Proactive Risk Mitigation for Cardiac Arrest Prevention in High-Risk Congenital Heart Disease Patients

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PII: S2666-2736(22)00374-6
DOI: https://doi.org/10.1016/j.xjon.2022.10.008
Reference: XJON 674

To appear in: JTCVS Open

Received Date: 12 May 2022
Accepted Date: 26 October 2022

Please cite this article as: Cosgrove TC, Gauntt J, Carrillo SA, Cassidy SC, Gajarski RJ, Galantowicz M, Krawczeski CD, Proactive Risk Mitigation for Cardiac Arrest Prevention in High-Risk Congenital Heart Disease Patients, JTCVS Open (2022), doi: https://doi.org/10.1016/j.xjon.2022.10.008.

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Disclosure Statement: None
Funding Statement: None

Institutional Review Board: The Institutional Review Board at NCH determined that this project was quality improvement and not human subjects research therefore review and approval was not required per institutional policy.
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AATS 2022 Annual Meeting Manuscript

Glossary of Abbreviations and Acronyms:
CA = cardiac arrest

CHD = congenital heart disease

CICU = cardiac intensive care unit

CT = cardiothoracic

ECMO = extracorporeal membrane oxygenation

EHR = electronic health record

IHI = Institute for Healthcare Improvement

LOS = length of stay

NCH = Nationwide Children’s Hospital

O/E = observed to expected

pCA = post-procedure cardiac arrest

PC4 = Pediatric Cardiac Critical Care Consortium

PDSA = plan, do, study, act

PROMISE = PRO-active MITigation to decrease Serious adverse Events

QI = quality improvement

SPC = statistical process control

STAT = The Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery
Central Message: Use of peri-procedural proactive risk mitigation strategies in high-risk pediatric heart patients reduced post-procedural cardiac arrest and was associated with a decrease in overall length of stay.

Perspective Statement: Many consider cardiac arrest a modifiable outcome in congenital heart patients with prior local and national success in cardiac arrest prevention via interventions targeting situational awareness. We expanded this work using proactive safety principles in high-risk cardiac patients with peri-procedural huddles to facilitate risk mitigation, shared decision making and psychological safety.

Structured Abstract:

Objective: The prevalence of post-operative cardiac arrest (CA) increases with cardiothoracic surgical case complexity and is associated with a 40-50% mortality. Despite having a low overall surgical mortality rate at our center, our post-operative CA rates were higher than expected, with an observed to expected (O/E) ratio of 2.6. Utilizing quality improvement methodology, we evaluated the impact of proactive risk mitigation on post-procedural CA (pCA) in a high-risk cohort of pediatric cardiac patients.

Methods: This single-center study utilized the Institute for Healthcare Improvement model. We created and implemented our PROMISE (PRO-active MIitigation to decrease Serious adverse Events) program in July 2020, prospectively enrolling pre-identified high-risk patients. Enrolled patients underwent scheduled multi-disciplinary reviews via virtual platform at two peri-procedural timepoints with discussion of patient-specific risks and the subsequent development of proactive risk mitigation plans. Primary outcome measures were derived from the Pediatric
Cardiac Critical Care Consortium (PC4) national registry and included: rate of pCA within 7 days and an institution-specific O/E ratio for post-operative CA.

**Results:** Our baseline median number of high-risk cases between pCAs was 3. Following project initiation, median high-risk cases between events increased to 7 (Figure 2). Our O/E ratio for post-operative CA decreased from 2.56 in the 12 months before PROMISE to 1.01 in the 12 months after PROMISE, and hospital LOS decreased by ~10 days.

**Conclusions:** Implementation of peri-procedural proactive risk mitigation strategies in high-risk pediatric cardiac patients led to improvement in pCA with a 133% increase in high-risk cases between events.

**Keywords:** Cardiac Arrest Prevention, Safety II, Proactive Safety, Risk Mitigation, Quality Improvement, Congenital Heart Disease

**Introduction:**

Each year in the U.S., more than 35,000 babies are born with congenital heart disease (CHD) which represents the most common type of birth defect.\(^1\)\(^2\) As many forms of CHD require intervention, approximately 40,000 children undergo surgery annually.\(^3\) Over the last few decades, perioperative mortality rates have improved significantly, especially for complex surgeries, shifting the target for improvement to reducing morbidity.\(^4\)

In the current era, approximately 2-3% of pediatric patients undergoing cardiothoracic surgery experience a post-operative cardiac arrest (CA) with the prevalence ranging from 0.7% to 12.7% depending on case complexity.\(^5\) Of these, only 40-50% survive to discharge with approximately 30% experiencing a significant decline in objective functional status.\(^5\)\(^6\) Given
that CA rates vary substantially between pediatric cardiac intensive care units (CICUs), CA prevention has been targeted by individual institutions and national quality collaborates as a modifiable outcome.\(^7\)

In healthcare and other high-risk industries, efforts to improve safety have typically followed a Safety I approach (retrospective review of adverse events and design of interventions to prevent recurrence). As safety efforts evolve, there is recognition that complex adaptive systems require an additional approach, termed Safety II, which attempts to proactively mitigate risk prior to an event with efforts to enhance learning from what goes right. Proactive safety huddles and communication plans are two ways in which Safety II theory can be operationalized in healthcare, aiming to enhance interdisciplinary communication by preparing mitigation plans for unique or complex patient situations thus increasing situational awareness.\(^8\) While Safety II theory is gaining momentum in healthcare, there has been limited application with measurable impact on clinical outcomes.

