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Reducing Mortality and Infections After Congenital Heart Surgery in the Developing World

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abstract

BACKGROUND: There is little information about congenital heart surgery outcomes in developing countries. The International Quality Improvement Collaborative for Congenital Heart Surgery in Developing World Countries uses a registry and quality improvement strategies with nongovernmental organization reinforcement to reduce mortality. Registry data were used to evaluate impact.

METHODS: Twenty-eight sites in 17 developing world countries submitted congenital heart surgery data to a registry, received annual benchmarking reports, and created quality improvement teams. Webinars targeted 3 key drivers: safe perioperative practice, infection reduction, and team-based practice. Registry data were audited annually; only verified data were included in analyses. Risk-adjusted standardized mortality ratios (SMRs) and standardized infection ratios among participating sites were calculated.

RESULTS: Twenty-seven sites had verified data in at least 1 year, and 1 site withdrew. Among 15 049 cases of pediatric congenital heart surgery, unadjusted mortality was 6.3% and any major infection was 7.0%. SMRs for the overall International Quality Improvement Collaborative for Congenital Heart Surgery in Developing World Countries were 0.71 (95% confidence interval [CI] 0.62–0.81) in 2011 and 0.76 (95% CI 0.69–0.83) in 2012, compared with 2010 baseline. SMRs among 7 sites participating in all 3 years were 0.85 (95% CI 0.71–1.00) in 2011 and 0.80 (95% CI 0.66–0.96) in 2012; among 14 sites participating in 2011 and 2012, the SMR was 0.80 (95% CI 0.70–0.91) in 2012. Standardized infection ratios were similarly reduced.

CONCLUSIONS: Congenital heart surgery risk-adjusted mortality and infections were reduced in developing world programs participating in the collaborative quality improvement project and registry. Similar strategies might allow rapid reduction in global health care disparities. *Pediatrics* 2014;134:e1422–e1430

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KEY WORDS

congenital heart surgery, mortality, hospital-acquired infection, quality improvement

ABBREVIATIONS

CI—confidence interval
IQIC—International Quality Improvement Collaborative for Congenital Heart Surgery in Developing World Countries
NGO—nongovernmental organization
RACHS-1—Risk Adjustment for Congenital Heart Surgery
SIR—standardized infection ratio
SMR—standardized mortality ratio

Dr Jenkins conceptualized and designed this study, interpreted the data, and drafted and critically revised the initial manuscript; Drs Castañeda, Cherian, Novick, and Christenson and Bistra Zheleva conceptualized and designed this study, and reviewed and critically revised the manuscript; Chris A. Couser managed the study, oversaw data collection and acquisition at sites, and drafted and critically revised the manuscript; Ms Dale supported data collection and acquisition at several sites, and reviewed and critically revised the manuscript; Dr Gauvreau conducted all statistical analyses, interpreted the data, contributed to the initial draft, and critically revised the manuscript; Dr Hickey conceptualized and designed this study, contributed to the initial draft, and critically revised the manuscript; Ms Koch Kupiec contributed to data interpretation, and drafted and critically revised the initial manuscript; Ms Morrow and Dr Rangel contributed to study concept and design, contributed to the initial draft, and critically revised the manuscript; and all authors approved the final manuscript as submitted. All authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Only 7% of the population has access to life-saving congenital heart surgery in the developing world,[1] where congenital anomalies are the eighth leading cause of death in children.[2] Approximately 90% of births worldwide occur in developing countries that have limited resources and high expected morbidity and mortality due to congenital heart disease.[3,4] The establishment of surgical programs allows an increasing number of children access to life-saving surgery. Congenital heart surgery carries considerable risk for death, even in programs in the developed world. Congenital heart surgery has the potential to offer repair or palliation for children who would otherwise die, but requires a highly skilled multidisciplinary team and a reliable institutional framework. These factors are often limited in resource-poor environments, where survival also may be limited by late identification of poor nutrition and other morbidities.[5] Translation of quality improvement activities, now common in developed world surgical programs, can catalyze rapid improvement in surgical outcomes.

One cornerstone of quality improvement is the need to monitor clinical outcomes and benchmark performance. A major problem faced by health care professionals in the developing world is the lack of benchmarking data for purposes of evaluating performance of their congenital heart surgery programs and guiding efforts to make improvements. The Global Forum on Humanitarian Medicine in Cardiology and Cardiac Surgery was established for nongovernmental organizations (NGOs) to discuss opportunities to help address challenges for cardiac surgery programs in the developing world. The need for improved data collection and clinical outcomes was identified during the Global Forum by developing country practitioners and NGOs supporting capacity-building in developing world pediatric cardiac surgery programs. To address these gaps and strengthen health care systems, the International Quality Improvement Collaborative for Congenital Heart Surgery in Developing World Countries (IQIC) was conceived in 2007 by Boston Children's Hospital representatives and NGOs at the Global Forum in Geneva, Switzerland. The IQIC aims to (1) collect information about site-specific outcomes, including in-hospital mortality, major infection, and 30-day mortality, after congenital heart surgeries performed in the developing world; (2) determine patient and procedural predictors of site-specific outcomes; and (3) use quality improvement methodology and collaboration between programs in developed and developing countries to reduce mortality in the developing world. Initial sites had attended Global Forum meetings or had affiliations with NGOs. Later, participation was opened to other interested, similar programs that were self-identified as performing congenital heart surgery in resource-constrained environments based on the amount of gross domestic product available to health care. Between 2010 and 2012, 28 sites in 17 countries participated in the IQIC and submitted data (Table 1).

