Reexamining Interstage Home Monitoring After the Norwood Operation

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Survival for children born with congenital heart disease has improved dramatically over the past 3 decades. Of the >35,000 children undergoing congenital heart surgery across the United States each year, >95% now survive to hospital discharge.1 Even for complex lesions such as hypoplastic left heart syndrome that were once uniformly fatal as recently as the early 1980s, early survival is now >90% at experienced centers. However, as we have begun to learn more about the longer-term outcomes of these patients in recent years, it has become apparent that, despite these gains in early survival, continued mortality over the mid- and long-term remains a challenge. For example, in the recent Pediatric Heart Network Single Ventricle Reconstruction Trial, which enrolled 549 patients undergoing the Norwood operation (randomly assigned to a right-ventricle-to-pulmonary-artery shunt versus modified Blalock-Taussig shunt), transplant-free survival in the overall cohort was 64% at a mean follow-up of 4.8 years.2 One of the most high-risk periods is known to be the interstage period between discharge from the Norwood operation (stage 1) and stage 2 palliation (bidirectional Glenn or hemi-Fontan operation) typically performed at 4 to 6 months of age. In the Single Ventricle Reconstruction Trial, the interstage mortality rate was 12%.3

In 2006, the National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) was formed, and now includes >50 congenital heart programs engaged with patients and families in promoting collaboration across sites and quality improvement activities.4 The first project initiated by the collaborative focused on the interstage period, with a primary goal of reducing interstage mortality and improving quality of life. The key drivers that were deemed necessary to achieve these goals included engaging parents, improving care transitions at Norwood discharge, optimizing growth, and improving coordination among the care team and families.4 Multiple change strategies or activities in these areas were recommended for centers participating in the collaborative including caregiver preparation during the Norwood hospitalization; providing caregivers with a red flag action plan; establishing collaboration between the family, primary physician, cardiologist, and other team members; activities related to assessment and optimization of feeding and weight gain; standardization of assessments and action plans at clinic visits; and home monitoring during the interstage period of oxygen saturation and weight gain.4 The latter component is integrated with many of the other activities, and was included primarily based on a 2003 study from the Children’s Hospital of Wisconsin that demonstrated a decrease in interstage mortality from 16% in historical controls to 0% following the introduction of a comprehensive home-monitoring program at their institution.5

In this issue of Circulation, Oster and colleagues6 evaluate the association between home monitoring and interstage mortality, readmissions, and weight gain in a multicenter cohort of NPC-QIC centers. For this study, data were combined from 2008 to 2012, and home monitoring was evaluated based on the planned frequency of daily, weekly, or no monitoring. The study found that neither daily nor weekly home oxygen or weight monitoring was associated with improved interstage mortality or readmissions in comparison with no monitoring. Daily home weight monitoring was associated with improved weight gain in comparison with no monitoring.

Taken at face value, these findings suggest that home monitoring has little effect on one of the major outcomes the collaborative was aiming to impact (interstage mortality) and appear to contradict single-center reports. Why might this be the case? Previous work by the Northern New England Cardiovascular Disease Study Group and others has demonstrated that a key component of collaborative efforts geared toward reducing mortality is a detailed understanding of the epidemiology of why patients die after surgery.7 Within the patient population undergoing adult cardiac surgery, the Northern New England Cardiovascular Disease Study Group found that 65% of the deaths overall were due to low-output failure after surgery, and that differences in low-output failure also accounted for 80% of the variation in mortality across sites. This subsequently led to further studies and collaborative efforts across sites to better identify, prevent, and treat this specific complication. This type of data-driven approach was successful at reducing the rate of death due to low output, and the overall mortality rate within the Northern New England Cardiovascular Disease Study Group collaborative.7 In the case of single-ventricle patients, however, the etiology of interstage death remains unclear in many cases. Because many of these deaths occur at home and are relatively rare overall, investigating the seminal events leading to death has been challenging.8 This in turn can make it difficult to target improvement strategies. For example, if deaths are related

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to worsening cardiac function over time, or progressive narrowing of the source of pulmonary blood flow, regular home monitoring may be useful in identifying changes in weight gain or oxygen saturations preceding more serious events. If, however, the event is more suddenly precipitated, such as an arrhythmia or shunt thrombosis, even once-daily monitoring may be too infrequent to detect such events and allow for intervention.

If home monitoring truly proves to be ineffective in improving interstage outcomes on multicenter level, it may add to examples such as hormone replacement therapy in women and risk of cardiovascular disease, which emphasize the potential limitations of widespread implementation of treatments or strategies into practice based solely on observational data or small single-center studies. A multicenter randomized trial of home monitoring in the single-ventricle population was proposed several years ago, but even at that time was deemed not to be possible because of the lack of equipoise and incorporation of home monitoring into standard practice at many centers already based on initial single-center observational studies. The inclusion of home monitoring as a quality metric in the US News and World Report Survey, which publically ranks pediatric heart programs, may also have played a role in its early widespread adoption.

