (days) Significance level of *p=.05*	Average LOS decreased from 18.9 to 10.6 days (44%), *p<.001*	(-)Did not monitor pt satisfaction, other outcomes (-)Different pt population (+)Substantial predicted annual cost

undergoing prosthetic hip replacement surgery. *Journal of Evaluation in Clinical Practice*	surgery to improve quality & reduce costs Lean Six Sigma		outliers excluded) Italy (Italian University Medical Center)	LOS		Test of normality – Shapiro-Wilk, *t*-test	savings related to decreased LOS (+)Utilized same theory as project
McNamara *et al.* (2014). Use of Lean principals to improve flow of patients with fractured neck of femur—the HOPE study. *Journal of Irish Medicine*	Evaluate use of Lean Six Sigma to aid in process of implementing a clinical pathway for uncomplicated fractured neck of femur (NOF) patients Lean Six Sigma	Retrospective and prospective quantitative cohort study Level IV	59 pre- and 86 post-pathway, uncompli-cated fractured NOF patients Ireland (University of Limerick)	Clinical pathway Admission w/in 4 hrs, surgery w/in 24 hrs of presenting, LOS	ED to admission, waiting time until surgery, OR start time, OR time usage,	32/86 (37%) admitted within 4 hrs vs 16/59 (27%) prior; earlier mean OR start time =38 extra OR mins; +12% of pts had surgery w/in 24 hrs of admission = LOS reduced by 1 night	(-)Different patient population (-)Analysis used not reported, nor were p-values (+)Based on British Orthopaedic Association evidence-based guidelines (+)Improved efficiency using same theory as project
Toledo *et al.* (2013). Reducing liver transplant length of stay: A Lean Six Sigma approach. *Progress in Transplant-tation*	Use a systematic process to identify factors affecting LOS and then implement targeted interventions Lean Six Sigma	Retrospective and prospective cohort quantitative study Level IV	49 pre, 10 pilot, 62 post adult, single-organ, primary liver transplant recipients University of North Carolina Health Care	Clinical pathway LOS, re-admissions, mortality rates	LOS (days) & re-admissions (30 days, 90 days) after liver transplant, mortality at 30 days & 1 year	Median LOS decreased 11 to 8 days ($p<.05$); 30-day readmissions decreased 53.1% to 48.4% ($p=.63$), 90-day 65.3% to 56.5% ($p=.35$) – decreasing LOS no impact on readmissions, 30-day & 1 yr mortality 2-sample *t* test	(-)Different patient population (+)Utilized same theory as project and had pilot (+)Significant reduction in LOS without increase in re-admissions or mortality = also financially beneficial

Gayed *et al.* (2013). Redesigning a joint replacement program using Lean Six Sigma in a Veterans Affairs hospital. *Journal of American Medical Association of Surgery?*	To increase efficiency and reduce costs for total hip arthroplasty (THA) and total knee arthroplasty (TKA) Lean Six Sigma	Retrospective cohort quantitative study Level IV	Medical record review 638 pts = 150 pre, 98 during, 390 post Richard L. Roudebush Veterans Affairs Medical Center, Indiana-polis, IN	Joint Replace-ment Program (standard-izing work, preop education of patients) LOS, costs	LOS, cost savings	Mean LOS reduced 36% (5.3 to 3.4 days, *p<.001*). 100% reduction of non-VA care for THA & TKA w/ est ROI $1 million annually, increased volume. Analysis of variance, Fisher's, Duan's smearing est	(-)Different patient population (+)Utilized same theory as project (+)Large post sample size with statistically significant decrease in LOS
Niemeijer *et al.* (2012). The usefulness of Lean Six Sigma to the development of a clinical pathway for hip fractures. *Journal of Evaluation in Clinical Practice*	Demonstrate usefulness of using Lean Six Sigma for improving the efficiency of a clinical pathway for elderly patients with hip fractures Lean Six Sigma	Retrospective & prospective, non-randomized controlled study Level III	137 pre and 195 post, ages 75 or older, surgery for hip fracture Nether-lands (University Medical Centre Groningen)	Clinical pathway LOS, duration of surgery	LOS (days), duration of surgery (minutes)	LOS decreased 13.5 to 9.3 days (-33%, *p=.000*), surgery time decreased 154 min to 98 min (*p=.000).* Analysis of variance (ANOVA), regression analysis, Chi squared test	(-)Different patient population (+) controlled study, significant findings (+)Utilized same theory as project
Yousri *et al.* (2011). Lean thinking: Can it improve the outcome of fracture neck of femur in patients in a	Evaluate impact of Lean on the outcome for fracture NOF patients Lean	Retrospective & prospective quantitative cohort study Level IV	309 pre- and 299 post-, cons pts w/ surgical repair of fracture NOF	Lean Value-Stream approach Overall mortality, 30-day mortality,	Overall mortality, 30-day mortality, admission to OR time, admission to trauma ward, LOS	Mortality pre 20.7%, post 11.4% (*p=.002*) 30-day mortality pre 11.7%, post 6.7% (*p=.034*) Door to OR time, admission	(-)Different patient population (-)Improved mortality but not other efficiency outcomes (+)Large sample size