METHODS

Database Creation and Data Collection

A Web-based data entry tool was developed with the goal of collecting data to assess in-hospital and 30-day mortality, as well as surgical site infections and bacterial sepsis. Data elements collected include patient characteristics, preoperative status, and variables necessary to use the Risk Adjustment for Congenital Heart Surgery (RACHS-1) methodology.[6,7] Physician-nurse teams from each site oversee data collection and project management, and sites submit diagnostic, procedural, and clinical information for all congenital heart surgeries in patients $<$18 years of age into the Web-based entry tool. Sites report de-identified patient data only. The Boston Children's Hospital institutional review board approved this project. Participating sites obtained local institutional review board or other approvals if necessary.

Development of Key Driver Diagram

Discussions at Global Forum meetings outlined key challenges facing developing world programs. Using this information, along with current quality improvement priorities in the developed world, 3 "key drivers" to reduce mortality associated with congenital heart surgery were selected: safe perioperative practice, reduction of surgical site infections and bacterial sepsis, and team-based practice through nurse empowerment (Fig 1).

Learning Modules

The quality improvement component of the collaborative began in 2010, using a targeted educational program to address each of the 3 key drivers. Sites began participating in monthly webinars, with training to develop targeted quality improvement strategies at their respective institutions. The learning modules include educational videos and Web content related to each key driver. In 2011, additional curricula with advanced nursing content were incorporated, and site-led webinars were introduced in 2012. A total of 44 webinars were conducted between 2010 and 2012, in which participating sites were highly engaged. Webinars included topics on surgical safety checklist implementation, health care–associated infection prevention, hand hygiene, clear communication, effective teamwork, nursing postoperative care, postoperative respiratory management, pain management, nutrition, emergency situations, crisis resource management, surgical repairs of common congenital heart defects, arrhythmias, fetal circulation and physiology, cardiac embryology, endotracheal tube suctioning, data entry,

TABLE 1 Participating Sites and Locations

Name of Institution	Location	Included in Aggregate Data		
		2010	2011	2012
Amrita Institute of Medical Sciences	Kochi, India	Yes	Yes	Yes
Armed Forces Institute of Cardiology, National Institute of Heart Disease	Rawalpindi, Pakistan	Yes	No	Yes
Care Hospital	Hyderabad, India	N/A	N/A	Yes
Clinica Infantil Colsubsidio	Bogota, Colombia	Yes	Yes	Yes
Federal State Budgetary Institution "Research Institute for Complex Problems of Cardiovascular Diseases," Siberian Branch of the Russian Academy of Medical Sciences	Kemerovo, Russia	N/A	N/A	Yes
First Hospital of Lanzhou University	Lanzhou, Gansu Province, China	N/A	Yes	Yes
Frontier Lifeline Hospital	Chennai, India	Yes	Yes	Yes
Fundacion Cardioinfantil de Bogota	Bogota, Colombia	N/A	Yes	Yes
Fundacion Cardiovascular Adulto-Pediatrica Clinica San Rafael	Bogota, Colombia	Yes	Yes	Yes
Hospital Arturo Grullon	Santiago de los Caballeros, Dominican Republic	Yes	No	No
Hospital de Base	Sao Jose do Rio Preto, Brazil	Yes	Yes	Yes
Hospital de Ninos	Cordoba, Argentina	N/A	N/A	Yes
Hospital Garrahan	Buenos Aires, Argentina	N/A	Yes	Yes
Hospital Nacional de Ninos Benjamin Bloom	San Salvador, El Salvador	N/A	No	No
Innova Children's Heart Hospital	Hyderabad, India	Yes	Yes	Yes
Institute of General and Urgent Surgery, Academy of Medical Sciences	Kharkov, Ukraine	No	Yes	Yes
Instituto do Coracao (InCor)	Sao Paulo, Brazil	N/A	N/A	Yes
Instituto Nacional Cardiovascular (INCOR)	Lima, Peru	N/A	N/A	Yes
Kardias A.C. (Instituto Nacional de Pediatria & Centro Medico ABC)	Mexico City, Mexico	N/A	N/A	Yes
KJ Hospital	Chennai, India	N/A	Yes	Yes
Kokilaben Dhirubhai Ambani Hospital & Medical Research Center (KDA Hospital & MRC)	Mumbai, India	N/A	No	Yes
National Children's Cardiac Surgical Center	Minsk, Belarus	Yes	Withdrawn	Withdrawn
Nhi Dong 1 (Children's Hospital #1)	Ho-Chi Minh City, Vietnam	Yes	Yes	Yes
Shanghai Children's Medical Center	Shanghai, China	No	Yes	Yes
Star Hospital	Hyderabad, India	Yes	No	Yes
Uganda Heart Institute, Mulago Hospital	Kampala, Uganda	Yes	No	Yes
Unidad de Cirugía Cardiovascular Pediátrica (UNICARP) de Guatemala	Guatemala City, Guatemala	Yes	No	No
United Hospital	Dhaka, Bangladesh	N/A	Yes	Yes

