National Pediatric Cardiology
Quality Improvement Collaborative

INTERSTAGE CHANGE PACKAGE

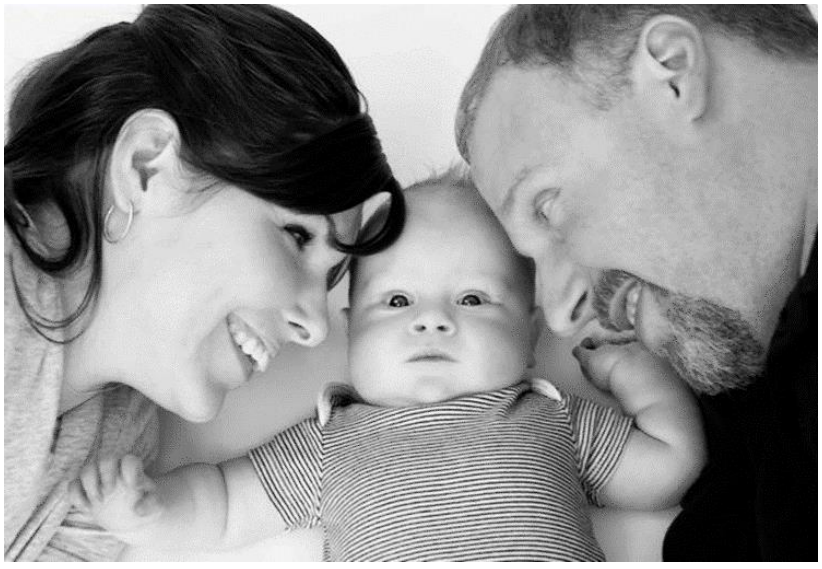


Table of Contents

Section 1 | Introduction & Background

The "Interstage" is the time period, typically 4-6 months, between the first surgical palliation (SP1 – typically a Norwood procedure) and the second (Glenn) operation. It is historically a time of risk for HLHS infants. Although Interstage mortality has recently declined in centers participating in NPC-QIC,(1) collaborative-wide it remains approximately 5%. During the Interstage period, these children are medically fragile and often have serious health problems, including heart failure, difficulty feeding, poor growth, delays in development, and seizures. Parents must carefully monitor their child's weight and blood oxygen levels and give them multiple medications daily. These children commonly need home tube feedings, and have frequent outpatient office visits and unplanned hospital readmissions. Some are not discharged from the hospital between the two surgeries.

Since the Collaborative's inception, NPC-QIC centers and parent partners have worked together to improve care and outcomes during the Interstage period. This change package outlines strategies for NPC-QIC clinicians, parents and researchers to use as they begin or advance Interstage quality improvement (QI) efforts.

What is a Change Package?

A change package is a concise and practical document that includes ideas and inspiration for teams seeking to apply QI methods to increasing the effectiveness and efficiency of their care processes and outcomes. Change packages focus on a specific condition, care process, or health system feature and generally include background material; a summary of evidence or best practices; and specific tools, strategies, and examples that can be applied to improvement work.

How Was This Change Package Developed?

This change package was inspired by and grounded in research completed using the NPC-QIC database, as well as tools, methods and approaches developed or tested by NPC-QIC centers.

What is in this Change Package?

This change package is comprised of four sections:

- ***Section 1*** | *Introduction and Background*

  This section provides a general overview of the Interstage, quality improvement, and the purpose of a change package.

- ***Section 2*** | *Interstage Key Driver Diagram*

  This section provides a depiction of the NPC-QIC Key Driver Diagram that shows the theory behind the Collaborative's improvement efforts.

- ***Section 3*** | *Change Strategies and Examples of Changes to Test*

  This section includes a discussion of change strategies to guide your Interstage improvement work, and specific examples of changes to test.

- ***Section 4*** | *Measures*

  This section outlines the key care process and outcome measures that NPC-QIC uses to assess our performance and improvement for the Interstage period.

