

Quality Improvement

A Risk Management Strategy for Managing Critical Human Resource Changes in a Pediatric Heart Program

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ABSTRACT

Background: Relocation, recruitment, or retirement of critical team members may lead to changes in the expertise pool that could threaten patient outcomes in a pediatric heart program. We developed a quality initiative aimed at risk management that uses risk-stratified case complexity and outcomes to guide a program during critical fluxes in the expert staff. The Ramp Down/Up protocol is a systematic, voluntary reduction in the complexity of cases performed, followed by a transparent and intentional escalation of case complexity.

Methods: Institutional Ethics Review Board approval for this quality initiative was obtained. Patient/caregiver consent for quality data collection is obtained at the time of hospital admission. Every surgical patient having their index cardiac surgical procedure at the Izaak Walton Killam (IWK) from January 1, 2003, to December 2015 is included. The Ramp Down/Up protocol evolved to have to 4 critical elements: (1) a trigger and a reduction in case complexity; (2) an external/objective expert observer; (3) an escalation in case

RÉSUMÉ

Contexte : La relocalisation, le recrutement ou le départ à la retraite de membres critiques d'une équipe peuvent amener des changements dans le bassin d'expertises pouvant compromettre les résultats obtenus par les patients au sein d'un programme de pédiatrie cardiaque. Nous avons conçu une initiative relative à la qualité de la gestion des risques, qui évalue la complexité des cas et les résultats, stratifiés selon le risque, afin d'orienter le programme durant les flux critiques de personnel spécialisé. Le protocole de réduction/d'augmentation réalise une diminution méthodique et délibérée de la complexité des cas suivie d'une intensification transparente et intentionnelle de celle-ci.

Méthodologie : Cette initiative sur la qualité a obtenu l'approbation du comité d'examen de l'éthique des établissements. Le consentement du patient/de l'aidant requis pour la collecte de données sur la qualité est obtenu au moment de l'admission à l'hôpital. L'initiative incluait tous les patients de chirurgie pour lesquels on disposait de l'indice de chirurgie cardiaque établi au centre Izaak Walton Killam (IWK) entre

Clinical care of patients with complex congenital heart disease has been recognized as a genuinely multidisciplinary undertaking, as reflected in the guidelines published independently by the American Academy of Pediatrics and the European Association of Cardiothoracic Surgery Congenital Heart Disease Committee.^{1,2} These guidelines outline minimum staff and infrastructure requirements for safe and effective delivery of pediatric cardiac surgery, but quantitating the expertise in a program, or the amount of "wisdom" that can

come to bear on any given case, is difficult. Dr David Jones has written about the critical role of expertise and hypothesized that differences in outcomes for subspecialty care areas (eg, pediatric cardiac surgery) are not necessarily a reflection of volume-outcome relationships, but of expertise and outcome relationships.³ To maintain program continuity, there needs to be critical mass and optimal function, in and between, each of the disciplines that comprise the pediatric heart team. Ideally, there is sufficient redundancy within the program (numbers and expertise) to allow it to maintain a stable standard of care during the inevitable team changes that result from retirement, relocation, or recruitment, but this is not necessarily so. Data that speak to the number of pediatric heart programs that are likely to have small numbers of practicing physicians in important specialty roles come from the Society of Thoracic Surgeons (STS) Congenital Heart Surgery database. Of the 116 pediatric cardiac surgical programs voluntarily reporting data to the STS Congenital Heart Surgery database, 75 of 116 programs (65%) perform fewer

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Ethics Statement: Institutional Ethics Review Board approval for this quality initiative was obtained (Project #1024225).

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complexity; and (4) data (qualitative and quantitative) collection and analysis.

Results: The Ramp Down/Up protocol was used 3 times over a 12-year period to address critical expert human resource challenges. The protocol was used for variable duration (3.5-9 months). Patient operative mortality was benchmarked to the Congenital Cardiac Surgery database, and outcomes were stable during and after protocol employment.