N/A, not yet participating in International Quality Improvement Collaborative.

and annual benchmarking report interpretation. All webinars are archived on the IQIC Web site for participants' future reference and are translated from English locally by sites as needed. In addition, NGOs actively supported adoption of key IQIC activities to facilitate implementation. In June 2013, an in-person learning session reinforcing outcomes and interventions was held at the ninth Global Forum meeting in Geneva, Switzerland; 66 participants from 23 sites attended.

Safe Perioperative Practice

Using design principles outlined by the World Health Organization's Safe Surgery Saves Lives campaign and a previously published pediatric surgical safety checklist as a conceptual framework,[8,9] a checklist designed specifically to meet the needs of pediatric congenital heart surgery was created (Fig 2). The checklist was disseminated to all institutions, which were encouraged to make any necessary modifications to meet unique needs of their institutions. Perioperative care team members at sites were trained on effective checklist utilization through interactive webinars and one-on-one site mentoring.

Infection Reduction

Learning modules were developed to introduce the concept of evidence-based "practice bundles" and teach specific components of infection reduction. A bundle is defined as a set of evidence-based practices that improve patient outcomes when implemented by every member of the health care team.[10] An initial module focused on developing a hand hygiene program and included strategies to improve hand-washing compliance, recognizing that health care workers' hands are responsible for the transmission of most pathogens in hospitals.[11] Additional modules focused on practice bundles to improve sterility for central venous catheter insertions, central line access, and central line dressings; to reduce surgical site infections, emphasizing correct antibiotic timing, hair removal with clippers, preoperative skin disinfection, and postoperative wound management; and to reduce urinary tract infections and ventilator-associated pneumonia. The importance of standardizing care, auditing practice, and the feedback of practice audit results and infection rates were common themes across modules.

Team-Based Practice Through Nurse Empowerment

To achieve the goal of team-based practice through nurse empowerment, numerous tools were provided for empowering nurses, including high-fidelity case-based teaching videos, standardized scripts for nurses to give comprehensive patient reports in ICUs and wards, as well as techniques of assertion, closed loop communication, and a structured situation briefing framework with 4 components: Situation, Background, Assessment, and Recommendation. This

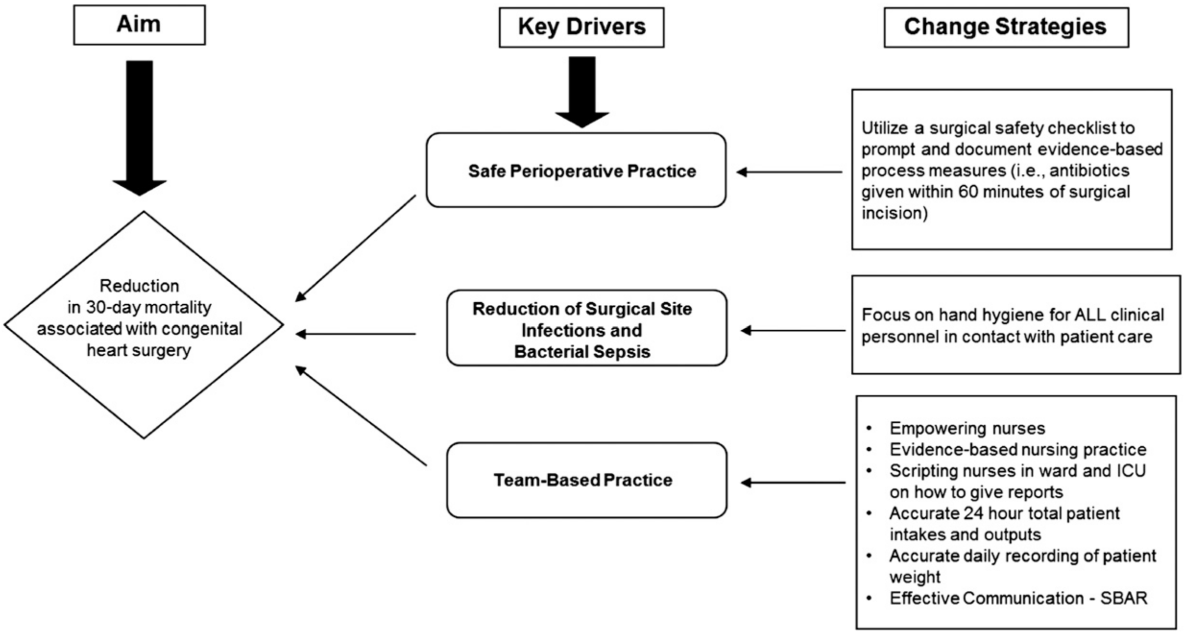


FIGURE 1
Implementation of quality improvement methodology to reduce mortality.

framework of Situation, Background, Assessment, and Recommendation, a communication model adopted from the US Nuclear Navy,[12] has been found to be beneficial in health care settings. An example of assertion training that reinforces infection reduction strategies includes empowering nurses to speak up in a professional manner when sterility is compromised or when practice bundles are not followed. Detailed demonstrations of fundamental and advanced competencies for pediatric cardiovascular nurses were also presented.