The Heart Center and Center for Clinical Excellence at Nationwide Children’s Hospital (NCH) are committed to continuous quality improvement. In 2019, despite having a low operative mortality (2.01%), we observed a relatively high incidence of post-operative CA with an observed to expected ratio of 2.6. Stemming from multi-disciplinary code reviews aimed at discovering root causes, a failure to recognize and act on clinical deterioration, delayed escalation, and delay in diagnostic testing were identified as opportunities for improvement. Concurrently, there was ongoing institutional work to enhance patient safety through the application of Safety II principles.\(^8,9\) We sought to apply novel Safety II strategies to a high-risk cohort of cardiac patients in the peri-procedural period with the global aim of reducing morbidity and mortality. Our primary aim was to increase the number of high-risk cardiothoracic (CT)
surgery or interventional catheterization cases between post-procedural cardiac arrest (pCA) from a baseline median of 3 cases to \( \geq 6 \) cases (a 100% increase) within 6 months and sustain indefinitely.

**Materials and Methods:**

**Context**

This project is a single-center quality improvement (QI) initiative conducted at NCH, the second largest freestanding pediatric hospital in the U.S. The Heart Center performs over 450 cardiothoracic surgical cases per year and 550 cardiac catheterization cases per year.

As standard of care, all patients being considered for surgical or catheter-based intervention are formally discussed at our twice weekly multidisciplinary conference to gain consensus on global management decisions such as the need for and timing of a cardiac intervention. All post-operative care is delivered in the CICU by a specialized medical team following a bedside handoff with input on management decisions from the proceduralist available upon request. This handoff involves key peri-procedural stakeholders and includes a summary of the procedure and intraoperative course with post operative management directed by the CICU attending. Routine CICU management decisions occur during twice-daily bedside family-centered rounds.

Prior to project implementation, defined mechanisms for acute patient management discussions outside the biweekly case conference were lacking. Informal discussions did occur, but the timing, content, and attendees were variable and would often occur *after* a patient deviated from the expected course and/or was acutely decompensating. Additionally, when consensus could not be reached, there was a lack of shared decision-making that negatively
impacted culture and psychological safety. CICU provider comfort in escalating acute clinical concerns to necessary parties was variable with no formal process to facilitate communication.

**Medical Ethics Approval**

The Institutional Review Board at NCH determined that this project was quality improvement and not human subjects research therefore review and approval was not required per institutional policy.

**Pre-intervention**

In the spring of 2020, we assembled a multidisciplinary QI team consisting of Heart Center faculty and our service line QI coordinator. The team utilized strategies derived from the Institute for Healthcare Improvement model for improvement, including Aim Statement and Plan-Do-Study-Act cycles. Using internal historical data, we focused initial efforts on developing criteria (Table 1) to identify high-risk patients for whom interventions could be targeted. Baseline data for patients fulfilling high-risk criteria were collected retrospectively with prospective collection of measures following project initiation.

**Intervention**

The PROMISE (PRO-active MItigation to decrease Serious adverse Events) program was implemented in July 2020 with prospective enrollment of pre-identified high-risk patients. Eligible patients underwent scheduled multi-disciplinary reviews (“PROMISE calls”) via virtual platform with two required timepoints: pre-procedure and immediate post-procedure. Additional calls could be convened at the discretion of the CICU attending within the context of multiple factors including patient clinical status, projected trajectory, and outcome of previous
discussions. Required participants in PROMISE calls were key stakeholders including the
primary proceduralist(s), cardiac anesthesiologist, and cardiologists including intensivists,
imagers, interventionalists, and divisional medical and surgical leadership. Additional members
were invited ad hoc depending on patient specific risks.

To ensure consistency with high-quality calls, a checklist was created containing key
elements of PROMISE calls (Figure 1). The checklist facilitates review of the procedural plan
by the proceduralist and anesthetic plan by the anesthesiologist. Then, current, and anticipated
patient specific risks are discussed with subsequent development of mitigation strategies to
address identified risks, including thresholds for activating invasive interventions (e.g., sternal
opening). Finally, follow-up plans for additional reviews are discussed. This physical checklist
was completed in real time by the call facilitator (typically the CICU attending) with completed
forms entered into REDCap (Research Electronic Data Capture) and tracked by the QI team as a
process measure.

After observing initial encouraging improvements in our outcomes of interest, we enacted
changes in the electronic medical record (EMR) to aid in the sustainability of our results. In
November 2021, we implemented a “Proactive Safety Plan” EMR order which flags the patient
as high-risk to improve situational awareness amongst all caregivers entering the patient chart.
Additionally, PROMISE call note templates were developed within the EMR to allow for
documentation of call timing, call participants, and patient-specific clinical risks and mitigation
strategies. The electronic notes replaced the paper key element checklist and aided in tracking
compliance.

Measures and Definitions
Primary Outcome Measures:

1. High-Risk Cases Between Post-Procedural Cardiac Arrests: High-risk cases are defined in Table 1. pCA was defined as (1) cardiopulmonary arrest requiring (any) chest compressions and/or defibrillation, or (2) acute respiratory compromise requiring emergency assisted ventilation and/or leading to cardiopulmonary arrest requiring chest compressions and/or defibrillation. Given that our interventions were limited to the acute post-procedural period, we included pCAs if they occurred within 7 days following the surgery or catheter intervention. Multiple pCAs in the same patient were not counted separately.

