CARDIOLOGY 2025

The Value of a Single Ventricle Registry and Learning Network: SV-ONE

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February 21, 2025

Children's Hospital of Philadelphia
Cardiac Center

HOPE. HEAL. LEARN.

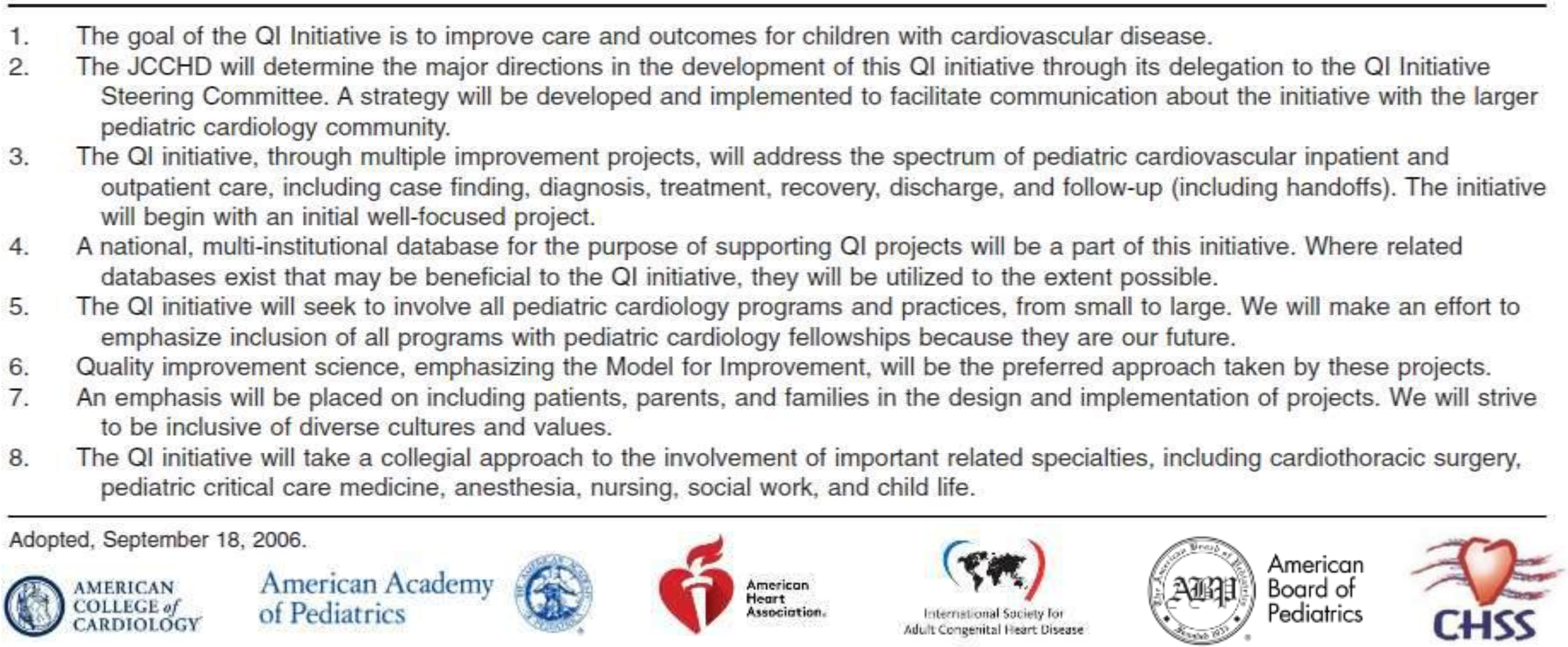
Disclosures

- We have no relevant disclosures

LOOKING ACROSS THE LIFESPAN:

The Road to SV-ONE

2006 Joint Council on Congenital Heart Disease



1. The goal of the QI Initiative is to improve care and outcomes for children with cardiovascular disease.
2. The JCCHD will determine the major directions in the development of this QI initiative through its delegation to the QI Initiative Steering Committee. A strategy will be developed and implemented to facilitate communication about the initiative with the larger pediatric cardiology community.
3. The QI initiative, through multiple improvement projects, will address the spectrum of pediatric cardiovascular inpatient and outpatient care, including case finding, diagnosis, treatment, recovery, discharge, and follow-up (including handoffs). The initiative will begin with an initial well-focused project.
4. A national, multi-institutional database for the purpose of supporting QI projects will be a part of this initiative. Where related databases exist that may be beneficial to the QI initiative, they will be utilized to the extent possible.
5. The QI initiative will seek to involve all pediatric cardiology programs and practices, from small to large. We will make an effort to emphasize inclusion of all programs with pediatric cardiology fellowships because they are our future.
6. Quality improvement science, emphasizing the Model for Improvement, will be the preferred approach taken by these projects.
7. An emphasis will be placed on including patients, parents, and families in the design and implementation of projects. We will strive to be inclusive of diverse cultures and values.
8. The QI initiative will take a collegial approach to the involvement of important related specialties, including cardiothoracic surgery, pediatric critical care medicine, anesthesia, nursing, social work, and child life.

Adopted, September 18, 2006.

AMERICAN COLLEGE of CARDIOLOGY

American Academy of Pediatrics

American Heart Association.