Conclusions: A quality initiative aimed at risk management has allowed 1 pediatric heart team to ensure that patient outcomes were maintained during critical human resource changes.

than 249 index cardiac operations per year (2017 Fall Report), and these index cardiac operations may be on-pump cardiovascular operations or off-pump cardiovascular operations. Of 307 hospitals performing Risk Adjustment in Congenital Heart Surgery 1 (RACHS-1) categorizable cases in the Nationwide Inpatient Sample 1998-2005, 239 (78%) were classified as small (21-100 cases) or very small (< 20 cases) according to annual case volume.⁴ Even in large-volume programs (> 350 cardiopulmonary bypass cases/year), the number of surgeons is rarely more than 3 or 4, and there are often subspecialty areas of cardiology or anesthesia that are staffed by only 1 or 2 individuals. In these situations, one person retiring or relocating may shift the total expertise pool significantly.

To limit risk to patients as our pediatric heart team evolved and the expertise level changed over time, we developed and used a Ramp Down/Up protocol. The Ramp Down/Up protocol is a voluntary, systematic reduction in the complexity of cases performed followed by a transparent and intentional escalation of case complexity based on quantitative and qualitative assessment of program performance.

Methods

Institutional Ethics Review Board approval for this quality initiative was obtained. Patient and caregiver consent for quality data collection are obtained at the time of hospital admission. Every surgical patient undergoing their index cardiac surgical procedure at the IWK from January 1, 2003, to December 31, 2015, with a RACHS-1 category is included. Quantitative outcome data were collected by one expanded role nurse (ATL). Mortality and length of stay data were submitted for each patient to the Congenital Cardiac Surgery database, a web-based registry database for recording and reporting clinical experience and outcomes of surgery for congenital cardiac disease.⁵ Complication data collection evolved over the 12 years spanning this report from retrospective chart review with nonstandardized definitions (2002-2009) to retrospective chart review using standardized definitions (2007-2010) to prospective collection based on the STS short list of complications.⁶

le 1^{er} janvier 2003 et décembre 2015. Le protocole de réduction/d'augmentation a évolué pour intégrer quatre éléments critiques : 1) un facteur déclencheur et une réduction de la complexité des cas; 2) un observateur externe/expert objectif; 3) une intensification de la complexité des cas; 4) la collecte et l'analyse des données (qualitatives et quantitatives).

Résultats : Le protocole de réduction/d'augmentation a été utilisé à trois reprises sur une période de 12 ans et sur des durées variables (de 3,5 à 9 mois) dans le but de relever des défis majeurs liés aux ressources humaines spécialisées. Les taux de mortalité opératoire des patients ont été comparés à ceux de la base de données sur les chirurgies cardiaques congénitales, et les résultats se sont révélés stables durant et après l'emploi du protocole.

Conclusions : Une initiative sur la qualité ciblant la gestion des risques a permis à une équipe de pédiatrie cardiaque de s'assurer que les patients continuaient d'obtenir des résultats similaires lors de changements critiques des ressources humaines.

Risk stratification

Case-by-case risk stratification was provided using the expert consensus-derived RACHS-1 categories in which early mortality risk is assigned a category from 1 to 6.⁷ RACHS-1 category 1 cases are the lowest risk cases and include atrial septal defect repair, ventricular septal defect repair, and pulmonary valve replacement as examples. RACHS-1 category 5 cases have the highest risk of perioperative mortality and include, for example, stage 1 Norwood procedures, double switch procedures, and truncus arteriosus repair with VSD closure. There are a number of procedures that do not have RACHS-1 categories assigned to them (because they are rare or heterogeneous), and thus they are captured as “nonclassified.” For example, RACHS-1 does not have categories for surgical closure of patent ductus arteriosus in infants less than 30 days of age, primary extracorporeal membrane oxygenation, pacemaker implantation or defibrillator implantation, tumor resection, or false aneurysm resection. The unclassifiable cases comprise up to 25% of index procedures.⁸ The Society for Thoracic Surgery and European Association of Cardiothoracic Surgery Category risk classification category is currently used for risk stratification, but during the era being described in this article, RACHS-1 was used.