2. Post-operative Cardiac Arrest Observed to Expected Ratio (O/E): Calculated by dividing the observed rate of post-operative CA from all surgical encounters by the expected rate of post-operative CA. The expected rate of post-operative CA was obtained from the Pediatric Cardiac Critical Care Consortium (PC4). A ratio of greater than 1 indicates that there were more arrests observed than expected based on case-mix. Notably this outcome metric was limited to surgical patients only.

Secondary Outcome Measures:

1. Post-procedural 30 Day Mortality: Death occurring within 30 days of high-risk procedure and includes both in-hospital and post-discharge mortality. We chose 30-day mortality instead of in-hospital mortality given the acute peri-procedural focus of our intervention.

2. Post-procedural Extracorporeal Membrane Oxygenation (ECMO): Denoted if patient required ECMO following the high-risk procedure.
3. Post-procedural Length of Stay (LOS): Number of days from high-risk procedure to hospital discharge.

4. Hospital LOS: Number of days from hospital admission to hospital discharge.

5. Program Impact: Internal survey performed 8 months following project implementation to assess perceived impact of PROMISE. Contained the following question: “The Heart Center’s PROMISE program is improving communication and teamwork amongst staff” with answers ranging from strongly agree to strongly disagree.

Process Measures included compliance with specific interventions:

1. Percent of High-Risk Patients Enrolled in PROMISE Program: Assessed monthly to evaluate effectiveness of processes developed to identify and enroll eligible high-risk patients. A percentage calculated by comparing the number of eligible patients per month to the number of completed PROMISE calls in the same month.

2. PROMISE call Key Element Checklist Compliance: Assessed to evaluate compliance with PROMISE call key elements. Each checklist element was assessed individually by calculating a percent compliance for documented PROMISE calls: number of calls with completed element divided by total calls. This measure was limited to PROMISE calls entered into REDCap.

Balancing Measures were tracked to monitor for unintended consequences:

1. Unplanned Interventions: Defined by PC4 as one or more unplanned procedures including cardiac reoperation(s) and/or cardiac catheterization(s).
2. Open Sternum: Defined by PC4 as any planned or unplanned event where the patient’s sternum was left open, including patients who return from the OR with an open chest and those who were reopened following primary closure.

Data Analysis and Study of Interventions

Data were retrieved from the PC4 database. Given the rarity of CA events, our primary outcome measure was plotted as high-risk cases between pCA on a g-chart. The g-chart is a type of Statistical Process Control (SPC) chart utilized in QI methodology to measure improvement for rare outcomes with higher values (more cases between incidents) indicating improvement. Hospital and post-procedural LOS were plotted on an X-bar chart, which is a type of SPC chart utilized to measure improvement for continuous outcome variables. Our SPC charts were generated using QI Macros SPC Software Version 2020.10, an add-in to Microsoft Excel. We applied established rules from the Healthcare Data Guide to identify signals of special cause variation.

We compared patient demographics, clinical factors, secondary outcome measures and balancing measures for the pre-PROMISE cohort (January through June 2020) and post-PROMISE cohort (July 2020 through December 2021) with inclusion of all high-risk patients. We performed a sensitivity analysis excluding high-risk catheterization cases to understand the impact of PROMISE on surgical patients. Data were summarized using frequency (percentage) for categorical variables and median (interquartile range) for continuous variables. Differences in characteristics of the pre-PROMISE and intervention cohorts were evaluated using Pearson’s chi-square, Fisher’s exact, or Wilcoxon rank sum tests with \( p \)-value <0.05 defining statistical
Results

There were 106 total patients meeting high-risk criteria; 33 in the pre-PROMISE cohort and 73 post-PROMISE. We identified no significant differences in demographic and clinical variables between cohorts (Table 2) with similar frequencies of neonates, single ventricle diagnoses, and STAT 4/5 surgical procedures. We observed no intergroup differences in high-risk criteria.

Our baseline median number of high-risk surgical cases between pCA events was 3 (Figure 2). Since PROMISE launch, we observed multiple signals of special cause variation. The first occurred in October 2020 with a single point outside the upper control limit (“outlier”). We noted additional special cause variation after the February and August 2021 pCA events, as these fulfilled the “outer third rule” (two of three successive points on the same side of and greater than 2 σ from the centerline). Given multiple signals of special cause variation occurring temporally with our intervention, the centerline shifted with an increase in median cases between events to 7, representing a 133% increase from baseline. Utilizing traditional statistics, we saw a clinical reduction in pCA following PROMISE implementation (21% versus 8% respectively) (Table 3), though this did not reach statistical significance (p=0.11). Sensitivity analysis excluding high-risk catheterization patients revealed similar outcomes to our full cohort (Supplemental Table 1). Chart review on all pCA events during the study period revealed 100% of arrests were cardiac in etiology.
Our baseline unit-level post-operative CA rate for surgical patients in the twelve months prior to PROMISE implementation was 3.79% with an O/E ratio of 2.56 based on a PC4-derived expected CA rate of 1.48%. In the twelve months following PROMISE implementation, our observed post-operative cardiac arrest rate was 1.74% giving an O/E ratio of 1.01 based on a PC4-derived expected CA rate of 1.73%.

