

APPLICATION PACKET

Thank you for your interest in the National Pediatric Cardiology Quality Improvement Collaborative. The NPC-QIC Quality Improvement Task Force is organizing this project with improvement support from the Center for Health Care Quality at Cincinnati Children's Hospital Medical Center.

This application packet is to guide you in understanding the project, getting started with your IRB application and reviewing the collaborative activities and expectations.

We are grateful for the support for this project from:

The Children's Heart Association

The Pediatric Center for Education and Research in Therapeutics at Cincinnati Children's Hospital
Medical Center, the Agency for Healthcare Research and Quality U18 HS016957



PACKET CHECKLIST FOR TEAMS

- ☐ Please review the following documents in this packet:
 - Project Overview and Requirements
 - Project Timeline
 - Improvement Project Charter
 - Key Driver Diagram
 - Intent to apply form
 - Site Application
 - Site Application- Core Improvement Team Information
 - Senior Leader Agreement
 - IRB application materials (separate attachment)
 - Protocol
 - Parental Permission form (in the protocol)

- ☐ After reviewing the above materials, please submit the following:
 - Intent to apply form at your earliest convenience
 - Site Application within 2 weeks of receiving this packet including:
 - Senior Leader Agreement
 - Site Application- Core Improvement Team Information

Teams will be notified of receipt of the above information via email and kept apprised of application status.

- ☐ Submit IRB application to your local site.

The IRB Protocol and Parent Consent is available in a separate attachment to assist you in your IRB application. We encourage you to prepare and submit your IRB application to your committee as soon as possible. Only sites who have received their IRB approval can initiate data collection. The project team will assist you in beginning data collection, obtaining access to REDCap and entering patients into the registry/database.

 - Please let the project team at jchdqj@cchmc.org know when you have submitted your IRB and again when you have received approval.

- ☐ Please visit the project website at: www.jchdqj.org

Please do not hesitate to contact Ashwini Roy-Chaudhury at 513-636-2073 or at Ashwini.Roy-Chaudhury@cchmc.org at any time with any questions you may have.

PROJECT OVERVIEW & REQUIREMENTS

MISSION STATEMENT FOR THE JOINT COUNCIL

The mission of the National Pediatric Cardiology Quality Improvement Collaborative , a JCCHD Initiative is to improve dramatically the outcomes of care for children with congenital heart disease (CHD).

Project Introduction

The mission of the first initiative of the NPC-QIC QI Task Force is to improve the quality of life and outcomes of infants with single ventricle physiology. The project has two objectives:

1. Design and implement an improvement project to improve survival and reduce morbidity of infants with hypoplastic left heart syndrome in the interstage period and,
2. Build a sustainable collaborative network involving all pediatric cardiologists in North America, including a database to inform future improvement projects. This network will provide opportunities for pediatric cardiologists to collaborate on both quality improvement and research projects.

NPC-QIC QI Task Force Members and initial participating Sites

Robert H. Beekman, III, MD, Cincinnati Children's Hospital Medical Center
Kathy Jenkins, MD, Children's Hospital Boston
Thomas Klitzner, MD, PhD, Mattel Children's Hospital at UCLA
John Kugler, MD, Children's Hospital Omaha
Gerard Martin, MD, Children's National Medical Center
Steven Neish, MD, Texas Children's Hospital
Geoffrey Rosenthal, MD, PhD, Children's Hospital Cleveland Clinic

Quality Design and Implementation Support: Center for Health Care Quality at Cincinnati Children's Hospital Medical Center

Carole Lannon, MD MPH, Quality Improvement Design Lead
Divvie Powell, MSN, RN, Collaborative Director
Ashwini Roy-Chaudhury, MPH, Project Manager
Srikant Iyer, MD MPH, Measurement Advisor
Abigail Chandler, MHA, Project Coordinator

Project Overview

This project will involve two phases. The initial phase began in Fall 08 involving six pilot sites testing and implementing the database/registry of infants with hypoplastic left heart syndrome discharged home from the Norwood Surgery. Data collection included information about care processes in addition to clinical data. In the second phase of this project, additional teams will join the pilot sites to participate in an improvement collaborative that will involve three learning sessions, collaboration with experts and national colleagues, implementation and testing of improvement strategies locally, and involvement in monthly calls and listserv discussion intended to facilitate sharing of successful strategies.