Evolution of a risk management quality initiative

Because a systematic approach to disruption in the expertise pool has not been described, there was no a priori protocol that we were able to apply when we experienced critical fluxes in the expertise pool because of acute human resource changes. What we are describing is a process that is the result of an organic evolution. This process was created, used, and changed over time to help a pediatric heart team stabilize and verify that results were maintained during critical human resource changes. The first time we used this strategy we did not anticipate that we would require a similar intervention 2 more times over the next 10 years. We named the protocol “Ramp Down/Up” and have distilled it to 4 critical elements: (1) a trigger and a reduction in case complexity; (2) an external/objective expert observer; (3) an escalation in case complexity; and (4) data collection and analysis (qualitative and quantitative).

In brief, after a disruption to the expertise pool occurred (retirement, relocation, or recruitment), the Ramp Down/Up protocol was triggered. With the protocol triggered, the program reverted to performing lower-complexity cases. During this time, an objective reviewer intermittently attended cases and performed iterative assessment of team and program performance (qualitative and quantitative), which in turn determined the rate at which the team progressed to performing higher complexity cases (Fig. 1A). Qualitative assessment of team performance was provided by direct observation by the external evaluator of team function in the operating room during handover in the pediatric critical care unit and on daily rounds.

Results

Program constituents and volume

In the time period of the report (January 1, 2003, to December 31, 2015), the IWK Pediatric Heart Program was composed of 5 pediatric cardiologists, variably 1 to 2 pediatric cardiac surgeons, 1 to 4 pediatric cardiac anesthesiologists, and 3 to 4 pediatric intensive care physicians. The IWK Pediatric Heart Program provides care to all patients with congenital cardiac pathologies in the 4 provinces of Atlantic Canada, a catchment of approximately 2 million. The program performs all pediatric cardiac surgical operations with the exception of ventricular assist device implantation and heart