Of the patients who arrested during the study cohort (n = 13), 54% were neonates, 38% intubated at the time of the procedure, 30% undergoing Stage 1 Hybrid procedure, 23% on vasoactive support and 8% with critical aortic stenosis undergoing cardiac catheterization. 54% of patients who experienced an arrest fulfilled one high-risk criteria while a minority (38% and 8%) fulfilled 2 or ≥ 3 high-risk criteria respectively. Regarding diagnosis/procedure type, 46% of arrests occurred in patients undergoing the first stage of single ventricle palliation (Norwood or Stage 1 Hybrid procedure) while 31% occurred in patients with D-TGA status post Arterial Switch. The remaining 23% (n = 3) had the diagnosis of Truncus Arteriosus, Double Outlet Right Ventricle and Total Anomalous Pulmonary Venous Return with a single patient in each category.

We observed no statistically significant difference between the two cohorts for post-operative ECMO or 30-day mortality (Table 3). Our baseline mean overall hospital LOS for high-risk patients was 77 days with baseline mean post-procedural LOS of 45 days. We observed a shift on SPC charts plotting these secondary outcome measures occurring temporally with PROMISE initiation with a new mean overall hospital LOS of 33 days and mean post-procedural LOS 19 days (Figures 3 and 4). Using traditional statistics, reductions in overall median hospital LOS reached statistical significance (29 days vs. 19 days, p=0.015) but differences in post-procedural median LOS did not.
Following project launch, 80% of eligible high-risk patients had at least one PROMISE call. Specific reasons for non-adherence for the remaining high-risk patients was not formally captured. For enrolled patients with a single PROMISE call, insufficient data was collected to determine which of the calls was missed. Compliance with individual discussion elements on the PROMISE call key element checklist was high, ranging from 80-100% depending on the specific element. Importantly, we observed 100% compliance regarding discussion of “anticipated concerns and mitigation strategies” for documented calls.

PROMISE calls averaged 10 minutes with complete attendance of required participants. The program was well-received, with 70% of surveyed participants in this project agreeing that PROMISE improved communication and teamwork amongst staff. Supplemental Table 2 contains themes of patient management strategies that were altered because of PROMISE call discussions. There were no unintended consequences of the program with no significant differences in rates of open sternum or unplanned interventions between the pre- and post-intervention cohort (21% versus 22%, p=0.9; 27% versus 12%, p=0.058, respectively).

Discussion

Given the unexpectedly high rate of post-operative cardiac arrests in our CTICU, our team implemented peri-procedural “PROMISE calls” for high-risk cardiac patients. These calls have facilitated multidisciplinary discussions of current and anticipated patient-specific risks along with the development of risk mitigation strategies. With project initiation, we observed a marked increase in the number of high-risk cases between pCAs, a reduction in the incidence of post-operative cardiac arrests, a lower post-operative CA O/E ratio and a reduction in overall and
post-procedural LOS without unintended consequences (please see Video 1 for a summary of the project).

Given the small sample size coupled with the low frequency of clinical events, it is not surprising that traditional statistics failed to detect a significant difference in pCA following PROMISE initiation despite a clinically important reduction from 21% to 8%. Similarly, we observed no significant impact on 30-day post-procedural mortality, likely given our low observed mortality rate. QI methodology circumvents some of these challenges by utilizing the g-chart as a statistical tool to detect special cause when tracking rare events with a set of well-established criteria to signal a statistical change in the system (shift). The center line of our g-chart (median) plotting cases between pCA shifted after observing two signals of special cause variation occurring temporally with PROMISE initiation which would be extremely unlikely to occur by chance. During the study period, there were no known changes to routine procedural or post-procedural care and no concurrent initiatives related to improving pCA rates in high-risk patients. We, therefore, suggest that our interventions had an impact on outcomes of interest.

We additionally observed a reduction in both mean hospital and post-procedural LOS utilizing SPC chart methodology and median hospital LOS utilizing traditional statistics. We observed multiple statistical outliers with very high LOS following CA in the pre-PROMISE cohort with less outliers in the post-PROMISE cohort. We postulate that the reduced incidence of CA more dramatically affected mean post-procedural LOS as median is robust to outliers especially considering procedural complexity and clinical risks were similar between the cohorts.

Single centers and multi-institution quality collaboratives are working to prevent CA as the paradigm has shifted to consider this outcome, at least in part, modifiable. Riley et al. has
spearheaded proactive risk mitigation for CA prevention in children with cardiac disease. They implemented “high-risk precautions,” a bedside tool to promote formal recognition of high-risk patients (including both medical and post-surgical patients) with subsequent discussion points aimed at creating a shared mental model of patient specific risk(s) and escalation parameters. Interestingly, they did not achieve sustained improvement until multidisciplinary engagement was achieved through multiple interventions focusing on team dynamics and communication. This work informed national quality collaborative (PC4) efforts with preliminary data presented by Alten et al. showing a 45% reduction in CICU CA rate across 19 centers following CA prevention bundle implementation with similarly focused interventions.\textsuperscript{13}