Quality Improvement Method

The work of quality improvement teams participating in NPC-QIC is guided by the Model for Improvement.(2) The Model asks three key questions as teams test changes in care processes: *What are we trying to accomplish? How will we know that a change is an improvement? What changes can we make that will result in improvement?*

The final element is the Plan-Do-Study-Act (PDSA) cycle in which a change to be tested or implemented is planned and carried out, outcomes are monitored and analyzed, and then, based on the lessons learned, the change is fully implemented or the next change cycle is planned.

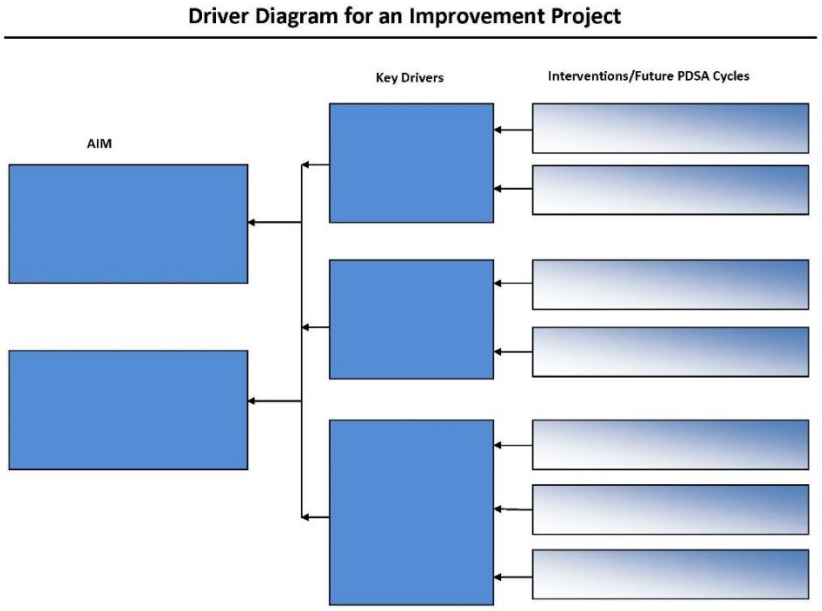
A brief video that reviews the Model for Improvement is available here. NPC-QIC quality improvement teams use a PDSA Worksheet to plan and track their tests of changes.

