Procedural Quality Best Practices for the Pediatric Cath Lab

Pediatric
SCAI-Quality Improvement Toolkit

Working on QUALITY, One Cath Lab at a Time

Procedural Quality

Procedural Quality Best Practices for the Pediatric Cath Lab

SCAI
November 5, 2014
Procedural Quality Best Practices for the Pediatric Cath Lab

This module includes the following:

- Background information
- Goals of an ‘ideal’ procedural quality program
- Stepwise proposal to establish and run a Pediatric Cardiac Catheterization Lab Procedural Quality Program
- Samples & Examples
- Bibliography

Goals of a Procedural Quality Program

The goals of a procedural quality program are to assess the status of procedural quality and to bring it to par with accepted standards of practice through a structured, efficient and just process. Secondarily, the procedural quality program may participate in establishing risk adjustment models & benchmarks.
Steps of a Procedural Quality Program

STEP 1: Review SCAI position paper on cath lab quality
STEP 2: Assemble Cath Lab Quality Improvement Committee
STEP 3: Establish metrics & define outcome goals for your Lab
STEP 4: Identify & capture data
STEP 5: Analysis of adverse event (AAE)
STEP 6: Audit
STEP 7: Analysis of data: risk adjustment & benchmark comparison
STEP 8: Identify deficiencies of procedural quality & outcomes
STEP 9: Corrective Actions
STEP 10: Identify-Plan-Do-Check-Follow up Cycle

Recommended Committee Members

- **Chairperson:** Cardiologist
- **Members:**
  - Interventional cardiologists
  - Cardiologists
  - Pediatric cardiac anesthesiologist
  - Cath lab technologist
  - Cath lab and recovery area nursing staff
  - Cath lab administrator
  - Representative from hospital QI/risk management
  - Radiation Safety Officer
Procedural Quality Best Practices for the Pediatric Cath Lab

Committee Responsibilities

- Identify metrics of procedural quality and outcome
- Maintain an institutional data base
- Maintain a calendar of scheduled meetings (ref. Pediatric QIT Conferences module)
- Conduct review of adverse events
- Perform scheduled audits
- Generate quarterly reports on outcomes

Committee Responsibilities (continued)

- Review existing benchmarks and compare
- Identify deficiencies of procedural quality and outcomes
- Communicate with institutional bodies (risk management/medical staff officer)
- Develop a remediation plan in collaboration with risk management
- Implement & follow up on remediation plan (plan – do – check – act cycle)
**STEP 3: Metrics & Outcomes Definitions**

*Patient metrics* are patient characteristics that impact outcomes; These are addressed under risk adjustment

*Process metrics* are organizational parameters (infrastructure, facility, procedural process, team dynamics) that impact outcomes

*Performance metrics* are operator & staff parameters (competencies, skills, decision making, training, support/mentorship, opportunities for upkeep of skills & experience) that impact outcomes

Outcomes reflect the total impact of organizational, patient & performance factors

---

**STEP 3: Patient Metrics**

- **Patient characteristics**: age, disease severity (hemodynamic vulnerability), associated medical conditions pose a risk for adverse events. Sicker patients have poorer outcomes overall (4)

- **Procedure types**: complexity & invasiveness of a procedure impact outcomes; more invasive & complex procedures have a higher risk of adverse event. Classification of cases based on procedure type allows equitable comparison of outcomes (4).
Organizational parameters that impact procedural quality and outcomes:

- Facility and infrastructure
- Procedural process
- Team dynamic

Each parameter should receive inspection to assess impact on procedural quality and undergo revisions directed at improving procedural quality.

Physician & staff performance impact outcomes. Optimal performance depends on:

- Training
- Competencies
- Skill sets
- Experience
- Expertise
STEP 3: Outcome Metrics

Outcomes result from the sum impact of organizational, patient & performance factors. Examples of outcome metrics are:

- Accomplishment of procedure objectives
- Incidence of adverse events
- Radiation exposure data (ref. Pediatric QIT Radiation Safety module)
- Contrast volume data
- Incidence of redo procedures
- Risk avoidance at the expense of forfeiting objectives

Undefined: what risks are to be considered acceptable to achieve best outcomes ???

