

**NATIONAL PEDIATRIC CARDIOLOGY QUALITY IMPROVEMENT COLLABORATIVE:  
DEVELOPMENT AND EARLY YEARS**

**From the Joint Council on Congenital Heart Disease Quality Improvement Taskforce**

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**Running title:** Establishment of a Pediatric Cardiology Improvement Collaborative

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**Abstract**

The National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) was established by the Joint Council on Congenital Heart Disease to dramatically improve the outcomes of care for children with congenital heart disease (CHD) through a national collaborative network of multidisciplinary clinical teams and families, working together to collect longitudinal data, use improvement science methods and conduct research intended to accelerate the development and translation of new knowledge into practice. The initial project selected for this learning network is focused on care processes and outcomes of the initial interstage period for infants with hypoplastic left heart syndrome. A practice-based registry is being used to understand variation in care and outcomes of infants and children with complex CHD. The NPC-QIC has effectively recruited and engaged a large number of U.S. centers caring for infants with complex CHD and provides the infrastructure needed to support the implementation of practice changes across the collaborative that will ultimately improve outcomes in this high-risk group of patients. We describe here the development and early years of NPC-QIC as well as the challenges this collaborative faces moving forward.

**Key words:** quality improvement, collaborative, outcome improvement

## **Introduction**

Infants with congenital heart disease (CDH) manifest broad anatomical and physiological heterogeneity, often making medical decision making complex. Clinical assessments regarding medical and surgical management in an individual patient are frequently made based on individual or group past experience rather than on scientific evidence.<sup>1</sup> The relative paucity of patients with complex CHD and the variation in their anatomy and physiology has made it difficult to perform rigorous studies defining best practices that are associated with improved outcomes in this field of medicine. *The purpose of this report is to describe the development of the Joint Council on Congenital Heart Disease (JCCHD) National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) and the use of a multi-site network, practice-based registry data and improvement science methods to identify variation in management and to improve outcomes in patients with hypoplastic left heart syndrome.*

## **Background**

Advances in surgical technique and medical management over the past decades have led to improvement in clinical outcomes in even the most complex of congenital heart defects.<sup>2</sup> Yet, despite this progress, there continues to be major variation in management practices among individuals and institutions caring for children with CHD.<sup>3-5</sup> It has been demonstrated in both industry and healthcare that reduction in variation leads to safer practices, cost reduction and improved outcomes.<sup>6-10</sup> Standardization of healthcare practices reduces process variation and provides a foundation on which new approaches can be tested more effectively.

### *Role of Clinical Networks and Registries*

Clinical networks and registries are useful vehicles to aid in understanding variation in clinical care, and to test changes in clinical practice that can standardize care and improve clinical outcomes. Large networks and registries provide the infrastructure to gather information on patients across treatment centers and to understand differences in care processes and clinical outcomes. Regional and national networks and databases have been established to better understand care of pediatric cancer, neonatal management, and cystic fibrosis.<sup>11-14</sup> Implementing a registry has been shown in multiple trials to be important in reducing variation and improving care for patients with chronic illness.<sup>11</sup> In pediatric cardiology and cardiac surgery, registries (e.g., Pediatric Heart Network, Society for Thoracic Surgery Registry, Mid-Atlantic Group of Interventional Cardiology (MAGIC) Registry, Pediatric Cardiology Care Consortium, Pediatric Electrophysiology Society

Ablation Registry, IMPACT Registry) have generated comparative data between centers and identified clinical outcomes that are related to variation in care.<sup>15-18</sup>

A learning network is a multi-site clinical network that uses data for *both* research and improvement. Successful models include the Northern New England Cardiovascular Disease Study Group, Vermont Oxford Network (VON), and the Children's Oncology Group (COG).<sup>19-21</sup> Research and improvement networks can offer epidemiologic, statistical and translational advantages allow for creation of "laboratories" for conducting comparative effectiveness and translational research.<sup>22-24</sup> Creation of total population registries within and across network sites provides large, diverse, and representative study samples. By facilitating spread of changes that standardize practice, variations in outcomes due to variations in care delivery are reduced and statistical power is increased. By linking research to care delivery and engaging clinicians directly, these networks can conduct research about how to effectively implement changes to improve care and outcomes and accelerate the translation of new evidence into practice. Clinician end-users of such effectiveness research are in a unique position to identify critical healthcare knowledge gaps and design interventions to bridge those gaps. Finally these care providers, along with their patients, are the final benefactors of change at the point-of-care.

