Data-driven Quality Care Initiatives Through the NPC-QIC: A Methodology for Improving Outcomes after Fontan Operation

CHANGING THE OUTCOME TOGETHER

NATIONAL PEDIATRIC CARDIOLOGY
Quality Improvement Collaborative

Sisters by Heart™

Carole Lannon, MD MPH
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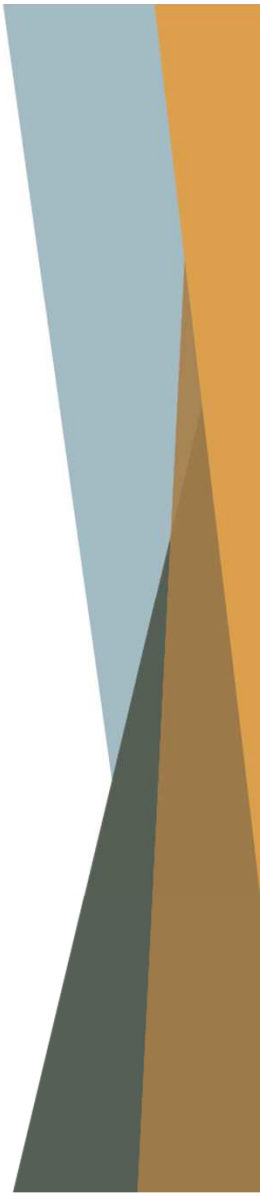
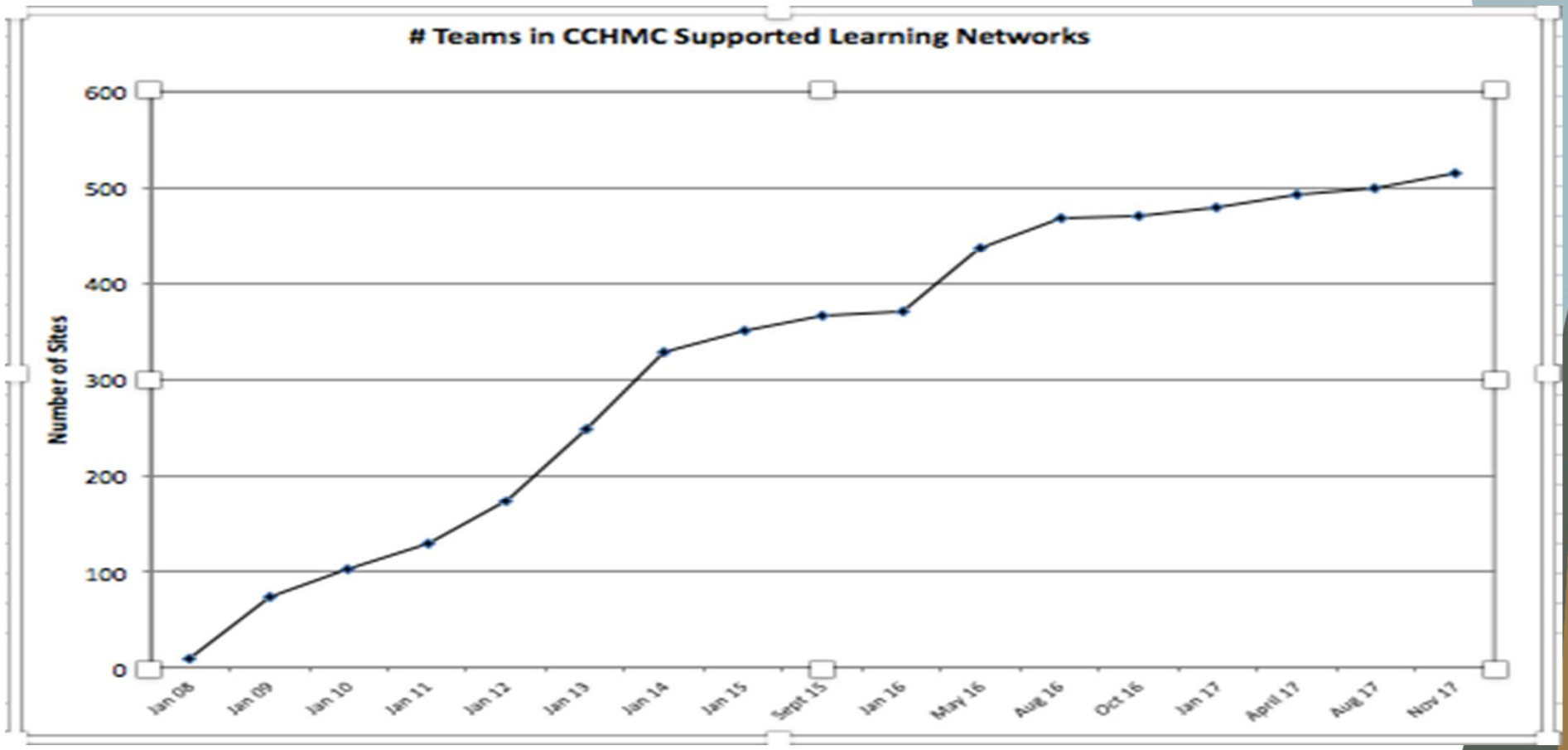
Anderson Center for Health Systems Excellence
Cincinnati Childrens Hospital Medical Center
Senior Quality Advisor
American Board of Pediatrics

Learning Networks

Communities of patients, families, clinicians and scientists who use data for clinical care, improvement, discovery, and innovation



Learning Networks *supported by CCHMC*
516 teams, 289 sites, 43 states + DC, 5 countries



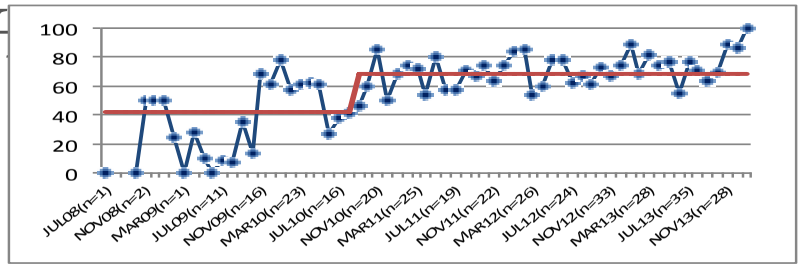
“The Heart of the Matter”

National Pediatric Cardiology Quality Improvement Collaborative and *Sisters by Heart*

