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Camille L. Hancock Friesen, MD, Amy T. Lockhart, RN, Stacy B. O'Blenes, MD, Dagmar T. Moulton, MD, John P. Finley, MD, Andrew E. Warren, MD

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A Pathway for Managing Critical Expert Human Resource Fluxes in a Pediatric Heart Program

Short title: The Ramp Down/Up Protocol

Camille L. Hancock Friesen MD[1,2,3], Amy T. Lockhart RN[4], Stacy B. O'Blenes MD[3], Dagmar T. Moulton MD[4], John P. Finley MD[3,4], Andrew E. Warren MD[3,4]

[1]University of Texas Southwestern, 5323 Harry Hines Blvd, Dallas, TX 75390, [2]Children's Health19335 Medical District Drive, Dallas, Texas, 75235, [3]Dalhousie University, 5849 University Avenue, Halifax, Nova Scotia, B3H 4R2, [4]IWK Department of Pediatrics, 5980 University Ave, Halifax, NS B3K 6R8,

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Corresponding author:

Camille L. Hancock Friesen

Professor University of Texas Southwestern Medical Center, Department Cardiothoracic Surgery, Division Pediatric Cardiothoracic Surgery

Surgical Cardiothoracic Director, Adult Congenital Heart Disease Program

Tel: (214)456-7889

Fax: (214)456-5015

Email: Camille.HancockFriesen@UTSouthwestern.edu

Brief Summary

Relocation, recruitment or retirement may lead to changes in the expertise pool that could threaten patient outcomes in a pediatric heart program. We describe a quality initiative aimed at risk management in the form of a pathway (the Ramp Down/Up protocol). The protocol evolved and was used three times in twelve years to allow the heart team to adjust to critical changes in its expert human resource composition and to stabilize patient outcomes.

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-adjusted 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/care-giver consent for quality data collection is obtained at the time of hospital admission. Consecutive surgical patients having their index cardiac surgical procedure at the IWK from Jan 1 2003 through Dec 2015 are included. The Ramp Down/Up protocol evolved to have to four critical elements; 1) a trigger and a reduction in case complexity; 2) an external/objective expert observer; 3) an escalation in case complexity; 4) data (qualitative and quantitative) collection and analysis

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

Conclusions: A quality initiative aimed a risk-management has allowed one pediatric heart team to ensure that patient outcomes were maintained during critical human resource fluxes.

Abbreviations

STS Society of Thoracic Surgeons

EACTS European Association of Cardiothoracic Surgery

RACHS-1 Risk Adjustment in Congenital Heart Surgery version 1

STAT Category: Society for Thoracic Surgery and European Association of Cardiothoracic Surgery Category

Background

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 very difficult. Dr. David Jones has written about the critical role of expertise and hypothesized that differences in outcomes for subspecialty care areas (such as pediatric cardiac surgery) are not necessarily a reflection of volume-outcome relationships, but of expertise-outcome relationships[3]. In order 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 and/or recruitment, but this is not necessarily so. Data which speak to the number of pediatric heart programs which are likely to have small numbers of practicing physicians in important specialty roles come from the Society of Thoracic Surgery (STS) Congenital Heart Surgery database. Of the 116 pediatric cardiac surgical programs voluntarily reporting data to the STS Congenital Heart Surgery database, 75/116 (65%) programs perform fewer than 249 index cardiac operations/year (2017 Fall Report), and these index cardiac operations may be 'on-pump cardiovascular operations' or 'off-pump cardiovascular operations'. Of 307 hospitals performing 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) based on 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 which are staffed by only one or two individuals. In these situations, one person retiring or relocating may shift the total expertise pool significantly.

In order to limit risk to patients as our pediatric heart team evolved and the expertise level changed over time, we developed and employed 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/care-giver consent for quality data collection is obtained at the time of hospital admission. Consecutive surgical patients having their index cardiac surgical procedure at the IWK from Jan 1 2003 through Dec 31, 2015 are included. Quantitative outcome data was collected by one expanded role nurse (ATL). Mortality and length of stay data was submitted for each patient to the Congenital Cardiac Surgery database, (https://ccsdb.org/Home/Dashboard), a web-based registry database for recording and reporting clinical experience and outcomes of surgery for congenital cardiac disease. Complication data collection evolved over the 12-years spanning this report from retrospective chart review with non-standardized definitions (2002-2009) to

retrospective chart review using standardized definitions (2007-2010) to prospective collection based on the STS short list of complications[5].

Risk-Adjustment: Case-by-case risk-adjustment was provided using the expert-consensus derived RACHS-1 categories in which early mortality risk is assigned a category from 1-6[6]. RACHS-1 category 1 cases, are the lowest risk cases and include ASD repair, VSD 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 which do not have RACHS-1 categories assigned to them (because they are rare or heterogeneous) and thus they are captured as "non-classified". 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 [7]. STAT category is currently used for risk-stratification, but during the era being described in this manuscript, RACHS-1 was used.