district general hospital? *Injury*			United Kingdom (Goodhope Hospital, Bristol)	admission to OR time, admission to trauma ward, LOS		to trauma ward & LOS not stat significant Chi-squared test, Mann-Whitney *U* test	(+)Based on BOA evidence-based guidelines
Van Herck *et al.* (2010). Key interventions and outcomes in joint arthroplasty clinical pathways: A systematic review. *Journal of Evaluation in Clinical Practice*	Determine key interventions that multidisc teams select as pathway components, what outcomes are measured, and what is overall effect of a joint arthroplasty clinical pathway Atheoretical	Systematic literature review Level II	34 of 4055 pubs, inclusion criteria = pts w/ hip or knee replace-ment, pathway assessed via process or outcome measures, original pubs only	Clinical pathway Functional outcome, complica-tions, place of d/c, wound status, pain, QOL, pt satisfaction, LOS, cost, utilization rate	Functional outcome, complications, place of d/c, wound status, pain, QOL, pt satisfaction, LOS, cost, utilization rate. Leuven Clinical Pathway Compass–clinical, service, team, process, financial	# & % pubs in terms of measures given, # of indicators, & content of top 5 indicators. Effect size calculated, expressed as % of change. LOS reduced significantly in all 21 studies (1 w/ no diff).	(-)Different patient population (-)Recommends but does not do meta-analysis on outcomes (+)Multiple reviewers, very detailed search and screening strategy (+)Identifies key strengths, weaknesses, gaps regarding clinical pathway studies
Kelly *et al.* (2000). The effects of a pediatric unilateral inguinal hernia clinical pathway on quality and cost. *Journal of Pediatric Surgery*	Determine whether use of a clinical pathway for pediatric inguinal hernia surgery improves outcomes Atheoretical	Retrospective cohort & randomized case-controlled study Level IV	25 pre-, 46 control, 46 intervent, randomly selected, age/gender/ medical hx matched Children's Hospital Medical Center, Cincinnati	Surgical clinical pathway Frequency of wound infections, return visits, times associated with surgical repair, costs	Times for anesthesia, procedure, PACU, total (OR to d/c) Total cost Wound infections Readmissions ED visits within 72 hrs of d/c	No diff in control & intervention groups No significant diff in times Cost reduced by 10% ($p<.05$) No diff in # infections, no readmissions in either group, no ED visits ANOVA, Chi-squared testing	(-)15+ yrs old (-/+)Only costs reduced, no impact other outcomes = similar quality (+)Pre-pathway & case-controlled groups for intervention (+)Pediatric surgical pathway, historically important

Warner *et al.* (1998). An evidence-based clinical pathway for acute appendicitis decreases hospital duration and cost. *Journal of Pediatric Surgery*	Determine impact of evidence-based clinical pathway for acute appendicitis in pediatrics Atheoretical	Retrospective & prospective quantitative cohort study Level IV	122 pre- and 120 post-pediatric surgery for acute appy Children's Hospital Medical Center, Cincinnati	Surgical clinical pathway Patient care outcomes, costs	Labs/imaging, (-) explorations, perfs, time until consult, ED to OR time, pre-op abx, LOS, costs Sample to detect 25% change LOS w/ 90% power & alpha error of 0.05	Negative appy, perf similar Nonperf LOS & costs decreased (*p=.014, p=.001).* Perf LOS & costs decreased (*p=.0001, p=.0001*). *t* tests,Wilcoxon Rank Sign, Chi-squared	(-)20 yrs old (+)Evaluated outcomes throughout entire pathway process (+)Pediatric surgical pathway, historically important
Efficiency							
Beck & Gosik (2015). Redesigning an inpatient pediatric service using Lean to improve throughput efficiency. *Journal of Hospital Medicine*	Determine impact Lean Six Sigma has on improving throughput efficiency for inpatient pediatric service Lean Six Sigma	Prospective concurrent control cohort study Level IV	Control group pre-1390, post-1146; Interven-tion pre-421, post-552 Penn State Hershey Medical Center	Service redesign - daily standard work, d/c checklist, interdisci-plinary huddles. LOS, d/c order time, re-admissions	Mean LOS, median d/c order time and actual d/c, d/c prior to noon and 1400, 7-, 14-, & 30-day readmissions	Stat significant d/c order time (*p<.0001*), d/c from hospital (*p<.0001*), d/c before noon/1400 (*p<.0001*). LOS, readmissions same Wilcoxon, logistic regression, OR, Chi-squared test, *t* test	(-)Inpatient service, not surgical focus (+)Improved efficiency, no negative affect on LOS or readmissions (+)Concurrent control group (+)Utilized same theory as project
El-Eid *et al.* (2015). Improving hospital discharge time: A successful	Assess efficiency of using Six Sigma to improve patient	Retrospective quantitative cohort study Level IV	pre-N=8494 & post-N=8560	Intervention to improve d/c process Discharge time,	Discharge time (time from order to actual d/c), % pts d/c order written before noon, %	d/c time decreased by 22.7% (*p<.001*), d/c prior to noon (*p<.001*), hospital LOS	(-)Inpatient & ED focus, not surgical (-)d/c focused, no clinical pathway (+)Utilized similar theory as project

