



National Pediatric Cardiology
Quality Improvement Collaborative

Research Explained

THE FONTAN OUTCOMES NETWORK:

FIRST STEPS TOWARDS BUILDING A LIFESPAN REGISTRY FOR INDIVIDUALS WITH FONTAN CIRCULATION IN THE UNITED STATES

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ABOUT THIS STUDY

This study describes the systematic design of the FON, including the initial steps in development of the lifespan registry and pilot testing of the feasibility of data collection at 10 Children's hospitals.

Why is this study important?

- Outcomes of single ventricle congenital heart disease continue to improve and an increasing numbers of individuals with Fontan circulation are reaching adolescence and adulthood.
- However, a variety of cardiac and extracardiac complications and comorbidities have been recognized which negatively impact physical and mental health, quality of life, and longevity.
- As demonstrated for other chronic conditions, prevention or early recognition of morbidities, along with standardized management strategies, may lead to better

understanding of disease mechanism, risk stratification, and development of targeted therapies.

- To optimize wellness and overcome complications scientists and care providers must work together to better understand mechanistic origins of single ventricle congenital heart disease and its comorbidities and complications, the trajectory of organ-specific health to predict the course of each patient over time, and prevent and treat complications and co-morbidities to optimize outcome.
- In August 2017, a systematic design process was launched to create a learning health network to improve the long-term outcomes of individuals with Fontan circulation across the nation names the Fontan Outcomes Network (FON).
- This manuscript describes the systematic design of the FON, including the initial steps in development of the lifespan registry and pilot testing of the feasibility of data collection at 10 Children's hospitals.

How was this study performed?

- The study explained initial design process- defining the Mission and Vision of FON:
 - *The vision* is to dramatically improve the outcomes of individuals with Fontan physiology.
 - The FON *mission* is to optimize the longevity and quality of life for individuals with Fontan physiology and their families by improving their physical health and functioning, neurodevelopment, and emotional health and resilience.
- *Establishment of Design Workgroups to Define Outcome Aims, Measures, and Required Registry Data Elements:*
- Workgroups were established targeting three areas of focus: 1) physical health and functioning, 2) neurodevelopment and 3) resilience and emotional health. Each workgroup was co-led by a patient or family member and clinician experts.
- A national registry for patients with a Fontan circulation is being built and this study tested the data collection forms in terms of feasibility and data availability.

What were the results of the studies?

- The study describes the work groups and the establishment of the FON
Nine program tested the data collection forms on 33 patient charts. No identified patient data was shared between the programs.

The findings from the feedback on the data collection forms:

1. All participants supported data collection as an important process to populate the registry, start the improvement cycle, and provide input for research for patients with Fontan.
2. The participants identified the importance of the data quality checks and having clear data definitions since much of the collected data will not fit into diagnostic codes.
3. The centers acknowledged the time needed to complete these forms which ranged from 32 – 365 minutes.
4. Source data for multiple variables were not available for adult patients, e.g. details of prior surgical interventions and the early post-operative course.
5. Some of the data that were often missing were variables related to extracardiac end organ disease, neurodevelopmental testing, mental health diagnosis and therapy, and measures of quality of life which were available in only 44% of the cases.
6. There is a need to incorporate patient reported outcomes and quality of life measures into clinical practice and, therefore, into the data collection forms.

What it all means?

- As the number of individuals with the Fontan circulation rapidly grows, an improved understanding of their physical, neurodevelopmental and emotional health needs is critically needed.
- FON is designed as a registry-based, multicenter, learning network to improve our understanding of the healthcare needs of the Fontan population through collaboration, quality improvement, research and innovation, and the learning network has taken important initial steps towards establishing a national registry of Fontan patients in the United States.
- Participation and consents from the patients and families is very important for the success of FON. The registry will likely start recruiting patients in the next 1-2 years.