Phase One – Implementing the registry and collecting data

Six pilot sites have completed their IRB and are testing a web-based data capture system, REDCap. The project team will develop feedback reports from the database and reviewing with sites to make sure the reports are accurate and helpful to the project participants. This phase will also provide an opportunity to test the improvement measures we have selected for the project and establish baseline performance. The pilot sites will test some changes from the key driver diagram in the areas of discharge processes, nutritional assessment and interstage surveillance. The learning from the pilot sites will inform the activities for the improvement collaborative.

Phase Two – Participation in the Improvement Learning Collaborative

This phase is scheduled to begin in late spring/early summer 2009. New teams will join the pilot sites to participate in the activities of the Improvement Learning Collaborative to more thoroughly assess their current care delivery system and test change strategies developed by the JCCHD QI Task Force in their own sites. Feedback reports will be provided on a monthly basis. Teams will come together via workshops (learning sessions) and conference calls to discuss their challenges and successes in order to learn from each other how to implement the proposed changes to achieve the target goals. A timeline outlining improvement team activities is included in this packet on **page 5**.

Participation in the Learning Collaborative

Effective participation in a Learning Collaborative requires a small, multidisciplinary team with representatives who can effect change in the three areas of focus for the collaborative:

- Care Transition: Discharge protocols and communications
- Nutritional assessment and monitoring (Optimizing nutritional status)
- Care Coordination with parents and medical home: including interstage surveillance

Please reference the charter on **page 6** and key driver diagram on **page 12** for more detail about the improvement learning collaborative.

The expectations for a core team interested in participating in this Learning Collaborative include:

- 1) Full participation of the team for approximately 18 months, including:
 - Participation in an Orientation conference call, database orientation call and monthly conference calls between learning sessions. At least one individual call with each site will occur during the course of the collaborative. Details will be sent to all team members as soon as we have this information.
 - Attendance at three two-day learning sessions (workshops) with the first Learning Session scheduled for September 11th-12th 2009 in Cincinnati OH.

The “core team” should consist of:

- Cardiologist
- NP/RN from clinics responsible for interstage care, parent education and parent management of child with hypoplastic left heart syndrome.
- Data coordinator – person who can facilitate data entry into web database, who is familiar with medical record documentation and points of care
- Representative from nutrition department and/or discharge coordinator

Formal commitment by a Senior Leader of your site or organization to support you in this endeavor and to provide necessary resources and time to devote to testing and implementing changes in the site. If needed, we will be happy to speak with your leadership to explain the project and its