International Society for Adult Congenital Heart Disease

American Board of Pediatrics

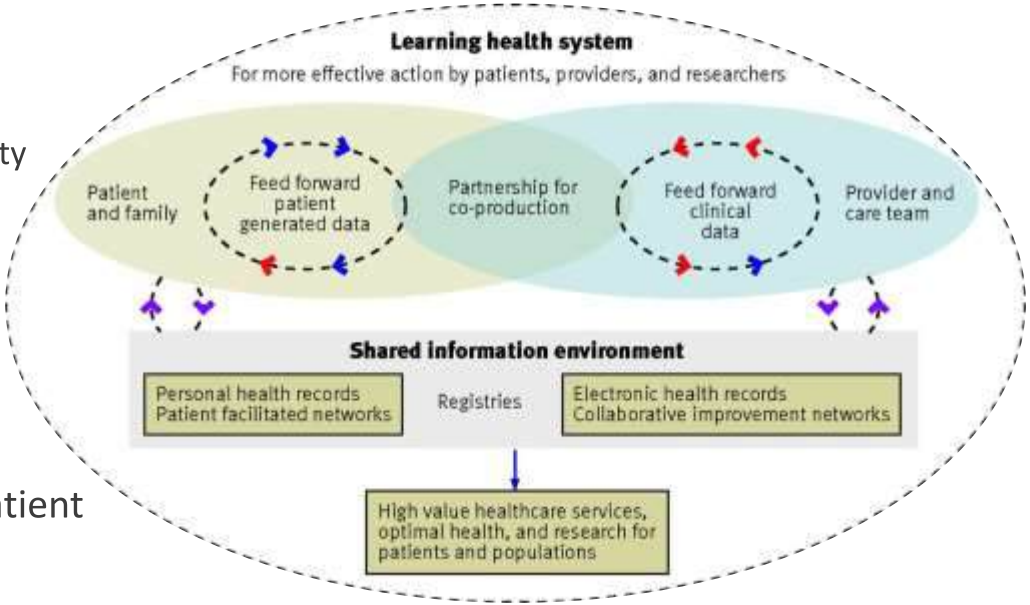
CHSS

National Pediatric Cardiology

Quality Improvement Collaborative

What is a Learning Network?

- Multisite collaboration that focuses on:
  - Improvement science (QI)
  - Research
  - Patient and family engagement and community building
  - Understanding variations in clinical care
  - Determining best practices and reducing unnecessary variation
- Can be particularly useful for rare medical problems
- Often includes a patient registry to pool patient data and clinician experience



Eugene C Nelson et al. BMJ 2016;354:bmj.i3319

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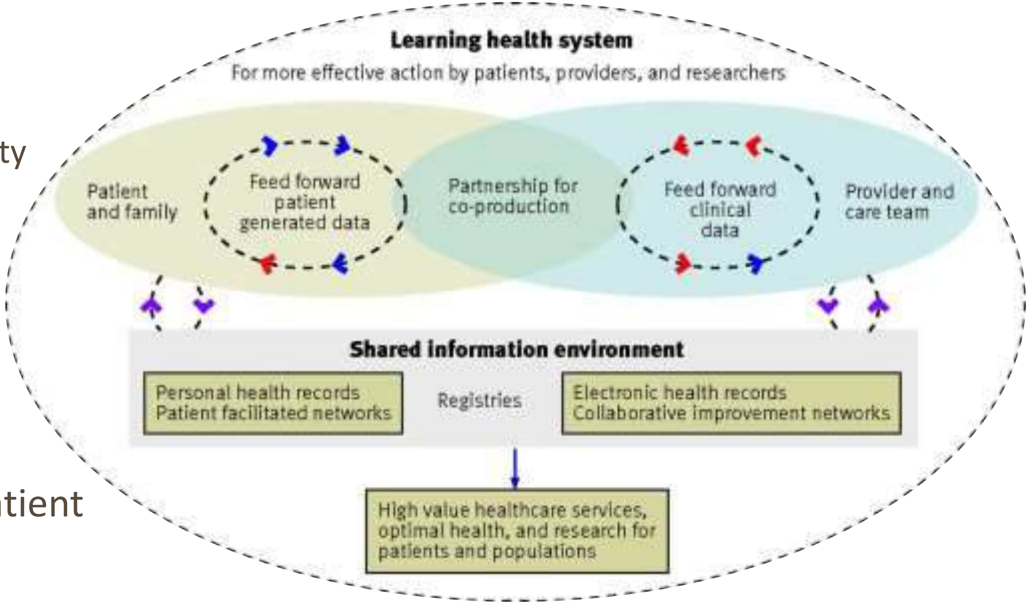


Lots of small experience adds up to BIG experience

Eugene C Nelson et al. BMJ 2016;354:bmj.i3319

What are the key ingredients?

What are the key ingredients?

+

What are the strengths of the Learning Network Model?

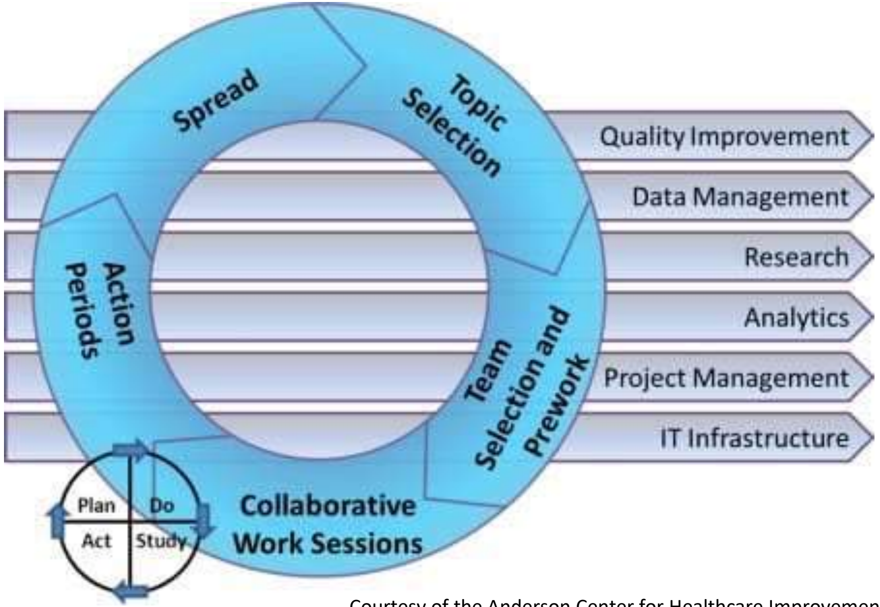
Data + Expert Team is used to fuel:

- Quality Improvement
- Research
- Community Outreach
- Advocacy

What are the strengths of the Learning Network Model?

Quality Improvement Collaboratives/Learning Networks can:

- Help spread knowledge and skill



Courtesy of the Anderson Center for Healthcare Improvement

What are the strengths of the Learning Network Model?