implementation of Six Sigma methodology. *Medicine*	discharge process Six Sigma		Tertiary Academic Hospital in developing country (Beirut, Lebanon)	hospital & ED LOS	pts leaving by noon, hospital LOS, LOS of ED admitted pts	decreased 3.4 to 3.1 days ($p<.001$), ED mean LOS lower ($p<.001$) *t* & Chi-squared, multivariate & multiple linear regression	(+)Large sample size w/ statistically significant improvements in efficiency
Cima *et al.* (2011). Use of Lean and Six Sigma methodology to improve operating room efficiency in a high-volume tertiary-care academic medical center. *Journal of American College of Surgeons*	To use the combined methodology of Lean Six Sigma to improve OR efficiency for 3 specific surgical specialties Lean Six Sigma	Retrospective & prospective quantitative cohort study Level IV	Thoracic surgery pre- 735, post-2430; Gyn pre-1740, post-2430; Gen/ colorectal pre-1685, post- 1907 Academic medical center – Mayo Clinic, Rochester, MN	Surgical process improve-ment: min. volume variation, streamline pre-op, reduce non-op time, eliminate redundancy, engage employees On-time starts, late OR cases, costs	% on-time starts, OR past 5pm, avg turnover (mins), avg staff OT, OR saved, change in OR margins	Stat significant improvement in on-time starts for all 3 ($p<.05$); OR past 5 for Gyn ($p<.05$) & General ($p<.05$). Gains achieved in non-OR time, staff overtime, and ORs saved = financial benefit. Analysis used not reported	(-)Statistical analysis used not reported (-)Different patient population (+)Standardized & streamlined process, improving efficiency (+)Utilized same theory as project
Niemeijer *et al.* (2010). Quality in trauma care: Improving the discharge procedure of patients by means of Lean Six Sigma. *The Journal of*	To reduce average LOS by improving the discharge process for trauma patients using the Lean Six Sigma method	Retrospective & prospective quantitative cohort study Level IV	Pre 747, post 946, pts admitted to Trauma Nursing Department Nether-lands	Process improve-ment intervention % unnecessary hospital stay, average	Dutch Appropriate-ness Evaluation Protocol, % inappropriate hospital stay, average LOS	50% reduction inappropriate hospital stay Avg LOS reduced from 10.4 days to 8.5 days 118 extra admissions = financial benefit	(-)Different patient population (-)Statistical analysis used not reported (+)Increased efficiency but unclear if significance reached (+)Utilized same theory as project

Trauma Injury, Infection and Critical Care	Lean Six Sigma		(University Medical Center Groningen)	LOS, quality (re-admissions, mortality), cost		No increase in readmissions, mortality rate decreased (*p=.017*)	
Effectiveness							
Rotter *et al.* (2008). A systematic review and meta-analysis of the effects of clinical pathways on length of stay, hospital costs and patient outcomes. *BMC Health Services Research*	To determine the effect of using clinical pathways on LOS, hospital costs, and patient outcomes Atheoretical	Systematic review with random effects meta-analysis Level 1	17 trials (clinical pathway children or adults; 13 RCTs and 4 controlled clinical trials), N=4070 pts Clinical (in- & out-patient), & inpt rehab	Clinical pathway vs standard care Outcome measures – LOS, hospital costs, quality of care	Effective Organization of Care Group model, 2 reviewers Review Manager Cochrane Collaboration - pooled effect estimate (WMD), chi-squared, degrees of freedom to determine variance	Moderate quality studies 12/16 sign improved LOS. Pathways for invasive procedures stronger LOS reduction (WMD -2.5 vs -0.8 days). No diff in re-admissions (OR 1.1) or in-hospital complications (OR 0.7).	(-)Meta-analysis evidence exploratory in nature (-)Small # of studies met inclusion criteria (+)Clinical pathways effective for invasive care (+)Positive effects on LOS & costs without compromising quality
Lemmens *et al.* (2008). Systematic review: Indicators to evaluate effectiveness of clinical pathways for GI surgery. *Journal of Evaluation in Clinical Practice*	To study indicators used to evaluate gastrointestinal surgery clinical pathways and effects reported Atheoretical	Systematic literature review Level II	23 studies, of which 16 controlled, clinical pathway for GI surgery in English, German or Dutch, study size range 13-846	Clinical pathway Complica-tions, re-admissions, LOS, costs, resource use, deviations in process, communica-tion, satisfaction	Leuven Clinical Pathway Compass – clinical, service, team, process, financial % of # of studies/total that report positive vs no effect for each domain	Studies most frequently assessed complication rates, re-admissions, mortality, LOS with no reported adverse effects	(-)Different patient population (+)Discusses key gaps in studies regarding clinical pathways (lack of evaluation of service, process, team domains)