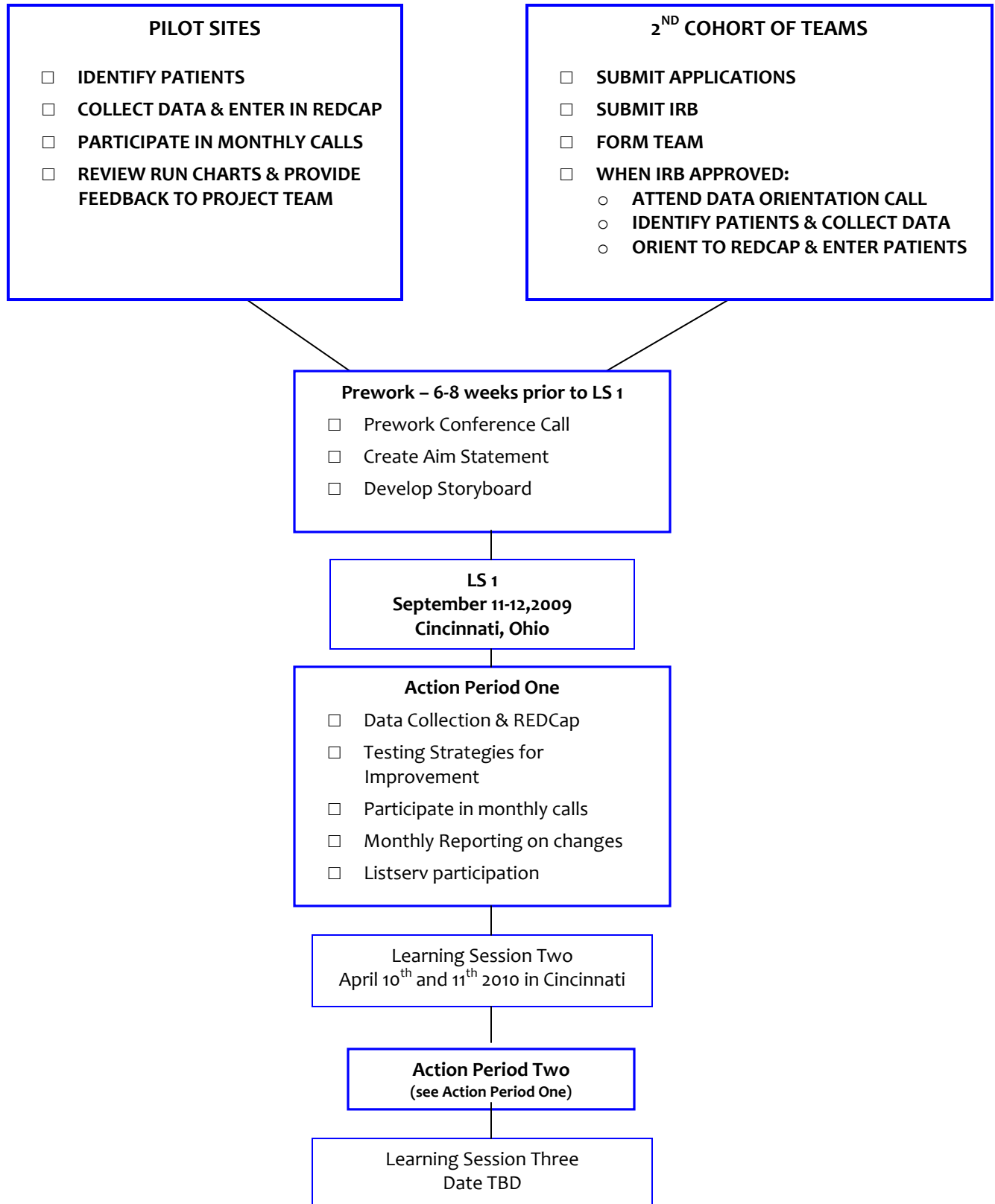
expectations, and how it could fit in with organizational quality improvement goals. The Senior leader should be someone outside the improvement team that has administrative responsibilities/oversight for the clinic area.

- 2) One member of the core team should be designated as the site's **Key Contact**. A Key Contact is defined as the individual who is responsible for organizing day-to-day activities, including coordinating regular team meetings, managing improvement responsibilities, and ensuring that reports and/or data are collected and reported by their due date. Because the Key Contact is the site's primary communicator with the JCCHD project team, it is important that they are easily accessible and can disseminate information quickly.
- 3) Participation in a web-based data collection tool (REDCap) to develop a network database and ensure that the changes you are making are resulting in improvements.
- 4) Submission of monthly progress reports to the Collaborative and use of the extranet to share progress with other teams in the collaborative.
- 5) Willingness and commitment to test and implement changes for improvement
- 6) Regular access to, and use of, email, listserv and the extranet for ongoing support, information, and communication among teams.
- 7) Formation of an "extended team" to support the core team in planning and implementing changes to your system. They are not expected to travel to learning sessions. Suggested members of the extended team include:
 - Clinic manager or delegate
 - Representative from discharge planning (if not on core team)/nursing education/nursing practice*
 - A parent of a child with hypoplastic left heart syndrome
 - Representative from surgical staff
 - Representative from administrative/support staff
 - Representative from quality improvement department
 - Representative of IT department within your site
 - Nursing and Administrative Leaders, if not on the core team

Beginning on page 13 an Intent to Apply form and Site Application materials will assist the project team to learn about your site. We ask that you return to us **within 4 weeks** of receiving this application packet.

National Pediatric Cardiology Quality Improvement Collaborative

Collaborative Timeline



**THE NATIONAL PEDIATRIC CARDIOLOGY
QUALITY IMPROVEMENT COLLABORATIVE:
A JCCHD Initiative**

Improvement Project Charter

May 15 2008

(rev. 06-30-09)

MISSION

The mission of the National Pediatric Cardiology Quality Improvement Collaborative: a JCCHD Initiative is to improve dramatically the outcomes of care for children with congenital heart disease (CHD). There are two initial activities:

1. Plan and implement an improvement project to improve survival and reduce morbidity of infants with hypoplastic left heart syndrome between stage 1 and stage 2.
2. Build a sustainable collaborative network involving all pediatric cardiologists in North America, including a database to inform future improvement projects. This network will provide opportunities for pediatric cardiologists to collaborate on both quality improvement and research projects.