However, a deeper examination of the methodology used in the present study suggests that the jury may still be out regarding the effectiveness of interstage home monitoring and related activities. The current analysis aggregated all NPC-QIC data from 2008 to 2012 and did not examine trends over time. In addition, a true control group outside of the collaborative was lacking. It is also important to note that home monitoring is just 1 component of the overall efforts supported by the NPC-QIC (and individual institutions who have adopted these methods) and intertwined with numerous other activities related to engaging families and the care team, and coordination and standardization of care. Considering hypothetical trends over time both within the NPC-QIC and in a control group, the Figure highlights some of the different scenarios in which the findings reported in the present study could be true: (1) the overall improvement strategy used by the NPC-QIC (of which home monitoring is 1 component) has no impact on outcome; (2) the improvement strategy has improved outcomes in all groups within the NPC-QIC to a similar extent, and these outcomes are better than those at centers not participating in the collaborative; or (3) outcomes in general across all centers have improved over time regardless of participation in the NPC-QIC. These are just a few of the potential scenarios that might be present. In all 3 of these examples, one might find the same results comparing data from the various home-monitoring groups in aggregate within the collaborative itself (no difference between groups); however, these 3 scenarios all have very different implications. In the first scenario, it may be advocated that resources should not continue to be expended in this area if home monitoring and related activities are not effective. In the second scenario, one could argue that the improvement activities overall are useful in improving outcomes and should be continued, and in the third scenario, it could be concluded that everyone’s outcomes have improved independent of NPC-QIC participation such that there may be other key drivers at work. Recently published data in a separate NPC-QIC study including more contemporary data may begin to shed some light on some of these questions. Results of that study, which examined interstage mortality rates over time within the NPC-QIC by using statistical process control methodology, suggest no change in mortality rates initially (during the time period of the present study), but trends toward decreasing mortality within the collaborative more recently beginning in 2013.

Another important factor to consider is the impact of the center. In the present study, it is reported that 1 type of strategy or frequency of home monitoring was typically used at each center within the collaborative. Thus, the comparisons between groups are really center-level comparisons. It is well known that there is wide variation overall in the structure of congenital heart programs (eg, surgical volume, personnel), care processes, and outcomes across centers. For example, in-hospital mortality has been reported to range from <10% to ≈40% across US centers performing the Norwood operation. With regard to home-monitoring and interstage programs, it is also known that there is variation across centers in how these programs are implemented. For example, some centers keep high-risk patients in the hospital until their stage

### Figure

**Figure.** Possible scenarios in which no difference would be found among NPC-QIC groups. **A.** The overall improvement strategy used by the NPC-QIC (of which home monitoring is 1 component) has no impact on outcome. **B.** The improvement strategy has improved outcomes in all groups within the NPC-QIC to a similar extent, and these outcomes are better than those at centers not participating in the collaborative. **C.** Outcomes in general across all centers have improved over time regardless of participation in the NPC-QIC. NPC-QIC indicates National Pediatric Cardiology Quality Improvement Collaborative.
2 surgery, which may in and of itself have an impact on interstage outcomes. It is unclear how these center-level differences impact the findings of the present study, and it is possible that there may be differential effects of home-monitoring/interstage improvement programs on outcome at different types of centers. Particularly given the small sample size in the group with no home monitoring (n=36 patients in the no oxygen saturation monitoring group), there may be limited power, and issues regarding generalizability, as well, because it is likely that these results reflect the outcomes at no more than a handful of centers. It is unclear how these centers are similar to or different from those using other strategies. Previously published single-center studies suggest that the success of home-monitoring strategies varies across programs. For example, as mentioned above, implementation of a home-monitoring program at 1 center has resulted in an initial decline in interstage mortality from 16% to 0%, and a 2% overall mortality rate over 10 years. However, as described in a recent review article, other programs have reported more limited changes associated with home monitoring; for example, a reduction in interstage mortality from 12% to 8% in 1 study, and 24% to 21% in another.

In summary, it can be challenging to evaluate the impact of complex interventions such as home monitoring, which do not occur in isolation, but are intertwined with many other care coordination and engagement activities. Added to this are the challenges associated with the early adoption of home monitoring before a broader evaluation of its effectiveness. The present study in Circulation and other recent analyses are necessary initial steps toward understanding how and if home monitoring and related activities are able to improve interstage outcomes across centers. These studies are important because of the significant time and resources invested around the country in these efforts. Although it seems clear from this study and others that weight monitoring and related efforts to optimize feeding and growth are effective in promoting weight gain in these patients, further evaluation is needed to evaluate the impact on interstage mortality. A better understanding of the underlying causes of interstage mortality is still needed to target improvement strategies. It is possible that newer remote sensing and continuous monitoring technologies could be useful in this setting. Because of the known wide heterogeneity in care and outcomes for children undergoing heart surgery across sites, it is likely that home monitoring may have a differential impact on outcomes in different settings, and further study in this area may also prove useful. In addition, taking advantage of the potential for a natural experiment by comparing outcomes over time in those centers participating in the NPC-QIC (>50 centers) versus outcomes at centers not participating in the collaborative could answer further questions through providing a true control group. Current data from the Society of Thoracic Surgeons Congenital Heart Surgery Database indicate that there are 104 centers in the United States that performed a Norwood operation from 2010 to 2014.

With the increasing volume of pediatric cardiovascular data collected across numerous sources, we now have the ability to better understand variation in care and outcomes across centers. However, it has been said that “Data are not information, information is not knowledge, knowledge is not understanding, and understanding is not wisdom.” Better leveraging the data available to us, along with an understanding of the factors driving variation, and the wisdom to foster collaboration across sites to use this information to effect change (as exemplified by groups such as the NPC-QIC), provides an important opportunity to not only understand variation, but also to improve outcomes across centers for children with congenital heart disease.

Disclosures
None.

References


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