Section 2 | Interstage Key Driver Diagram

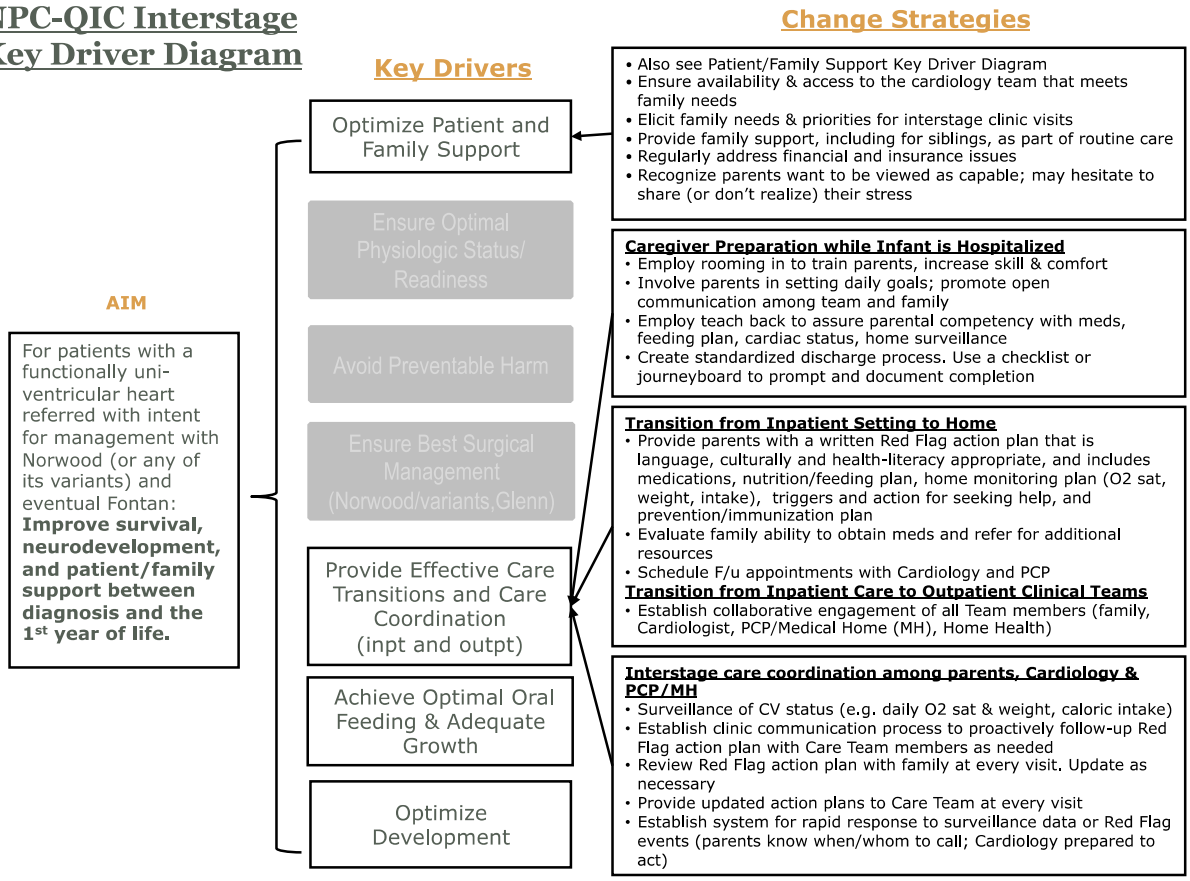
A Key Driver Diagram is a visual depiction of the theory behind an improvement effort—a roadmap of sorts. It illustrates the linkages between an overall aim (in this case, improving survival, neurodevelopment, and patient/family support), key drivers (the conditions that need to be in place for you to achieve your aim), and the interventions that can help you get there (changes like those included in this change package).

The current NPC-QIC key driver diagram for the Interstage period is depicted on the next two pages. Evidence (literature, where available) and expert opinion were used to identify clinical practices expected to be related to improvement in NPC-QIC aims. These care processes are grouped into four domains or key drivers: 1) supporting patients and families; 2) effective care transitions and care coordination; 3) feeding and Interstage growth; and 4) optimizing development. Over time, the collaborative will likely identify additional drivers and interventions that will lead to improvement.