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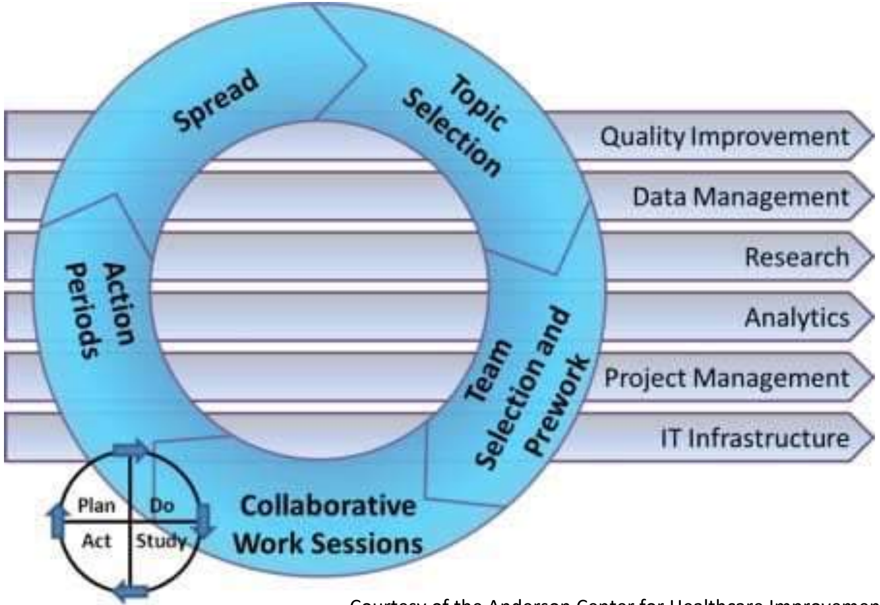
- Pool resources to overcome barriers



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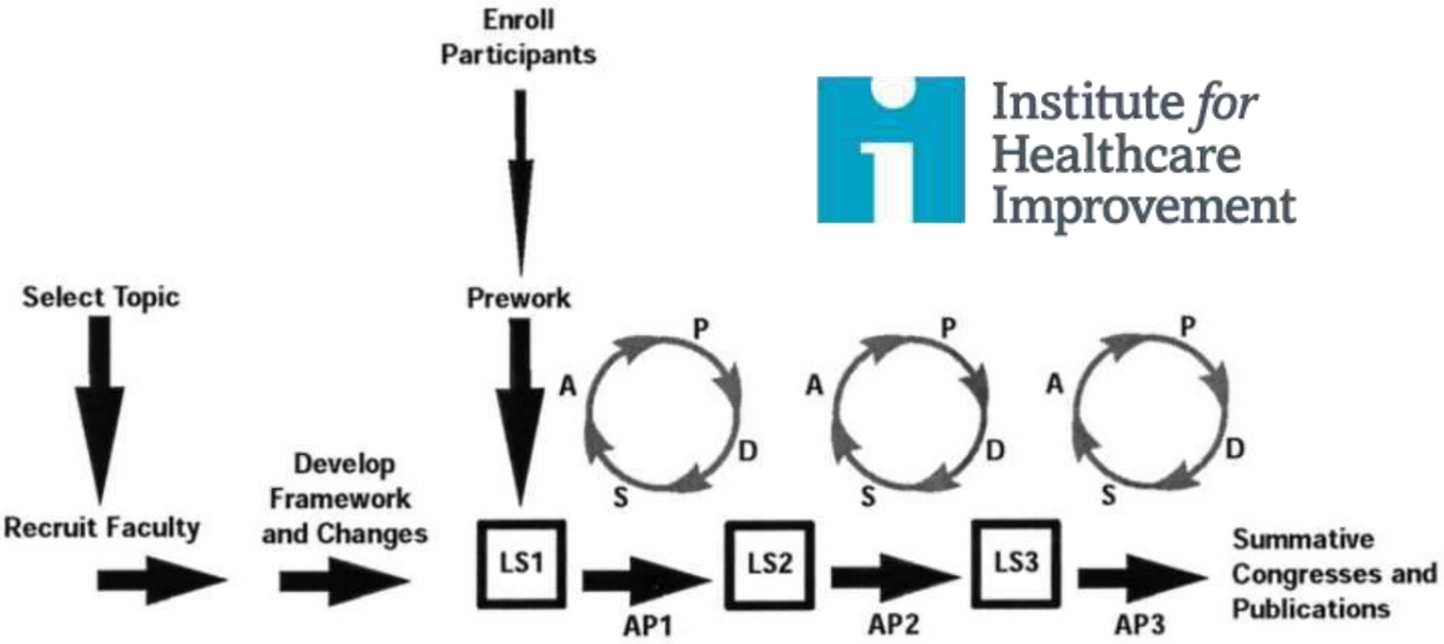
What are the strengths of the Learning Network Model?

Quality Improvement Collaboratives/Learning Networks can:

- Help spread knowledge and skill
- Pool resources to overcome barriers
- Build social pressure to engage clinicians
- Empower patients and families

How does it work?