Discharge Process Measures

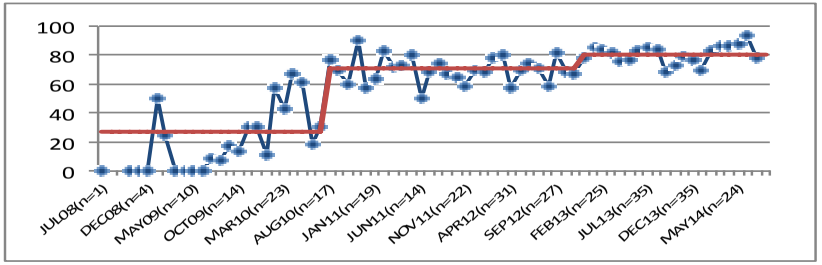
1. Complete Care Plan

*Discharged patients with all discharge measures** completed*



2. Complete Care Plan Communicated to PCP

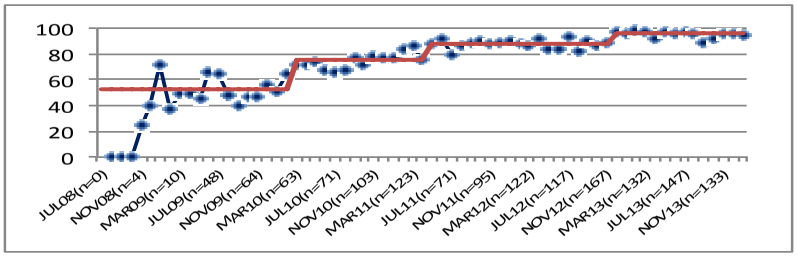
*Discharged patients with communication to PCP regarding all discharge measures**



Clinic Visit Process Measures

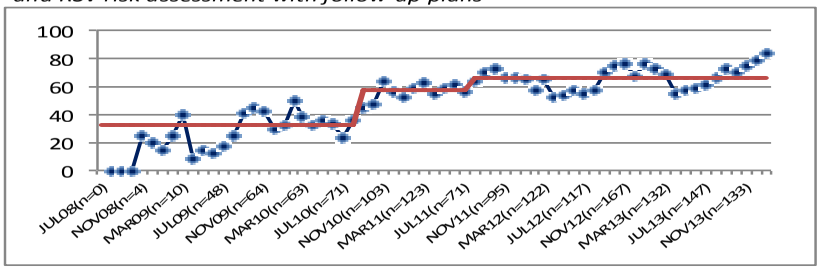
3. Post-Care Coordinator Identified

Individual or group identified to coordinate outpatient management of this patient



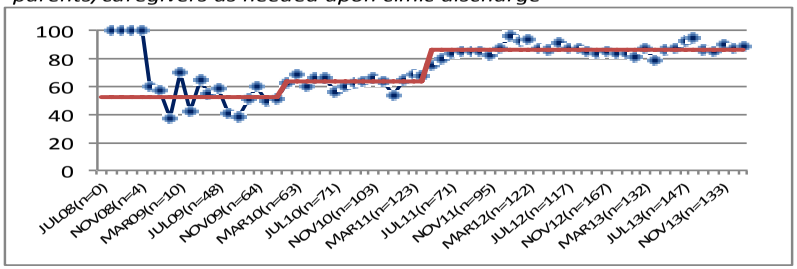
4. Preventive-Care Plan Updated

Clinic visits having documented review of immunization status and RSV risk assessment with follow-up plans



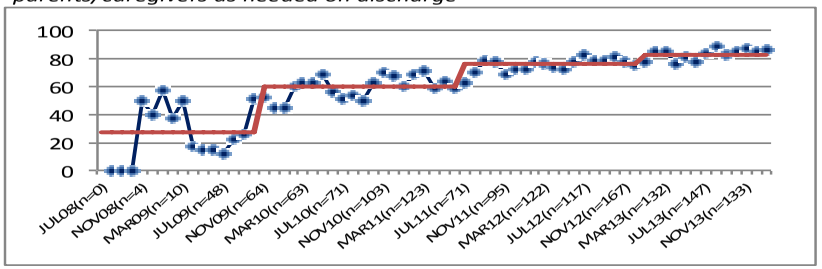
5. Written Medication List Updated

Written medication list reviewed, discussed, or updated with parents/caregivers as needed upon clinic discharge



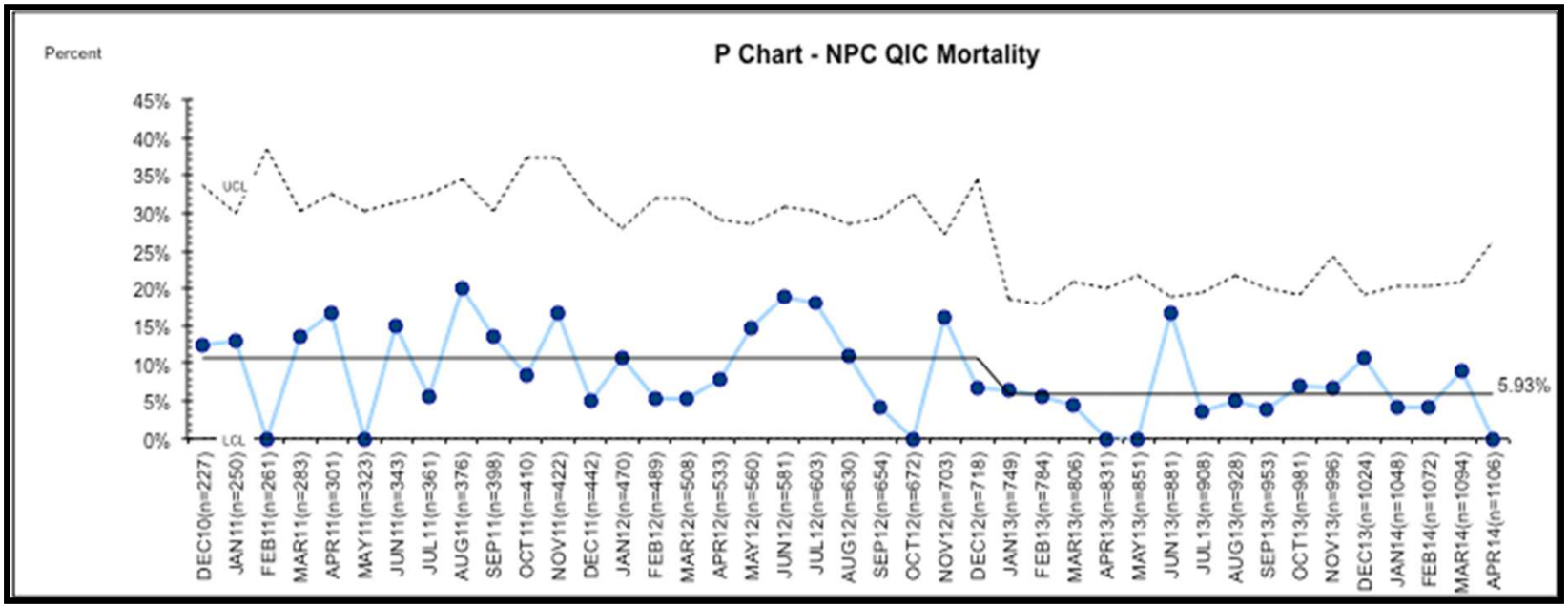
6. Written Red-Flag Action Plan Updated

Written red flag action plan reviewed, discussed, or updated with parents/caregivers as needed on discharge