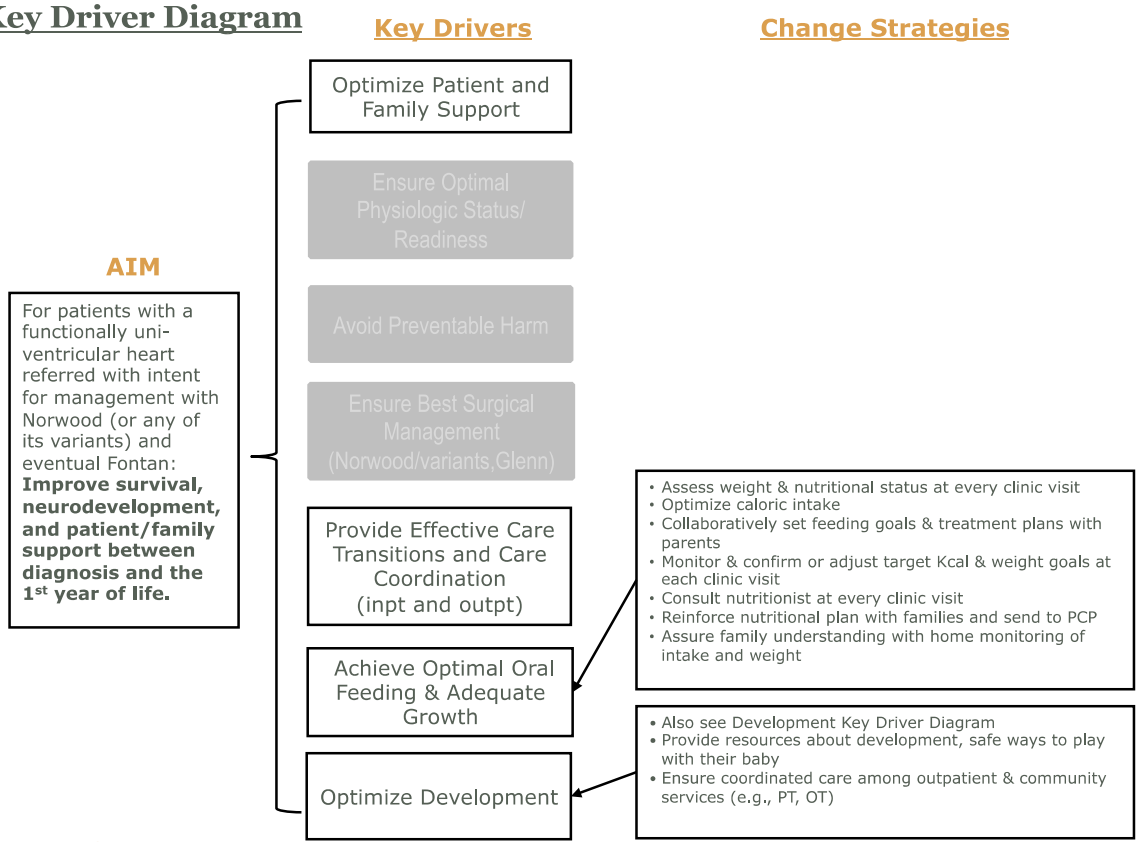
If you would like additional information on creating and using key driver diagrams, a tutorial is available here, and you can view a short video on the purpose and value of a driver diagram.



NPC-QIC Interstage Key Driver Diagram



NPC-QIC Interstage Key Driver Diagram



Section 3 | Change Strategies & Examples of Changes to Test

Change Strategies

Change strategies are "big ideas" for the kinds of actions that are likely to yield improvement. These change strategies will help focus your team on what matters most for Interstage care, but it's up to you to determine the specific ideas to test that will have the most impact for your care center and patient population.

A Change Strategy is a general notion or approach to change found to be useful in developing specific ideas that lead to improvement.

http://www.ihi.org/resources/Pages/Changes/UsingChangeConceptsforImprovement.aspx

From Change Strategies to Concrete Ideas to Test at Your Care Center

Starting on the next page are specific examples of changes to test as you work to improve Interstage care. These ideas and examples are organized around each of the key drivers outlined above.

OPTIMIZE PATIENT AND FAMILY SUPPORT

Support for patients and families in the Interstage period may come from members of the care team, and from other families who have children with HLHS.

EXAMPLES

Sisters by Heart website and informational brochures in English and in Spanish

Linked by Heart provides regional and local support and resources to families affected by HLHS

Brochure describing the Parent-to-Parent program at the Heart Center at Nationwide Children's Hospital that matches parents who have already experienced CHD with those who are facing it for the first time

A full Key Driver Diagram and associated tools for optimizing patient and family support can be found in the Patient and Family Support Change Package.

"Attempting to proactively view and approach care from the patient/parent perspective and partnering with them in the Collaborative has been career-changing for me. And I believe it has been transformational for the Collaborative."

Dr. John Kugler

Cardiologist,

Children's Hospital and Medical Center, Omaha

PROVIDE EFFECTIVE CARE TRANSITIONS AND CARE COORDINATION

Preparation for care transition after the Norwood hospitalization begins while the child is hospitalized.

Most NPC-QIC teams have a period of 24-48 hours of "rooming in" where parents stay at the hospital and demonstrate they can provide all necessary care for their child.

A number of NPC-QIC teams have also begun discharge teaching earlier, in the post-op ICU, once the child is stable enough to anticipate discharge.