Institute *for* Healthcare Improvement

Enroll Participants

Select Topic

Prework

Recruit Faculty

Develop Framework and Changes

LS1

AP1

LS2

AP2

LS3

AP3

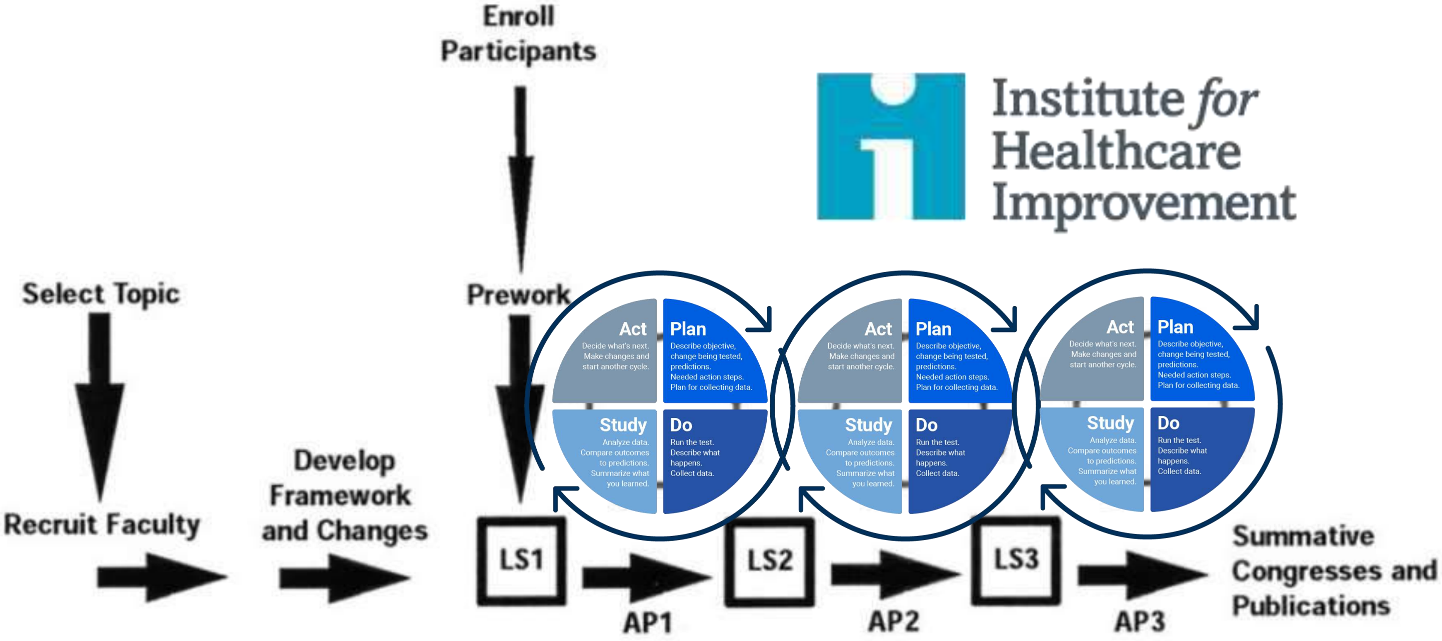
Summative Congresses and Publications

LS1: Learning Session
AP: Action Period
P-D-S-A: Plan-Do-Study-Act

Supports:
Email • Visits • Phone Conferences • Monthy Team Reports • Assessments

How does it work?

Institute *for* Healthcare Improvement



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LS1

AP1

LS2

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LS3

AP3

Summative Congresses and Publications

Act
Decide what's next.
Make changes and start another cycle.

Plan
Describe objective, change being tested, predictions.
Needed action steps.
Plan for collecting data.

Study
Analyze data.
Compare outcomes to predictions.
Summarize what you learned.

Do
Run the test.
Describe what happens.
Collect data.

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AP: Action Period
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All Teach, All Learn

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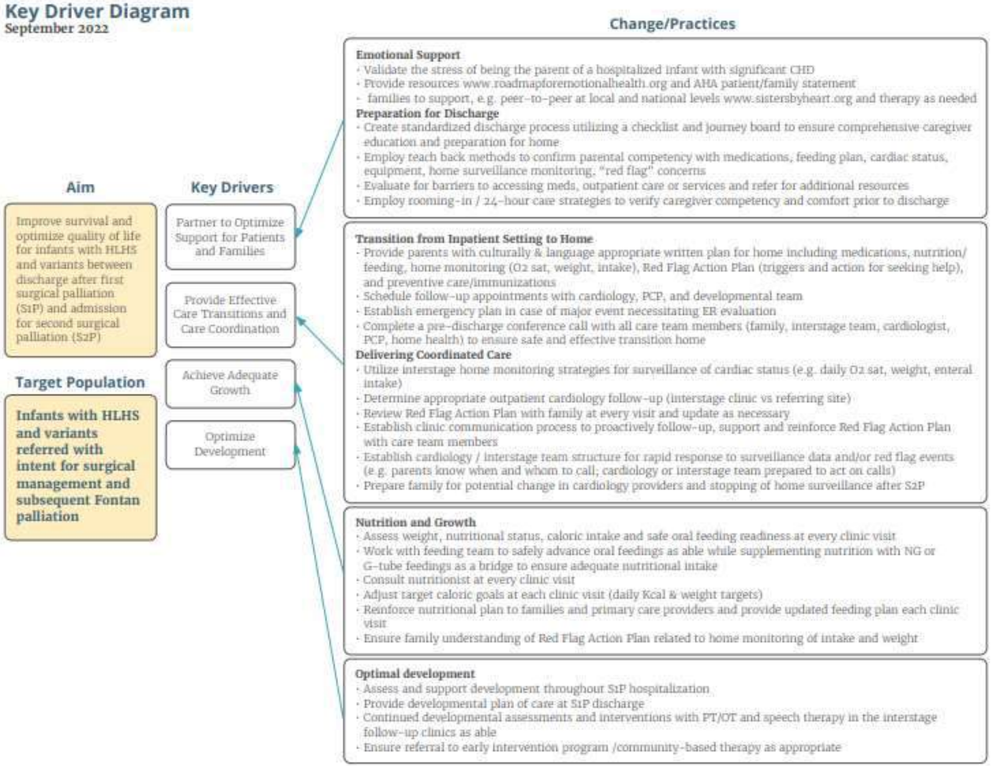
MEASURE
SUCCESS
1 2 3 4 5 6 7 8 9 10 11


National Pediatric Cardiology
Quality Improvement Collaborative
CELEBRATING
6,000
patients
ENROLLED IN THE
NPC-QIC REGISTRY

Interstage Change Project & Toolkit

NPC-QIC Toolkit

Patient Management Strategies for Interstage Care



Key Driver Diagram

September 2022

Aim

Improve survival and optimize quality of life for infants with HLHS and variants between discharge after first surgical palliation (S1P) and admission for second surgical palliation (S2P)

Target Population

Infants with HLHS and variants referred with intent for surgical management and subsequent Fontan palliation

Key Drivers

- Partner to Optimize Support for Patients and Families
- Provide Effective Care Transitions and Care Coordination
- Achieve Adequate Growth
- Optimize Development

Change/Practices

Emotional Support
- Validate the stress of being the parent of a hospitalized infant with significant CHD
- Provide resources www.roadmapforemotionalhealth.org and AHA patient/family statement
- families to support, e.g. peer-to-peer at local and national levels www.sistersbyheart.org and therapy as needed