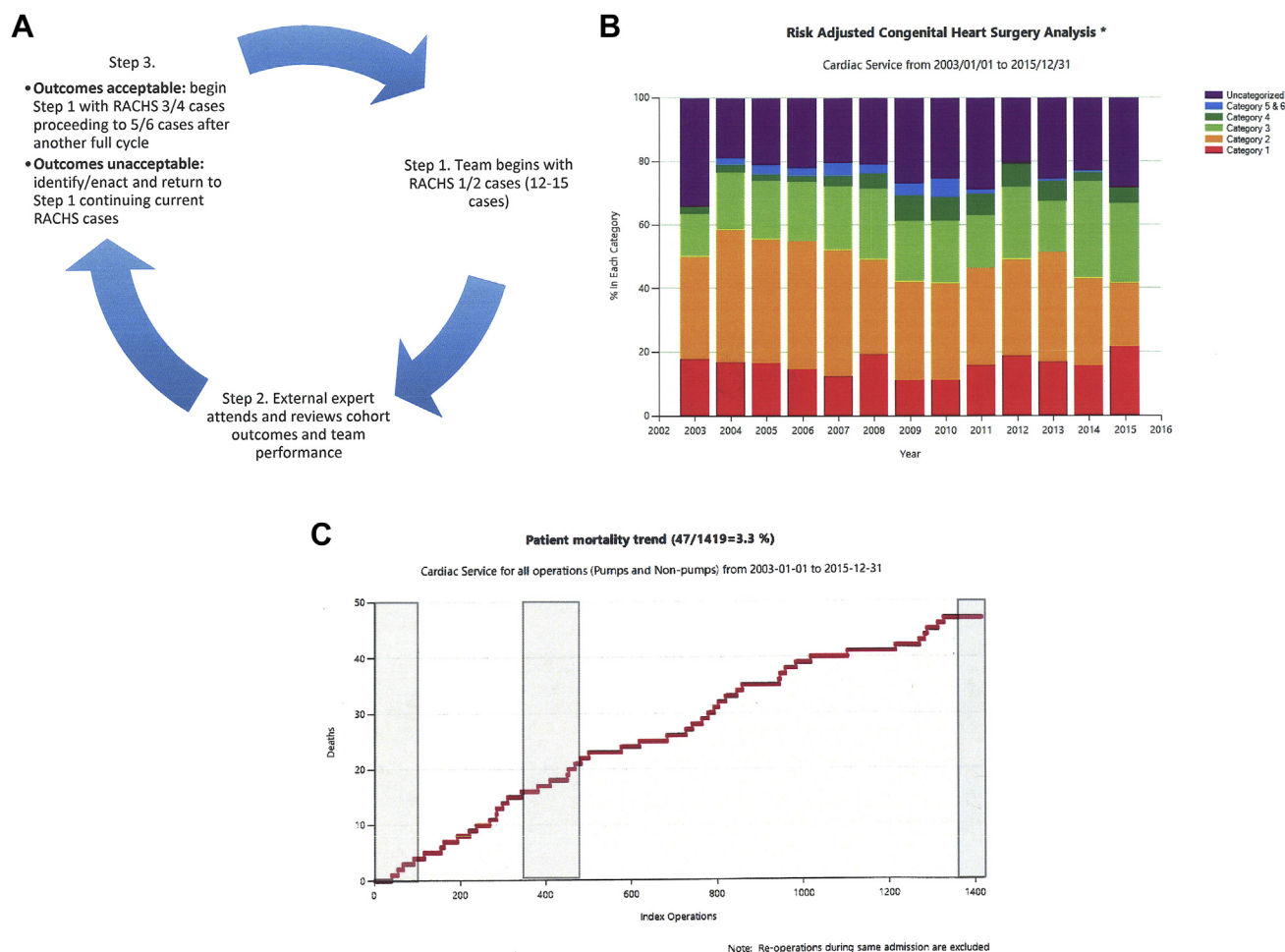


Figure 1. (A) The Ramp Down/Up protocol. After a program identifies the need to revert to low-complexity cases, an external surgical expert is contracted to provide overview of the process. Each stage involves scheduling a cohort of patients within a specified risk strata, performing the cases and evaluating outcomes. Preparedness to escalate to higher-risk strata is established by the external surgeon/observer along with team input. **(B)** Risk Adjustment in Congenital Heart Surgery (RACHS) 1 Category Prevalence. Except for the absence of RACHS-1 category 5/6 cases in 2003, 2012, and 2015, there is consistent annual prevalence of various RACHS-1 categories. All data are based on in-hospital mortality for index operations only. Index operation is defined as the first operation after admission and excludes reoperations during the same admission. Graph provided by Canadian Cardiovascular Surgery Database (<https://CCSdb.org/Home/Dashboard>). **(C)** Cumulative Sum (CUSUM) Trend for all Index Operations. Overall, the slope of the CUSUM graph represents mortality rates (3.3%), which remains consistent over the 12-year era. **Grey boxes** mark each of the 3 Ramp Down/Up protocol deployments (January 1, 2003, to September 30, 2003, cases 1-74; April 1, 2006, to July 31, 2006, Cases 316-468; August 15, 2015, to November 30, 2015, cases 1387-1412). There is no change in the slope of the CUSUM mortality plot before, during, or after these 3 eras indicating consistent program performance. All data are based on in-hospital mortality for index operations only. Graph provided by Canadian Cardiovascular Surgery Database (<https://CCSdb.org/Home/Dashboard>).

transplantation. The annual program case volume was stable with an average of 80 index on-pump cardiovascular operations per year.