EXAMPLES

NPC-QIC's transition bundle of 11 key activities for effective transition from inpatient to Interstage care

Teach back to confirm parents' understanding of information

List of top 10 ways hospitals can prepare parents for the Interstage, developed by Sisters by Heart

Discharge readiness assessment checklist used by Children's of Alabama

Journeyboard (in English and Spanish) used by Arizona Pediatric Cardiology Consultants and Phoenix Children's Hospital

Nationwide Children's Hospital Journeyboard

A Red Flag Action Plan is a key component of the transition from inpatient to home.

A Red Flag Action Plan is a written plan for acting on clinical "Red Flags" (e.g., feeding or breathing problems, increased cyanosis, poor weight gain or fever) that arise in the Interstage.

EXAMPLES

Red Flag Action Plan Template designed by NPC-QIC teams and parents

Spanish translation of their Red Flag Action Plan from Yale New Haven Children's Hospital

Wallet card from Children's Healthcare of Atlanta with Red Flags on one side and information for PCPs or emergency physicians on the other

PROVIDE EFFECTIVE CARE TRANSITIONS AND CARE COORDINATION

Transitioning from inpatient care to outpatient clinical teams requires establishing the collaborative engagement of all of the team members.

This includes the parents, cardiologist, the pediatrician primary care provider / Medical Home, and Home Health, if involved. Many NPC-QIC teams are scheduling a conference call prior to discharge with all of the members of the Interstage care team.

EXAMPLES

Cardiac shunt-dependent patient discharge instructions from Children's Healthcare of Atlanta

Hospital discharge conference call checklist from Nationwide Children's Hospital

Template letter for communication from the discharging hospital to the PCP from Miami Children's Hospital

Introduction to single ventricle physiology for PCPs from Lucille Packard Children's Hospital

Care coordination during the Interstage includes:

- Reviewing & updating the Red Flag Action Plan with family & Care Team at every visit.
- Establishing a system for rapid medical response to Red Flag events.
- Interstage surveillance of the child's CV status including O2 saturation monitoring, daily weight, and assessment and documentation of caloric intake. (9)

EXAMPLES

Telephone Triage Plan when parents call with a potential red flag at Children's National Medical Center

Boston Children's Hospital uses this family binder in their Interstage Home Monitoring Program

Daily home monitoring worksheet from University of Iowa Children's Hospital

Summary of *Withings* app for recording and transmitting home monitoring data from Lucille Packard Children's Hospital

LeBonheur Children's Hospital's Access Database for Pre-Visit Planning

ACHIEVE OPTIMAL ORAL FEEDING AND ADEQUATE GROWTH

Poor growth and nutrition are common in infants with congenital heart disease (CHD) and poor nutrition in children with complex CHD is associated with infection risk and increased hospital stay and mortality following cardiac surgery.(3–5) Research using the NPC-QIC database identified a "growth bundle" of clinical processes that are associated with improved infant-growth during the interstage.(6) These nutritional processes are common to NPC-QIC centers with a positive infant weight gain during the Interstage period:

- Using a standard post-Norwood feeding evaluation.
- Use of a home scale for Interstage weight monitoring.
- Specific weight gain/loss "red flags" to identify patients with growth failure in the Interstage.
- Regular phone contact with families during the Interstage regarding nutrition and growth.
- Having a dietitian available for each cardiology outpatient visit during the Interstage.

Spread of these optimal nutritional practices across NPC-QIC led to decreased variation in Interstage growth with most improvement observed at sites with the worst baseline growth outcomes.(7)