NPC-QIC Phase I:
HLHS interstage between Norwood and Glenn

- Reduced interstage mortality by >40%; stable ~5%

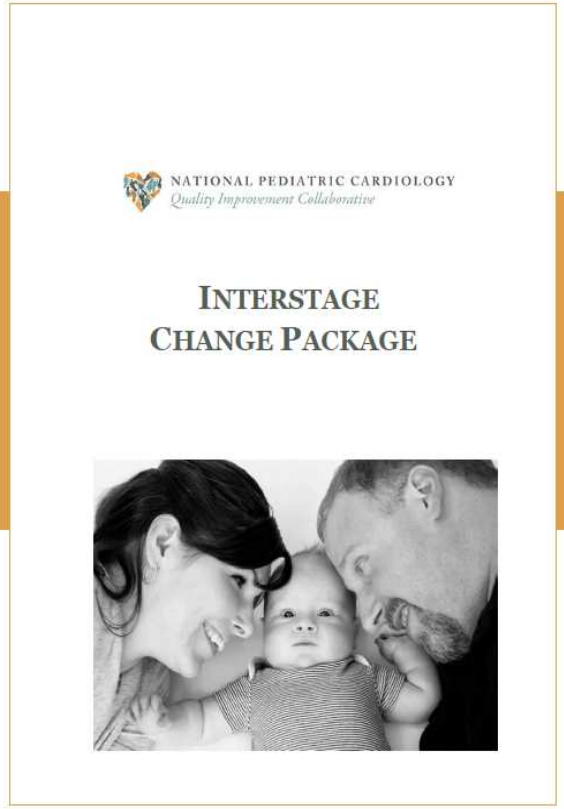


Anderson et al. *Circ Qual and Outcomes*. 2015;8:428-436

National Pediatric Cardiology Quality Improvement Collaborative

Zoe Madison (Age 6, HLHS)

Phase I Change Package



Highlights:

Patient and Family Support
- Sisters by Heart website and informational brochures in English and in Spanish

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

Oral Feeding and Growth
- Using a standard post-Norwood feeding evaluation.
- Use of a home scale for Interstage weight monitoring

Journal of the American Heart Association

OPEN ACCESS

Digoxin Use Is Associated With Reduced Interstage Mortality in Patients With No History of Arrhythmia After Stage I Palliation for Single Ventricle Heart Disease

David W. Brown, MD; Colleen Margeot, MS; Jeffrey B. Anderson, MD; Laura E. Peterson, BSN, SM; Eileen C. King, PhD; Stacey L. Lihn, BA; Steven R. Neish, MD; Craig Fleishman, MD; Christina Phelps, MD; Samuel Hanke, MD; Robert H. Beekman III, MD; Carole M. Lannon, MD, MPH; on behalf of the National Pediatric Cardiology Quality Improvement Collaborative

Background—Interstage mortality (IM) remains significant after stage 1 palliation (S1P) for single-ventricle heart disease (SVD), with many deaths sudden and unexpected. We sought to determine whether digoxin use post-S1P is associated with reduced IM, utilizing the multicenter database of the National Pediatric Cardiology Quality Improvement Collaborative (NPCQIC).

Methods and Results—From June 2008 to July 2013, 816 infants discharged after S1P from 50 surgical sites completed the interstage to stage II palliation, transplant, or IM. Arrhythmia during S1P hospitalization or discharge on antiarrhythmic medications were exclusions (n=270); 2 patients were lost to follow-up. Two analyses were performed: (1) propensity-score adjusted logistic regression with IM as outcome and (2) retrospective cohort analysis for patients discharged on digoxin versus not, matched for surgical site and other established IM risk factors. Of 544 study patients, 119 (21.9%) were discharged on digoxin. Logistic regression analysis with propensity score, site-size group, and digoxin use as predictor variables showed an increased risk of IM in those not discharged on digoxin (odds ratio, 8.6; lower confidence limit, 1.9; upper confidence limit, 38.3; $P<0.01$). The retrospective cohort analysis for 60 patients on digoxin (matched for site of care, type of S1P, post-S1P ECMO use, genetic syndrome, discharge feeding route, ventricular function, tricuspid regurgitation, and aortic arch gradient) showed 0% IM in the digoxin at discharge group and an estimated IM difference between the 2 groups of 9% ($P=0.04$).

Conclusions—Among SVD infants in the NPCQIC database discharged post-S1P with no history of arrhythmia, use of digoxin at discharge was associated with reduced IM. (*J Am Heart Assoc.* 2016;5:e002376 doi: 10.1161/JAHA.115.002376)

Key Words: cardiovascular disorders • cardiovascular surgery • congenital heart disease • mortality • quality improvement

Association of Digoxin With Interstage Mortality: Results From the Pediatric Heart Network Single Ventricle Reconstruction Trial Public Use Dataset

Matthew E. Oster, MD, MPH; Michael Kelleman, MSPH; Courtney McCracken, PhD; Richard G. Ohye, MD; William T. Mahle, MD

Background—Mortality for infants with single ventricle congenital heart disease remains as high as 8% to 12% during the interstage period, the time between discharge after the Norwood procedure and before the stage II palliation. The objective of our study was to determine the association between digoxin use and interstage mortality in these infants.

Methods and Results—We conducted a retrospective cohort study using the Pediatric Heart Network Single Ventricle Reconstruction Trial public use dataset, which includes data on infants with single right ventricle congenital heart disease randomized to receive either a Blalock-Taussig shunt or right ventricle-to-pulmonary artery shunt during the Norwood procedure at 15 institutions in North America from 2005 to 2008. Parametric survival models were used to compare the risk of interstage mortality between those discharged to home on digoxin versus those discharged to home not on digoxin, adjusting for center volume, ascending aorta diameter, shunt type, and socioeconomic status. Of the 330 infants eligible for this study, 102 (31%) were discharged home on digoxin. Interstage mortality for those not on digoxin was 12.3%, compared to 2.9% among those on digoxin, with an adjusted hazard ratio of 3.5 (95% CI, 1.1–11.7; $P=0.04$). The number needed to treat to prevent 1 death was 11 patients. There were no differences in complications between the 2 groups during the interstage period.