Ronellenfitsch *et al.* (2008). Clinical pathways in surgery—should we introduce them into clinical routine? A review article. *Langenbecks Archives of Surgery*	Provide evidence on effects of using clinical pathways in surgery Atheoretical	Systematic literature review of quantitative studies Level II	Common surgical procedures, 30 studies: 24 before-after trial; 4 interven-tion only group; 1 non-RCT; 1 RCT. Study size range 6-1200; mean 119 tx, 120 comparison	Implement-ing surgical clinical pathway Economic effects, quality of care – morbidity & mortality, patient satisfaction	Table 1 = each study rated with regards to dependent variables as (+) "significant" advantage, (O) no significant difference, (-) significant disadvantage, blank not assessed	23 = cost savings 1 = reducing LOS did not increase readmissions 6 = decreased M&M 3 = increase in pt satisfaction 4 = high degree of satisfaction 1 = no difference	(-)No meta-analysis (-)Unclear why specific studies chosen (+)Qualitative components (+)Strong association in decease in LOS w/o negative effect on other outcomes

Appendix D

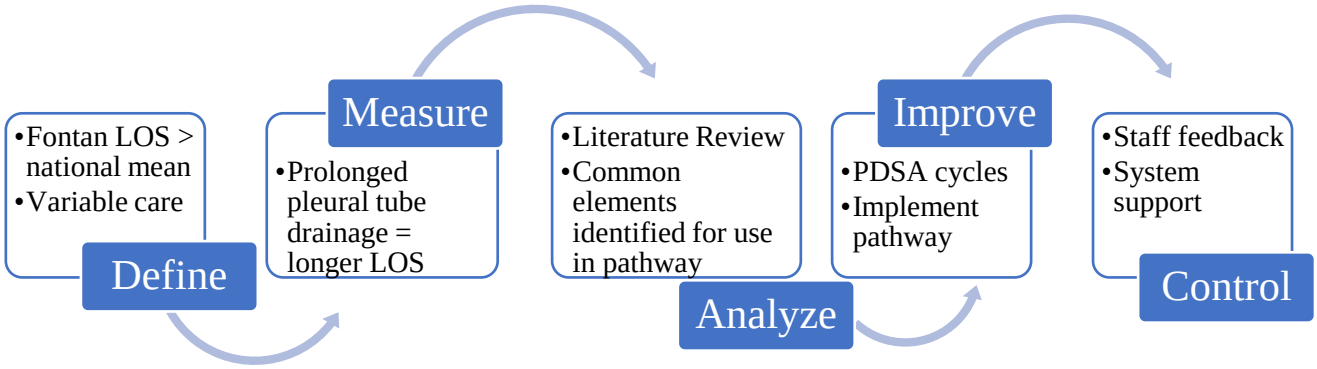
Rating System for the Hierarchy of Evidence For an Interventional Inquiry (Modification by Dr. Lindholm for course N5613)	
Level I	Evidence from a systematic review or meta-analysis of all relevant RCTs. *Evidence-based clinical practice guidelines based on systematic reviews of RCTs).**
Level II	Evidence obtained from well-designed RCT. *Quantitative systematic review of well-designed controlled trial without randomization.*
Level III	Evidence obtained from well-designed controlled trial without randomization *(quasi-experimental).* *Quantitative systematic review of case-control, cohort, or correlational studies.*
Level IV	Evidence from well-designed case-control or cohort study *(or cross-sectional study)*
Level V	Evidence from systematic review of *quantitative* descriptive *(no relationships to examine)* or qualitative studies.
Level VI	Evidence from a single *quantitative* descriptive *(no relationships to examine in the study) or* qualitative study
Level VII	Evidence from the opinion of authorities and/or reports of expert committees

Melnyk, B.M. & Fineout-Overholt., E. (2015). *Evidence-based practice in nursing and healthcare.* Philadelphia Lippincott Williams & Wilkins.