BACKGROUND

Why is JCCHD interested in forming a National Collaborative for Research and Improvement?

A long-term goal of the JCCHD is to involve all pediatric cardiologists in a research and improvement network. Because many of the conditions encountered in pediatric cardiology practice are rare and heterogeneous, there is a critical need for evidence-based approaches to diagnosis and treatment of these disorders. A national repository of patients can facilitate quality improvement and clinical research studies. This would allow the most cost-effective, efficient and safe methods for the diagnosis of diseases can to be more rapidly analyzed. New therapeutic and practice improvement approaches can also be more quickly assessed and results disseminated, providing more timely and optimal patient care. Creation of detailed databases will facilitate power analysis and sample size calculations for future quality improvement projects and clinical research studies. Uniformity in protocols and expertise of centralized personnel will promote quality and decrease the variability of performance. Multi-center studies will more likely attract the favorable attention of study sponsors, foundations and the National Institutes of Health.

Understanding differences in practice that result in differences in outcomes will be critical to transforming pediatric cardiology practice. In the network, quality improvement activities can be more broadly encouraged, standardized and assessed, leading to better patient care and outcomes. In addition, ongoing quality improvement activities will be required by the American Board of Pediatrics for maintenance of certification in pediatric cardiology. It is desirable for JCCHD to be proactive in the design of these activities.

American Board of Pediatrics

The American Board of Pediatrics (ABP) and the Center for Health Care Quality (CHCQ) have developed activities with the aim of *improving the health of all children with serious chronic illness in the United States by improving the quality of pediatric sub-specialty care*. The model for these activities includes 1) national databases/registries of key childhood illnesses (such as congenital heart disease) developed and coordinated with existing databases and 2) subspecialty-wide multi-center collaborative improvement and research efforts to coordinate improvement activities among pediatric sub-specialists. This NPC-QIC Improvement project will enable pediatricians to fulfill Part 4 of the Program of Maintenance of Certification for Subspecialists (PMCP-S), evidence of satisfactory performance in practice.

The remainder of this document will focus on the first activity of the National Pediatric Cardiology Collaborative, improving care for children born with hypoplastic left heart syndrome.

Statement of problem: Congenital heart disease

Approximately 800,000 children in the US have CHD and each year another 40,000 infants are born with CHD. Of the myriad cardiac defects that may be present at birth, univentricular heart (or single ventricle) is the most complex and is associated with the highest rates of morbidity and mortality. Hypoplastic left heart syndrome accounts for approximately 10% of congenital heart defects overall. Therefore, there are approximately 4000 infants born with these defects in the US each year.

The term univentricular heart is applied to children born with hypoplastic left heart syndrome, tricuspid atresia, pulmonary atresia with intact ventricular septum, double inlet left ventricle, and unbalanced atrioventricular canal defects. Virtually all will require surgical palliation in the newborn period (e.g. a Norwood procedure, a shunt or pulmonary artery band) and will proceed along a common univentricular treatment pathway that includes a bidirectional Glenn shunt at 4-6 months, and a Fontan procedure at 2-4 years of age. The ultimate goal of therapy is to provide unobstructed ventricular outflow to the systemic circulation, to protect the pulmonary circulation from elevated pressure and flow, and to eventually establish divided systemic and pulmonary circulations in series.

For families that choose surgical palliation in the newborn period (e.g. a Norwood procedure), Infants will proceed along a common treatment pathway that includes a bidirectional Glenn shunt at 4-6 months, and a Fontan procedure at 2-4 years of age. The ultimate goal of therapy is to provide unobstructed ventricular outflow to the systemic circulation, to protect the pulmonary circulation from elevated pressure and flow, and to eventually establish divided systemic and pulmonary circulations in series.

A substantial risk for morbidity and mortality is encountered by children born with a hypoplastic left heart syndrome. Mortality risk alone in children with hypoplastic left heart syndrome can be 15-20% at the Norwood stage, 10-15% interstage mortality prior to the Glenn procedure, 3-5% at the Glenn and another 3-5% at the Fontan surgery; this amounts to a total 30-45% mortality risk in the first 4 years of life. Children who survive surgical palliation of a hypoplastic left heart syndrome also encounter substantial morbidities that may include vocal cord paralysis, phrenic nerve injury, inability to feed orally, poor growth, gastrointestinal complications, renal dysfunction, seizures, developmental delay, the need for supplemental oxygen and numerous medications, as well as frequent and often prolonged hospitalizations.