STEP 4: Data identification & Capture

- Maintain an institutional database/registry (Example of a data base)
- Dedicated personnel for data collection and data entry (e.g. nurses, nurse practitioners)
- Auto-population of database from in-lab monitoring system
- Ensure adverse event entry to database is derived through M & M conference process
STEP 5: Analysis of Adverse Event (AAE)

- Analysis is best conducted as a team
- Practitioner participation essential to the process
- Review of all pertaining data (e.g. cines, medical records)
- Practitioner & staff perspectives obtained

(continued)

- Was the adverse event directly or indirectly due to suboptimal care?
- Was the adverse event directly or indirectly related to the procedure?
- Is the adverse event a known risk of the procedure?
- Were there patient factors that contributed to the occurrence of the adverse event?
- Is this an opportunity for improvement of process, facility and/or performance?
Example of adverse event reporting form
Step 6: Audit

- Regularly scheduled methodical examination of case records for verification of best practice and protocol
- Audit identifies lapses in protocol or best practice which are otherwise not evident

Step 7: Data Analysis

- Risk adjustment
- Graph outcome data
- Quarterly reports
- Establish trends
- Identify and flag problem areas (e.g. adverse event rate >90th percentile)
- Compare to benchmarks
- Compare to peer hospitals
Risk Adjustment

- Risk adjustment (4, 7) is a tool that examines the impact of intrinsic patient characteristics and procedure complexity on the outcome.

- Risk adjusted benchmarks permit equitable comparison of outcomes.

- Outcomes & adverse event rate are expected to be used for compensation and accreditation in the future.

- Risk adjustment is necessary to avoid penalizing centers performing high risk cases and high risk procedures.

Risk adjustment example (7)

Impact of left ventricular function (left) and age (right) on outcome of aortic balloon valvuloplasty.
Risk adjustment has been applied in coronary interventions (Cath PCI Registry) and pediatric cardiac surgery (RACHS-1 & Aristotle system) \(^{(8-11)}\).

Pediatric cardiac catheterization data registries exist with sizable data; risk adjustment models expected in the future.

A preliminary model (CHARM) for risk adjustment in congenital cardiac catheterization has been proposed in 2011 \(^{(4)}\).

Risk adjustment may be compromised due to the following: \(^{(4)}\):

- Lack of reliable and consistent event reporting
- Differential reporting between practitioners and centers
- Compromise of procedure efficacy in pursuit of safety
- Risk averse operator behavior
Procedural Quality Best Practices for the Pediatric Cath Lab

Risk adjustment model must allow cross communication between centers for comparison and benchmarking

- Easily understandable, commonly used terminology
- Stringently collected data in a standardized manner
- Data audited for flaws
- Ideal risk adjustment model should be applicable to all catheterization labs

Benchmarks

- A benchmark is a widely accepted standard by which outcomes can be gauged & judged
- External benchmarks allow comparison of outcomes between peer institutions
Procedural Quality Best Practices for the Pediatric Cath Lab

Questions to be asked regarding ‘Benchmarks’

• Are there benchmarks that are widely accepted & endorsed by professional organizations?
• Is the benchmarked patient population comparable to individual institution’s patient population for patient & procedure type, institutional volume and experience?
• Is the benchmarked patient population risk adjusted?

Status of Benchmarking

Pediatric/Congenital Catheterization QI Registries (12, 13) with intent to collect data for benchmarking:

• IMPACT (12) https://www.ncdr.com/webncdr/impact/
• CCISC http://www.ccisc.net/
• C3PO-QI
Procedural Quality Best Practices for the Pediatric Cath Lab

**IMPACT Registry**

- Improving Pediatric and Adult Congenital Treatment
- Sponsors: NCDR and ACC
- Established: 2010
- Voluntary Data Registry for Pediatric and Adult Congenital Catheterizations
- Collecting Limited Data set on all catheterizations performed
- Goal is to develop quality metrics to be shared with participating sites and catheterization community

**CCISC Data Registry**

- Sponsor: CCISC; Established: 2010
- Congenital Cardiovascular Interventional Study Consortium
- Voluntary Data Registry for Pediatric and Adult Congenital Catheterizations
- Collecting Limited Data set on all catheterizations performed
- Have developed a reporting tool and report risk adjusted complication rates to participating centers and physicians
- Goal is to develop quality metrics to be shared with participating sites and catheterization community
**C3PO-QI Registry**