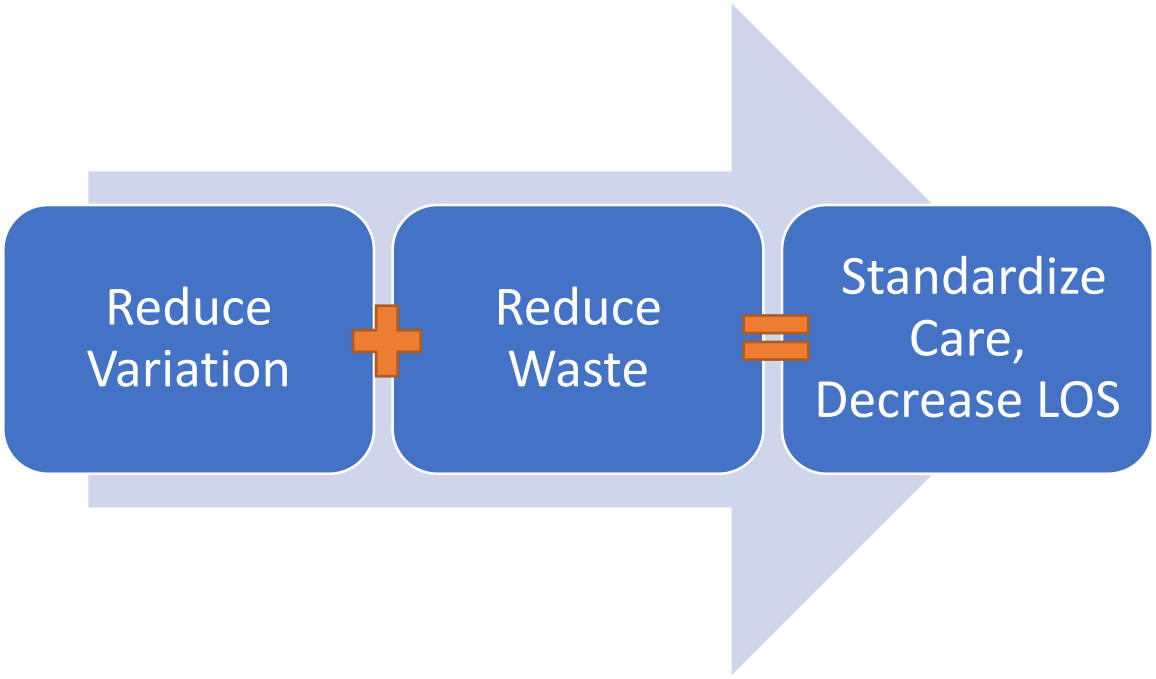
**Italics, appropriate in this category, modification by LL 2017 based on opinions from experts to place SR at one level higher than single study design level.*

Appendix E

Theoretical and Conceptual Application of Lean Six Sigma to EBP Project



Adapted from Nave, 2002



Adapted from Lighter, 2014

Appendix F

IRB Approval Letter

Children's Research Institute
CHILDREN'S MERCY KANSAS CITY

NOT ENGAGED IN HUMAN SUBJECTS RESEARCH

October 23, 2018

Sarah Lagergren
smlagergren@cmh.edu

Dear Dr. Lagergren,

On 10/23/2018, the ORI staff reviewed the following protocol:

Type of Review:	Initial Study
Title:	Retrospective review of the implementation of a post-operative clinical pathway for the management of the Fontan patient
Investigator:	Sarah Lagergren
myIRB ID:	STUDY00000246
Funding:	100.1001070100 CMH ADELE HALL CAMPUS
Documents Reviewed:	• Fontan Clinical Pathway QI - Retrospective Review, Category: IRB Protocol;

ORI staff determined that the proposed activity does not involve research as defined by DHHS regulations.

This project involves a measurable, specific goal to decrease length of stay (LOS) for patients from the current average of 14 days to national average of 11 days. Therefore, this project is not designed to create or contribute to generalizable knowledge. Hence it is not considered a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge according to 45 CFR 46.102(d) (not research).

IRB review and approval by this organization is not required. This determination applies only to the activities described in the myIRB submission listed above and does not apply should any changes be made. If changes are made and there are questions about whether these activities engage CM in human subjects research, please submit a new request in myIRB for a determination.

Sincerely,
Dane Sommer, DMin
Co-Chair, CM Institutional Review Board
Doug Swanson, MD
Co-Chair, CM Institutional Review Board
Ryan McDowell
Director, Office of Research Integrity

Appendix G

Proposed Project Cost Table

Direct Costs				
Supplemental oxygen via nasal cannula		$3.10/unit[2]	40 units	$124.00
Fluid Restriction and Nutrition		No extra cost		$0
Standardized Diuretic Therapy		No extra cost		$0
Central Access: [3] Referred to Interventional Radiology		$1500	40 pts (20 pts*)	$60,000 ($30,000*)
Salary for APRN				
	Education of nursing staff (preparation plus education sessions)	$55/hour	10 hrs	$550
	Implementation (email reminders, monitoring adherence to pathway, meetings)	$55/hour	30 hrs	$1650
	Data collection/analysis	$55/hour	80 hrs	$4400
Direct Costs TOTAL				**$66,724 ($36,724*)**
Indirect Costs				
Benefits for APRN		$10/hour	120 hrs	$1200
Additional education by unit educators		$30/hour	10 hrs	$300
Unable to calculate, estimated		Use of space		$1000
		Use of computers		
		Use of electronic medical record		
Indirect Costs TOTAL				**$2500**
TOTAL ALL COSTS				**$69,224 ($39,224*)**

*Pre-pathway, approximately 50% of patients were already receiving PICC lines. Post-pathway implementation will require 100% of patients to obtain PICC lines, representing a 50% increase in costs for this intervention.