Evidence-based guidelines for the inpatient and outpatient care of children with a hypoplastic left heart syndrome are lacking, and there is little guidance for pediatric cardiologists about how best to care for these children. In addition, there are too few patients at any one center to accumulate sufficient evidence about optimal care. Dissemination of new information about improving care for these children is slow and inefficient. Outcome measures to determine the effect of therapies are evolving slowly, and there is no standardized clinical record to monitor a patient's course, disease activity or quality of life.

Most pediatric cardiologists provide care for children with a hypoplastic left heart syndrome. In fact, the inpatient and outpatient care of these children requires the input from and expertise of virtually all subspecialties within the field of Pediatric Cardiology. For example and chronologically, fetal cardiologists often make the initial diagnosis, cardiac intensivists provide pre- and post-operative intensive care, echocardiographers are involved in diagnostic studies, cardiac catheterizations specialists perform invasive diagnostic and interventional catheterization procedures, electrophysiologists diagnose and treat early and late post-operative arrhythmias, and outpatient pediatric cardiologists provide long-term management including recommendations concerning chronic medical therapy, exercise participation, birth control and other lifestyle issues. Clearly, quality improvement initiatives for children with a hypoplastic left heart syndrome have the potential to involve the entire Pediatric Cardiology community.

Care transitions

A study about transitions of care for patients suggests that caregivers are often unprepared for their role in the next care setting, don't understand essential steps in care management, and do not have the appropriate contact information for appropriate health care providers.[†] Of note, there is rarely feedback to discharge planners regarding the execution or outcomes of proposed discharge plans.

An intervention to address these issues in the care of geriatric patients has been developed. The Care Transitions Intervention, developed at the University of Colorado Health Sciences Center, is a patient-centered, interdisciplinary team intervention designed to improve transitions across sites, including home, of geriatric care. The intervention includes providing patients tools to promote cross-site communication, encouragement to communicate assertively with medical personnel, and guidance from a "transition coach."[‡] Patients who received the intervention reported high levels of confidence in understanding their medication regime and obtaining essential information for managing their condition.[§] The Care Transitions Intervention is associated with reduced rates of subsequent hospitalization. This work has been adopted by the Center for Health Care Quality for use in the American Board of Medical Specialties Patient Safety Improvement Program.

What parents need

In February and March of 2006, the Washington State Department of Health and Seattle Children's Hospital and Regional Medical Center conducted a web-based survey of parents of children with special health care needs. The survey was publicized through parent organizations, support groups, public health nurses, and selected clinics at Children's Hospital. At the time of the survey *only 31% of parents reported having a written care plan for their child.* However, 86% believed it was important to

[†] Parry C, Coleman EA, Smith JD, Frank J, Kramer AM. The Care Transitions Intervention: A Patient-Centered Approach to Ensuring Effective Transfers Between Sites of Geriatric Care. *Home Health Care Services Quarterly*. 2003; 22:1-17.

[‡] Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing Patients and Caregivers to Participate in Care Delivered Across Settings: The Care Transitions Intervention. *Journal American Geriatrics Society*. 2004; 52:1817-1825.

[§] *Ibid*, p1817.

have such a plan. Parents believed that a written care plan would help with the quality of health care their child receives in different settings, help with transitions between hospital and home, facilitate communications between parents and health care professionals, and summarize health information such as medications, therapies and treatments. Parents suggested that written care plans be simple, brief and flexible.

Efforts to provide increased monitoring of infants

Children's Hospital of Wisconsin developed a home surveillance program for parents of infants with hypoplastic left heart syndrome to detect daily variances in arterial oxygen saturation according to pulse oximetry, weight loss and failure to gain weight. A case series suggested this program was associated with improved interstage survival.**

** Ghanayem NS, Hoffman GM, Mussatto KA, Cava JR, Frommelt PC, Rudd NA, Steltzer MM, Bevandic SM, Frisbee SJ, Jaquiss RDB, Litwin SB, Tweddell JS. Home Surveillance Program Prevents Interstage Mortality after the Norwood Procedure. *Journal Thoracic and Cardiovascular Surgery*. 2003; 126:1367-77.