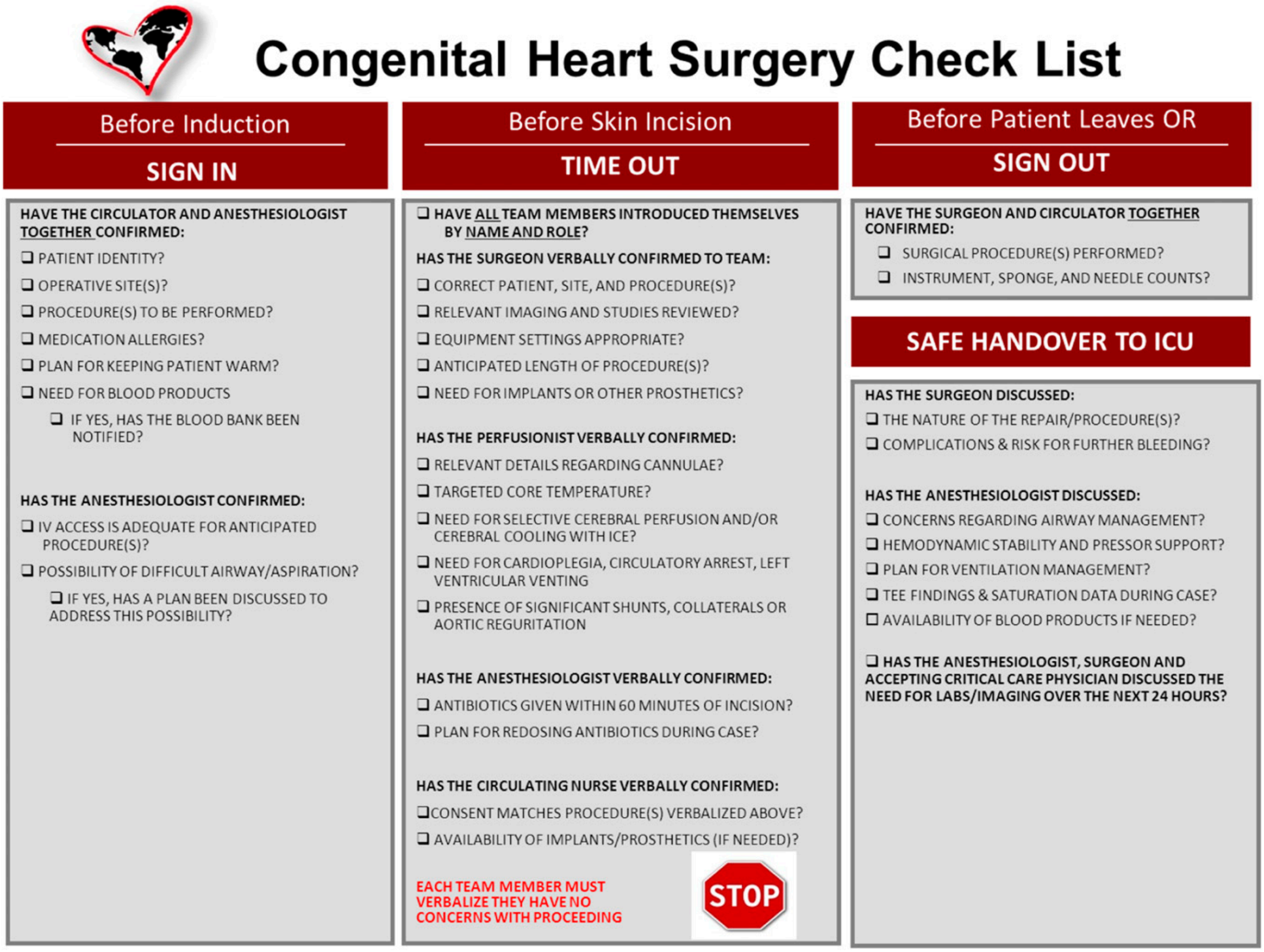
Outcomes

The following outcome variables were collected: in-hospital mortality, 30-day mortality, surgical site infection, and bacterial sepsis. Any major infection was defined as surgical site infection and/or bacterial sepsis. Surgical site infection was defined according to Centers for Disease Control and Prevention/National Healthcare Safety Network definitions.[13] Bacterial sepsis was defined as known or presumed bacterial sepsis with fever or hypothermia, tachycardia, hypotension, tachypnea, leukocytosis, or leukopenia.

