International quality improvement initiatives

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Abstract Across the globe, the implementation of quality improvement science and collaborative learning has positively affected the care and outcomes for children born with CHD. These efforts have advanced the collective expertise and performance of inter-professional healthcare teams. In this review, we highlight selected quality improvement initiatives and strategies impacting the field of cardiovascular care and describe implications for future practice and research. The continued leveraging of technology, commitment to data transparency, focus on team-based practice, and recognition of cultural norms and preferences ensure the success of sustainable models of global collaboration.

Keywords: Congenital heart disease; quality improvement sciences; global collaborative learning; inter-professional; cardiovascular care

Received: 15 September 2017; Accepted: 15 September 2017

We have made much progress in improving care, quality, and outcomes for children with cardiovascular disease across the world. Over the past decade, global health strategies have been initiated, including the following:

- Development of global clinical databases to facilitate data collection.
- Development of risk-adjustment to support outcome assessment.
• Identification of quality metrics to benchmark individual centre performance.
• A commitment to using improvement science methodologies.

These efforts have advanced the collective expertise and performance of inter-professional healthcare teams caring for children with cardiovascular disease worldwide. In this section, we highlight selected quality improvement initiatives and strategies affecting the field of cardiovascular care and describe implications for future practice and research.

International Quality Improvement Collaborative for Congenital Heart Surgery in Developing World Countries (IQIC)

During the 2007 Global Forum on Humanitarian Medicine in Cardiology and Cardiac Surgery in Geneva, Switzerland, clinical leaders discussed the global burden of CHD and the need for benchmarking outcome data in evolving world congenital heart surgery programmes. Representatives from Boston Children’s Hospital and non-governmental organisations joined forces to form a quality improvement collaborative focused on evaluating performance and driving improvement efforts for the care of CHD in resource-limited settings. The IQIC seeks to reduce mortality and major complications for children with CHD undergoing surgery or catheterisations. Led by an international steering committee and managed at Boston Children’s Hospital, the IQIC facilitates and empowers a collaborative of healthcare teams around the world to create a culture of patient safety and quality.

Since its inception in 2008, IQIC has grown from five to 58 sites in 24 countries. IQIC began with the establishment of a web-based congenital heart surgical database. De-identified data are entered for all surgical patients under 18 years of age, focusing on nutritional status, prematurity, age, surgical procedure, co-morbidities, and outcomes such as mortality and infections. Annual visits are conducted by Boston Children’s Hospital, non-governmental organisations partners, or virtually, to audit 10% of key data elements to ensure validity and review the IQIC goals. In 2016, 93% of sites passed data verification and were included in the annual benchmarking report. These reports are an opportunity for teams to determine their individual progress in improving outcomes and to benchmark centre performance in resource-limited settings.

The IQIC database has over 62,000 cases and uses the risk adjustment for congenital heart disease (RACHS-1) methodology to examine centre performance across participating sites. In 2015, among 10,728 cases, 5.5% were operated on ≤30 days of age, 39.8% were operated on 31 days to <1 year, and 52.6% 1–17 years. In all, 5.8% were premature and 2.8% had major non-cardiac structural anomalies. Cases were categorised as RACHS-1: 15.7% Category 1, 48.9% Category 2, 24.4% Category 3, 6.7% Category 4, and 0.7% Categories 5–6. The overall in-hospital mortality rate was 4.9%, bacterial sepsis rate was 3.5%, and surgical site infection rate was 1.7%. Overall, risk-adjusted mortality and risk-adjusted infections decreased over time.

In 2010, a quality improvement effort to further reduce mortality and morbidities was instituted. Key drivers included safe perioperative practices, reduction of surgical site infections and bacterial sepsis, team-based practice, and nursing empowerment and education (Fig 1). Monthly webinars were facilitated

Figure 1.
International Quality Improvement Collaborative for Congenital Heart Surgery in Developing World Countries Key Driver Diagram.
by Boston Children’s Hospital highlighting the IQIC
key drivers. These presentations have been translated
into multiple languages and restructured to fit the
needs of sites. The IQIC has also held a series of
international learning sessions throughout 2013–
2017. These inter-professional meetings are designed
to enhance learning and sharing of each other’s work.

In 2017, the IQIC added a new key driver of
nutritional management. Also new is the develop-
ment of a catheterisation registry to examine out-
comes for interventional procedures, and quality
improvement activities related to interventional
catheterisation and intraoperative perfusion. Data
collection focused on the resources needed to perform
cardiac surgery in low-resource settings is underway.
The IQIC collaborative is free to join and may be
contacted at internationalqi@childrens.harvard.edu.