Improvement Project Aim

The aim of the improvement project is to eliminate mortality, morbidity and to improve quality of life and outcomes of infants with hypoplastic left heart syndrome (HLHS) s/p Norwood between Stages 1 and 2 by July 2010. Our target goals include:

TARGET GOALS

- Eliminate interstage mortality (Initial goal will be to: decrease by 50%).
- Eliminate interstage major events (e.g. cardiovascular and renal compromise, neurologic deficit, etc.) (Initial goal will be to: decrease by 50%)
- Achieve minimum growth goal for 90% all interstage patients
- 100% of patients are discharged with:
 - Written plan for outpatient follow up and care
 - Assessment of need for preventive care
 - Written expectations for care, ‘red flag’ action plan, nutrition plan and medication list for parents
 - Communication of above to medical home, primary care provider
- Centers utilize standard discharge protocols and ensure there is ‘process owner’ for patient discharge and home health coordination.
- 100% Clinic visits include
 - Assessment of need for preventive care
 - Measurement of caloric intake and growth parameters
 - Review and update of nutrition plan
 - Written expectations for care, ‘red flag’ action plan, nutrition plan and medication list for parents

Balancing Measures

Balancing measures assess whether improvements to one part of the system cause unintended consequences. Appropriate measures will be considered and determined during initial data collection.

Key Driver Analysis

The interstage period will be the primary focus of improvement. The key driver diagram below illustrates the areas we will strive to improve to reach our target goals.

Collaborative Expectations

The JCHD Collaborative Leadership Team will:

- Provide evidence-based information on care of patients with hypoplastic left heart syndrome disease
- Offer coaching to improvement teams on applying the Model for Improvement to implement key changes at the learning sessions, on conference calls and through the listserv
- Provide each team **regular (monthly or quarterly, as appropriate)** feedback charts/reports on data collected at each site
- Provide an extranet for posting of individual charts, submitted monthly report and aggregate information and a library of tools and training materials
- Provide communication methods to keep participants connected to the faculty and to colleagues during the Improvement Collaborative

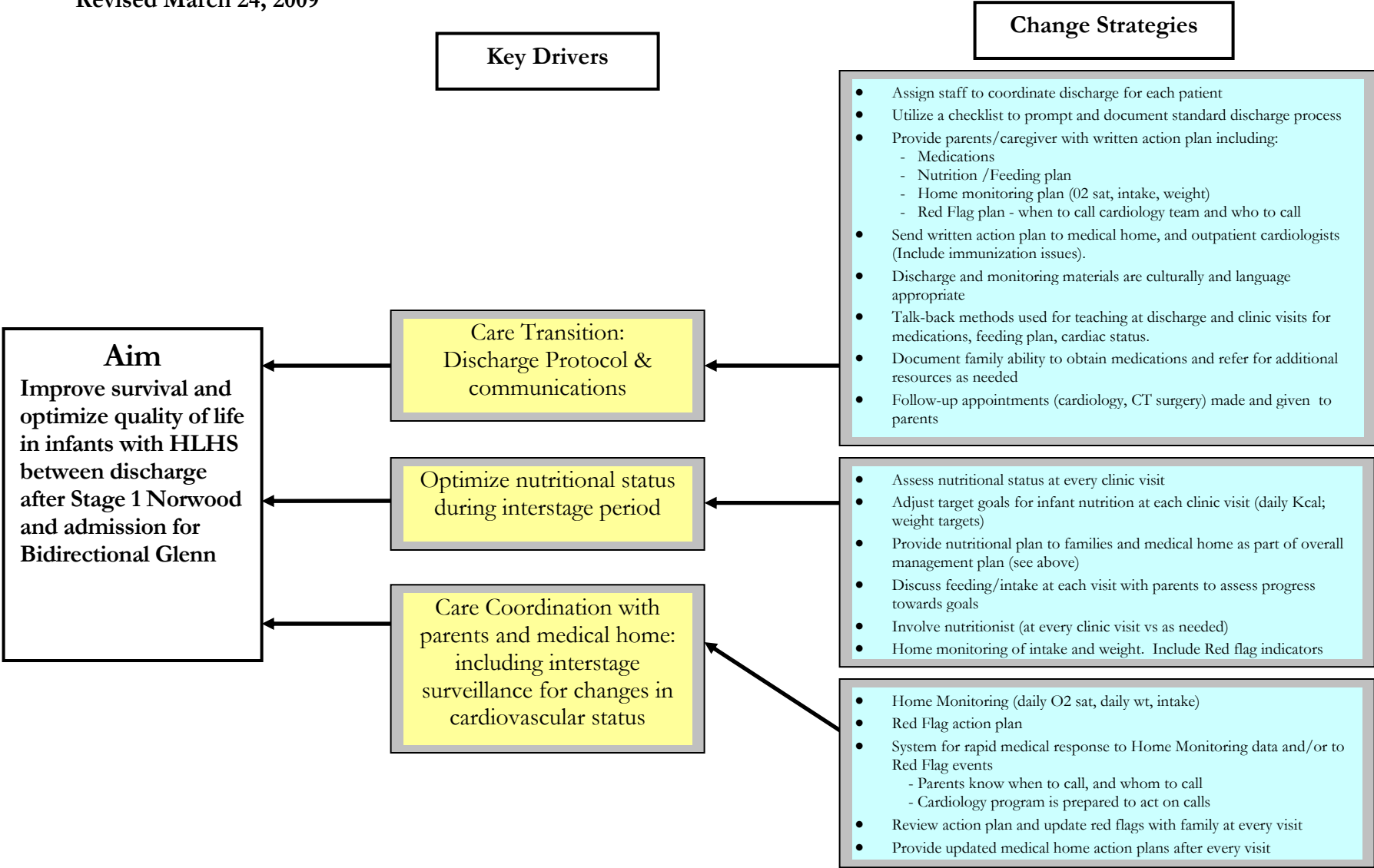
- Provide tools, forms, and other aids to help with implementation of key areas of care
- Provide data entry support and facilitate utilization of REDcap database