Evolution of a Risk Management Quality Initiative: As a systemic approach to disruption in the expertise pool has not previously been described, there was no *apriori* protocol which we were able to apply when we experienced critical fluxes in the expertise pool due to acute human resource changes. What we are describing thus, 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 fluxes. The first time we used this strategy we did not anticipate that we would require a similar intervention two more times over the next ten years. We named the protocol "Ramp Down/Up" and have

distilled it to four critical elements; 1) a trigger and a reduction in case complexity; 2) an external/objective expert observer; 3) an escalation in case complexity; 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 (Jan 1, 2003-Dec 31, 2015) the Izaak Walton Killam (IWK) Pediatric Heart Program was comprised of 5 pediatric cardiologists, variably 1-2 pediatric cardiac surgeons, 1-4 pediatric cardiac anesthestists, and 3-4 pediatric intensive care physicians. The IWK Pediatric Heart Program provides care to all patients with congenital cardiac pathologies in the four 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 transplantation. The annual program case volume was stable with an average of 80 index on-pump cardiovascular operations/year.

Ramp Down/Up Protocol Deployment: The three 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 employed, the clinical leadership of the pediatric heart program (surgeon(s) and/or cardiologists) triggered the protocol. Following a decision to employ 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 three cases of Ramp Down/Up protocol deployment. The disruptions at the IWK that lead to triggering the Ramp Down/Up protocol included; a) restarting the surgical program after an hiatus with no local surgeon for many months (Jan 1, 2003- Sept 30, 2003; cases 1-74); b) surgeon relocation (Apr 1, 2006-July 31, 2006; cases 316-468); and c) the return from maternity leave for a solo junior pediatric cardiac anesthetist at the physicians' own request (Aug 15, 2015-Nov 30, 20-15; cases 1387-1412).

Case-by-case decision-making during the Ramp Down/Up protocol, as at any other time, was guided by the principle that operations would be performed at the site which 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 one year, and two pediatric cardiac surgeons directly out of training were hired. In this instance, as 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 one-week period and directly supervised the operation and post-operative management of eight RACHS-1 category1 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; twelve RACHS-1 category 1 and 2 cases were scheduled and performed over the next 6-8 weeks in the absence of the external surgeon. The external surgeon then attended the hospital for another one-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 two surgeons on a series of more complex cases which 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 (Jan 1 2003-June 30 2003; cases 1-161); Ramp Down/Up #2 was 4 months in duration (Apr 20 2006-Aug 20 2006; cases 370-440) and Ramp Down/Up #3 was 3 months in duration (Aug 28 2012-Nov 30 2012, cases 1280-1410).

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 were possible (i.e. 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 three 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, 1,688 operations were performed, 1,420 were index procedures and 1,066 were RACHS-1 classifiable. The average number of total index operations/week 2003-15 (RACHS-1 classifiable only) were 1.57/week. During a Ramp Down/Up period the average number of total index operations/week (RACHS-1 only) were 1.32/week, 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 CUSUM plot of all index cases; the slope of the CUSUM plot provides evidence that there was no significant increase in mortality in spite of three Ramp Down/Up periods (Fig 1c). As with all other processes, there was evolution over the 12-year span of this report with regards 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 did submit our mortality data to the Canadian Cardiovascular Surgery Database. By 2012 we had designed and

deployed a novel real-time prospective dashboard reporting local program risk-adjusted mortality and complications. Prospective complication monitoring, once available (beginning October 2012), verified program-wide rates of complication occurrence similar to that reported by larger datasets[7,8].

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 themes that have emerged as our pediatric heart team has qualitatively reviewed the three Ramp Down/Up protocol enactments 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 as there may be competing agendas for keeping patients in the local center. However, the with 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 will inevitably 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 were greatly heightened after the very public events in Bristol and Winnipeg[9,10]. 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[11]. The concept of a trigger and a reduction in case complexity, the first two phases of The Ramp Down/Up protocol, was in part inspired by the very honest and transparent "pause" which Marc de Leval reported triggered by a sudden "run" of adverse outcomes in a series of arterial switch procedures[12]. 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) a senior consultant pediatric cardiac surgeon from Syndey, 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 of 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 could also be triggered by a series of unanticipated outcomes where there is concern that the outcomes are a sign of a system moving towards the edges of the confidence limits of outcomes.

It would also be possible to have a team revert to any risk-strata (i.e. not necessarily go back to RACHS-1 category 1) and/or to advance by a single risk strata (rather than two-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 nine months in the first Ramp Down/Up (and didn't require a Ramp Down) as two freshly trained surgeons had arrived at a program which had only been itinerantly performing pediatric heart operations. Clearly there are other "disruptions" to the expertise pool which might be less significant and require less time. Our Ramp Ups were variable in length and ranged from 3.5-9 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 also 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/ more experienced pediatric heart team 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 which can be managed by employment of local expert opinions, which is what the IWK clinical leadership elected to utilize 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, comprised of both quantitative and qualitative outcomes, which could be shared with the members of the team[13].

Limitations

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

Conclusions

The Ramp Down/Up protocol is a quality initiative that was spear-headed 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 expert human resource fluxes.