Auditing and Analysis

Multidisciplinary teams from Boston Children's Hospital, as well as NGO representatives and volunteers, conducted site visits consisting of hospital tours, round table discussions, and formal presentations to reinforce collaborative goals. In addition, data source verification was performed by using a minimum 10% sample of all cases entered into the IQIC database. Key variables audited included type of procedure, RACHS-1 risk category, age, prematurity, major noncardiac structural anomaly, postoperative outcomes, and 30-day follow-up. Audit results determined whether data were sufficiently complete and accurate for inclusion in aggregate results. Annual benchmarking reports were provided to each site and discussed in detail during designated webinars; sites received aggregate collaborative data for the calendar year as well as data specific to their institution. Site-specific outcomes were compared with the aggregate, and trends over time were examined.

For the current analysis, patient characteristics, procedural information, and surgical outcomes were summarized for 15 049 cases of congenital heart surgery in patients <18 years of age from sites participating in the IQIC at any time between 2010 and 2012, and for which data were verified by audit (13 sites in 2010, 14 sites in 2011, 24 sites in 2012). To evaluate the effectiveness of the IQIC in reducing mortality and infections, risk-adjusted outcomes for 2011 and 2012 were compared to the appropriate reference population. The previously validated RACHS-1 method was used to risk adjust in-hospital mortality; patient risk factors included in the model are surgical risk category (categories 1 through 6), age group, prematurity, major noncardiac structural anomaly, and multiple congenital heart procedures during the admission. A risk adjustment model for occurrence of major infection was derived based on 2010 aggregate data; logistic regression analysis was used, and only patient risk factors significant at the 0.05 level of significance were retained in the final model. Factors included were RACHS-1 risk category, age group, major medical illness, malnourished or emaciated nutritional appearance, and oxygen saturation <90%. For both models, congenital heart


Congenital Heart Surgery Check List

Before Induction — SIGN IN

HAVE THE CIRCULATOR AND ANESTHESIOLOGIST TOGETHER CONFIRMED:
- ❑ PATIENT IDENTITY?
- ❑ OPERATIVE SITE(S)?
- ❑ PROCEDURE(S) TO BE PERFORMED?
- ❑ MEDICATION ALLERGIES?
- ❑ PLAN FOR KEEPING PATIENT WARM?
- ❑ NEED FOR BLOOD PRODUCTS
  - ❑ IF YES, HAS THE BLOOD BANK BEEN NOTIFIED?

HAS THE ANESTHESIOLOGIST CONFIRMED:
- ❑ IV ACCESS IS ADEQUATE FOR ANTICIPATED PROCEDURE(S)?
- ❑ POSSIBILITY OF DIFFICULT AIRWAY/ASPIRATION?
  - ❑ IF YES, HAS A PLAN BEEN DISCUSSED TO ADDRESS THIS POSSIBILITY?

Before Skin Incision — TIME OUT

- ❑ HAVE ALL TEAM MEMBERS INTRODUCED THEMSELVES BY NAME AND ROLE?

HAS THE SURGEON VERBALLY CONFIRMED TO TEAM:
- ❑ CORRECT PATIENT, SITE, AND PROCEDURE(S)?
- ❑ RELEVANT IMAGING AND STUDIES REVIEWED?
- ❑ EQUIPMENT SETTINGS APPROPRIATE?
- ❑ ANTICIPATED LENGTH OF PROCEDURE(S)?
- ❑ NEED FOR IMPLANTS OR OTHER PROSTHETICS?

HAS THE PERFUSIONIST VERBALLY CONFIRMED:
- ❑ RELEVANT DETAILS REGARDING CANNULAE?
- ❑ TARGETED CORE TEMPERATURE?
- ❑ NEED FOR SELECTIVE CEREBRAL PERFUSION AND/OR CEREBRAL COOLING WITH ICE?
- ❑ NEED FOR CARDIOPLEGIA, CIRCULATORY ARREST, LEFT VENTRICULAR VENTING
- ❑ PRESENCE OF SIGNIFICANT SHUNTS, COLLATERALS OR AORTIC REGURITATION

HAS THE ANESTHESIOLOGIST VERBALLY CONFIRMED:
- ❑ ANTIBIOTICS GIVEN WITHIN 60 MINUTES OF INCISION?
- ❑ PLAN FOR REDOSING ANTIBIOTICS DURING CASE?

HAS THE CIRCULATING NURSE VERBALLY CONFIRMED:
- ❑ CONSENT MATCHES PROCEDURE(S) VERBALIZED ABOVE?
- ❑ AVAILABILITY OF IMPLANTS/PROSTHETICS (IF NEEDED)?

EACH TEAM MEMBER MUST VERBALIZE THEY HAVE NO CONCERNS WITH PROCEEDING

STOP

Before Patient Leaves OR — SIGN OUT

HAVE THE SURGEON AND CIRCULATOR TOGETHER CONFIRMED:
- ❑ SURGICAL PROCEDURE(S) PERFORMED?
- ❑ INSTRUMENT, SPONGE, AND NEEDLE COUNTS?

SAFE HANDOVER TO ICU

HAS THE SURGEON DISCUSSED:
- ❑ THE NATURE OF THE REPAIR/PROCEDURE(S)?
- ❑ COMPLICATIONS & RISK FOR FURTHER BLEEDING?