Learning networks allow not only for data collection but for structured implementation of changes in practice through quality improvement (QI) science methodology. QI activities in the pediatric subspecialties, including pediatric cardiology, have been catalyzed in part by the adoption of new Maintenance of Certification (MOC) requirements by the American Board of Pediatrics (ABP).<sup>25</sup> MOC emphasizes ongoing assessment and documentation of performance, and participation in QI activities, as a requirement for ongoing certification.

### **Establishment of the NPC-QIC**

In 2003, the Joint Council on Congenital Heart Disease (JCCHD) was formed as a leadership alliance to enhance communications and improve coordination among the various societies representing pediatric cardiologists, congenital heart surgeons and adult congenital heart disease specialists. Member organizations include: the American Academy of Pediatrics, the American Board of Pediatrics, the American College of Cardiology, the American Heart Association, with additional affiliate input from the Congenital Heart Surgery Society and International Society for Adult Congenital Cardiac Disease. In 2006, the JCCHD set out to develop a national, multi-institutional database for the purpose of supporting quality-improvement projects with a goal to

improve care and outcomes for children with cardiovascular diseases and organized the NPC-QIC. Details regarding the design and initial implementation initiation have been reported previously.<sup>26</sup> Initial seed funding was provided by the Children's Heart Association of Cincinnati, a parent-led organization which has a close working relationship with the Heart Institute of Cincinnati Children's Hospital Medical Center. The vision, support and guidance of key leaders in pediatric cardiology contributed to the development of a strong foundation for the collaborative. Three organizational representatives serving on the JCCHD agreed to lead the NPC-QIC; this trio invited an additional four members to constitute a seven-member Task Force. This has brought together key leaders with expertise in content, quality measurement, and family-centered care.

### Design and Development of the NPC-QIC

The mission of the NPC-QIC is to dramatically improve the outcomes of care for children with CHD through a national QI collaborative network of multidisciplinary clinical teams and families, working together to collect longitudinal data and conduct QI research intended to accelerate the development and transition of new knowledge into practice.<sup>26</sup> Thus, the NPC-QIC was intended to have a systems approach to the design, testing, and assessment of changes in care processes and outcomes, using a robust data registry and improvement science methods.

### Topic selection

The NPC-QIC Task Force defined the aim of the initial project as: "To reduce mortality and improve the quality of life of infants with hypoplastic left heart syndrome (HLHS) during the interstage period between discharge from the Norwood and admission for the bidirectional Glenn procedure.<sup>26</sup> Infants discharged home while awaiting their next surgical palliation, the bidirectional Glenn shunt, have reported mortality rates estimated at 10-15%.<sup>27-29</sup> Surviving infants experience significant morbidities, including poor feeding, chronic cyanosis, recurrent laryngeal or phrenic nerve injury, delayed growth and development. This group often requires numerous unscheduled clinic visits and readmissions to address these and other problems.<sup>30</sup> Thus, care for infants with HLHS presents an opportunity for caregivers to identify and decrease variation and improve clinical processes and outcomes.

Parents of infants with HLHS were interviewed during the design phase to better understand their needs and concerns. The drivers, or areas of focus, that were deemed to be necessary to reach this aim fell into three areas: engaging parents, improving care transitions at discharge following stage 1 surgical palliation, ensuring adequate growth by optimizing nutrition, and improved care

coordination among the cardiology team, the primary care team, and families. **See Figure 1.** Using this key driver diagram as a guide the Task Force developed metrics to address both the outcomes and processes thought important to achieving project goals. Key outcome measures are 1) the mortality of infants during the interstage period; 2) readmissions during the interstage due to adverse events; and 3) growth failure. Growth failure was initially defined as a weight-for-age percentage <10%ile at the time of the Glenn palliation. Later the definition was refined and currently is defined as negatively crossing two major weight-for-length percentiles during the interstage. Control charts demonstrating the tracking of these key outcome measures can be seen in **Figure 2.**

#### Team Recruitment:

Teams were invited to participate through an invitation circulated through the American Academy of Pediatrics Section on Cardiology and Cardiac Surgery, as well as multiple presentations at pediatric cardiology meetings. The involvement of the Task Force, a group of well-respected national leaders from within the pediatric cardiology community who hold key roles on national committees, were a key factor in raising awareness about this effort and in generating strong buy-in from the pediatric cardiology community.

