



Research Explained

The journal *Circulation* published a study in June 2015: "Reexamining Interstage Home Monitoring after the Norwood Operation".

The abstract can be found at the following link: <http://www.ncbi.nlm.nih.gov/pubmed/26115543>

The NPC-QIC Research and Publication Committee reviewed this article, and a summary of the findings can be found below.

Main Finding from this Study:

We should not be discouraged by this study! **While the authors did not find a strong association between the recommended frequency of measuring saturations and weights and improvements in interstage mortality rates, it does not mean that these programs are not beneficial.** It simply means that we still are not sure which interventions are the key ones and may not be appreciating how complicated interstage programs are to evaluate.

Background for Editorial:

When the NPC-QIC was formed in 2006, high interstage mortality rates became the first major problem targeted for improvement. While it is still not fully understood why infants have a high rate of mortality between the first and second operations (the interstage period), many interventions were started through the collaborative. Some of the key interventions included engaging parents, improving the discharge processes, optimizing growth and nutrition and improving care coordination through the use of home monitoring programs. Previous studies at single surgical centers suggested home monitoring programs had a very positive effect in reducing mortality during this high-risk period, hence making this a valuable project for the collaborative to undertake.

Every hospital that treats HLHS has a different way of monitoring infants at home between surgery one and two. Measuring oxygen saturations and weighing the infant on a regular basis are common monitoring tools that are used. At the time of discharge, and at the time of clinic visits, families are given recommendations by the care team as to how often to measure these values. Until recently, we have not really examined if there is any link between those recommendations and less interstage death. In other words, we don't really know if extra monitoring increases survival rates or improves growth. By examining data from 2008-2012 in the NPC-QIC, Oster and colleagues demonstrated that improved

interstage mortality was not associated with how frequently the families were told to measure oxygen levels and weights. These findings suggest that maybe home monitoring did not drive the reduction in interstage mortality that we are currently seeing.

About this Study:

1. In a perfect world, we could do an actual experiment where one group does home monitoring at certain frequencies and the other group is not monitored at all. Then we could compare the outcomes of the two. However, this is much easier said than done as monitoring babies between the first surgery and the second surgery is now considered “the standard” and previously thought to be effective. It would be hard to convince physicians and parents to not use certain tools to monitor their children in order to participate in an experiment to test whether home monitoring works.
2. Weighing the infants to demonstrate good nutrition and growth as well as measuring oxygen levels, is only a part (and maybe only a small part) of the interstage programs as a whole. Yet, they are tasks that are so wrapped-up with other aspects of interstage care that it is very challenging to separate them out from other aspects of the program that may be also helping to reduce mortality. Perhaps it is the significant engagement of parents in their child’s care, or better communication between parents and providers, or even a better understanding of nutrition and growth that is driving the improvements. The complexity of the programs at each center can make it difficult to evaluate.
3. The study really cannot account for the so-called “center effect.” For the most part, centers recommend the same frequency of monitoring for all patients in their program – it is what they are used to. Consequently we can never separate out that the results may just be due to some centers having lower interstage mortality than others for whatever reason, and this effect is not due to how frequently they monitor these kids.
4. The results of the study seem to suggest that the **recommended frequency** of weighing and gathering oxygen saturations did not seem to be related to a reduction in mortality. It does not say whether the **recommendation of home monitoring overall** is related to a reduction in mortality. The reason is that nearly the entire group, by being in the NPC-QIC, was monitored in some way so you cannot really determine within this group if the monitoring itself had an effect.
5. We still do not really know what **causes** most interstage mortality. Thankfully, they are rare events but that also makes them very challenging to study. One reason that the study did not find an association could be because there are just not enough events to look at. Having a better understanding of what causes interstage mortality would allow us to better evaluate what specific factors are leading to improvements in interstage survival.
6. Just because there are big limitations in this study does not mean that the results are not important! A lot of resources are invested into these monitoring programs and this is an

excellent first step to attempt to figure out what portions of them, among which types of patients, are the most effective at reducing mortality rates. Monitoring programs were adopted so quickly across the country that finding a good comparison group that is not monitored or not part of the NPC-QIC will always prove to be challenging in the future.