Conclusions—Digoxin use in infants with single ventricle congenital heart disease is associated with significantly reduced interstage mortality. (*J Am Heart Assoc.* 2016;5:e002566 doi: 10.1161/JAHA.115.002566)

Key Words: congenital • digoxin • heart defects • mortality • pediatrics • single ventricle

NATIONAL PEDIATRIC CARDIOLOGY
Quality Improvement Collaborative

Sisters by Heart™

Research Explained

Research Explained: The Association between Digoxin Use and Reduced Interstage Mortality

An Evaluation of Two National Databases

Background of the Study Questions and Digoxin

When the National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) was formed in 2006, it had an initial goal to reduce interstage mortality for patients with Hypoplastic Left Heart Syndrome (HLHS) and other similar conditions. This was done by putting into place various quality improvement projects aimed at improving and standardizing care as well as evaluting the data stored in the database to examine any factors associated with interstage mortality.

Discovery and Spread: changing the field

Congenital Heart Disease

Enalapril in Infants With Single Ventricle
Results of a Multicenter Randomized Trial

Daphne T. Hsu, MD; Victor Zak, PhD; Lynn Mahony, MD; Lynn A. Sleeper, ScD; Andrew M. Atz, MD; Jami C. Levine, MD; Piers C. Barker, MD; Chitra Ravishankar, MD; Brian W. McCrindle, MD; Richard V. Williams, MD; Karen Altmann, MD; Nancy S. Ghanayem, MD; Renee Margossian, MD; Wendy K. Chung, MD; William L. Border, MBChB, MPH; Gail D. Pearson, MD, ScD; Mario P. Stylianou, PhD; Seema Mital, MD; for the Pediatric Heart Network Investigators

Background—Angiotensin-converting enzyme inhibitor therapy improves clinical outcome and ventricular function in adults with heart failure. Infants with single-ventricle physiology have poor growth and are at risk for abnormalities in ventricular systolic and diastolic function. The ability of angiotensin-converting enzyme inhibitor therapy to preserve ventricular function and improve somatic growth and outcomes in these infants is unknown.

Methods and Results—The Pediatric Heart Network conducted a double-blind trial involving 230 infants with single-ventricle physiology randomized to receive enalapril (target dose 0.4 $mg \cdot kg^{-1} \cdot d^{-1}$) or placebo who were followed up until 14 months of age. The primary end point was weight-for-age z score at 14 months. The primary analysis was intention to treat. A total of 185 infants completed the study. There were 24 and 21 withdrawals or deaths in the enalapril and placebo groups, respectively ($P=0.74$). Weight-for-age z score was not different between the enalapril and placebo groups (mean±SE -0.62 ± 0.13 versus -0.42 ± 0.13, $P=0.28$). There were no significant group differences in height-for-age z score, Ross heart failure class, brain natriuretic peptide concentration, Bayley scores of infant development, or ventricular ejection fraction. The incidence of death or transplantation was 13% and did not differ between groups. Serious adverse events occurred in 88 patients in the enalapril group and 87 in the placebo group.

Conclusions—Administration of enalapril to infants with single-ventricle physiology in the first year of life did not improve somatic growth, ventricular function, or heart failure severity. The results of this randomized trial do not support the routine use of enalapril in this population.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00113087.

(*Circulation*. 2010;122:333-340.)

2010

ORIGINAL RESEARCH

American Heart Association | American Stroke Association

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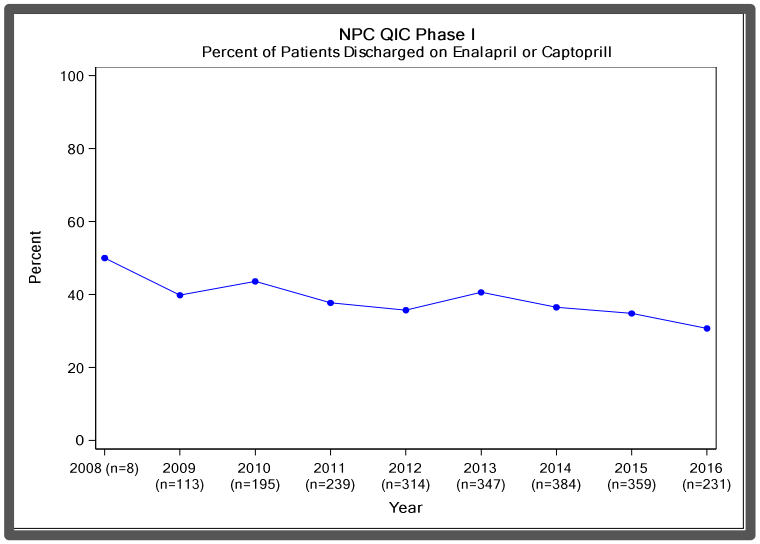
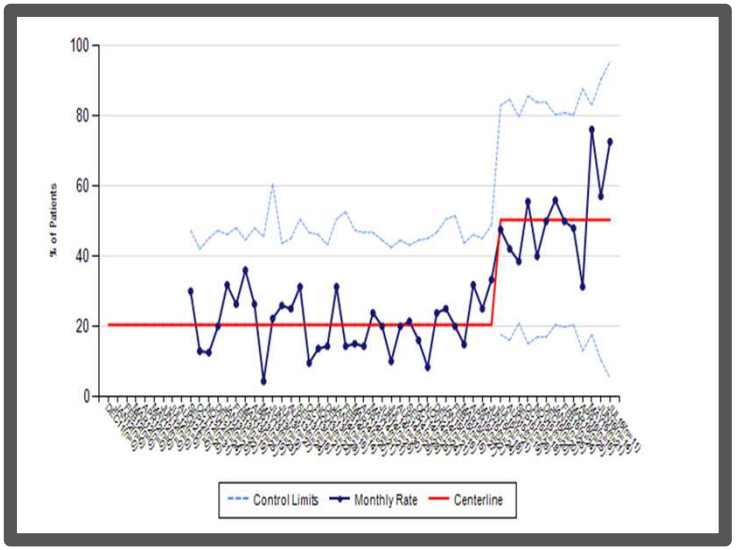
2016