While our study corroborates the impact of multidisciplinary situational awareness on clinical outcomes noted in previous work, differences between the studies merit additional discussion. The PROMISE program was focused on preventing post-procedural CA and was limited to interventions in the immediate peri-procedural timeframe. This intentional focus stems from the fact that over half of post-operative CA occurs in the first 24-48 hours following intervention, making this a particularly vulnerable time.\textsuperscript{5} Moreover, when exploring local factors contributing to our unacceptable CA rates, we identified deficiencies in the immediate post-operative period resulting in a suboptimal psychological safety, communication, and shared decision making which negatively impacted situational awareness not highlighted in the previous studies. Additional disparities between studies are methodological with notable differences in outcome measures. Both Alten and Riley assessed the impact of their interventions by tracking overall CA rates (CA per 1,000 CICU days) despite limiting their interventions to a smaller high-risk cohort (neonatal bypass, infants after single-ventricle palliation and medical patients intubated within 4 hours of admission). In contrast, except for our expected CA measure
the impact of the PROMISE program was based on data that included only patients exposed to the intervention rather than all CICU patients.

Unique to the PROMISE program, multidisciplinary calls were structured so all team member’s concerns could be heard. A virtual platform was initially chosen given the COVID-19 pandemic and has remained the preferred venue for calls given excellent attendance, engagement, and convenience. The key element checklist used to facilitate calls not only contained critical elements to review but identified specific stakeholders as the “responsible party” for that portion of the call to ensure contribution from all members of the team and to maintain participant engagement. Survey feedback revealed overwhelming agreement that the PROMISE program positively impacted communication and teamwork within the division.

Creating a psychologically safe environment allows individuals to offer ideas, ask questions, and share concerns freely and without fear.\textsuperscript{14} Psychological safety recognizes that high performing teams require flexibility and openness especially in complex or evolving situations.\textsuperscript{14} The PROMISE program has positively impacted psychological safety and shared decision making in the peri-operative period allowing for more robust and fruitful discussions that impact situational awareness of patient specific risks and acute management strategies with criteria for escalating clinical concerns.

To aid in sustainability, program high-risk criteria will be revisited periodically following multi-disciplinary code reviews as additional risk factors may be identified. Future opportunities exist both locally and nationally as proactive risk mitigation strategies and Safety II principles can be applied broadly to any high-risk cohort. There are likely opportunities to expand and collaborate with other PC4 centers on peri-operative specific CA prevention. Considering the association of CA to short- and long-term complications, there are opportunities to assess the
impact of cardiac arrest prevention on neurodevelopmental outcomes, patient/family satisfaction and cost savings analyses.

Study Limitations

The findings from this quality improvement project should be interpreted mindful of several limitations. This study was limited to a single center that has a strong culture rooted in continuous improvement coupled with a dedicated Center for Clinical Excellence which allocates resources for QI. Institutions without these resources may have difficulty duplicating our work. Additionally, the small absolute number of patients experiencing our outcome of interest makes detection of statistical differences challenging. Implementation of multiple concurrent interventions combined with insufficient compliance data makes determining causality a limitation of this study. Finally, other factors may have impacted our outcomes that were beyond our control including case mix, acuity and volume that were unaccounted for and beyond the scope of this analysis.

Conclusions

Implementation of proactive risk mitigation strategies peri-procedurally in a high-risk cohort of pediatric and congenital cardiac patients was associated with improvement in pCA with a 133% increase in the number of high-risk cases between events. We additionally observed a decrease in post-operative CA incidence and O/E ratio. Efforts to prevent CA were associated with a reduction in the mean overall hospital and post-procedural LOS utilizing SPC methodology. Future studies are needed to assess the impact on other variables such as neurodevelopmental outcomes.

Conflict of Interest Statement
The authors have nothing to disclose

Acknowledgements

The authors thank the following individuals for their substantial contributions to this project; Catherine Dimes, RN, Kevin Dolan, BTS, MSHA, Mariah Eisner, MS, Elizabeth Grogan, MD, and Jenna Merandi PharmD, MS, CPPS. We additionally thank the clinical faculty within the Heart Center for their outstanding participation in the PROMISE program and dedication to continuous quality improvement.

References


Tables:

Table 1: Pre-Identified High-Risk Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>All neonatal surgeries requiring cardiopulmonary bypass (≤ 30 days of life)</td>
</tr>
<tr>
<td>All Stage 1 Hybrid procedures</td>
</tr>
<tr>
<td>All new surgical aortopulmonary connections</td>
</tr>
<tr>
<td>Any patient on a vasoactive infusion at the time of the procedure</td>
</tr>
<tr>
<td>Any patient intubated at the time of the procedure</td>
</tr>
<tr>
<td>Any diagnostic or interventional cardiac catheterization procedure on patients with the following diagnoses: Neonatal pulmonary atresia with intact ventricular septum (PA/IVS), Critical aortic stenosis (AS)</td>
</tr>
<tr>
<td>Cardiac catheterization with placement of a patent ductus arteriosus (PDA) stent</td>
</tr>
<tr>
<td>High-risk heart transplant or mechanical circulatory support patients</td>
</tr>
<tr>
<td>Any other patient deemed higher risk for morbidity/mortality based on status</td>
</tr>
</tbody>
</table>

Table 2: Demographics, clinical characteristics, and risk factors by cohort.
## Cohort