United States quality improvement
collaboratives in cardiac critical care

Quality improvement collaboratives in the United
States represent one of the most effective approaches
for improving patient outcomes. The Northern New
England Cardiovascular Disease Study Group3 and
the Michigan Blue Cross/Blue Shield collaboratives1
have both demonstrated reduced surgical morbidity
and mortality among adult patients. The core prin-
ciples of collaborative quality improvement illu-
strated by these successful programmes include the
following:

- Purposeful collection of granular clinical data.
- Timely feedback of clinician performance.
- Continuous quality improvement using empirical
data and collaborative learning.

Increasingly, transparency between hospitals has
proven to be a very effective method for promoting
quality improvement efforts.5,6 Collaborative learning
approaches in congenital cardiac care have used
these principles focusing on perioperative and
critical care. The National Pediatric Cardiology
Quality Improvement Collaborative has demon-
strated improved weight gain and lower mortality
during the inter-stage period for children undergoing
stage 1 palliation for hypoplastic left heart syndrome
and related diagnoses.7,8 Mahle et al from the NHLBI
Pediatric Heart Network used a collaborative learning
intervention to reduce the length of mechanical
ventilation after repair of tetralogy of Fallot and
coracation in infants.9,10

The Consortium of Congenital Cardiac Care Mea-
asurement of Nursing Practice (C4-MNP) is a nurse-led
collaborative committed to developing and evaluating
paediatric cardiovascular nurse-sensitive quality indica-
tors to improve and standardise nursing practices.11,12
Established in 2011, the consortium is a national
community of nurse leaders, clinical experts, and
nurse scientists committed to rigorous measurement
of nursing care to achieve optimal outcomes for
children with cardiac disease.11 The C4-MNP has
developed evidenced-based nurse-sensitive measures
to use for assessment and improvement in nursing
practice across the 31 collaborative paediatric cardi-
avascular programmes.11–13

The Pediatric Cardiac Critical Care Consortium
(PC4; pc4quality.org) is a quality collaborative dedi-
cated to improving care and outcomes for children
and adults with critical congenital cardiovascular
disease.14 Started in 2009 with funding from the
National Institutes of Health, PC4 began with the
launch of its clinical database. The effort has
increased from six hospitals in 2013 to 28 hospitals
submitting data across North America. PC4 aims to
expand its membership to other continents and to
disseminate its findings widely to improve care across
the globe.

The granular PC4 cardiac critical care database
powers a reporting platform displaying real-time
benchmark data on clinical outcomes and resource
utilisation metrics (Fig 2). Data collection for the PC4
clinical registry is harmonised with other clinical
registries including the Society of Thoracic Surgeons
Congenital Heart Surgery Database and the ACC
IMPACT Database. PC4 aims to use a robust, on-site audit
method to ensure data integrity.15

A unique feature of PC4 is its commitment to
transparency: hospitals can identify one another
internally on the reporting platform by viewing
outcome reports that are unblinded. The unblinding
feature allows hospitals to recognise high performers,
thus facilitating conversations between participating
hospitals who desire to improve the quality of their
care through reduction of complications or optimis-
ing cost-effectiveness and efficiencies. This level of
transparency is a condition of participation in PC4.
Teams routinely interact remotely and in-person to
share practices and care protocols; champions from
high-performing centres are given the opportunity to
describe their approach to specific aspects of critical
care in which their hospital is achieving excellent
outcomes. In addition to providing the infrastructure
for ad hoc local quality improvement efforts, PC4 has
generated data suggesting opportunities for more far-
reaching, multi-institutional collaborative learning
projects. A collaborative-wide cardiac arrest prevention
intervention is being implemented based on data
showing wide variation in rates of cardiac arrest across
PC4 cardiac ICUs.

In addition to providing a quality improvement
infrastructure, PC4 maintains an active scientific
portfolio. PC4 has primarily focused on two main
domains of research: developing risk-adjustment methods to generate quality metrics for cardiac ICUs and surgical programmes, and describing variation in outcomes across cardiac ICUs. As an example, PC4 investigators performed an analysis to create a risk-adjustment model specifically designed to assess the quality of cardiac ICU post-operative care. This model, which is complementary to existing surgical risk-adjustment methods, incorporates postoperative illness-severity variables at the time of postoperative admission to the cardiac ICU in order to more accurately describe population risk at the time of transfer of care to the critical care team. Other early PC4 work has described variation in extubation failure rates across hospitals,16 the epidemiology and centre variation in chylothorax rates,17 and the development of novel case mix-adjusted duration of postoperative mechanical ventilation metrics.18

These successful examples illustrate that the core concepts presented above can lead to important improvements in the care of critically ill children and adults with congenital cardiovascular disease: these collaborations collected detailed data on practice and outcomes, identified the highest-performing hospitals in their collaborative, disseminated this information back to participants, and identified the practices at high-performing hospitals that could be implemented at lower-performing hospitals to improve outcomes.