Spread in the Network

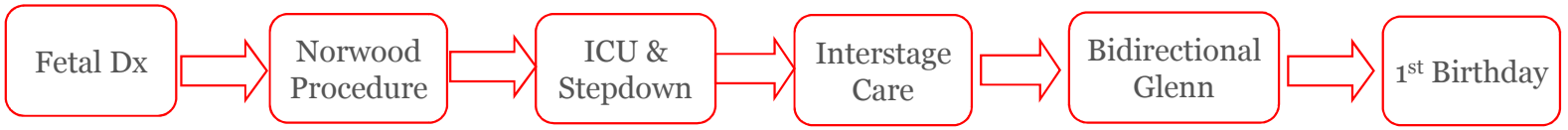


Enalapril



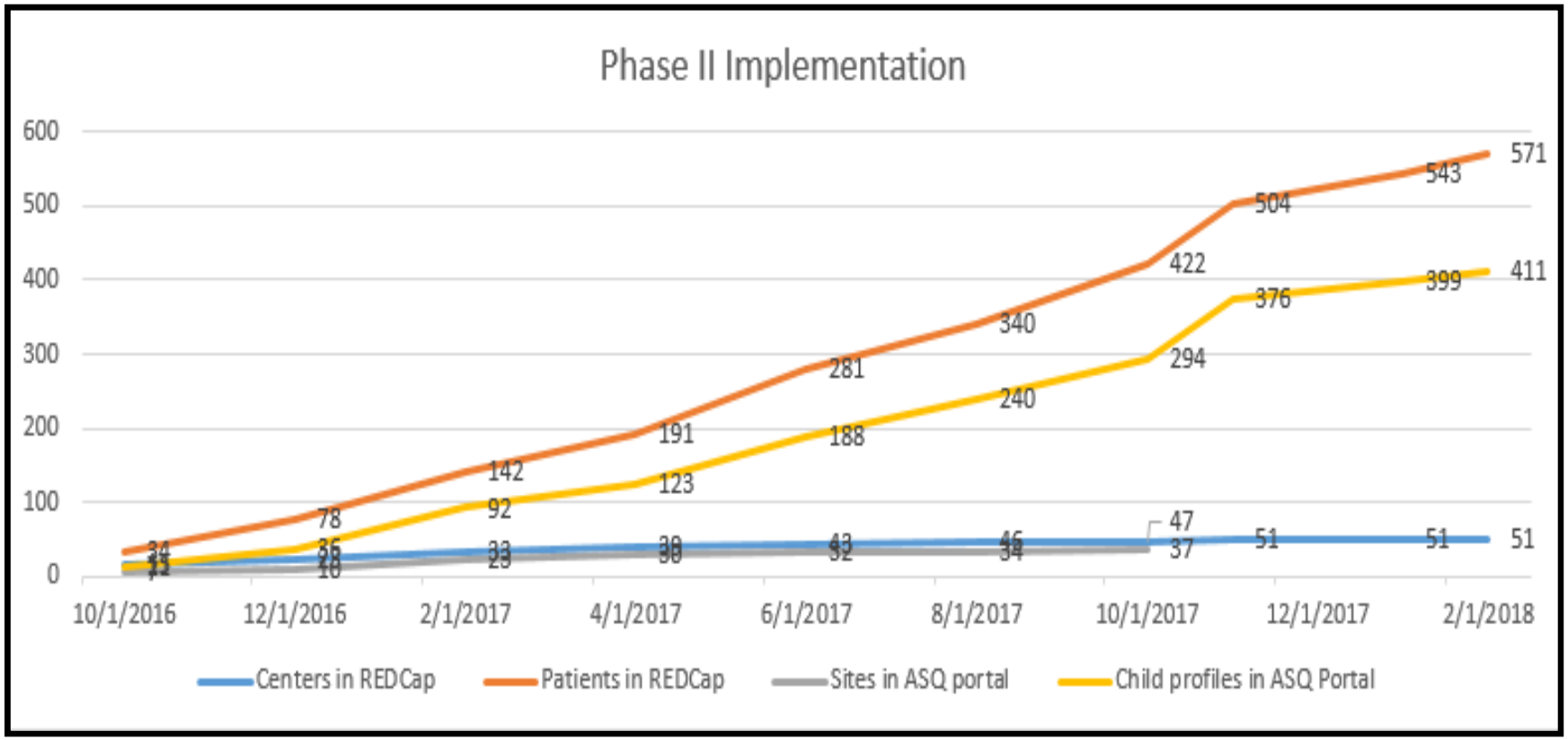
Digoxin

Current: NPC-QIC Phase II



To improve survival and optimize quality of life for infants (and their families) with a single ventricle requiring Norwood –
between diagnosis and first birthday

Phase II registry launch October 2016: 571 patients to date from 51 centers



Phase II Learning Labs – 65 Improvement Measures

Fetal and Perinatal

- Prenatal Diagnosis
- Prenatal Support
- Connection to Parent Support - Prenatal
- Third Trimester Echo and Consultation
- Comprehensive Counseling - Prenatal
- Perinatal Management
- Coordinated Delivery
- Full Term Delivery
- Time From Delivery to ICU Admission At Surgical Center
- Center's HLHS Palliative Surgical Outcomes Discussed
- Developmental Plan at Enrollment

Surgical and ICU

- Time From Delivery to ICU Admission At Surgical Center
- Center's HLHS Palliative Surgical Outcomes Discussed
- Daily Assessment of Physiological Readiness Prior to Stage 1 Palliation
- Stage 1 Palliation Surgery Delayed
- Adverse Event Prior to Stage 1 Palliation
- Patient/Family Pre-Operative Preparation
- Care Team Multidisciplinary Planning Conference
- Connection to Parent Support - Pre Op
- Comprehensive Counseling - Pre Op
- Additional Cardiopulmonary Bypass Run or ECMO
- Care Team Surgical and Perioperative Communication
- Post Op Anatomy and Function
- Unplanned Re-Intervention
- Timely Extubation Post Stage 1 Palliation
- Reintubation after Initial Extubation
- Timely Wean of Inotropes/Vasoactive Medications
- Adverse Events Following Stage 1 Palliation
- Post Stage 1 Enteral Feeds
- Feeding Evaluation
- Patients Hospitalized From Stage 1 to Stage 2 Palliation

Patient and Family Support

- Prenatal Support
- Connection to Parent Support - Prenatal
- Comprehensive Counseling - Prenatal
- Developmental Plan at Enrollment