Preparation for Discharge
- Create standardized discharge process utilizing a checklist and journey board to ensure comprehensive caregiver education and preparation for home
- Employ teach back methods to confirm parental competency with medications, feeding plan, cardiac status, equipment, home surveillance monitoring, "red flag" concerns
- Evaluate for barriers to accessing meds, outpatient care or services and refer for additional resources
- Employ rooming-in / 24-hour care strategies to verify caregiver competency and comfort prior to discharge

Transition from Inpatient Setting to Home
- Provide parents with culturally & language appropriate written plan for home including medications, nutrition/feeding, home monitoring (O2 sat, weight, intake), Red Flag Action Plan (triggers and action for seeking help), and preventive care/immunizations
- Schedule follow-up appointments with cardiology, PCP, and developmental team
- Establish emergency plan in case of major event necessitating ER evaluation
- Complete a pre-discharge conference call with all care team members (family, interstage team, cardiologist, PCP, home health) to ensure safe and effective transition home

Delivering Coordinated Care
- Utilize interstage home monitoring strategies for surveillance of cardiac status (e.g. daily O2 sat, weight, enteral intake)
- Determine appropriate outpatient cardiology follow-up (interstage clinic vs referring site)
- Review Red Flag Action Plan with family at every visit and update as necessary
- Establish clinic communication process to proactively follow-up, support and reinforce Red Flag Action Plan with care team members
- Establish cardiology / interstage team structure for rapid response to surveillance data and/or red flag events (e.g. parents know when and whom to call; cardiology or interstage team prepared to act on calls)
- Prepare family for potential change in cardiology providers and stopping of home surveillance after S2P

Nutrition and Growth
- Assess weight, nutritional status, caloric intake and safe oral feeding readiness at every clinic visit
- Work with feeding team to safely advance oral feedings as able while supplementing nutrition with NG or G-tube feedings as a bridge to ensure adequate nutritional intake
- Consult nutritionist at every clinic visit
- Adjust target caloric goals at each clinic visit (daily Kcal & weight targets)
- Reinforce nutritional plan to families and primary care providers and provide updated feeding plan each clinic visit
- Ensure family understanding of Red Flag Action Plan related to home monitoring of intake and weight

Optimal development
- Assess and support development throughout S1P hospitalization
- Provide developmental plan of care at S1P discharge
- Continued developmental assessments and interventions with PT/OT and speech therapy in the interstage follow-up clinics as able
- Ensure referral to early intervention program /community-based therapy as appropriate

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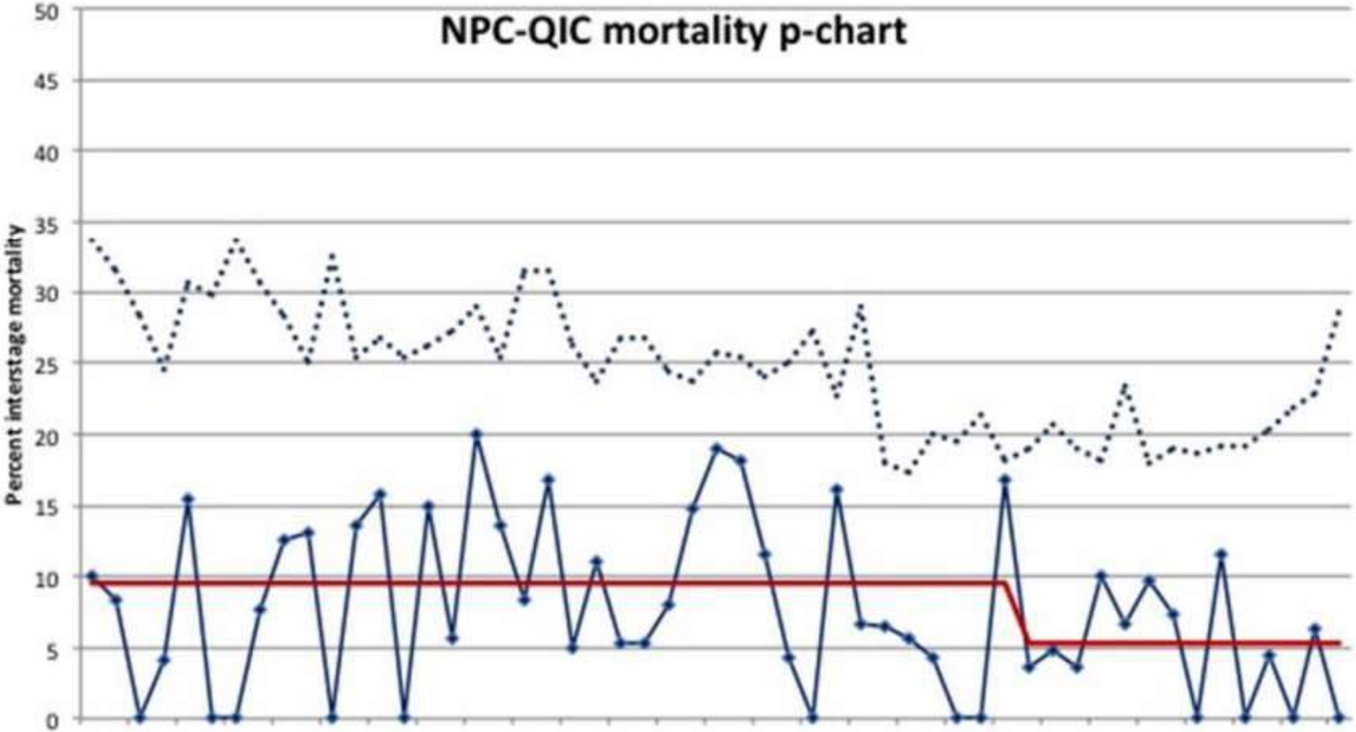
Quality Improvement Collaborative