Participating organizations and teams are expected to:

- Secure senior leader support for the improvement team's work in the collaborative
- Organize a team and complete prework activities prior to Learning Session One
- Send a team of at least three, including the physician champion to all Learning Sessions
- Provide resources and support to the improvement team (including support to attend the 3 learning sessions, time to devote to testing and implementing changes at the site, and active senior leadership involvement)
- Perform prework activities to prepare for the Learning Sessions
- Align the goals of the Collaborative work to the work of the organization.
- Use the REDCap database to track patients and their care
- Perform tests of change in their setting that lead to improvements towards the desired outcomes
- Participate in Collaborative calls and the listserv to share with and learn from others
- Submit a monthly report in order to share information with Collaborative faculty and other participants. This report includes details of changes made and data to evaluate the impact of these changes.

KEY DRIVER DIAGRAM

Revised March 24, 2009



Key Drivers

Change Strategies

Aim
 Improve survival and optimize quality of life in infants with HLHS between discharge after Stage 1 Norwood and admission for Bidirectional Glenn

Care Transition:
 Discharge Protocol & communications

Optimize nutritional status during interstage period

Care Coordination with parents and medical home: including interstage surveillance for changes in cardiovascular status

- Assign staff to coordinate discharge for each patient
- Utilize a checklist to prompt and document standard discharge process
- Provide parents/caregiver with written action plan including:
 - Medications
 - Nutrition /Feeding plan
 - Home monitoring plan (O2 sat, intake, weight)
 - Red Flag plan - when to call cardiology team and who to call
- Send written action plan to medical home, and outpatient cardiologists (Include immunization issues).
- Discharge and monitoring materials are culturally and language appropriate
- Talk-back methods used for teaching at discharge and clinic visits for medications, feeding plan, cardiac status.
- Document family ability to obtain medications and refer for additional resources as needed
- Follow-up appointments (cardiology, CT surgery) made and given to parents

- Assess nutritional status at every clinic visit
- Adjust target goals for infant nutrition at each clinic visit (daily Kcal; weight targets)
- Provide nutritional plan to families and medical home as part of overall management plan (see above)
- Discuss feeding/intake at each visit with parents to assess progress towards goals
- Involve nutritionist (at every clinic visit vs as needed)
- Home monitoring of intake and weight. Include Red flag indicators

- Home Monitoring (daily O2 sat, daily wt, intake)
- Red Flag action plan
- System for rapid medical response to Home Monitoring data and/or to Red Flag events
 - Parents know when to call, and whom to call
 - Cardiology program is prepared to act on calls
- Review action plan and update red flags with family at every visit
- Provide updated medical home action plans after every visit

INTENT TO APPLY

Please complete this brief Intent to Apply Form and email to jchdqj@cchmc.org

[Please complete the application documents in the Word document available at www.jchdqj.org]

- We intend to apply to participate in the Joint Council on Congenital Heart Disease Project.
By submitting this intent to apply, we intend to submit the full application within two weeks