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Disclosures

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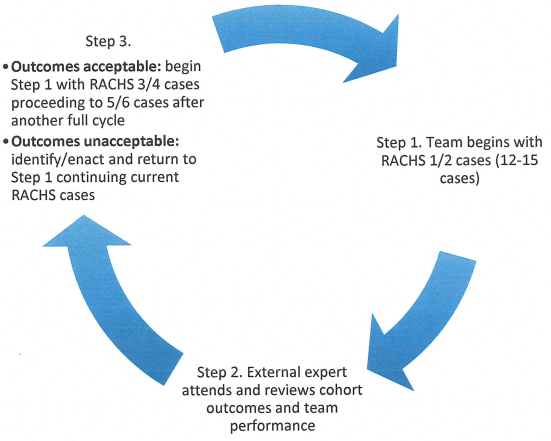
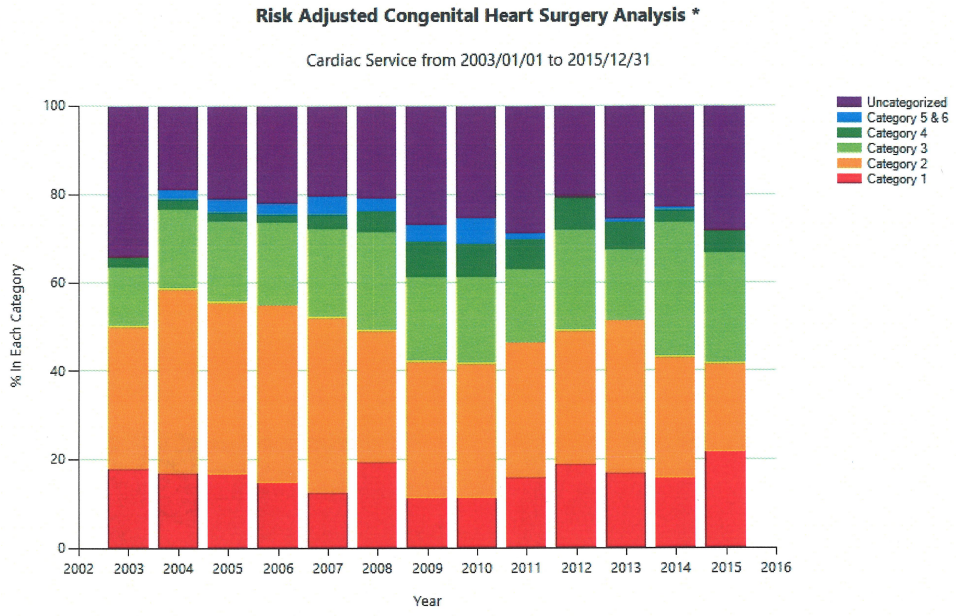
Figure Legends

Fig 1a. 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.

Fig 1b. 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 upon in-hospital mortality for index operations only. Index operation is defined as the first operation following admission and excludes reoperations during the same admission. Graph provided by Canadian Cardiovascular Surgery Database (https://CCSdb.org/Home/Dashboard).

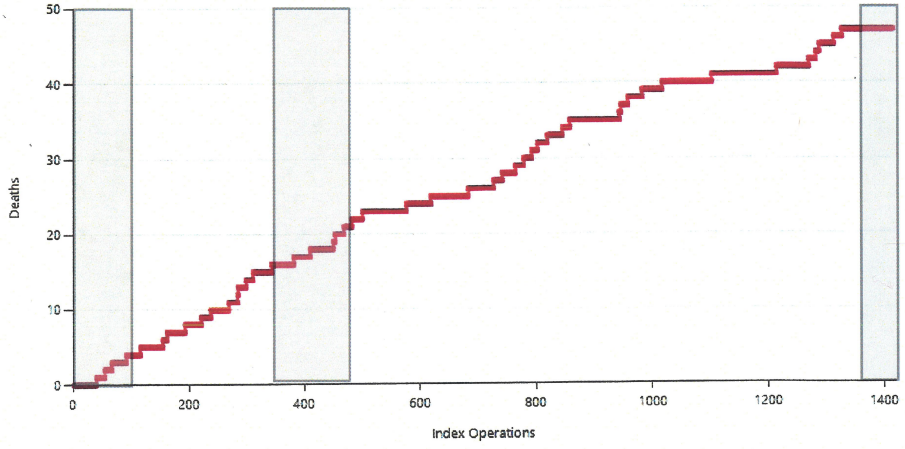
Fig 1c. CUSUM Trend for all Index Operations. Overall the slope of the CUSUM graph represents mortality rates (3.3%), which remains consistent over the twelve-year era. Grey boxes mark each of the three Ramp Down/Up protocol deployments (Jan 1 2003-Sept 30 2003, Cases 1-74; Apr 1 2006-July 31 2006, Cases 316- 468; Aug 15 2015-Nov 30 2015, Cases 1387-1412). There is no change in the slope of the CUSUM mortality plot before, during or after these three 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).





Patient mortality trend (47/1419=3.3 %)

Cardiac Service for all operations (Pumps and Non-pumps) from 2003-01-01 to 2015-12-31



Note: Re-operations during same admission are excluded