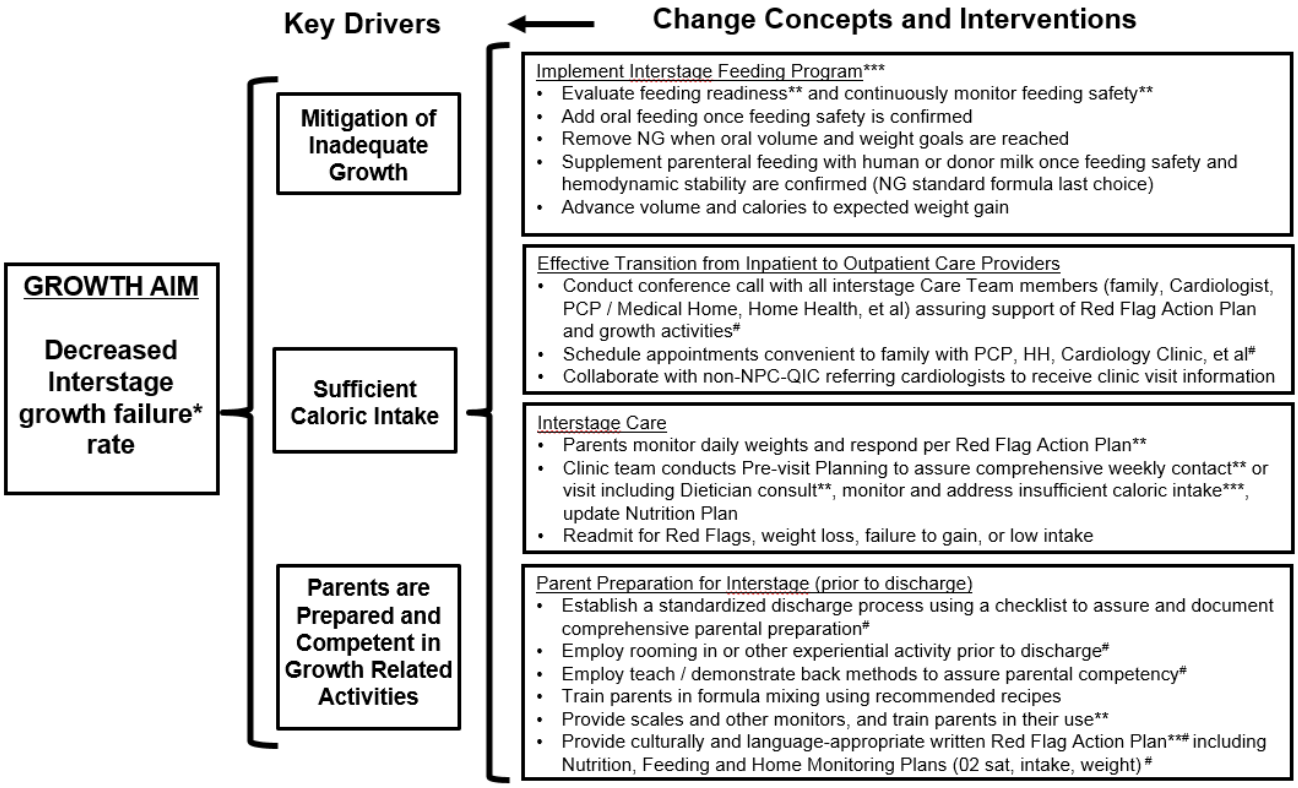
The NPC-QIC Feeding Work Group focused on identifying best nutritional practices in order to improve growth in this high-risk population. Their published guideline outlines evidence-based best feeding and nutrition practices during the pre-Norwood, post-Norwood, and Interstage phases.(8)

The NPC-QIC Key Driver Diagram for growth is depicted on the next page.

"Three to five years ago, we thought: this child has a single ventricle and he is not going to grow. (As a result of NPC-QIC research), we don't accept that anymore!

Julie Slicker, RD
Cardiac Dietician,
Children's Hospital of Wisconsin

NPC-QIC Growth Key Driver Diagram



Care Transition Bundle

*defined as decreasing 2 or more weight for length percentile bands over the course of the interstage (Norwood discharge to Glenn admission)

**Variation in Growth of Infants with a Single Ventricle. J Pediatr. 2012;161(1):16-21. Anderson JB, Iyer SB, Schidlow DN, et al, NPC-QIC.

*** Nutrition Algorithms for Infants with HLHS: Birth through the First Interstage Period. Slicker J, Hehir DA, Horsley M, et al. Congenit Heart Dis. 2013;8(2):89-102

ACHIEVE OPTIMAL ORAL FEEDING AND ADEQUATE GROWTH

Achieving adequate Interstage growth begins with ensuring that parents are prepared, competent and comfortable with growth-related activities including preparing formula (if necessary) and monitoring their child's weight and intake.