Developmental

- Developmental Plan at Enrollment
- Inpatient Developmental Plan at 4 weeks Post Stage I Palliation
- Developmental Plan at Stage I Palliation Discharge
- Inpatient Developmental Plan at 4 weeks Post Stage II Palliation
- Developmental Plan at Stage II Palliation Discharge
- Developmental Screening at 4 Month Interval
- Developmental Screening at 6 Month Interval
- Developmental Screening at 9 Month Interval
- Developmental Screening at 12 Month Interval
- Developmental SE Screening at 6 Month Interval
- Developmental SE Screening at 12 Month Interval
- Referral to Early Intervention Program by 6 Months
- Referral for Formal Developmental Evaluation

Nutrition and Growth

- Post Stage 1 Enteral Feeds
- Feeding Evaluation
- Average Daily Weight Achieved For Patients Discharged Home After Stage I Palliation
- Average Daily Weight Achieved For Patients Hospitalized From Stage I Palliation to Stage II Palliation
- Growth Failure P Chart For Patients Discharged Home After Stage I Palliation
- Growth Failure P Chart For Patients Hospitalized from Stage I Palliation to Stage II Palliation
- Growth Failure G Chart For Patients Discharged Home After Stage I Palliation
- Growth Failure G Chart For Patients Hospitalized from Stage I Palliation to Stage II Palliation

Transparency

- Feeding Evaluation
- Post Stage 1 Enteral Feeds
- Growth Failure P Chart For Patients Hospitalized from Stage I Palliation to Stage II Palliation
- Growth Failure P Chart For Patients Discharged Home After Stage I Palliation

A Parents Guide to HLHS:

Coping During Interstage

The "interstage" period (the months between stage 1 and stage 2 heart surgeries) can be an emotionally challenging time for families. This bulletin was designed by parents of children with hypoplastic left heart syndrome (HLHS), in collaboration with mental health and healthcare providers, to provide information and resources that may be helpful for your family as you prepare for the months ahead.

Feelings: You are not alone

Many parents feel alone during interstage. It is common to feel alone physically, as opportunities to connect with family/friends may be limited by hospitalization or concern for germs. It is also common to feel alone emotionally, as parents may feel that others can't relate to what they are going through.

Although these feelings are normal, you are not alone in this journey. There is a whole HLHS community of parents who have walked a mile in your shoes and want to provide you with support and connection.

- Find other HLHS parents, either through your hospital, a local support group or online.
- Identify a trusted caregiver for your child who can give you a few hours to connect with friends or have dinner with your partner.
- Getting out of the house will give you perspective, a much needed break, and an opportunity to connect with others.

Friendship is born at the moment when one person says to another "What! You too! I thought I was the only one" - Adapted from C.S. Lewis

Being a Parent: Your role may be different than expected

Caring for a baby during interstage can involve keeping track of weight/oxygen saturation, operating medical equipment, and navigating the healthcare system. While these tasks are certainly important, they are not what most parents expect for the first few months with their baby. It is common to feel overwhelmed when adjusting to being both a parent and a care provider for your baby. It is also common to feel sadness or grief about the loss of "typical" parenting experiences, such as breast/bottle feeding.

- Find some "typical" parenting experiences to focus on, like bathing or dressing your baby.
- Share responsibilities with other family members when possible. Caring for an HLHS baby is not a one-person job and taking time to care for yourself is a necessary part of this job.
- Connect with other parents further along in their HLHS journey who can provide support/wisdom.

"We canceled most of our plans during interstage because of my son's tube feeding schedule or fear of illness. Connecting with other heart families, both locally and online, really helped improve my feelings of loneliness and isolation."
Lacie, *Heart Mom*

"Having so many responsibilities during interstage was difficult and sometimes interfered with the joy of becoming a parent. But we had all these tasks and responsibilities for a good reason: to see her survive and thrive through this fragile period."
Arman, *Heart Dad*

A Parents Guide to HLHS:

Adjusting Post-Glenn

For parents of children with hypoplastic left heart syndrome (HLHS) or another single ventricle heart condition, the time after Glenn completion can be exciting, yet scary at the same time. This bulletin was designed by parents of children with HLHS, in collaboration with mental health and healthcare providers, to provide information and resources that may be helpful for your family as you adjust to life post-Glenn and beyond.

Feelings: You are not alone

A wide range of feelings after the Glenn is normal. Parents often express feeling a "rollercoaster" of emotions:

- Relief
- Self-blame or guilt
- Hopeful but still anxious
- Overwhelmed by responsibility
- Proud
- Lonely and unprepared

It is often hard to know when you need more support. Try doing "emotional check-ins" on yourself. At least once a day, stop and think what emotion(s) you are feeling and how strong the emotion. If your emotions are negative, try using a coping strategy. If you notice your emotions are usually or strongly negative or are impacting your sleep, work, relationships, or parenting, it may be time to get more support.

Stress: A natural reaction

Parents often report new stressors as they move beyond the interstage period. Knowing what to expect can often help.

- Change in care providers
- Cold/flu season and illness
- Feeding issues
- Developmental milestones and delays
- Child's and family limitations

It is common to feel stress, even if your child is doing well. This stress often goes down over time, but if it does not, seeking additional support is recommended.

Coping: There are many ways

One of the best ways to take care of your family is to take good care of yourself. After the Glenn, you have the chance to find your family's "new normal," as well as recharge and refocus on yourself and relationships. Take at least 5 minutes a day to do something for you.

- Pay attention to the basics: Diet, Sleep, Physical Activity, and Support

Admin here..

"The post Glenn period was filled with highs, lows, and mixed emotions. Ultimately, at discharge, I felt a sense of pride and relief. We'd made it to safer ground."
Alexis, *Heart Mom*

"Not having interstage monitoring when we returned home after the Glenn was stressful. It took several weeks to feel at ease and adjust to this new normal."
Caleb, *Heart Dad*

The Relentless Effects of the Fontan Paradox

Jack Rychik[1]

The Fontan operation is the anticipated palliative strategy for children born with single-ventricle type of congenital heart disease. As a result of important circulatory limitations, a series of end-organ complications are now increasingly recognized. Elevated central venous pressure and impaired cardiac output are the hallmarks of cavo-pulmonary flow, which result in a cascade of pathophysiological consequences. The Fontan circulation likely impacts all organ systems in an indolent and relentless manner, with progressive decline in functionality likely to occur in many. Liver fibrosis, altered bone density, decreased muscle mass, renal dysfunction, lymphatic insufficiency, and a host of other conditions are present. Standardized screening and evaluation of survivors as they grow through childhood and beyond is indicated and can be facilitated through dedicated multidisciplinary clinical programs. Invasive assessment at specific milestones can provide important actionable information to optimize individual status. More detailed characterization and understanding of these end-organ complications is necessary to contribute to the goal of achieving a normal duration and quality of life for these unique individuals.