Ramp Down/Up protocol deployment

The 3 critical disruptions at the IWK during the 12-year era were related to surgical and anesthetic staff changes. Each time the Ramp Down/Up protocol was used, the clinical leadership of the pediatric heart program (surgeon or cardiologist) triggered the protocol. After a decision to use the protocol, the entire heart program team was engaged, and consensus to proceed was established. It was relatively clear to the team when the Ramp Down/Up protocol was necessary, and it became easier with the subsequent decisions to trigger it. Significant disruption of the pool of expertise was the trigger in all 3 cases of Ramp Down/Up protocol deployment. The disruptions at the IWK that led to triggering the Ramp Down/Up protocol included (1) restarting the surgical program after an hiatus with no local surgeon for many months (January 1, 2003, to September 30, 2003; cases 1-161); (2) surgeon relocation (April 20, 2006, to August 20, 2006; cases 370-440); and (3) the return from maternity leave for a solo junior pediatric cardiac anesthetist at the physicians' own request (August 28, 2015, to November 30, 2015; cases 1280-1412).

Case-by-case decision-making during the Ramp Down/Up protocol, as at any other time, was guided by the principle that an operation would be performed at the site that was in the best interest of the patient, for patient safety, and the best possible outcome. The first time the Ramp Down/Up protocol was enacted was when the surgical program had been in hiatus for more than 1 year, and 2 pediatric cardiac surgeons directly out of training were hired. In this instance, because there was only itinerant surgery being performed at the IWK at the time, there was no Ramp Down required. The team began with RACHS-1 category 1 and 2 cases. An external surgeon was hired as a consultant to the process. The external surgeon attended the hospital for a 1-week period and directly supervised the operation and postoperative management of 8 RACHS-1 category 1 and 2 cases. After that week of operating and observing team performance, the team was commissioned to move forward independently with RACHS-1 category 1 and 2 cases; 12 RACHS-1 category 1 and 2 cases were scheduled and performed over the next 6 to 8 weeks in the absence of the external surgeon. The external surgeon then attended the hospital for another 1-week period. He reviewed the data from the first series of RACHS-1 category 1 and 2 cases (now a total of 20 cases) and operated with the 2 surgeons on a series of more complex cases that had been pre-booked (RACHS-1 category 3 and 4 cases). The external consultant also observed team interaction and performance and provided written and verbal feedback to the team and hospital administration. The outcomes were acceptable (both qualitative and quantitative), and the team was commissioned to move forward with more complex cases. If the outcomes had been deemed to be unacceptable, the identified issue(s) would have been addressed, and the team would have returned to the prior risk strata for another specified period of time (or number of cases), at which time the consultant would return and reassess. The duration of the Ramp Down/Up was

variable each time it was triggered and was determined first by outcomes and objective evaluation, then by personal physician self-assessment and team consensus regarding readiness to move forward to more complex cases. Ramp Down/Up 1 was 6 months in duration (January 1, 2003, to September 30, 2003; cases 1-161); Ramp Down/Up 2 was 4 months in duration (April 20, 2006, to August 20, 2006; cases 370-440); and Ramp Down/Up 3 was 3 months in duration (August 28, 2012, to November 30, 2012, cases 1280-1412).

Risk management during Ramp Down/Up protocol

Prenatal echocardiographic diagnosis in our population approaches 80%; thus, any preterm mother with a fetus having a high-risk diagnosis was referred out for delivery at a center with the resources to care for the child at birth. As a result of prenatal triage of more complex cases, there were several cases referred to Toronto or Montreal hospitals for delivery and postnatal care during the Ramp Down/Up protocol deployments. In the event of the birth of an unexpected high-risk case, if the patient could be stabilized with mechanical circulatory support and transferred out, that option would be offered to the family and enacted. If no stabilization was possible (ie, obstructed TAPVC), the family would be given the option of proceeding with surgical repair and the family would be presented with local mortality rates in the consent process or continuing locally with palliative care. High-risk catheterization procedures were deferred if elective, or referred out if urgent, during the Ramp Down/Up. No surgical emergencies occurred during any of the 3 times the Ramp Down/Up protocol was used.