EXAMPLES

Example discharge form including a feeding plan for parents from Children's Mercy Hospital

Powder formula mixing recipes created by members of the Feeding Work Group

Spanish version of nutritional status and goals sheet from Yale New Haven Hospital

Failure to thrive is common in infants with HLHS and its variants. The etiology of growth failure in this population is multifactorial and complex, but may be impacted by nutritional intervention. The NPC-QIC Feeding Work Group performed a literature review and assessment of best nutrition practices from centers participating in the collaborative to provide nutritional recommendations and levels of evidence for those caring for infants with SV physiology.

EXAMPLES

Interstage Feeding Program for SV infants developed by the NPC-QIC Feeding Work Group

Journal article outlining nutritional algorithms from birth through Interstage from Feeding Work Group

OPTIMIZE DEVELOPMENT

We have undergone a paradigm shift in our thinking about development in infants and children with CHD. Traditionally, CHD therapies have been employed based upon available knowledge and technology that posed the least risk over the short-term. The long-term outcomes were of little concern if the patient did not survive. Now that survival has improved, development and quality of life are important considerations.

Children with CHD are at risk for developmental delays or disabilities. Their patterns of deficits are typically characterized as "high prevalence – low severity" with multiple mild impairments in areas such as cognitive function (mild), social interaction, communication (language and pragmatics), inattention, executive functioning and emotional/behavioral functioning.

Developmental concerns in infants with HLHS include feeding problems (growth, oral motor coordination deficits or oral aversion), gross motor delays (hypotonia and lack of "tummy time"), anxiety, and sleep problems.

It is important to detect developmental concerns early and intervene. Although babies with HLHS have "been through a lot", being delayed should not be considered "normal" and dismissed. Development impacts quality of life of both the infant and family. Development is cumulative: a delay in one domain will eventually impact others. Issues often are more easily addressed the sooner they are detected. And effective therapies and interventions are available, such as Early Intervention and outpatient therapies (e.g., Physical Therapy, Occupational Therapy, and Speech Therapy).

Given the heightened understanding of its importance, NPC-QIC is designing a Change Package specifically addressing optimizing development.

Section 4 | Measures

Measurement is the way we answer the second question in the Model for Improvement: "How do we know that a change is an improvement?" Collecting and reporting measurement data allows us to determine if progress is being made toward our aim.

Process measures evaluate the particulars of care that a patient receives, and outcome measures, such as mortality, evaluate the end results of care.

	Measure Name	Calculation
NPC-QIC Process Measures	**Percent of Patients without an Arrhythmia Discharged on Digoxin**	**Numerator:** number of patients discharged on digoxin; **Denominator:** number of patients discharged after Norwood surgery without a history of arrhythmia.
	Proportion of Discharges where "Complete" Care Plan was Communicated to PCP	**Numerator:** number of discharges with documented communication to PCP regarding immunization plan, medication list, red flag action plan and nutrition plan; **Denominator:** number of patients discharged after Norwood
	Proportion of Clinic Visits with updated written Red Flag Action Plan	**Numerator:** number of clinic visits with updated written red-flag action plan provided; **Denominator:** total number of clinic visits for interstage population that month
	Proportion of Clinic Visits with Growth Parameter Documentation	**Numerator:** number of clinic visits with documentation of the following items: weight, weight for age percentile, average daily weight gain and calculation of current actual caloric intake. **Denominator:** total number of clinic visits for interstage population that month
	Proportion of Clinic Visits where "Complete" Clinic Visit Information was Communicated to PCP	**Numerator:** number of clinic visits with documented communication to PCP regarding updated immunization plan, medication list, red flag action plan, and nutrition plan; **Denominator:** total number of clinic visits for interstage population that month