SYSTEM DRIVERS

Family & Patient Support

Optimal Fetal & Perinatal Management

Improve Morbidity & Mortality during Pre-op ICU, Periop & Post-op

Optimize Neurodevelopment for Single Ventricle Infant Survivors

Achieve Optimal Oral Feeding & Adequate Growth

	Project	Lead(s)
	Gross Motor Development	Julia Anixt, Jennie Briend, Lauren Malik
	Oral Feeding Pre Stage 1 Palliation	Jennifer Fogel, Rachael Satake, Sharon Sable-Baues, Erin Gordon
NEW 	Unplanned Reinterventions	Titus Chan, Stephanie Handler
	Health Equity	Katie Bales, Benton Ng, Nelangi Pinto, Laura Watson
	Tube Weaning	Lacie Patterson, Sarah Watson, Christina Celin, Elisa Marcuccio, Nancy Slater, Michelle Spader, Kiona Allen, Lacie Patterson, Amanda Kogan, Michelle Steltzer
	Surgical Coaching	Adil Husain

Our Network & Reach

69

care centers in **3** countries

NPC-QIC publications have been **cited more than**

1,500 times

in other works in more than **150 separate journals.**

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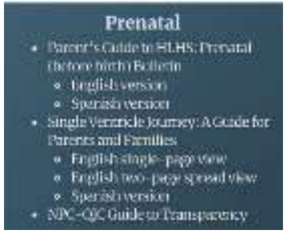
Resources for the HLHS Journey

Our Milestones

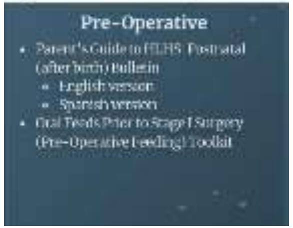
84 shared learnings **published**

45 **Research Explained summaries** express the significance of research findings to families



Prenatal

- Parent's Guide to HLHS: Prenatal (before birth) Bulletin
  - English version
  - Spanish version
- Single Ventricle Journey: A Guide for Parents and Families
  - English single-page view
  - English two-page spread view
  - Spanish version
- NPC-QIC Guide to Transparency



Pre-Operative

- Parent's Guide to HLHS: Postnatal (after birth) Bulletin
  - English version
  - Spanish version
- Oral Feeds Prior to Stage I Surgery (Pre-Operative Feeding) Toolkit

Stage I

- Parent's Guide to HLHS: Tube Feeding Bulletin
- Heart University Webinar: Norwood Procedure and Post-Operative Care

Interstage

- Parent's Guide to HLHS: Interstage Bulletin
  - English version
  - Spanish version
- Interstage Change Package
- Heart University Webinar: Medications in the Interstage Period

Stage II

- Parent's Guide to HLHS: Post Glenn Bulletin
  - English version
  - Spanish version
- Parent's Guide to HLHS: Raising a Toddler Bulletin
- Optimizing Neurodevelopment & Supporting Infant Gross Motor Outcomes Toolkit
- Tube Weaning Toolkit
- Tube Weaning Preparedness for Parents

Fontan Preparation

- Parent's Guide to HLHS: Preparing for Fontan Bulletin
- Parent's Guide to HLHS: Fontan Hospitalization Bulletin
- Heart University Webinars:
  - Hot Topics in Fontan Circulation
  - Surgical Considerations in Fontan Patients
  - Ventricular Assist Devices in Individuals with Fontan Circulation

How far we've come…

Impact of NPC-QIC

SV Infant Born in 2006

- Minimal home monitoring
- Interstage mortality 15-20%
- Growth failure in ~30%
- Lack of community even at individual centers
- Significant clinical variation from site to site and provider to provider
- Lack of transparent data sharing

SV Infant Born in 2022

- Home monitoring is the national standard
- Interstage mortality 5%
- Growth failure <10%
- ~70 centers learning, improving, and building community together
- Standardized approach to nutrition & growth, discharge planning and risk stratification, neurodevelopmental screening
- Data shared transparently at twice yearly learning sessions

But a family navigating a Norwood Procedure in 2022 is moving into a different phase of care in 2025

FON Development

National Pediatric Cardiology
Quality Improvement Collaborative

FONTAN
OUTCOMES NETWORK

FON developed as a collaboration between various stakeholders, most directly emerging from and with support from NPC-QIC.

2008	2016-	2017-2021	2024
Phase I	Phase 2	Fontan Outcomes Network	
HLHS Interstage	HLHS Diagnosis - 1st Birthday	Single Ventricle Lifespan	
65 Care Centers	69 Care Centers	12 Pilot Care Centers	38 Care Centers
SUSTAIN PHASE	ACTIVE PHASE	DESIGN (2017) AND PILOT (2021)	CURRENT STATE

FON Vision & Mission

Our Mission

To optimize longevity and quality of life for individuals with Fontan circulation by dramatically improving:

- Physical health & functioning
- Neurodevelopment
- Emotional health & resilience

Our Vision

To improve outcomes and quality of life for all individuals with single ventricle heart disease and Fontan circulation.