Quantitative outcomes

Overall, there was consistent annual prevalence of conditions classified in each of the various RACHS-1 categories (Fig. 1B). There was a notable absence of RACHS-1 category 5/6 cases in 2003, 2006, and 2015, representing natural variation in birth rates of these various pathologies, as well as transfer out of higher-risk strata cases during periods of using the Ramp Down/Up protocol. Over the 12-year period, 1688 operations were performed, 1420 were index procedures, and 1066 were RACHS-1 classifiable. The average number of total index operations per week in 2003 to 2015 (RACHS-1 classifiable only) were 1.57. During a Ramp Down/Up period, the average number of total index operations per week (RACHS-1 classifiable only) were 1.32, representing a 21% reduction in index operations during protocol use. Program mortality rates remained stable (3.3% over the 12-year period) with a straight-line Cumulative Sum (CUSUM) plot of all index cases; the slope of the CUSUM plot provides evidence that there was no significant increase in mortality despite 3 Ramp Down/Up periods (Fig. 1C). As with all other processes, there was evolution over the 12-year span of this report with regard to the granularity of data available. For most of the duration of this report, mortality data were the only outcomes available (to anyone in the field) to use for benchmarking and we submitted our mortality data to the Congenital Cardiovascular Surgery Database.⁵ By 2012, we had designed and deployed a novel real-time prospective dashboard reporting local program risk-stratified mortality and complications.⁸ Prospective complication monitoring, once

available (beginning October 2012), verified program-wide rates of complication occurrence similar to that reported by larger datasets.⁹

Qualitative outcomes

The qualitative reports from the external surgeon were not shared with the clinical team but did contribute to the recommendation for the team to progress to more complex cases. The 3 themes that have emerged as our pediatric heart team has qualitatively reviewed the Ramp Down/Up protocol deployment are as follows: (1) Buy-in from all team members is critical. This includes clinical and administrative teams. It also includes actively involving referring physicians who may or may not be integrally involved in the heart center operations. Global buy-in for sending cases to another hospital may be challenging because there may be competing agendas for keeping patients in the local center. However, adherence of the entire team to the core principle of insisting on the optimal approach for each patient facilitated correct and objective decision making. In our experience, this was not as difficult a process as it might sound. Ad hoc team meetings or weekly scheduled surgical conference were the forum to discuss critical patient care decisions, and it was our practice to routinely obtain consensus on treatment algorithms for every surgical patient. The team equally applied this consensus process to determining when a patient should be transferred out. (2) An objective expert surgical observer (external or internal) is key to the protocol. This is an expert who can be retained to spend time locally and review data, operate with the team, and provide candid observations about procedure outcomes, as well as comment on team strengths and weaknesses. (3) A referral site (or sites) that is (are) willing and able to accept variable surgical and interventional catheterization transfers. Without this capability, our process as described, would be impossible.

Discussion

There inevitably will be episodic critical changes in the complement of specialty physicians in pediatric heart programs. The Ramp Down/Up protocol allows a program to electively reduce the complexity of cases, followed by careful escalation through a continuum of increasing case complexity, to minimize patient risk and maintain consistent outcomes. General sensitivity to the challenges of developing and delivering pediatric cardiac surgical services was greatly heightened after the public events in Bristol and Winnipeg.^{10,11} The notion that direct engagement of clinical leaders is critical for development of effective quality improvement, which the Ramp Down/Up protocol is a prime example of, was also a key component of the development of the protocol.¹² The concept of a trigger and a reduction in case complexity, the first 2 phases of The Ramp Down/Up protocol, was in part inspired by the very honest and transparent “pause” that Marc de Leval and colleagues¹³ reported triggered by a sudden “run” of adverse outcomes in a series of arterial switch procedures. The concept of stepwise escalation of case complexity while establishing a pediatric cardiac surgical program was modelled on a similar protocol developed at the Princess Margaret Jones Hospital for Children in Perth, Australia, the results of which were observed by one of the senior pediatric

cardiologists from the IWK (JPF). In their ramp-up scheme (unpublished 1999) a senior consultant pediatric cardiac surgeon from Sydney, Australia, attended and itinerantly performed surgery while the hospital’s infrastructure was developed. A junior surgeon was subsequently recruited and mentored through early career and escalating case complexity.