HAS THE ANESTHESIOLOGIST DISCUSSED:
- ❑ CONCERNS REGARDING AIRWAY MANAGEMENT?
- ❑ HEMODYNAMIC STABILITY AND PRESSOR SUPPORT?
- ❑ PLAN FOR VENTILATION MANAGEMENT?
- ❑ TEE FINDINGS & SATURATION DATA DURING CASE?
- ❑ AVAILABILITY OF BLOOD PRODUCTS IF NEEDED?

❑ HAS THE ANESTHESIOLOGIST, SURGEON AND ACCEPTING CRITICAL CARE PHYSICIAN DISCUSSED THE NEED FOR LABS/IMAGING OVER THE NEXT 24 HOURS?

FIGURE 2
Congenital heart surgery check list.

surgery cases either ineligible for RACHS-1 risk adjustment (such as premature infants or neonates undergoing patent ductus arteriosus ligation only) or unable to be assigned to a risk category were excluded. The c statistic, a measure of discrimination, was provided for each model; a c statistic of 0.5 indicates that the model is no better than chance at predicting who will experience the outcome of interest and who will not, whereas a value of 1.0 indicates that the model predicts the outcome perfectly every time. Standardized mortality ratios (SMRs), standardized infection ratios (SIRs), and their 95% confidence intervals (CIs) were calculated for aggregate data from 2011 and 2012, using 2010 as the reference population. An SMR is defined as the observed mortality rate in a calendar year divided by the mortality rate expected in that year based on patient case mix; an SMR $>$1.0 suggests higher than expected in-hospital mortality relative to the reference population, whereas an SMR $<$1.0 indicates lower than expected mortality. If a 95% CI for the SMR does not contain the value 1.0, then risk-adjusted mortality is significantly different from the reference population ($P < .05$). SIRs are similarly interpreted. Because different institutions contributed data in different years, SMRs and SIRs for 2011 and 2012 relative to 2010 were also generated for the 7 sites contributing data for the entire time period, using these 7 sites' 2010 data as the reference population rather than the entire collaborative. Similarly, SMRs and SIRs for 2012 relative to 2011 were generated for the 14 sites contributing data in both 2011 and 2012. Statistical analyses were conducted by using SAS version 9.2 (SAS Institute, Inc, Cary, NC).

RESULTS

Among 28 sites, 15 joined by 2010, 7 joined in 2011, and 6 joined in 2012. One site officially withdrew after 2010. All sites except one met data audit requirements in at least 1 calendar year. A total of 16 979 cases of congenital heart surgery were entered into the IQIC database between 2010 and 2012. Of these, 15 049 cases in patients $<$18 years of age at the time of surgery, representing 27 sites in 16 countries, were verified by

TABLE 2 Patient Demographics

	Number	Percent
Total cases	15 049	100.0
Age at surgery		
≤30 d	969	6.4
31 d to <1 y	5942	39.5
1 to 17 y	8138	54.1
Gender		
Female	6661	44.3
Male	8378	55.7
Not reported	10	—

TABLE 3 Patient Preoperative Status and RACHS-1 Risk Classification

	Number or Median	Percent or Range
Nutritional appearance		
Normal	9282	61.9%
Malnourished	3839	25.6%
Emaciated	1797	12.0%
Overweight	86	0.6%
Not reported	45	—
WHO weight for age percentile (if age at surgery <10 y)		
<5th percentile	3965	52.3%
≥5th, <15th percentile	1003	13.2%
≥15th percentile	2617	34.5%
Not reported[a]	7364	—
Preoperative procedures		
Balloon atrioseptostomy	121	0.8%
Resuscitation	46	0.3%
Inotrope therapy	126	0.8%
Ventilation preoperatively	524	3.5%
No preoperative procedure reported	14 232	94.6%
Prematurity		
Yes	808	5.4%
No	14 097	94.6%
Not reported	144	—
Major noncardiac structural anomaly		
Yes	433	2.9%
No	14 595	97.1%
Not reported	21	—
Major chromosomal abnormality		
Yes	848	5.7%
No	14 058	94.3%
Not reported	143	—
Major medical illness		
Yes	835	5.6%
No	14 175	94.4%
Not reported	39	—
Weight, kg	8.2	0.1–139
Height, cm	74	10–198
Hematocrit	37	1.3–99
Oxygen saturation, %	95	4–100
RACHS-1 risk category		
1	2724	18.1%
2	7254	48.2%
3	3347	22.2%
4	750	5.0%
5	9	0.1%
6	78	0.5%
Unassigned	436	2.9%
Not eligible	451	3.0%

[a] Available for cases enrolled in 2012 only.

data audit. Patient demographics, patient preoperative status and RACHS-1 classification, and postsurgery patient outcomes are shown in Tables 2, 3, and 4.