Semin Thorac Cardiovasc Surg Pediatr Card Surg Ann 19:37-43

The Children's Hospital *of* Philadelphia®

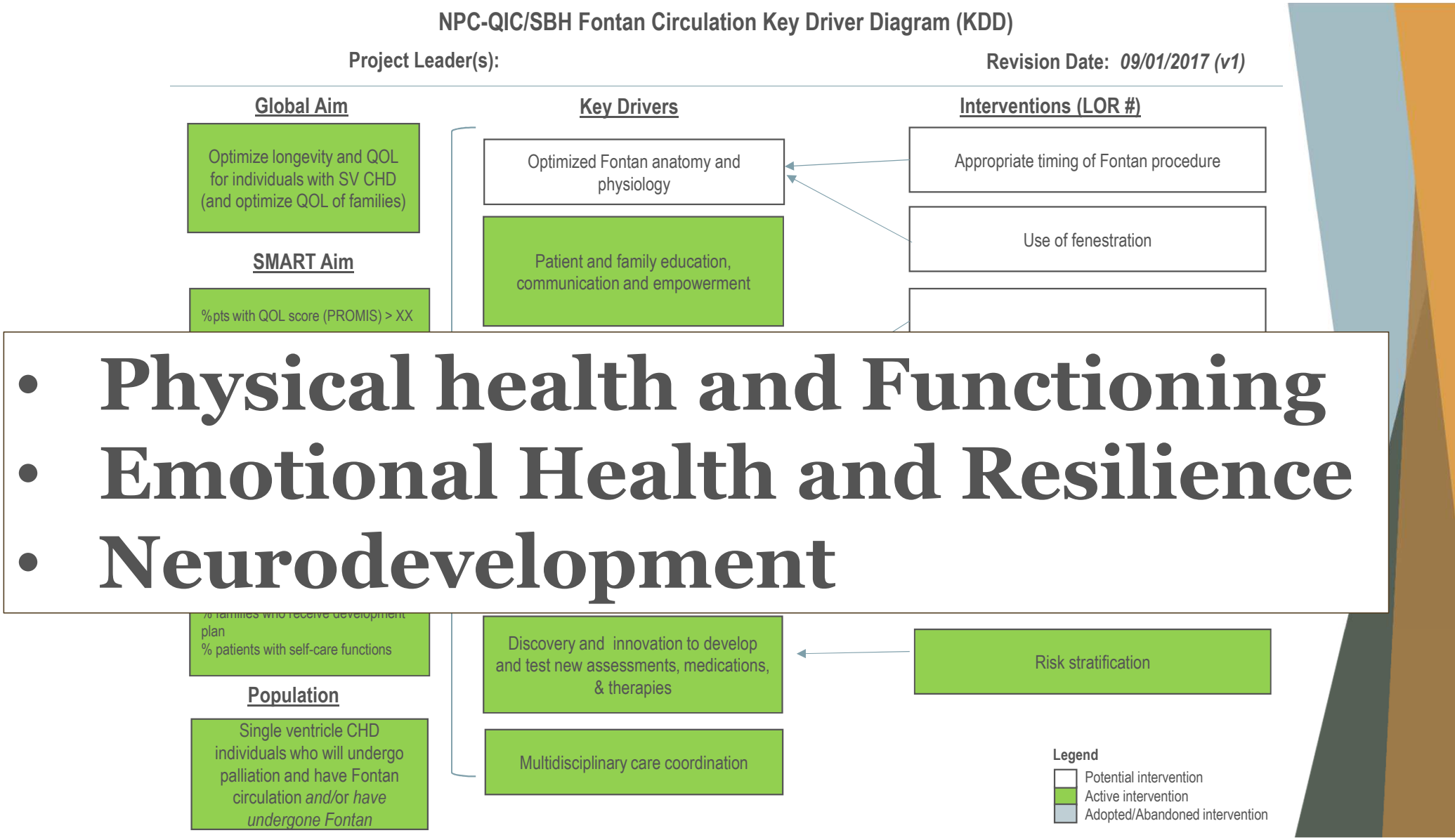
Sisters by Heart
Supporting Families Newly Diagnosed with Hypoplastic Left Heart Syndrome

NPCQIC Fall Learning Session October 2016
Loews Hotel, Chicago, IL

Planning for Phase 3:
Individuals with Fontan circulation

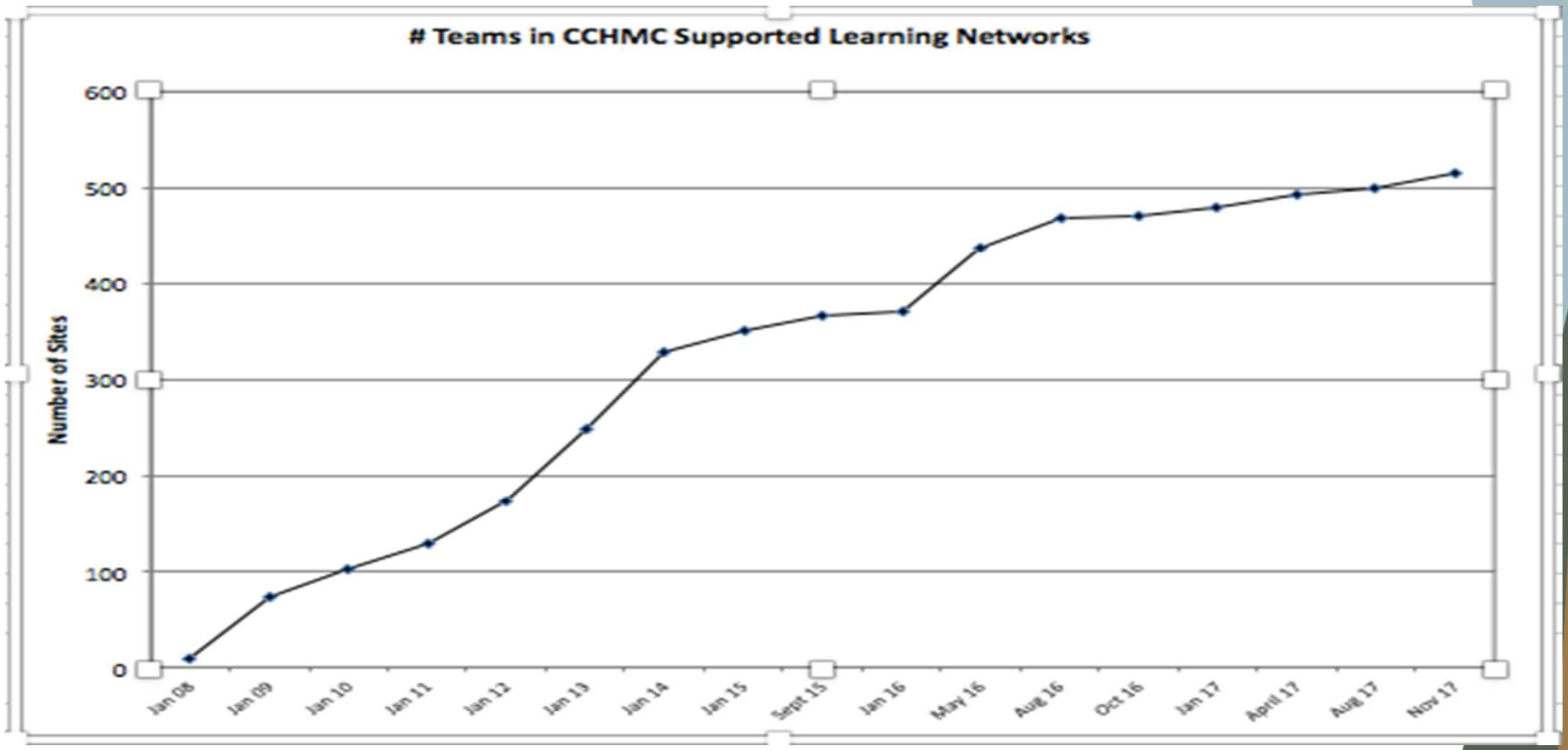
NPC-QIC Phase 3
“Things are looking up for Fontan patients”.