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall N = 106</th>
<th>Pre-PROMISE N = 33</th>
<th>Post-PROMISE N = 73</th>
<th>p-value³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics &amp; Clinical</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td>0.7</td>
</tr>
<tr>
<td>Male</td>
<td>61 (58%)</td>
<td>20 (61%)</td>
<td>41 (56%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>45 (42%)</td>
<td>13 (39%)</td>
<td>32 (44%)</td>
<td></td>
</tr>
<tr>
<td>Diagnosis physiology</td>
<td></td>
<td></td>
<td></td>
<td>0.6</td>
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<tr>
<td>Single ventricle</td>
<td>39 (37%)</td>
<td>11 (33%)</td>
<td>28 (38%)</td>
<td></td>
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<tr>
<td>Biventricular</td>
<td>67 (63%)</td>
<td>22 (67%)</td>
<td>45 (62%)</td>
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<tr>
<td>STAT category (surgical patients)</td>
<td></td>
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<td>0.7</td>
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<tr>
<td>2</td>
<td>5 (5.6%)</td>
<td>1 (3.4%)</td>
<td>4 (6.6%)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>15 (17%)</td>
<td>6 (21%)</td>
<td>9 (15%)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>47 (52%)</td>
<td>13 (45%)</td>
<td>34 (56%)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>23 (26%)</td>
<td>9 (31%)</td>
<td>14 (23%)</td>
<td></td>
</tr>
<tr>
<td>Neonatal CPB (≤ 30 days), n = 53</td>
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<td></td>
<td></td>
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<tr>
<td>Prematurity</td>
<td>8 (15%)</td>
<td>1 (6.7%)</td>
<td>7 (18%)</td>
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<td>Chromosomal abnormality</td>
<td>16 (30%)</td>
<td>4 (27%)</td>
<td>12 (32%)</td>
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<tr>
<td>Extracardiac abnormality</td>
<td>12 (23%)</td>
<td>5 (33%)</td>
<td>7 (18%)</td>
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<td>Weight at surgery (kg)</td>
<td>3.4 (3.1, 3.8)</td>
<td>3.5 (3.3, 3.6)</td>
<td>3.4 (3.0, 3.8)</td>
<td>0.4</td>
</tr>
<tr>
<td>PROMISE High Risk Inclusion Criteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neonatal CPB (≤ 30 days)</td>
<td>53 (50%)</td>
<td>15 (45%)</td>
<td>38 (52%)</td>
<td>0.5</td>
</tr>
<tr>
<td>Intubated at time of intervention</td>
<td>18 (17%)</td>
<td>6 (18%)</td>
<td>12 (16%)</td>
<td>0.8</td>
</tr>
<tr>
<td>Inotrope/vasoactive infusion at time of intervention</td>
<td>18 (17%)</td>
<td>9 (27%)</td>
<td>9 (12%)</td>
<td>0.058</td>
</tr>
<tr>
<td>Stage 1 Hybrid Procedure</td>
<td>16 (15%)</td>
<td>5 (15%)</td>
<td>11 (15%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Aortopulmonary shunt</td>
<td>4 (3.8%)</td>
<td>1 (3.0%)</td>
<td>3 (4.1%)</td>
<td>0.9</td>
</tr>
<tr>
<td>Cath: PDA Stent placement</td>
<td>14 (13%)</td>
<td>1 (3.0%)</td>
<td>13 (18%)</td>
<td>0.059</td>
</tr>
<tr>
<td>Cath: Diagnostic or interventional with diagnosis of PA/IVS or critical AS</td>
<td>6 (5.7%)</td>
<td>3 (9.1%)</td>
<td>3 (4.1%)</td>
<td>0.4</td>
</tr>
</tbody>
</table>

¹AS = aortic stenosis; CPB = cardiopulmonary bypass; PA/IVS = pulmonary atresia intact ventricular septum; PDA = patient ductus arteriosus; STAT = The Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery

²n (%); Median (IQR)
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall N = 106&lt;sup&gt;2&lt;/sup&gt;</th>
<th>Pre-PROMISE N = 33&lt;sup&gt;2&lt;/sup&gt;</th>
<th>Post-PROMISE N = 73&lt;sup&gt;2&lt;/sup&gt;</th>
<th>p-value&lt;sup&gt;3&lt;/sup&gt;</th>
</tr>
</thead>
</table>

<sup>1</sup> Pearson's Chi-squared test; Fisher's exact test; Wilcoxon rank sum test

<sup>2</sup> N = 106, N = 33, N = 73

<sup>3</sup> p-value
### Table 3: Clinical outcomes by cohort.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall N = 106</th>
<th>Pre-PROMISE N = 33</th>
<th>Post-PROMISE N = 73</th>
<th>p-value&lt;sup&gt;3&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac arrest w/in 7 days</td>
<td>13 (12%)</td>
<td>7 (21%)</td>
<td>6 (8.2%)</td>
<td>0.11</td>
</tr>
<tr>
<td>Mortality w/in 30 days</td>
<td>7 (6.6%)</td>
<td>2 (6.1%)</td>
<td>5 (6.8%)</td>
<td>0.9</td>
</tr>
<tr>
<td>ECMO</td>
<td>8 (7.5%)</td>
<td>3 (9.1%)</td>
<td>5 (6.8%)</td>
<td>0.7</td>
</tr>
<tr>
<td>Hospital LOS (days)</td>
<td>21 (15, 38)</td>
<td>29 (16, 100)</td>
<td>19 (15, 33)</td>
<td><strong>0.015</strong></td>
</tr>
<tr>
<td>Post-procedural LOS (days)</td>
<td>14 (9, 24)</td>
<td>15 (9, 43)</td>
<td>12 (8, 22)</td>
<td>0.11</td>
</tr>
</tbody>
</table>

<sup>1</sup>ECMO = extracorporeal membrane oxygenation; LOS = length of stay  
<sup>2</sup>n (%) ; Median (IQR)  
<sup>3</sup>Fisher’s exact test; Wilcoxon rank sum test

### Legends:

Central Picture: Proactive risk mitigation led to an increase in cases between cardiac arrest.