The unadjusted in-hospital mortality rate was 6.3%. The 30-day mortality rate was 7.4% among sites reporting 30-day mortality data for at least 90% of surgical cases (7 sites in 2010, 12 sites in 2011, 19 sites in 2012); sites were unable to capture 30-day mortality data for 24.4% of cases. The surgical site infection rate was 2.1%, the bacterial sepsis rate was 5.5%, and the rate of any major infection was 7.0%. In-hospital mortality was 1.5% in RACHS-1 risk category 1, 3.8% in category 2, 10.6% in category 3, 17.7% in category 4, and 51.1% in categories 5 and 6 combined.

The RACHS-1 risk adjustment model for in-hospital mortality applied to the 2010–2012 combined aggregate data is displayed in Table 5, with a c statistic for model discrimination of 0.740. SMRs for the aggregate data from 2011 and 2012, using 2010 as the reference population, are shown in Table 6. The SMR was 0.71 (95% CI 0.62–0.81) in 2011 and 0.76 (95% CI 0.69–0.83) in 2012. Therefore, risk-adjusted in-hospital mortality was significantly lower in both 2011 and 2012 relative to 2010.

Table 6 also shows SMRs for 2011 and 2012 for the 7 sites contributing data from 2010 to 2012, using 2010 data from these 7 sites as the reference population, as well as the SMR for 2012 for the 14 sites contributing data in 2011 to 2012, using 2011 data from these 14 sites as the reference. The SMRs for the 7 sites were 0.85 (95% CI 0.71–1.00) in 2011 and 0.80 (95% CI 0.66–0.96) in 2012, and for the 14 sites was 0.80 (95% CI 0.70–0.91) in 2012. Thus, among sites participating in all 3 years, or both 2011 and 2012, risk-adjusted in-hospital mortality decreased significantly.

When applied to the aggregate data from 2010 to 2012, the risk adjustment model for major infection yielded a c statistic of 0.747. SIRs for the aggregate data from 2011 and 2012, using 2010 as the reference population, are shown in Table 6. The SIR was 0.65 (95% CI 0.58–0.73) in 2011 and 0.53 (95% CI 0.48–0.58) in 2012. Therefore, risk-adjusted major infection decreased significantly in both 2011 and 2012 relative to 2010.

Table 6 also shows SIRs for 2011 and 2012 for the 7 sites contributing data from 2010 to 2012, using 2010 data from these 7 sites as the reference

TABLE 4 Postsurgery Patient Outcomes

	Number	Percent
In-hospital mortality		
Yes	926	6.3
No	13 882	93.7
Not reported	241	—
Surgical site infection		
Yes	312	2.1
No	14 711	97.9
Not reported	26	—
Bacterial sepsis		
Yes	822	5.5
No	14 175	94.5
Not reported	52	—
Any major infection		
Yes	1043	7.0
No	13 953	93.0
Not reported	53	—
	Mortality Rate, %	95% CI
RACHS-1 risk category[a]		
1	1.5	(1.0–2.0)
2	3.8	(3.4–4.3)
3	10.6	(9.6–11.7)
4	17.7	(15.0–20.7)
5+6	51.1	(40.1–62.1)
Unassigned	9.7	(7.0–13.0)
Not eligible	11.4	(8.6–14.8)

[a] The 241 cases where in-hospital mortality was not reported are excluded.

population, as well as the SIR for 2012 for the 14 sites contributing data in 2011 to 2012, using 2011 data from these 14 sites as the reference. The SIR for the 7 sites was 0.64 (95% CI 0.56–0.74) in 2011 and 0.53 (95% CI 0.43–0.62) in 2012, and for the 14 sites was 0.77 (95% CI 0.68–0.87) in 2012. Thus, among sites participating in all 3 years, or both 2011 and 2012, risk-adjusted major infection decreased significantly.

DISCUSSION

The IQIC was officially launched in 2008 to provide benchmarking data for congenital heart surgery in the developing world, with the overall goal of guiding quality improvement efforts and reducing mortality for congenital heart disease. Outcomes were reported for 15 049 surgeries in patients <18 years of age from 27 sites in 16 countries self-identified as developing world. Collaborative learning focused on 3 key areas: safe perioperative practice using a surgical safety checklist, reduction of surgical site infections and bacterial sepsis, and team-based practice through nurse empowerment and effective communication. Overall unadjusted in-hospital mortality was 6.3%; mortality rates within RACHS-1 risk categories look similar to those reported in the United States in 1994 to 1996.[6] Risk-adjusted mortality and infections were significantly lower in 2011 and 2012, compared to the appropriate reference population, for the collaborative overall and for institutions participating in the IQIC during consecutive years. Although these reductions cannot be attributed to the IQIC with certitude, the rapid improvements in both mortality and infections are highly suggestive of success.

Key driver diagrams create a useful framework for collaborative quality improvement.[14] The 3 key drivers chosen for the IQIC were identified by developing world cardiac surgeons and were common across diverse geographic locations. Increasing evidence has shown that use of surgical safety checklists in perioperative settings can reduce mortality and prevent complications by improving teamwork, communication, and overall quality of care,[15–18] and the World Health Organization strongly recommends worldwide adoption of surgical safety checklists.[19] The potential benefit of this intervention may be even greater for surgical procedures that are complex and involve high-risk patient populations.[20] Children with congenital heart disease represent a particularly high-risk population that could greatly benefit from the coordination of team-based care, and thus implementation of a surgical safety checklist was included as a key driver.