#### Data collection

Data on all infants with HLHS from practice site registries and electronic medical records (EMRs) are entered into the collaborative registry via the network's web-based, secure password-protected system for data management, creation of aggregate and peer comparison reports and ongoing analysis. Teams from five of the seven Task Force members' institutions participated in testing the data collection forms and use of the registry.

Infants become eligible for registry inclusion and initial data collection when they are discharged home from their Norwood surgery. Teams collect clinical information on HLHS patients at several time points. **See Figure 3.** At the time of discharge following Norwood surgical palliation patients are enrolled and data from their surgery and hospitalization are captured. Clinical information is then collected from each clinic visit and readmission to the hospital during the interstage period. Finally, data is collected upon readmission for stage 2 surgical palliation and the hospitalization that follows this surgery. Data is collected and entered into an electronic registry that was created using the Research Electronic Data Capture (REDCap) system.

### Collaborative structure

The collaborative is a longitudinal learning community that uses the Institute for Healthcare Improvement's Breakthrough Series (BTS) Model. The BTS utilizes what is known about dissemination and behavior change to support practice change.<sup>31</sup> The BTS methods are based on educational, statistical, and systems theory. These include 1) a focus on shared goals that are clear and explicit so that teams are aligned along a common purpose; 2) the use of data and feedback to allow teams to identify opportunities for individual improvement; and 3) the use of aggregate data, face-to-face meetings, and individual coaching to engage teams in working together to improve the systems of care for patients.<sup>32-36</sup>

Pediatric cardiology centers participate as a team comprised of a physician champion, nursing and administrative representatives, and a nutritionist. Teams are also encouraged to include a parent or family representative. Each month, teams collect data on patient status and care processes; post reports of their progress; participate in webinars and a listserv; and test changes to improve their systems. Semi-annual "learning session" workshops bring teams together to share lessons learned. Pediatric cardiologists provide content expertise and project staff support teams as needed, particularly with implementation of changes in practice. Along with education and support of quality improvement activities, parent-led presentations and parent panels have been key components of the learning sessions. Parents have played an essential role in providing feedback on the strategies to enhance of the care transitions and coordination. Primary care clinicians have also participated in the learning sessions and have provided insight into the coordination of care between subspecialists and primary medical homes for these complex patients. Participation in the collaborative provides cardiologists with American Board of Pediatrics-required MOC. Active participation in the NPC-QIC also provides centers credit toward U.S. News and World Report rankings.

Four face-to-face learning sessions have been held between September 2009 and May 2011. Forty-two separate cardiology practice teams have attended one or more of the learning sessions. Along with education and support of quality improvement activities, parent-led presentations and parent panels have been key components of the learning sessions.

The Anderson Center for Health Systems Excellence at Cincinnati Children's Hospital Medical Center has provided the improvement, project management and data infrastructure for the NPC-

QIC project. The Center has supported over 45 various collaborative multi-site improvement projects involving more than 1500 organizations.<sup>37-39</sup>

#### Current participation:

Since the pilot group of teams began in April 2008, there has been considerable growth in both the number of participating centers entering data and in the total number of patients enrolled in the collaborative. **See Figure 4.** Currently the NPC-QIC network consists of teams from 44 U.S. Pediatric Cardiology programs representing a wide range of program sizes and geographic locations. Thirty-five of these teams have completed the IRB process and are currently submitting data to the registry. These 44 centers represent at least 38% of the 121 centers in the U.S. that provide pediatric cardiac surgery services.<sup>37</sup> Therefore, the collaborative is capturing data regarding care and outcomes of a substantial proportion of the total population of children undergoing surgery for HLHS.

#### **Lessons learned in the early development of NPC-QIC**

The NPC-QIC has learned from its initial experience in ways that may offer opportunities for others considering participation in or development of a learning network.

#### Leadership and governance

A key factor in the success of this collaborative has been the committed and enthusiastic leadership of the Task Force. To plan for the future, the Task Force is currently developing a strategic plan for governance, leadership, and sustainable funding as the collaborative moves forward.