Design Day August 2017
Solar Eclipse “Day of Totality”



- **Physical health and Functioning**
- **Emotional Health and Resilience**
- **Neurodevelopment**

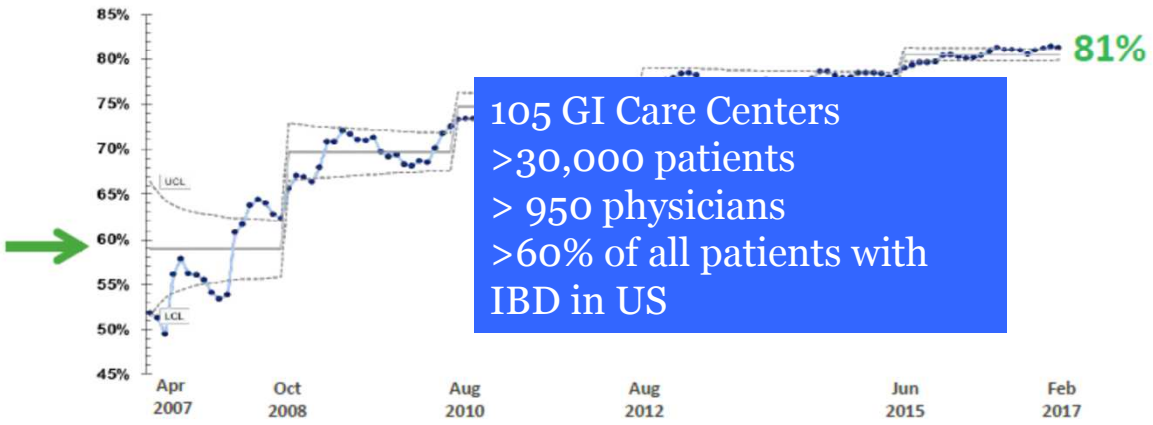
Learning Networks *supported by CCHMC*
516 teams, 289 sites, 43 states + DC, 5 countries



IMPROVECARENOW

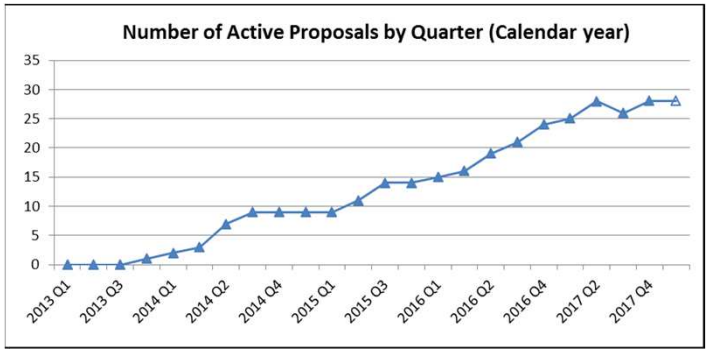
Clinical remission rate in CD and UC

PGA = Inactive (Physician Global Assessment)



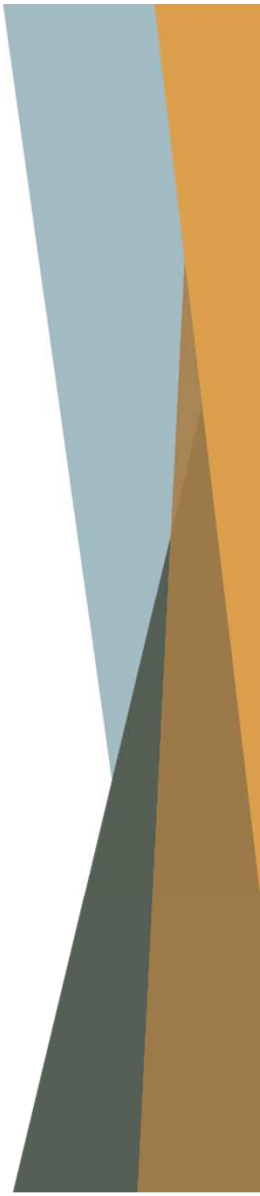
105 GI Care Centers
>30,000 patients
> 950 physicians
>60% of all patients with IBD in US

Current Active Studies



- **Mindfulness Study**: a $4 million research project to determine the optimal type and frequency of mindfulness-based treatment for managing stress
- **PRODUCE Study**: to understand the effectiveness of the specific carbohydrate diet (SCD) in reducing symptoms in patients with Crohn's disease and ulcerative colitis as compared to a modified SCD and unrestricted diet
- **COMBINE Study**: For kids with Crohn's disease who need to start an anti-TNF medication (Remicade or Humira), does adding another medication called Methotrexate lead to better outcomes?
- **Continued Statural Growth:** Predictors of continued statural growth in older adolescents and young adults with Crohn's disease and ulcerative colitis
- **ENROLL in Hubble:** to increase recruitment through the use of ICN infrastructure and engagement activities for twenty two ICN centers participating in the clinical trial with Takeda and PRA focused on evaluating Vedolizumab

- Automated chronic care reports
- QI Reports
- Transparent performance data
- Data quality reports
- Data (and technology) for research
  - Comparative effectiveness
  - Clinical trials
  - N of 1



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