The World Database for Pediatric and Congenital Heart Surgery

“A Tool for Global Quality Improvement in Congenital Heart Surgery”

To satisfy its mission to “promote the highest quality of comprehensive cardiac care to all patients with congenital heart disease”, members of the World Society for Pediatric and Congenital Heart Surgery (WSPCHS) strategised, developed, and have now implemented a global database. The WSPCHS database is supported by the James and John E. Kirklin Institute for Research in Surgical Outcomes and is currently housed at the University of Alabama, Birmingham. The World Database for Pediatric and Congenital Heart Surgery (WDPCHS) went live on January 1, 2017, following identification of the appropriate variables to collect, creating a design for implementation on a global scale regardless of socio-economic status, and engaging in strategies to encourage international participation.19

The World Database was developed to produce meaningful performance and quality analyses of surgical outcomes capturing important morbidities and mortalities for up to 1 year postoperatively. By using standardised terms and definitions developed and adjudicated by several national and international expert organisations, the database contains a global understanding, communication, and assessment of...
Table 1. World Database for Pediatric and Congenital Heart Surgery.

<table>
<thead>
<tr>
<th>Data collection forms</th>
<th>Institutional practice form</th>
<th>Demographic form</th>
<th>Surgery form</th>
<th>Postoperative events form</th>
<th>Annual follow-up form</th>
<th>Death form</th>
</tr>
</thead>
</table>

congenital cardiac practices. To provide individual centres adequately detailed outcomes analyses while remaining cognizant of limited financial and personnel resources, the variables believed to provide the greatest opportunities to evaluate programmatic deficiencies and to effect necessary improvements in preoperative selection, intraoperative performance, and postoperative management were selected. Institutions will be able to confidentially compare their centre-specific data with regional, national, and international aggregate data. Table 1 illustrates the organisation and types of information that is being collected by the database. Institutional Practice data are collected in sufficient detail to allow for the creation of an international registry of congenital cardiac centres. Such information collected includes annual centre case volumes, the number of congenital cardiac surgeons, geographic region served, population served, the number of other institutions within its geographic region, and a description of the services provided. This information will allow not only for the ongoing assessment of congenital cardiac care on a global basis but will provide critical data to justify allocation of needed resources within specific regions. The surgery form requires the input of only 19 variables. These variables, including prior cardiac operations, preoperative risk factors, weight, cardiovascular bypass times, and intraoperative complications, were chosen by international experts in the field of congenital cardiac surgery and felt to reliably represent the operative conduct of a surgical programme. The collection of follow-up information on readmission, morbidity, and mortality for up to 1 year postoperatively is a distinguishing feature that separates this database from others.

Data quality is critical, but collection of too many data may lead to the dilution of efficient analysis, increased expenditure of valuable resources, and loss of enthusiasm from participating members. For these reasons, surgical procedures are assigned to one of two categories within the database. This two-tiered system was created to allow for both the input of detailed data for a pre-selected group of surgical procedures and collection of a limited number of variables for all congenital cardiac procedures. Using the international prevalence and importance of specific CHD, a limited list of surgical procedures with the greatest power to ensure successful quality improvement initiatives were selected (Table 2). The information on surgical procedures includes data related to preoperative selection and intraoperative conduct. It further gathers follow-up information covering important morbidities, readmission for intervention related to the index surgical procedure, and mortality for up to 1 year postoperatively.

To facilitate participation in this database, the WSPCHS has provided this global quality improvement programme to all institutions that have an active congenital cardiac surgical programme free of charge. WSPCHS members from programmes that lack sufficient resources and facilities to undertake sophisticated outcomes analyses or whose country does not presently have a national database will be able to benchmark outcomes by comparing their analyses with national and international aggregate data. Participants will be blinded to individual programme outcomes other than their own. For members of the WSPCHS who are fortunate enough to possess the financial resources and manpower to use one of several national or intercontinental congenital databases — e.g., The European Congenital Heart Surgeons Association database, The Society of Thoracic Surgeons Congenital database, and the Japanese Society Congenital database — participation in the WDPCHS will provide critical benchmarking information and intellectual support on a global basis. To encourage participation of centres that already submit to these national databases, the WDPCHS has developed cross-maps that will allow for the input of files they currently submit. This will prevent the depletion of precious resources and duplication of effort, while supporting the mission of this society.