Strategies for preventing hospital-acquired infections are significantly less robust in the developing world.[21,22] Hospital-acquired infections are associated with increased morbidity, mortality, and hospital costs.[23] The occurrence of these infections in countries with limited resources imposes a significant burden on the health care system, and results in resources being directed away from care of additional patients.[24] In recent years, hospitals that have introduced evidence-based practice bundles to prevent occurrence of device-associated and surgical site infections have successfully decreased occurrence of these infections.[10,23,25,26] Hand hygiene is the cornerstone of every bundle to reduce device-associated and surgical site infections. These and other practices were incorporated into learning modules to reduce hospital-acquired infections, and infections also were included as secondary outcomes.

TABLE 5 RACHS-1 Risk Adjustment Model for In-Hospital Mortality (2010–2012 Aggregate Data)

	Odds Ratio	95% CI	*P* Value
RACHS-1 risk category			
1	1.0	—	—
2	2.4	(1.7–3.4)	<.001
3	6.7	(4.8–9.3)	<.001
4	9.1	(6.2–13.2)	<.001
5+6	36.8	(21.4–63.0)	<.001
Age at surgery			
≤30 d	3.0	(2.4–3.8)	<.001
31 d to <1 y	1.7	(1.4–2.0)	<.001
1 to 17 y	1.0	—	—
Prematurity	1.5	(1.1–2.0)	.007
Major noncardiac structural anomaly	2.1	(1.5–2.8)	<.001
Multiple cardiac procedures	1.0	(0.8–1.1)	.52

The c statistic for this model is 0.740.

TABLE 6 Risk-Adjusted Standardized In-Hospital Mortality and Infection Ratios

	SMRs		
	2010	2011	2012
Aggregate data	1.00	0.71 (0.62–0.81)	0.76 (0.69–0.83)
7 sites contributing data 2010–2012	1.00	0.85 (0.71–1.00)	0.80 (0.66–0.96)
14 sites contributing data 2011–2012	—	1.00	0.80 (0.70–0.91)
	SIRs		
	2010	2011	2012
Aggregate data	1.00	0.65 (0.58–0.73)	0.53 (0.48–0.58)
7 sites contributing data 2010–2012	1.00	0.64 (0.56–0.74)	0.53 (0.43–0.62)
14 sites contributing data 2011–2012	—	1.00	0.77 (0.68–0.87)

Standardized ratios are shown with 95% CIs.

It is widely recognized that effective communication and teamwork are essential for the delivery of high-quality and safe patient care. Ineffective communication has been linked to inadvertent patient harm.[27] Nurses must feel empowered to confidently communicate patient concerns. Educational and cultural barriers that preclude nurses from speaking freely are prevalent among developing world countries.[28] Thus, team-based practice through nurse empowerment and effective communication was included as a major key driver for reducing mortality.

Collaborations between programs in countries of the developed and developing world and NGO capacity-building partnerships provide an invaluable opportunity to build sustainable quality-driven cardiac surgery programs worldwide. The IQIC has, with the support and targeted technical assistance of NGO partners to facilitate implementation, fulfilled critical needs in monitoring clinical outcomes and providing benchmarking data, as well as educating developing programs with respect to key determinants of mortality, data collection, data analysis, and quality improvement techniques. The IQIC reports significant, reliable, previously unavailable outcome data from a substantial number of developing world surgical programs. Risk-adjusted mortality and infections were significantly lower in 2011 and 2012, compared to the appropriate reference population, for the collaborative overall and for institutions participating in the IQIC during consecutive years. Thus, in a mere 3 years, the IQIC appears to have successfully reduced both infections and mortality after congenital heart surgery among participating sites. Despite some limitations in our formal analysis, such as lack of standardized definitions for several infection variables, missing data, and, importantly, lack of a nonparticipating comparison group, audited results suggest substantial statistically significant improvements, and the focus and time frame are highly suggestive of success due to quality improvement efforts by teams through IQIC learning and NGO-supported implementation. These successes may be replicable in other medical conditions, thereby allowing rapid translation of knowledge and practice throughout developing world settings to reduce global health care disparities.

This collaborative effort also has yielded critical data on congenital heart surgery in low-resource environments, with audited results from more than 15 000 cases. Although data are pooled from sites self-identified as operating in low-resource settings without other inclusion criteria, this is nevertheless a rich source of useful, previously unavailable information. The data collected will allow further research regarding the outcomes of and risk factors for various types of congenital heart disease in these settings, as well as the development of improved risk adjustment methods, if required. Similarly, it will be possible to address important questions regarding the success of quality improvement activities in various low-resource settings, such as children's versus nonchildren's hospitals, free-standing heart centers versus full-service hospitals, sites differing in annual clinical volume, and sites supported by NGOs in different ways, as well as to gain an understanding of specific processes that led to improvement. Efforts are currently under way to increase this critical body of information, which should further enhance the rapid spread of access to successful congenital heart surgery.

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