Figure 1: PROMISE Call Key Element Checklist. POD, post-operative day; CICU, cardiac intensive care unit; CT, cardiothoracic; EP, electrophysiology; PAACT, pediatric and adult advanced cardiac therapies; ACHD, adult congenital heart disease.

Figure 2: High-Risk Cases between Post-procedural Cardiac Arrests: Each individual data point on this Statistical Process Control g-chart represents a cardiac arrest event with the x-axis containing the dates of events. The y-axis contains the number of high-risk cases between cardiac arrests with improvement represented by higher values (more cases between events).

The solid center line represents the theoretical median of the distribution. Baseline data revealed a median of 3 cases between CA which increased to a median of 7 cases following project initiation (July 2020) given multiple signals of special cause variation (circled). The red hashed line represent the upper control limit (3 standard deviations above the center line) with no lower control limit. CA = cardiac arrests; CL = center line.

Figure 3: Overall Hospital Length of Stay: Each individual data point on this Statistical Process Control X-bar chart represents the average hospital LOS for high-risk patients in a given month by procedure date (month/year on x-axis). The y-axis represents the average LOS in days with...
improvement represented by lower values (decreased LOS). The solid center line represents the average of all data points within a specific process stage with the baseline period defined as January through June 2020 (average LOS 77 days). Following project initiation (July 2020), the CL shifted (special cause variation circled with 8 consecutive data points below the CL) with a new average LOS of 33 days. Hashed lines represent the upper and lower control limits (3 standard deviations above and below the center line) with the lower control limit not visible as it overlaps with x-axis. CL = center line; LOS = length of stay.

Figure 4: Post-procedural Length of Stay: Each individual data point on this Statistical Process Control X-bar chart represents the average post-procedural LOS for high-risk patients in a given month by procedure date (month/year on x-axis). The y-axis represents the average LOS in days with improvement represented by lower values (decreased LOS). The solid center line represents the average of all data points within a specific process stage with the baseline period defined as January through June 2020 (average post-procedural LOS 45 days). Following project initiation (July 2020), the CL shifted (special cause variation circled with 8 consecutive data points below the CL) with a new average post-procedural LOS of 19 days. Hashed lines represent the upper and lower control limits (3 standard deviations above and below the center line). CL = center line; LOS = length of stay.

Video 1: Dr. Tara Cosgrove provides a brief summary of the background, methods and results of PROMISE, a QI project aimed at post-procedural cardiac arrest prevention.
High Risk Cases Between Post-procedural Cardiac Arrest

Date of Cardiac Arrest

Cases Between Cardiac Arrests

7/2020: PROMISS Go-Live

Chart Type: g-chart

[Graph showing data points and trend lines related to post-procedural cardiac arrest cases, with a noted intervention point in July 2020.]
# PROMISE Call Key Element Checklist

Patient Name: ___________________________  Date: ______________

**Timing of call:**
- [ ] Pre-Procedure
- [ ] Immediate Post-Procedure
- [ ] POD#1
- [ ] POD#2
- [ ] Other (specify)________

**Preferred Timing of Calls (if team available):**
- Pre-procedure: Day prior - weekdays between 3-4pm, weekends 4pm
- Immediately Post-procedure: 1 hour after arrival (if patient stable)
- POD#1/2: After CTICU am sign-out or morning rounds

<table>
<thead>
<tr>
<th>Call Element</th>
<th>Responsible Party</th>
<th>Completed?</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brief clinical overview</td>
<td>CICU Faculty or primary cardiologist</td>
<td>[ ] Yes [ ] No</td>
<td></td>
</tr>
<tr>
<td>Procedural plan or review</td>
<td>Primary CT Surgeon and/or Interventional Cardiologist</td>
<td>[ ] Yes [ ] No</td>
<td></td>
</tr>
<tr>
<td>Anesthesia plan or review</td>
<td>Cardiac anesthesiologist</td>
<td>[ ] Yes [ ] No</td>
<td></td>
</tr>
<tr>
<td>Diagnostics review (*for pre-procedural calls, may discuss prior to “Procedural plan or review”)</td>
<td>Imaging and/or Interventional Cardiology Faculty</td>
<td>[ ] Yes [ ] No [ ] NA</td>
<td></td>
</tr>
<tr>
<td>Echocardiography</td>
<td></td>
<td>[ ] Yes [ ] No [ ] NA</td>
<td></td>
</tr>
<tr>
<td>Advanced Imaging</td>
<td></td>
<td>[ ] Yes [ ] No [ ] NA</td>
<td></td>
</tr>
<tr>
<td>Catheterization Data/Images</td>
<td></td>
<td>[ ] Yes [ ] No [ ] NA</td>
<td></td>
</tr>
<tr>
<td>Input from other services (as needed)</td>
<td>EP/PAACT/ACHD/Fetal Cardiology</td>
<td>[ ] Yes [ ] No [ ] NA</td>
<td></td>
</tr>
<tr>
<td>Current risks or concerns</td>
<td>CICU Faculty</td>
<td>[ ] Yes [ ] No</td>
<td></td>
</tr>
<tr>
<td>Anticipated concerns and mitigation plans (*Include MCS plan and guidelines to activate invasive interventions)</td>
<td>CICU Faculty</td>
<td>[ ] Yes [ ] No</td>
<td></td>
</tr>
<tr>
<td>Summary</td>
<td>CICU Faculty</td>
<td>[ ] Yes [ ] No</td>
<td></td>
</tr>
<tr>
<td>Is follow-up call planned? How long did call take (approximately)?*</td>
<td>CICU Faculty</td>
<td>[ ] Yes [ ] No</td>
<td></td>
</tr>
</tbody>
</table>