FON Membership

2021: Launched FON with 12 founding centers

+

2022: Added 18 centers

+

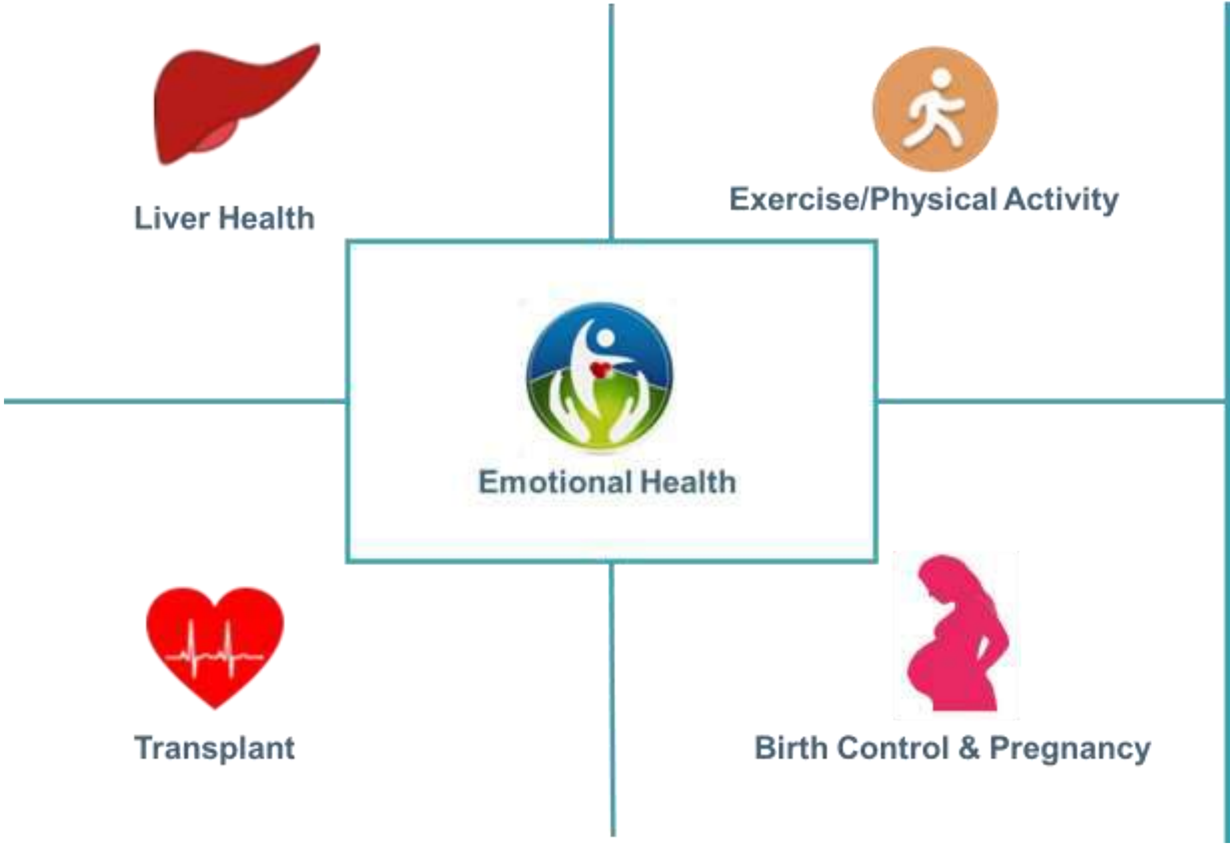
2023: Added 6 centers

+

2024: Added 2 centers

Total of 38 centers

Five Themes



Liver Health

Exercise/Physical Activity

Emotional Health

Transplant

Birth Control & Pregnancy

Physical Activity & Exercise QI Project

Global Aim
Support physical activity and wellbeing for individuals with Fontan circulation


Active Living With Fontan Circulation

YEARS
Pre–K
Grade School

How to Use This Toolkit

TEAM QI KICKOFF
MARCH 2025

Strategies
Assessment and promotion of physical activity
Use of FON Physical Activity & Exercise resource toolkit

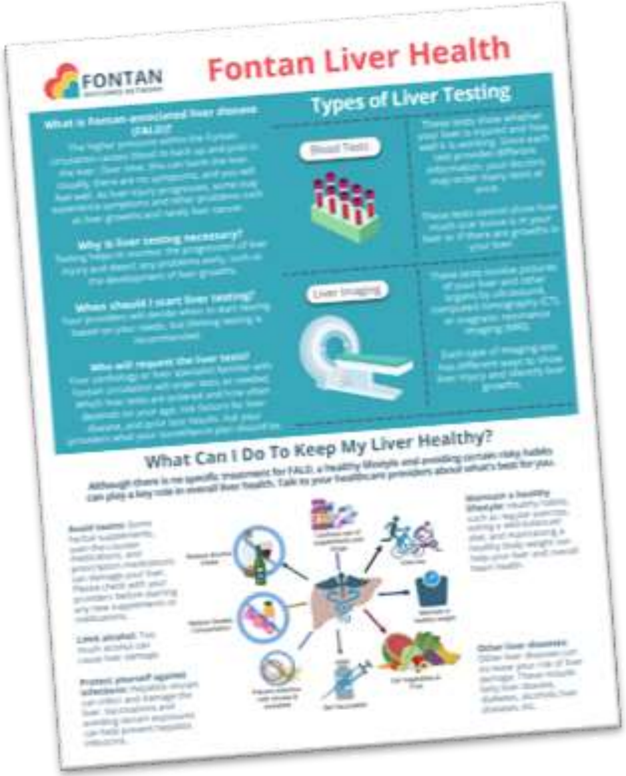
Liver Health QI Project

2023 and 2024 Milestones

- Create liver health workgroup
- Create liver health expert feedback group
- Create tools and interventions to improve outcomes for liver health

2025 Milestones

- Charter a Quality Improvement Project for improving liver health outcomes



FONTAN

Fontan Liver Health

What is Fontan-associated liver disease (FALD)?

Types of Liver Testing

Blood Tests

Why is liver testing necessary?