All aspects of the Ramp Down/Up protocol may readily be customized to a particular program’s needs, including trigger, duration and rate of escalation, and evaluation. For example, in all cases at the IWK, the protocol was triggered by Heart Program clinical leadership (cardiac surgery/cardiology), but any member of administration or the clinical care team could raise the possible benefit of triggering the pathway, and then discussion could be tabled at the Heart Program steering committee level. The protocol also could be triggered by a series of unanticipated outcomes when there is concern that the outcomes are a sign of a system moving toward the edges of the confidence limits of outcomes.

It would also be possible to have a team revert to any risk strata (ie, not necessarily go back to RACHS-1 category 1) or to advance by a single risk strata (rather than 2 at a time as we describe) followed by iterative review as many times as necessary, over whatever time period is necessary, and stopping at whichever risk strata was associated with best possible patient outcomes and team function.

Another of the customizable features of this protocol is the duration of time spent in Ramp Up. Our heart program spent 9 months in the first Ramp Down/Up (and did not require a Ramp Down) because 2 newly trained surgeons had arrived at a program that had only been itinerantly performing pediatric heart operations. Clearly, there are other “disruptions” to the expertise pool that might be less significant and require less time. Our Ramp Ups were variable in length and ranged from 3.5 to 9 months. There are both objective and subjective elements that need to be considered simultaneously to guide the decision making regarding a program’s readiness (or not) to progress to higher levels of case complexity. It is possible that applied honestly and transparently, this protocol might guide some programs to appropriately self-limit at lower levels of case complexity indefinitely.

The expert reviewer may be tailored to the situation. The external reviewer in our first application of the Ramp Down/Up protocol was a congenital cardiac surgeon from another Canadian centre. The external reviewer in the second and third applications of the protocol was the chief of the division of cardiac surgery (senior adult cardiac surgeon). Ideally, the expert clinician who reviews performance will be from the same discipline as that of the clinical group experiencing the human resource disruption. In certain circumstances, it might be ideal to have multidisciplinary teams from arms-length pediatric heart programs available to assess program performance. Rather than a formal program review, this mentorship role could be played by higher-volume and more experienced pediatric heart teams acting as a “buddy” system, not to be punitive or judgmental, but with the intent of objectively assessing and constructively helping another program achieve safe and reproducible outcomes. There may be less significant disruptions of the expertise pool that can be managed by use of local expert opinions, which is what the IWK clinical leadership elected to use for Ramp Down/Up 2 and 3. Clearly, care must be taken to engage informed expert opinion

if the type of vetting described herein is to be valid and useful. One of the improvements to the Ramp Down/Up protocol would be to apply a validated measure of team performance composed of both quantitative and qualitative outcomes that could be shared with the members of the team.¹⁴

Limitations

Our historic mortality outcomes are not risk stratified, now an industry gold standard. Equally critical is the absence of externally benchmarked, risk-stratified complication outcome data, data that are now being collected by the STS and European Association of Cardiothoracic Surgery Congenital Heart Surgery Databases. These data shortcomings highlight the importance of pediatric cardiac surgery programs participating in external, transparent database entities.

Conclusions

The Ramp Down/Up protocol is a quality initiative that was spearheaded by invested clinicians of a pediatric heart program. The Ramp Down/Up protocol is a voluntary, systematic reduction in the complexity of cases performed followed by a transparent and intentional escalation of case complexity based on quantitative and qualitative assessment of program performance. The protocol is a template that may be tailored to the needs of other programs that are challenged by critical human resource changes.

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Disclosures

The authors have no conflicts of interest to disclose.

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