By establishing the World Database, the World Society believes it is taking an important step in the global improvement of care for children with CHD. In the longer term, it is anticipated that the greater
numbers in a global database will allow for more accurate risk adjustment than is possible in national databases.

Fast-tracking pathways

Fast-tracking is a process in which patients are moved through the perioperative period in the most expeditious manner, balancing resource utilisation with patient safety and comfort.20 Time to extubation is one of the key components of this goal. Early extubation, very early extubation, and ultra-fast extubation have become common in both lower- and higher-resource environments. There is no consistent definition for these or similar terms – they may refer to patients whose endotracheal tube is removed at the conclusion of surgery, whereas other references include patients extubated up to 24 hours after arrival in the ICUs.22–25

Implementing these processes is multi-disciplinary, beginning preoperatively with patient selection, continuing with intraoperative events and anaesthetic decisions, and then into the ICU. For this to work effectively, all stakeholders need to understand and participate, including physicians, nurses, respiratory support, and other staff members.

The primary driver for fast-tracking is resource utilisation.20 In a low-resource environment, ventilators and other supplies may be limited; bringing a patient out of the operating room without the need for a ventilator may increase ICU throughput and decrease potential hazards associated with limited equipment. In countries without these constraints, fast-tracking protocols have the benefit of increasing patient safety and comfort, as well as the decreased equipment and personnel costs associated with ventilator management, medication expenses, and complications associated with prolonged mechanical ventilation. Fast-tracking also allows more rapid patient mobilisation, neurologic assessment, and patient-centred analgesia by facilitating patient communication and assessment.

Early extubation of paediatric cardiac surgical patients is not a new phenomenon. In its infancy, paediatric cardiac surgery was typically associated with intraoperative extubation because postoperative ventilators for children were unavailable.27 Its utility significantly waned with the development of better ventilators for children and publications that associated high-dose narcotic techniques and postoperative mechanical ventilation with improved cardiac surgical outcomes.28 However, successful reports from practitioners working in low resource countries on mission trips reinvigorated the concept.29

There are a variety of mechanisms to achieve the goal of early extubation, but all rely on limited intraoperative narcotic usage and adjunctive short-acting sedatives such as dexmedetomidine or propofol along with inhaled anaesthetics. Some physicians have advocated for long-acting neuraxial opioids to limit intravenous narcotic needs to facilitate early extubation.23,30 The specific techniques themselves are of less importance than adherence to a well-designed process and clear communication.

A recent systematic review and meta-analysis on early extubation in paediatric cardiac surgery by Alghamdi et al highlighted wide variation and poor statistical quality of the studies.31 A prospective randomised study on early extubation in paediatric cardiac patients included 100 consecutive patients ranging from infants to adolescents, whereas Neirotti et al described early extubation in over 1000 patients in a retrospective review and Garg et al described extubation in the operating room prospectively in 1000 patients.30,32,33 Despite certain limitations, all demonstrated that early extubation is achievable and feasible in neonatal patients undergoing complex cardiac repairs, albeit not at as high a rate as achieved in older patients.34

As shown in Tables 3 and 4, the risks of early extubation for congenital heart surgery patients can

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved pain control/patient comfort</td>
<td>Unprotected airway</td>
</tr>
<tr>
<td>Shorter intensive care unit stay</td>
<td>Loss of control of FiO₂/pCO₂**</td>
</tr>
<tr>
<td>Theoretically fewer infections/ventilator-associated pneumonia</td>
<td>Potential respiratory arrest</td>
</tr>
<tr>
<td>Lessened personnel requirements</td>
<td>Loss of positive end expiratory pressure in case of bleeding</td>
</tr>
<tr>
<td>Decreased risk of ventilator disconnection</td>
<td>Vomiting/aspiration risks</td>
</tr>
<tr>
<td>Decreased sedation medications</td>
<td>Potential for less pain control owing to narcotic fear</td>
</tr>
<tr>
<td>Decreased ventilator utilisation</td>
<td>Increased atelectasis</td>
</tr>
<tr>
<td>Early neurologic evaluation</td>
<td></td>
</tr>
<tr>
<td>Earlier enteral feeding</td>
<td></td>
</tr>
<tr>
<td>Early ambulation</td>
<td></td>
</tr>
</tbody>
</table>

*Fraction of inspired oxygen
**Partial pressure of carbon dioxide

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Table 3. Benefits and concerns associated with early extubation and fast-tracking.
Table 4. Relative contraindications for early extubation.