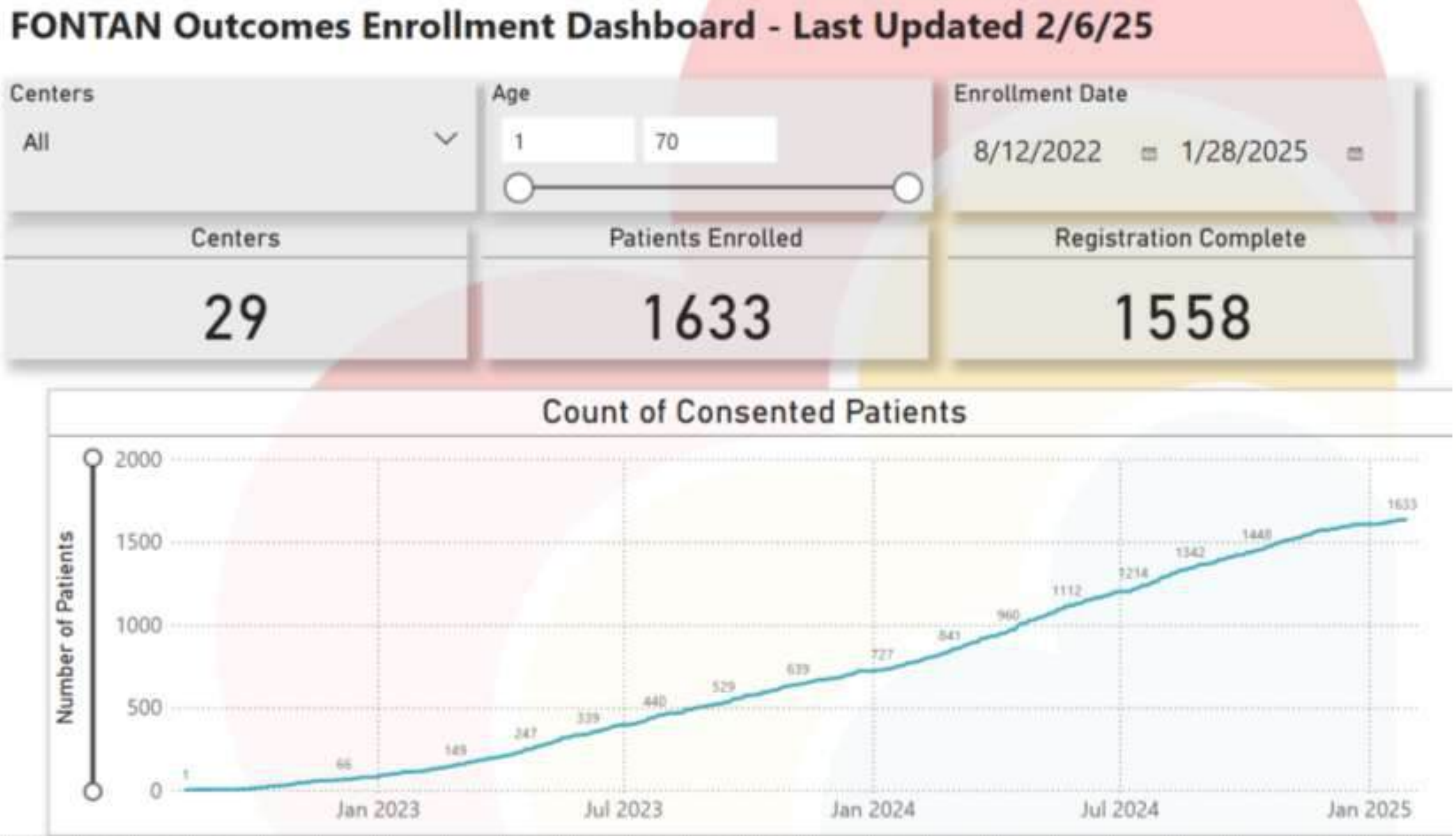
Liver Imaging

When should I start liver testing?

Who will request the liver tests?

What Can I Do To Keep My Liver Healthy?

FON Data Registry



FONTAN Outcomes Enrollment Dashboard - Last Updated 2/6/25

Centers: All

Age: 1 – 70

Enrollment Date: 8/12/2022 – 1/28/2025

Centers	Patients Enrolled	Registration Complete
29	1633	1558

Count of Consented Patients

Community Building & Engagement

PATIENT AND FAMILY INVOLVEMENT IN ALL WORKGROUPS, QI PROJECT, AND LEADERSHIP TEAMS

PATIENTS AND FAMILIES REPRESENT 25% OF ALL LEARNING SESSION ATTENDEES

6 YEARS RUNNING FOR SINGLE VENTRICLE PATIENT DAY

FON + NPC-QIC = SV-ONE

Given the overlapping missions and close collaboration between FON and NPC-QIC, the leadership teams of both organizations have decided that the networks will enhance collaboration, working towards becoming one organization: the Single Ventricle Outcomes Network (SV-ONE), with the goal to create a seamless lifespan registry for single ventricle patients.

Timing and Care Center requirements will be among the many details that will be thoughtfully considered in a robust plan before proceeding in FY26.

FONTAN
OUTCOMES NETWORK

National Pediatric Cardiology
Quality Improvement Collaborative

Single Ventricle Outcomes NEtwork (SV-ONE)

Vision: A future where all affected by single ventricle heart disease can thrive and live long, fulfilling lives.

Mission: To build a connected community, accelerate discovery, transform care, and improve single ventricle heart disease outcomes across the lifespan.

Guiding Principles:

- Center the patient and family in all that we do.
- Embrace whole-patient health, including psychosocial and emotional needs.
- Ensure broad representation and elevate voices from diverse expertise and experience.
- Design, measure, and promote equity in all our endeavors.
- Collect accurate, timely data to power impactful improvement and research.
- Support and empower clinicians.

July 2024

Q1

VISION & MISSION

Draft vision, mission, and guiding principles

STRATEGY

Charter joint-ELT working groups:
- Strategic Planning
- Leadership & Governance
- Business Model & Network Operations
- Data & Technology

Q2

COME TOGETHER

Joint Learning Session in St. Louis

PLANNING

Working group strategies approved by ELTs
Submit revised IRB protocol

Q3

RESOURCING

Prioritization and resourcing for SV-ONE for FY26

JOIN US

Care center commitment letters sent to current FON & NPC-QIC sites

Q4

CONVENE

Joint Learning Session (Virtual)

MEMBERSHIP

Legal/IRB documentation distributed

July 2025

SV-ONE

National Pediatric Cardiology
Quality Improvement Collaborative

FONTAN
OUTCOMES NETWORK

THE VALUE…BY THE NUMBERS

Over **70** participating cardiology care centers

46% sustained mortality reduction

Over **7,500** enrolled in our registries of individuals with SV heart disease

Over **80** research publications using data from the registry

6 toolkits designed with QI methodology to promote improved processes and outcomes across the lifespan

45 research explained summaries, to make medical research approachable for families

Over **15** resources for families to support and help navigate the single ventricle journey

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FONTAN
OUTCOMES NETWORK

Conclusions

The future is now!

- We have assembled a broad coalition of patients, families, providers, and allies
- SV-ONE provides an infrastructure to leverage the expertise of these key stakeholders to drive improvement in outcomes that matter for patients living with SV physiology and their families
- A national lifespan registry is long overdue
- The Learning Network model provides opportunities for ACTION and COLLABORATION rather than just data collection and reflection
- There are early opportunities to reduce unnecessary variation and establish guidelines to optimize care
- There are long-term opportunities to conduct transformative longitudinal research by pooling data to conduct network-wide QI initiatives and clinical research

Don't be left behind… **JOIN US!!**

"Individually we are one drop. Together we are an ocean." *Ryunosuke Satoro*

What now?

We are looking for care centers to join **SV-ONE** and partner with us in improving outcomes for these patients

If interested, please email:

info@fontanoutcomesnetwork.org