**Congenital Cardiac Catheterization Outcome Project – Quality Improvement**
- Sponsor: Children's Hospital of Boston
- Established: 2013
- Voluntary Data Registry for Pediatric and Adult Congenital Catheterizations
  - Collecting limited data set on all catheterizations performed
  - Have developed a reporting tool and report quality metrics to participating centers and physicians
  - Goal is to utilize QI reports to improve performance and quality collectively at participating centers

---

**Example of benchmark report**

**Interpreting Box and Whisker Plots**

- **10th Percentile**: 10% of the hospitals achieved "better" scores than the 10th percentile.
- **25th Percentile or 1st Quartile**: 25% of the hospitals achieved "better" scores than the 25th percentile.
- **50th Percentile or Median**: Middle of the distribution. Half of all hospital's data is above and half are below the median.
- **75th Percentile or 3rd Quartile**: 75% of the hospitals achieved "better" scores than the 75th percentile.
- **90th Percentile**: 90% of the hospitals achieved "better" scores than the 90th percentile.

- **Median**: The middle value in the dataset.
- **My Hospital**: Your hospital's position in relation to all hospital's data.
- **10th Percentile**: This means that 90% of the hospitals scored better than your hospital in this metric.
- **25th Percentile**: Your hospital is better than 75% of the hospitals.
- **50th Percentile**: Your hospital is better than 50% of the hospitals.
- **75th Percentile**: Your hospital is better than 25% of the hospitals.
- **90th Percentile**: Your hospital is better than 10% of the hospitals.
Procedural Success of ASD Device Closure & Comparison to Benchmarked Data

Example of an Outcome Metric:

- Atrial Septal Device Closure (14-17)
- Patent Ductus Arteriosus Occlusion (18,19)
- Coarctation of the Aorta Stenting (20)
- Transcatheter Melody Valve Implantation (21-23)
STEP 8: Identify Deficiencies

Identify deficiencies in procedural quality & outcome through following methods:

- Analysis of adverse event (step 5)
- Audit (step 6)
- Benchmark comparison (step 7)
- Performance evaluation (step 8)

**Ongoing Professional Practice Evaluation (OPPE)**

**Focused Professional Practice Evaluation (FPPE)**

Background: Performance Evaluation

- Optimal outcomes require high quality performance by team members including physicians, nurses, technicians, other allied health staff
- JCAHO & ACGME require institutional policies that describe the process for assessment of individual performance and remediation practices
- Policies for and documentation of individual performance evaluation helps mitigate legal risk
- Performance evaluation processes:
  - Ongoing professional practice evaluation (OPPE)
  - Focused professional practice evaluation (FPPE)
• Routine and periodic assessment of physician & staff competencies
• Conducted by procedural quality committee
• Obtained twice a year
• Information contributes to maintenance of privileges
• Information may trigger FPPE

Focused professional practice evaluation (FPPE) is to be used...
• for new practitioners and for new privileges
• when there are issues or in response to triggers
The following must be clearly defined:
• Criteria for initiation
• Indications for an external performance review
• Guidelines for performance monitoring
Examples (Not in rank order)

- Procedural outcomes that raise questions of competence
- Patients with lengths of stay longer than standard practice
- Patterns of unnecessary diagnostic testing or treatments
- Failure to follow clinical practice guidelines
- Frequent readmission → inadequate initial treatment
- Inadequacies identified during Ongoing Professional Performance Evaluations (OPPE)

FPPE Triggers

Conduct of FPPE

- Quality Committee ensures independent chart abstraction for data
- Confidentiality mandatory per institutional bylaws
- FPPE may include direct observation and a monitoring plan
Principles of FPPE Conduct

Rational Policy

- Clear definition of adverse event (27)
  Definition of adverse event maintained by procedural quality committee in alignment with accepted definitions
- Clear definition of performance issue
- Bilateral clarification of expectations
- Transparency of process

- Just culture focusing on problem solving (human error versus at risk behavior) (28-30)
- Data compared to accepted benchmarks
- Independent adjudication process (e.g. by an external expert)
- Private counseling of serious and/or persistent outliers
- Clear probation & termination policies
Step 9: Corrective Action

- Correction of contributory infrastructure and facility deficiencies
- Correction of team dynamics
- Specific performance issues addressed by
  - education
  - training for skills
  - opportunities to develop experience
  - opportunities to develop expertise