NPC-QIC Health Outcomes	Measure Name	Calculation
	Mortality P-Chart	**Numerator:** number of deaths; **Denominator:** number of patients who had a Glenn, died, or had a heart transplant
	Mortality G-Chart	Number of patients who were admitted for Glenn surgery between patients who died
	Major Event Readmission	**Numerator:** number of interstage readmissions for a major event; **Denominator:** number of patients who had at least one interstage day in the month/100
	Major Event G-Chart	Number of patients who were admitted for Glenn surgery between patients who had a major event readmission
	Average Daily Weight Achieved	**Numerator:** Number of patients achieving a minimum age-appropriate daily weight gain between Norwoood discharge and Glenn admission; **Denominator:** Number of patients admitted for Glenn surgery
	Growth Failure P-Chart	**Numerator:** number of patients who had a weight for age z-score change less than -0.5 during the interstage (Norwood discharge to Glenn admission); **Denominator:** number of patients who completed the interstage (Norwood discharge to Glenn admission)
	Growth Failure G-Chart	Number of patients with adequate growth between patients with growth failure events. A growth failure event is defined by weight for age z-score change < -.5 during interstage (Norwood discharge to Glenn admission)
	Cumulative Mortality Funnel Plot	**Numerator:** cumulative number of deaths between discharge after Norwood repair and completion of Stage 2 repair (i.e., the interstage); **Denominator:** cumulative number patients who had a Glenn, died, or had a heart transplant

References

1. Anderson JB, Beekman RH, Kugler JD, Rosenthal GL, Jenkins KJ, Klitzner TS, et al. Improvement in Interstage Survival in a National Pediatric Cardiology Learning Network. Circ Cardiovasc Qual Outcomes. 2015 Jul;8(4):428–36.

2. Langley GJ, editor. The improvement guide: a practical approach to enhancing organizational performance. 2nd ed. San Francisco: Jossey-Bass; 2009. 490 p.

3. Leite HP, Fisberg M, de Carvalho WB, de Camargo Carvalho AC. Serum albumin and clinical outcome in pediatric cardiac surgery. Nutr Burbank Los Angel Cty Calif. 2005 May;21(5):553–8.

4. Sano S, Huang S-C, Kasahara S, Yoshizumi K, Kotani Y, Ishino K. Risk factors for mortality after the Norwood procedure using right ventricle to pulmonary artery shunt. Ann Thorac Surg. 2009 Jan;87(1):178–185; discussion 185–186.

5. Anderson JB, Beekman RH, Border WL, Kalkwarf HJ, Khoury PR, Uzark K, et al. Lower weight-for-age z score adversely affects hospital length of stay after the bidirectional Glenn procedure in 100 infants with a single ventricle. J Thorac Cardiovasc Surg. 2009 Aug;138(2):397–404.e1.

6. Anderson JB, Iyer SB, Schidlow DN, Williams R, Varadarajan K, Horsley M, et al. Variation in growth of infants with a single ventricle. J Pediatr. 2012 Jul;161(1):16–21.e1; quiz 21.e2–3.

7. Anderson JB, Beekman RH, Kugler JD, Rosenthal GL, Jenkins KJ, Klitzner TS, et al. Use of a learning network to improve variation in interstage weight gain after the Norwood operation. Congenit Heart Dis. 2014 Dec;9(6):512–20.

8. Slicker J, Hehir DA, Horsley M, Monczka J, Stern KW, Roman B, et al. Nutrition algorithms for infants with hypoplastic left heart syndrome; birth through the first interstage period. Congenit Heart Dis. 2013 Apr;8(2):89–102.

9. Ghanayem NS[1], Hoffman GM, Mussatto KA, Cava JR, Frommelt PC, Rudd NA, et al. Home surveillance program prevents interstage mortality after the Norwood procedure. J Thoracic and Cardiovascular Surg. 2003 Nov;126(5):1367-1375.

Acknowledgements: Information provided in this change package was supported by National Pediatric Cardiology Quality Improvement Collaborative enrolled centers, the Children's Heart Association of Cincinnati, 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 [#U19HS021114 AHRQ], and Laura Peterson, NPC-QIC Quality Improvement Consultant.