[2] http://www.rehabmart.com/product/pediatric-nasal-7ft-safety-cannula-50-per-case-30361.html
[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2869215/#R2

Appendix H

Logic Model for DNP Project

Student: Sarah Lagergren

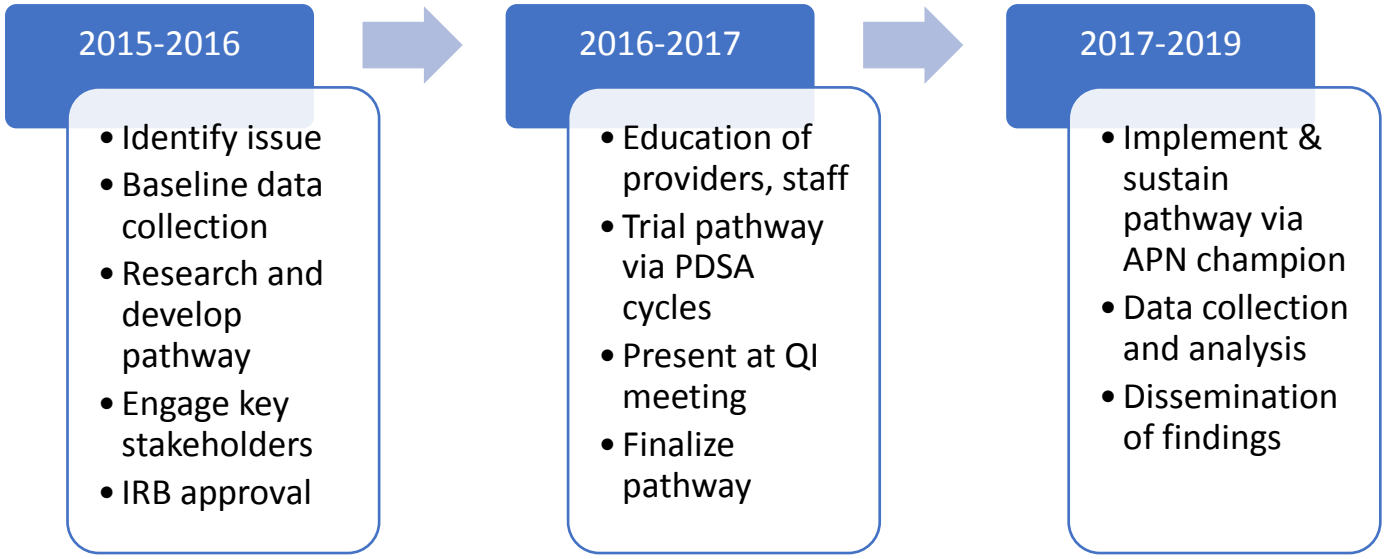
Inquiry, PICOTS: In the pediatric single ventricle patient who is status post Fontan procedure, does implementation of an evidence-based clinical pathway in 2017-2018 versus care provided in 2014-2015 standardize care and decrease LOS at an academic tertiary pediatric institution?

Inputs	Intervention(s) *Activities*	Outputs *Participation*	Outcomes -- Impact *Short*	*Medium*	*Long*
Evidence, sub-topics • Overall effectiveness of clinical pathways • Improving efficiency via standardization • Improving LOS & costs via clinical pathways • Clinical pathways in cardiac surgery—adults, pediatrics, Fontans **Major Facilitators or Contributors** • Lean institution • Heart Center leadership support • Small team initiative with APN as lead **Major Barriers or Challenges** • Physician resistance • Staff and family anxiety related to change in care and standardization • Coordination with interventional radiology (IR)	**EBP intervention** Implementation of an evidence-based clinical pathway for the management of the post-operative Fontan patient **Major steps of the intervention** • Continue use of a minimum of 0.5 liters oxygen via nasal cannula until removal of chest tubes • Standardized aggressive diuresis • Fluid restriction of 80% maintenance, 6 ounces of free water • Low fat diet with daily fat gram count • Central access obtained via peripherally inserted central catheter (PICC) within 48-72 hours post-op in IR	**Participants** Consecutive post-operative extracardiac Fontan patients, anticipated sample size of n = 80 **Site** Midwestern academic tertiary pediatric institution **Time Frame** 2014-2015 (pre-) 2017-2018 (post-) **Consent Needed or other** Not applicable – EBQI, retrospective chart review **Person(s) collecting data** Student investigator - Sarah Lagergren **Others directly involved** EBQI team – Suma Goudar, MD; Megan Jensen, APRN; Bryan Beaven, RN	**Outcomes to be measured** Primary • LOS (days) • Adherence to pathway (% for each step in intervention) Secondary • Readmissions within 30 days of discharge for pleural effusion (#) • Chylous effusions • Lab draws (#) • Complications requiring further interventions and PICC line complications (infection, thrombus #) • Costs **Statistical analysis** Descriptive, t-test, Wilcoxon Rank sum, Chi-square, Fisher's exact	**Outcomes to be measured** Sustainability of improvements • LOS (days) • Adherence to pathway (% for each step in intervention) • Readmissions within 30 days of discharge for pleural effusion (#)	**Outcomes that are potentials** • Provider, patient, family satisfaction • Standardized pre-operative education, in-hospital and discharge support for parents related specifically to challenges of Fontan patient • Development of outpatient diuretic weaning guidelines for Fontan patients to decrease readmissions

Rev. 7/09, 1/2015 http://www.uwex.edu/ces/lmcourse/interface/coop_M1_Overview.htm Logic-Model Worksheet content revisions by Lyla Lindholm for DNP Project. Not to be placed on web for public use. For UMKC DNP coursework only.