Step 10: Follow Up on Actions

1. Develop Strategy to improve and identify deficiencies
2. Implement Strategy
3. Measure Results
4. Repeat cycle until satisfactory results achieved
Summary of Steps

STEP 1: Review SCAI position paper on cath lab quality
STEP 2: Assemble Cath Lab Quality Improvement Committee
STEP 3: Establish metrics & define outcome goals for your Lab
STEP 4: Identify & capture data
STEP 5: Analysis of adverse event (AAE)
STEP 6: Audit
STEP 7: Analysis of data: risk adjustment & benchmark comparison
STEP 8: Identify deficiencies of procedural quality & outcomes
STEP 9: Corrective Actions
STEP 10: Identify-Plan-Do-Check-Follow up Cycle
Acknowledgements

• Kalyani Trivedi, MD
• Matt Zussman, MD
• Todd Gudausky, MD
• Krista Curell, Esq., RN
  • Contribution: Just Culture (Slide 62)
• Joel Harder, MBA - SCAI Director for Quality Initiatives and Clinical Documents
• Drew Voytal, MPA - SCAI Manager of Clinical Document and Core Curriculum

Bibliography


Bibliography


29. ISMP: Just Culture and it’s critical link to patient safety (Part I) May 17, 2012

Benchmarks: ASD closure


Benchmarks: PDA closure

**Benchmarks: Coarctation Repair**


**Benchmarks: Melody Valve Implantation**

Procedural Quality Best Practices for the Pediatric Cath Lab

Process Parameters

- Case preparation & work up
- Consent
- Family/patient education
- Check list (re: checklist module)
- Case plan discussion with anesthesia and cath lab staff
- Inventory check and preparedness
- Time out practice
- Adequacy and completion of cath reports (24-48 hours post procedure)
- Adequacy of communication to referring physician
- Discharge planning and follow up arrangements
- Follow-up of patients exposed to excess radiation or contrast
- Log of outcomes data (procedural success, minor & major complications)
- Regular scheduled meetings to review outcomes
- Provision of opportunities for upkeep of skills
- System of physician & staff support and mentorship

Database Example
Example of graphed data
Acute complications: stent implantation for aortic coarctation

Complications Prior vs Post Jan 2002

<table>
<thead>
<tr>
<th>Complication Type</th>
<th>Percentage</th>
<th>Prior Jan 2002 (n=301)</th>
<th>Post Jan 2002 (n=264)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Comp</td>
<td>20</td>
<td>p &lt; 0.01</td>
<td>p = NS</td>
</tr>
<tr>
<td>Aortic Wall Comp</td>
<td>15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technical Comp</td>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig. 1. Comparisons of complications, further broken down into aortic wall and technical complications prior to and following January 1, 2002.

Example of a quarterly report

<table>
<thead>
<tr>
<th>Category</th>
<th>Time Period</th>
<th>Cases</th>
<th>Time Period</th>
<th>Cases</th>
<th>Time Period</th>
<th>Cases</th>
<th>Time Period</th>
<th>Cases</th>
<th>Time Period</th>
<th>Cases</th>
<th>Time Period</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death within 24 hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac arrest within 24 hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CVA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac perforation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urogenital perforation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bariatral perforation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac injury</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rate of Expectation</td>
<td>1 Exception to expectation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rate of Non-Expectation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
What is a Just Culture?  

The Just Culture model was adopted in an effort to reconcile the tension between a “no blame” environment and the need to hold staff professionally accountable for their day to day activities. It fosters the creation of an open, fair, and just environment.

“No Blame” Model
- Create a learning environment
- Identify and address systems issues first
- Manage behavioral choices
  - Distinguish between human error and at-risk behavior
  - Maintain a zero tolerance policy for reckless/at-risk behavior
- Accountability based on the type of behavior versus the patient outcome or the severity of the event.
  - Accountable for the quality of your choice, not the outcome
  - There is no severity bias

“Just Culture” Model
- Create a learning environment
- Identify and address systems issues first
- Manage behavioral choices
  - Distinguish between human error and at-risk behavior
  - Maintain a zero tolerance policy for reckless/at-risk behavior
- Accountability based on the type of behavior versus the patient outcome or the severity of the event.
  - Accountable for the quality of your choice, not the outcome
  - There is no severity bias