program's influence on other variables such as neurodevelopmental outcomes.

Webcast

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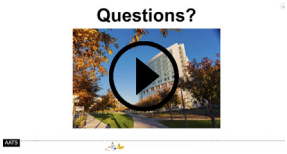

Conflict of Interest Statement

The authors reported no conflicts of interest.

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Key Words: cardiac arrest prevention, safety II, proactive safety, risk mitigation, quality improvement, congenital heart disease

Discussion

Presenter: Dr Tara Cosgrove

Dr Nathalie Roy *(Boston, Mass)*. So I'd like to thank the association for the opportunity to discuss the paper and I congratulate the authors and thank them for sending the manuscript early. You and your colleagues report important multidisciplinary quality improvement (QI) approach in high-risk patients to proactively mitigate cardiac arrest events after congenital cardiac surgery and also after interventional procedures. The Proactive Mitigation to Decrease Serious Adverse Events (PROMISE) strategy proposes a virtual multidisciplinary structure huddle pre- and postprocedure and ad hoc afterward with assigned tasks to certain members, joint decision making, and specific opportunities for any members to express concern. The study adds to the existing literature on prevention of cardiac arrest in cardiac intensive care units for a Pediatric Cardiac Critical Care Consortium initiative that identifies organizational and institutional factors. In addition, it builds on a long history of structured handoff in pediatric cardiac surgery and safety huddles. In addition, the PROMISE program offers a concrete roadmap to event mitigation through multidisciplinary collaboration. I have the following 5 questions. So, first is for your analysis of the events using the g-chart. You used the fourth rule, which is the 2 out of 3 events in a row near the upper limit following your intervention as a marker of specific cause variation. However, immediately after those 2 events, you had to return to your preintervention median for the following 2 events. Could you please comment

on the validity of the interpretation and also the sustainability of your process?

Dr Tara Cosgrove *(Columbus, OH)*. Yes, absolutely. Thank you, Dr Roy, for those questions. So, I think you're referring to this chart here which is the g-chart plotting our primary outcome measure. I didn't get to discuss it during the presentation but thank you for calling the evidence of special cause variation. So this is a type of statistical process control chart using QI methodology to specifically measure improvement for rare outcomes, which is often kind of underappreciated using traditional statistics, especially when you have, again, rare events and a small sample size. And so, there are 2 circles here designating the signals of special cause variation and again these signals are based on sort of well-established statistical rules that have been published on QI methodology and in QI science to signal that it would be very unlikely to happen by chance. And so, this first point was outside of our initial control limits which again, ± 3 SD would be extremely unlikely to happen by chance, and then you mentioned that there is an additional 2 points here that fall beyond ± 2 SD from the original center line, which again would be unlikely to happen by chance. These additional points following the evidence of special cause variation are taken into account when calculating the new median. So we don't only take into account the favorable numbers but we take into account all of these data points following those evidence of special cause variation when calculating a new median or a new centerline.

And so although these points aren't necessarily in the right direction, they're just sort of normal noise of the system. So there's nothing statistically interesting about them, right? It's just sort of the normal noise and so we don't want to overreact to common cause variation and so I would not look at that as necessarily a negative thing. But they were taken into account when sort of calculating the improvement.

Dr Roy. Yeah, no. I absolutely agree that you should continue your intervention. In your high-risk cohort, 20% did not have 1 PROMISE huddle and they were excluded from this analysis. Did the frequency of the events in those patients refer and was there a specific identified cause in your QI analysis, whether awareness, ease of lack of agreement?

Dr Cosgrove. Yeah. So thank you for bringing that up as well. So only 80% of our high-risk patients after July 2020, which is when the project went live, actually received the intervention and the patients who did not receive the intervention were excluded from our statistical portion of the analysis but they were included in the QI charts. And so they were definitely included because they still met high-risk criteria in this analysis. They were just excluded from that traditional pre–post statistical analysis because they didn't actually receive the intervention and we didn't want to sort of muddy the water there. And really, the barriers, I think, to those patients receiving the intervention was recognition that they met high-risk criteria. That was probably 1 of the more challenging aspects of the project, was ensuring that all stakeholders were aware what the high-risk criteria were, which actually did evolve a little bit initially in the project and sort of expanded to, again, include any and all patients that were at increased risk comorbidity and mortality. And so I think that whenever you're asking people to sort of remember what the high-risk criteria are, people are going to naturally sometimes forget. And so we have since kind of posted those criteria in the cardiothoracic intensive care workrooms so that, again, those intensivists can see those criteria on a day-to-day basis and sort of know when to escalate those calls.

Dr Roy. My third question is in terms of your methodology, you chose a virtual platform for your interventions and it happened during the pandemic but there's obviously significant distractibility and reduced engagement as well as lack of situational awareness versus in-person huddles. Was there a reason for that choice outside of the pandemic and also that, especially in relation to the postoperative huddle or postinterventional huddle?

Dr Cosgrove. Yeah. No. Thank you so much for that question. And I really attribute this success of the virtual calls to the pandemic. So I think if we had tried these virtual calls before COVID-19, we probably would have been very unsuccessful, right, like no one was really comfortable or familiar with utilizing Webex or Zoom. And so we did intentionally use that platform because of the pandemic initially, and it actually continued thereafter because a lot of these calls happen at odd hours. Some of them happen at 3:00 in the morning. For example, we had a tri-atresia baby come in with profoundly low sats, PROMISE caught 3:00 in the morning, went for an emergency [inaudible]. So you know how engaged our people are going to be at three in the morning who have to come in. Right? And so I think it really helps. It really helped to facilitate getting all those stakeholders together to share their thoughts and concerns, which I don't think would have been possible if the calls were not made virtual.

Unidentified Speaker 1. I'm going to ask you to keep the answers and questions a little bit shorter because we're running low in time.

Dr Roy. One more question. PROMISE was instituted in high-risk patients. Why not universal implementation?

Dr Cosgrove. We really wanted to focus our intervention to the high-risk cohorts as sort of a pilot in a test of change. We thought it might be too labor-intensive to apply more broadly. And so, we really wanted to focus in honing our efforts on those at highest risk for arrest and really also focusing on that acute periprocedural period because we

know that these patients are the most vulnerable in the first 24 to 48 hours following intervention. And so it was really to sort of reduce the lift of the project and to sort of prove that this would be sustainable.

Dr Roy. Congratulations.

Dr Cosgrove. Thank you.

Unidentified Speaker 1. One very brief question, please? Sorry.

Dr John Myer *(Boston, Mass)*. I guess I'm curious whether or not you think this is a Hawthorne effect. You sort of shine the light on this group of patients and everybody got more aware, or if you have any more—was it better nursing care, better nursing recognition? Was it better intensive care unit recognition? Do they have any more granular insights?

Dr Cosgrove. Yeah. I mean, sure, the Hawthorne effect is always a possibility. And usually, that leads to just very transient improvement. And we've seen improvement now over an 18-month period which, I think, would be unlikely to happen with the Hawthorne effect alone, which usually is that increased attention, at least, to that effect, and that's usually a very transient thing. There were no known other changes to this system with regard to nursing care or postoperative care. And certain, in talking with those key periprocedural stakeholders, there are very clear changes to the procedural plan and the postprocedure plan that's anecdotally led to improved outcomes. And so, I do think that the intervention itself is what led to the improvement.

Dr Myer. Great. Thank you very much.

Dr Cosgrove. Thank you.