#### Data and measurement issues

Almost all pediatric diseases can be classified as 'rare' using the NIH definition (a prevalence of fewer than 200,000 affected individuals in the U.S.). The low incidence of HLHS presents a challenge in the ability to measure changes in process or outcome performance.<sup>40</sup> Combining data from individual sites provides the statistical power to measure differences and effects of changes over time. Despite this increased statistical power, adapting innovative measurement methods are still required to measure effects over time in these small populations. We use statistical process control (SPC) methods to design and continually modify measures to maximize their capability of being sensitive to changes tested.<sup>41</sup> These methods allow meaningful



interpretation of data despite the relatively small numbers of patients in the population of interest.<sup>42,43</sup>

There was a paucity of multicenter data at baseline to use for benchmarking purposes. For example, the commonly reported interstage mortality rates of 10-15% are based on single center experiences. In addition, there were no data on rates of hospital readmissions, growth failure, or handoffs at care transitions for these infants with complex CHD. This means that sufficient data must be input before either process or outcome improvements are documented.

Data collection and registry data entry require resources at the individual site level. At sites where personnel resources are limited it has been more difficult to complete registry data entry in a timely fashion. At minimum, each participating center requires a person or team that screens for patients that qualify for entry into the registry and that data collection forms be completed at each stage of the patient's progress through presentation for stage 2 palliation. There are a large number of data elements to be collected on patients enrolled in the NPC-QIC registry. Unlike many improvement efforts which may target only a small number of performance metrics, NPC-QIC's database includes numerous data elements to be abstracted and recorded. This registry component is critical for research, particularly for the ability to compare the effectiveness of varying management methods between sites currently submitting data to the registry. It is important for the collaborative leaders to regularly evaluate the clarity and number of measures and to be flexible in responding to changing needs. Individuals who are working at the patient level completing registry forms have been key in helping evaluate and revise forms as necessary.

### Funding

Ongoing funding is essential to the sustainability and growth of the NPC-QIC. Current funding sources include 1) start-up and a five-year grant to support partial infrastructure funding from the Children's Heart Association of Cincinnati; 2) a federal grant to the pediatric Center for Education and Research in Therapeutics at Cincinnati Children's Hospital Medical center, funded by the federal Agency for Healthcare Research and Quality, and ending in August 2011; and 3) annual team participation fee of \$2500 beginning June 2010. A low participation fee was purposefully selected by The Task Force to make NPC-QIC as inclusive and accessible to optimally attract the pediatric cardiology community in these early years. Potential future funding sources include both private and public sources: research grants, philanthropy or private foundation support and increased individual center cost for collaborative involvement and support.

## **Early results and the next phase of the NPC-QIC**

As expected, analysis of data of the first 100 patients entered into the NPC-QIC registry demonstrated variation in care processes during Norwood surgical palliation, in the post-operative period following Norwood palliation, and in the interstage period leading to stage 2 palliations.<sup>44-46</sup> While the total interstage mortality in patients enrolled in the collaborative has been lower, at 8-9%, than that which has been previously reported in the literature, the low total number of interstage deaths has not yet allowed us to statistically show a difference between practices at surgical centers and the relationship between varying practices and mortality.<sup>2</sup> The question of best practices and the reduction of mortality will be addressed as the number of patients enrolled in the collaborative increases. Two other areas of outcomes have begun to be addressed. An interested collaborative subgroup of cardiologists, advanced practice nurses, specialty nurses and dieticians are learning from variation in outpatient growth between surgical centers to better understand 'best nutritional practices' in the centers with the best growth. The analysis of the nutritional practices associated with improved growth outcomes is currently underway. Once these strategies are identified, we will test their implementation across the collaborative and monitor outcomes.. We plan to use a similar process to understand and address readmissions to the hospital in the interstage period.

We expect that NPC-QIC will add to our understanding of care for children with HLHS, a population of children with an enormous mortality and morbidity burden currently, identifying clinical care changes that have the potential to lead to improvements in outcome. Furthermore, we believe that we are developing a community of clinicians, families, and researchers that will continue to work together to improve care and outcomes for children with complex congenital heart disease. With an increase in the number of teams participating and the potential for new project ideas, we will develop a sustainable and robust organizational infrastructure to support the collaborative and future network activities.

## **Figure titles and descriptions**

### **Figure1**

Title: NPC-QIC Key Driver Diagram

**Figure 2**

Title: NPC-QIC Outcome Measures

Description: Display of the three outcome measures followed by the NPC-QIC. A) Cumulative mortality, B) Readmission rate per 100 interstage patient days, C) Number of patients between interstage growth failures. Arrows above graphs A and C indicate the direction of expected movement with successful outcomes.

**Figure 3**

Title: Growth of NPC-QIC Over Time

Description: Growth in number of teams (red) and patients enrolled (blue) in the NPC-QIC over time.

**Figure 4**

Title: Process Flow of Data Collection in the NPC-QIC Registry

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