*If no follow up call, please check reason:
- [ ] Patient deemed no longer high-risk
- [ ] POD #2 call completed
- [ ] Other (specify) ________________

Please save completed forms and place in designated folder located in CICU workroom
Questions?
Supplemental Table 1: Sensitivity analysis of clinical outcomes by cohort excluding cardiac catheterization cases (surgical only).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall N = 90</th>
<th>Pre-PROMISE N = 29</th>
<th>Post-PROMISE N = 61</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac arrest w/in 7 days</td>
<td>13 (14%)</td>
<td>7 (24%)</td>
<td>6 (9.8%)</td>
<td>0.11</td>
</tr>
<tr>
<td>Mortality w/in 30 days</td>
<td>6 (6.7%)</td>
<td>2 (6.9%)</td>
<td>4 (6.6%)</td>
<td>0.9</td>
</tr>
<tr>
<td>ECMO</td>
<td>8 (8.9%)</td>
<td>3 (10%)</td>
<td>5 (8.2%)</td>
<td>0.7</td>
</tr>
<tr>
<td>Hospital LOS (days)</td>
<td>21 (15, 36)</td>
<td>29 (18, 100)</td>
<td>18 (14, 32)</td>
<td><strong>0.008</strong></td>
</tr>
<tr>
<td>Post-procedural LOS (days)</td>
<td>14 (9, 24)</td>
<td>15 (9, 37)</td>
<td>12 (8, 21)</td>
<td>0.15</td>
</tr>
</tbody>
</table>

1ECMO = extracorporeal membrane oxygenation; LOS = length of stay
2n (%); Median (IQR)
3Fisher’s exact test; Wilcoxon rank sum test

Supplemental Table 2: Themes of patient management strategies directly impacted by PROMISE call discussions.

<table>
<thead>
<tr>
<th>Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia induction plan</td>
</tr>
<tr>
<td>Invasive monitoring strategies (lines placed in the operating room)</td>
</tr>
<tr>
<td>Surgical plan including cannulation/perfusion strategies</td>
</tr>
<tr>
<td>Timing of sternal closure</td>
</tr>
<tr>
<td>Placement of intraoperative peritoneal drain</td>
</tr>
<tr>
<td>Timing of extubation</td>
</tr>
<tr>
<td>Vasoactive management strategies</td>
</tr>
<tr>
<td>Necessity of additional diagnostic tests</td>
</tr>
<tr>
<td>Thresholds for mechanical circulatory support</td>
</tr>
<tr>
<td>Thresholds for re-intervention</td>
</tr>
</tbody>
</table>
Dr. Nathalie Roy (Boston, MA):

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 QI approach in high-risk patients to proactively mitigate cardiac arrest events after congenital cardiac surgery and also after interventional procedures. The promised strategy proposes a virtual multidisciplinary structure huddle pre- and post-procedure and ad hoc afterwards 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 the cardiac ICU for a PC4 initiative that identify organizational and institutional factors. In addition, it builds on a long history of structured handoff in pediatric cardiac surgery and safety huddles. In addition, promise offered a concrete roadmap to event mitigation through multidisciplinary collaboration. I have the following five questions. So, first one is for your analysis of the events using the GChart. You used the fourth rule which is the two out of three events in a row near the upper limit following your intervention as a marker of specific cause variation. However, immediately after those two events, you had to return to your pre-intervention median for the following two 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 GChart 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 two 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, three standard
deviations would be extremely unlikely to happen by chance, and then you mentioned that there is an additional two points here which fall beyond two standard deviations 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 center line.

And so while 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 post-July of 2020, which is when the project went live, actually received the intervention and the patients that 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 one 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 CTIC 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 post-operative huddle or post-interventional 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 prior to COVID, 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-atrial baby come in with profoundly low sats, PROMISE caught 3:00 in the morning, went for an emergent [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, MA):

Well, John Myer from Boston. 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 ICU 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 post-operative care. And certain, in talking with those key periprocedural stakeholders, there are very clear changes to the procedural plan and the post-procedural plan that's anecdotally led to improved outcomes. And so, I do think that the intervention itself is what led to the improvement.

Unidentified Speaker 1:

Great. Thank you very much.

Dr. Cosgrove:

Thank you.