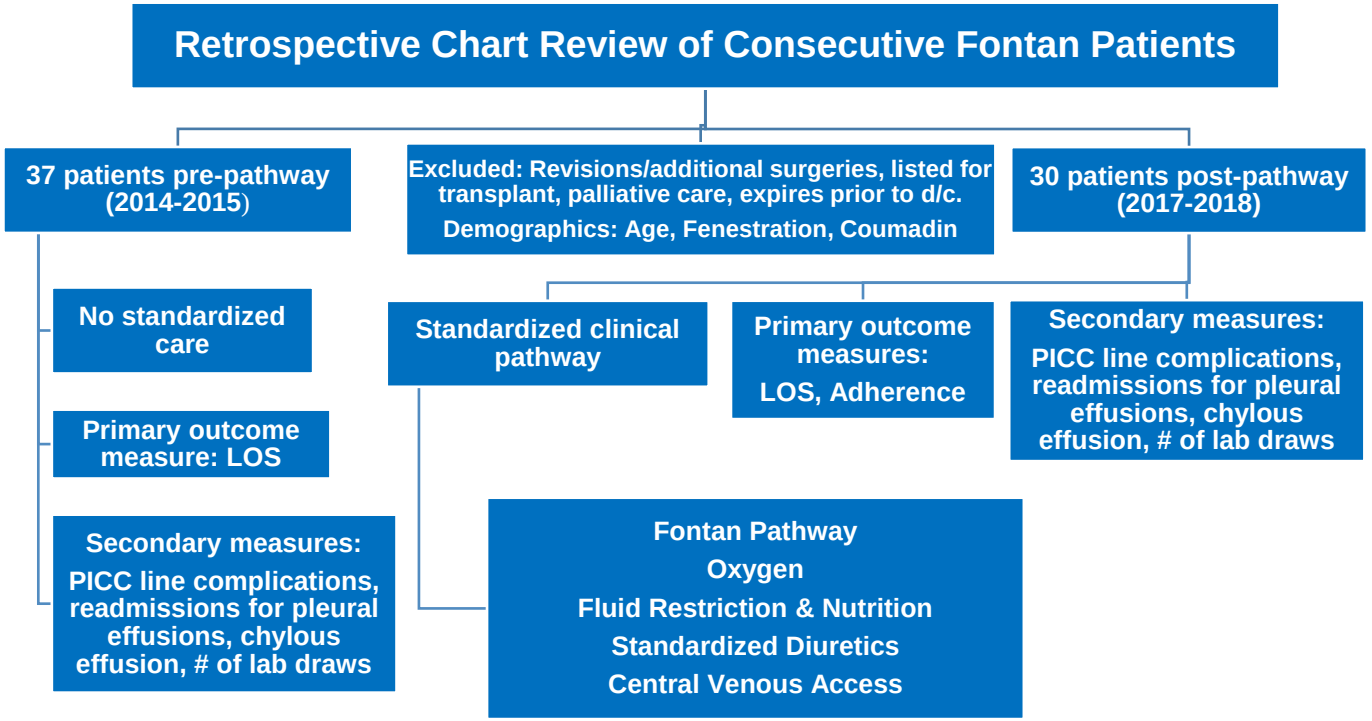
Appendix I

Project Timeline Flow Chart



Appendix J

Intervention Flow Diagram, Procedure



Appendix K

Educational Materials: Clinical Pathway & Bedside Checklist

Fontan Post-operative Clinical Pathway

1.Oxygen	• Continue use of minimum 0.5L NC oxygen until removal of chest tubes
2. Fluid Restriction & Nutrition	• Limit total intake volume to 80% maintenance (PO + IV). • Liberalize total volume to 100% maintenance 48 hours before discharge. • Free water restriction of 6 oz. • Liberalize to 12oz on discharge. • Water restriction will be removed at first post-op follow up. • Low fat diet. Consult nutrition for daily fat gram count, patient can order off regular menu. Continue low-fat diet for 2 weeks post chest tube removal. If chylous, will continue for 6 weeks. ****If patient is showing clinical signs of dehydration (tachycardia, elevated BUN) with significant negative fluid balance may consider suspending fluid restriction****
3. Standardized Diuretic Management	• Lasix IV 1 mg/kg/dose q8hr starting on POD #1. Lasix should stay IV until the day prior to anticipated chest tube removal. PO dosing 1 mg/kg/dose. • Add PO diuril 5-10 mg/kg/dose q12hr and PO aldactone 1 mg/kg/dose q12hr once tolerating PO. May use IV diuril 5 mg/kg/dose instead of PO if more diuresis is needed. • Minimum discharge diuretics should be PO Lasix TID. **** It is recommended that patient be stable on home diuretic regimen for 24-48 hours before discharge****
4. Central Access	• PICC Line placed within 24-72 hours post-op in interventional radiology. • Consider use of prophylactic continuous heparin in line for higher risk patients.