<table>
<thead>
<tr>
<th>Preoperative</th>
<th>Postoperative (if not extubated in operating room)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airway abnormalities</td>
<td>Ongoing cardio-respiratory issues (arhythmias, bleeding, residual lesions, hypoxia)</td>
</tr>
<tr>
<td>Preoperative mechanical ventilation</td>
<td>Unexpected neurologic issues (seizures, failure to wake appropriately)</td>
</tr>
<tr>
<td>Neuro-muscular diseases</td>
<td>Inadequate muscle tone/weakness</td>
</tr>
<tr>
<td>Genetic syndromes*</td>
<td>Excess sedation</td>
</tr>
<tr>
<td>Pulmonary hypertension (PH)**</td>
<td>Unavailability of personnel to reintubate if needed</td>
</tr>
<tr>
<td>Age and surgical plan***</td>
<td>Postoperative (if not extubated in operating room)</td>
</tr>
<tr>
<td>Intraoperative</td>
<td>Ongoing cardio-respiratory issues (arhythmias, bleeding, residual lesions, hypoxia)</td>
</tr>
<tr>
<td>Bleeding concerns (surgical or haemostatic)</td>
<td>Unavailability of personnel to reintubate if needed</td>
</tr>
<tr>
<td>Haemodynamic instability or compromise</td>
<td>Postoperative (if not extubated in operating room)</td>
</tr>
<tr>
<td>Pulmonary haemorrhage or oedema</td>
<td>Ongoing cardio-respiratory issues (arhythmias, bleeding, residual lesions, hypoxia)</td>
</tr>
<tr>
<td>Significant metabolic/respiratory disorders</td>
<td>Unavailability of personnel to reintubate if needed</td>
</tr>
<tr>
<td>Inadequate muscle tone/weakness</td>
<td>Postoperative (if not extubated in operating room)</td>
</tr>
<tr>
<td>Excess sedation</td>
<td>Ongoing cardio-respiratory issues (arhythmias, bleeding, residual lesions, hypoxia)</td>
</tr>
<tr>
<td>Unexpected neurologic issues (seizures, failure to wake appropriately)</td>
<td>Unavailability of personnel to reintubate if needed</td>
</tr>
</tbody>
</table>

*Trisomy 21 is commonly encountered and is not a direct contraindication, depending upon airway evaluation and ease of intubation

**PH is a relative contraindication. It is commonly found in developing countries in older patients with large shunts. Surgery may be the only therapeutic option and removing the endotracheal tube relieves a significant PH crisis stimulus

***Although neonates may be placed on a fast-track protocol, they have a significantly higher incidence of reintubation as do patients who have longer bypass times or higher Society of Thoracic Surgeons – European Association for Cardio-Thoracic Surgery Congenital Heart Surgery Mortality Categories (STAT)/Risk Adjustment for Congenital Heart Surgery (RACHS-1) surgeries

be mitigated by proper patient selection, appropriate analgesia, meticulous surgery with intraoperative assessment for significant residual lesions and haemostasis, well-conducted cardiopulmonary bypass, and strict monitoring in the postoperative ICU

Fast-tracking involves the entire care process beyond extubation and includes clinical pathways, starting from pre-anaesthetic assessment, preparation, admission through surgery, to admission into the ICU, that facilitate other related end points such as chest tube and line removal or transfer to non-ICU wards and discharge. Other items that may affect hospital stays include the availability of transportation home, outpatient pharmacy needs, and cardiology clinic follow-up.35

Fast-tracking is a paradigm shift to improve the quality of care while decreasing resource utilisation. Its development and implementation may strengthen clinical and non-clinical teams by improving communication.

Conclusions

The collaborative learning of inter-professional healthcare teams, implementation of quality initiatives, and rigorous evaluation has improved the global outcomes for congenital heart patients. As these and other efforts continue to evolve, there will be much opportunity to advance the practice and science of paediatric cardiovascular care. The continued leveraging of technology, commitment to data transparency, focus on team-based practice, and recognition of cultural norms and preferences ensure the success of sustainable models of global collaboration.

Acknowledgements

None.

Financial Support

This research received no specific grant from any funding agency, commercial, or not-for-profit sectors.

Conflicts of Interest

None.

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