Organization Name: _____ Date: _____

Key Contact Name: _____

Title: _____

Address: _____

City: _____ State: _____ Zip/Postal Code: _____

Phone: _____ Fax: _____

Email: _____

Site Application

[This application and forms are available in separate Word Document at www.jcchdqj.org]

Please complete this brief questionnaire and return to jcchdqj@cchmc.org

Date: _____ **Site Name:** _____

Name of person completing this questionnaire: _____

Title: _____

Email: _____ **Phone number:** _____

1. Briefly describe the aspects of your hospital/clinic/ organization that relate to care of the infant with univentricular heart disease (including type of organization, size, structure, location).
2. In addition, please complete the Core Improvement Team Information grid on page 16.
3. What does your organization want to accomplish as a participant in this Collaborative?
4. Please estimate the # infants with newly diagnosed hypoplastic left heart syndrome/year :
5. Please estimate the # infants with congenital heart disease your site sees each year :
6. Does your pediatric cardiology team utilize the “Tweddell protocol” or a modification (e.g. home monitoring of weight and pulse oximetry)? Please describe.
7. How soon after discharge after Stage 1 surgery is an infant with hypoplastic left heart syndrome usually seen in cardiology clinic for follow up? Estimate what percentage of your surgery patients are followed elsewhere.
8. Does your pediatric cardiology team utilize a nutritionist as part of your outpatient clinical team on a regular basis? Please describe resources available to you for nutritionist/dietician support.

9. What is the name & position of the Senior Leader who can remove whatever obstacles may arise or to obtain necessary resources during the Collaborative? In addition, please have your Senior Leader complete the Senior Leader/Administrator Agreement on **page 17**.

10. Briefly describe any experience that you or others have in initiating successful improvement activities, participating in a learning collaborative or any experience with measurement of quality outcomes. In what topic area(s)? Do you have quality improvement support within the unit structure or from the hospital? Examples of this support would be data collection, team facilitation, meeting documentation and planning for improvement activities aimed at helping you accomplish your goals.

11. Have the members of your proposed core team worked together on a prior project?

12. Is the proposed clinic setting currently involved in a major change process or research study that demands a great deal of time? Is your site experiencing significant organizational change (i.e., merger, change in leadership, vacancy in leadership, or EHR implementation)? Please explain.

13. Please add any additional information about your setting that may be relevant to this project.

Site Application

Core Improvement Team Information

Team Member 1 – Key Contact (See **page 4** for a description of this role)

Name: _____

Title: _____

Direct Phone: _____ Direct Fax: _____

Email: _____

Team Member 2 – Data Coordinator *

Name: _____

Title: _____

Direct Phone: _____ Direct Fax: _____

Email: _____

Team Member 3

Name: _____

Title: _____

Direct Phone: _____ Direct Fax: _____

Email: _____

Team Member 4 (optional)

Name: _____

Title: _____

Direct Phone: _____ Direct Fax: _____

Email: _____

*The Key Contact can serve as data coordinator initially. A minimum of three persons are needed for the improvement team.



Please EMAIL Site Questionnaire to jchdqj@cchmc.org



SENIOR LEADER/ADMINISTRATOR AGREEMENT


Name: _____

Title: _____

Organization: _____

Direct Phone: _____ Direct Fax: _____

Email: _____

 **As the Senior Leader*, I fully understand the project's objectives and expectations. Furthermore, I agree to support the team and will work with them to remove any barriers and/or provide the resources necessary for them to achieve their improvement goals. Finally, I understand that I will be invited to participate in a teleconference with other senior leaders between LS1 and LS2.**

Senior Leader Signature: _____

* The Senior leader should be someone outside the improvement team that has administrative responsibilities/oversight for the cardiology clinic.

Please FAX this Senior Leader signature page to:

Ashwini Roy-Chaudhury at 513-636-0171

Appendix One

Cincinnati Children's Hospital and Medical Center **IRB PROTOCOL**

The IRB Protocol and Parent Consent is available in a separate attachment to assist you in your application. Once you have made your decision to participate in the project and have submitted your application, we encourage you to prepare and submit your IRB application to your committee as soon as possible. Please let us know when you have submitted your IRB application and when you expect to be reviewed. When sites have received their IRB approval, the project team will assist them in beginning data collection, obtaining access to REDCap and entering patients into the registry/database.