Persistent or Excessive Chest Tube Output

Excessive Chest Tube Output	Chest tube output > 250-300ml/24hrs after POD #3 or 20ml/kg/day - excessive pleural drainage and below items need to be *considered*: - Labs: IGG, LFTs, PT, PTT, Fib and AT3- minimum biweekly - Consider liberalization of 80% fluid restriction (with techniques such as partial chest tube output replacement), but this plan needs to be clearly defined in daytime rounds with cardiology and surgeon input. If question arises outside of rounds, discuss with cardiology staff prior to initiation.

***Approved for use by Heart Center Leadership, April 2017, revised April 2018

Appendix K

Educational Materials: Clinical Pathway & Bedside Checklist

Fontan Post-operative Clinical Pathway: Provider/RN Bedside Checklist

PICU/POD #0-POD #1

□ Respiratory Care Plan – use order comments and specify the following: "Continuous use of a minimum of 0.5 L oxygen via nasal cannula until removal of chest tubes."

□ IV + PO order = 80% maintenance, calculate and set daily ml for max allowed

□ Free water restriction of 6 oz. per day – may use Enteral Free Water order, 180 ml, ad lib, daily water restriction

□ "Fat controlled diet" order. Consult to nutrition to assess current diet, provide family education as needed and identify daily fat gram limit. Patient may order off of regular menu as long as within daily fat gram count.

□ Start Lasix IV 1 mg/kg/dose q8hr

PICU/Blue Team/POD #1-POD #3

□ Consult to Radiology Interventional (if not already done), single lumen unless otherwise indicated. Tip of the line to lie at orifice of SVC (confluence of innominate, subclavian, and jugular veins); line will be in the subclavian or innominate vein.

Blue Team/POD #2-Discharge

□ If not done, nutrition consult for daily fat gram limit (low-fat). Will continue for 2 weeks after chest tubes removed, unless chylous, and then will continue for 6 weeks.

□ Add diuril PO 5-10 mg/kg/dose q12hr and aldactone PO 1 mg/kg/dose q12hr once tolerating PO diet. May use IV diuril 5 mg/kg/dose instead of PO if more diuresis is needed.

□ Transition to Lasix PO 1 mg/kg/dose q8hr the day prior to anticipated chest tube removal.

□ Minimum discharge diuretic regimen of Lasix PO TID. Should be on home diuretics for 24-48 hours prior to d/c.

□ Follow-up appt made for within 1 week of discharge for CXR, echo and BMP

Appendix L

Data Collection Templates: Pre-Pathway and Post-Pathway

Pre-Pathway

Patient Number	Age	Date of Surgery	LOS (days)	readmission within 30 days	Surgeon	Fenestration	Other Surgical Procedure	Coumadin	CT removal (POD day)	Additional Chest tube days	Chylous Drainage	Days of IV fluids	TPN	Tube feeds	PICC line

POD day PICC placed	Thrombus	Days On Oxygen	Complex Diuretic management	diuril used?	aldactone used?	Lasix used?	post op day oral diuretics started	Total # lab draws during hospitalization	CBC	BMP	LFT	Coags	NT-Pro BNP	AT3	IgG	Blood Gas

Appendix L

Data Collection Templates: Pre-Pathway and Post-Pathway

Post-Pathway

Age	Weight	Surgeon	Date of Surgery	LOS (days)	Readmission within 30 days	Fenestration	Other Surgical Procedure	Coumadin	CT removal (POD day)	On min. 0.5L O2 until CT removed	CT amount when removed (total and ml/kg)	Additional Chest tube days	Chylous Drainage	Excessive CT output	Low-fat diet followed	Days of IV fluids	80% maintenance fluids (IV +PO) maintained	Fluid restriction suspended or IVF given	Free H20 restricted to 6 oz and liberalized to 12 oz at d/c

PICC line	POD day PICC placed	How many PIVs	Thrombus/ Infection	Lasix TID started on POD1	Lasix IV day prior to CT removal	Diuril + aldactone when taking PO	IV diuril used?	Required electrolyte supplementation	Discharged on electrolyte supplemenation	D/C'ed on other PO diuretics?	On home diuretic regimen 24-48 hrs prior to d/c	Total # lab draws	CBC	BMP	LFT	Coags	NT-Pro BNP	AT3	IgG	Blood Gas	Albumin lab

Appendix M

Statistical Analysis Results Table and Graphs

	Pre-Pathway n = 37	Post-Pathway n = 30	p-value
Age, mean (sd)	5.84 (1.7)	3.73 (1.3)	<0.001
LOS, median (IQR)	12 (9-14)	9 (7-11)	0.007
Total lab draws, median (IQR)	28 (20-41)	28 (20-36.5)	0.837
Readmission within 30 days	4 (10.8%)	5 (16.7%)	0.500
Fenestration	11 (29.7%)	7 (23.3%)	0.557
Coumadin	12 (32.4%)	1 (3.3%)	0.003
Chylous	3 (8.1%)	2 (6.7%)	1.00
PICC line	13 (35.1%)	22 (73.3%)	0.002
Thrombus/Infection	0 (0%)	6 (20.0%)	0.006