SCAI Quality Improvement Toolkit

Working on QUALITY, One Cath Lab at a Time
Acknowledgements

The SCAI Quality Improvement Toolkit was developed with support from Daiichi Sankyo and Lilly. The Society gratefully acknowledges this support, while taking sole responsibility for all content developed and disseminated through this effort.
Vision

“We have talked for a number of years about the need for interventionalists to “own” the QI process in the cath lab.

SCAI QIT offers a unique opportunity for SCAI members to demonstrate their commitment to improving quality of care and to reassure our patients that their expectations of receiving the highest quality of care in the cath lab are being met.

It’s time for you to get involved. It’s time for you to get to work.”

– Christopher J. White, MD, MSCAI
Defining Quality in the Cath Lab
Defining Quality in the Cardiac Cath Lab (CCL)

- **Purpose**
  - To understand the domains that build the framework by which CCL physicians and staff can measure, review, and improve quality to enhance patient care

- **Intended Audience**
  - CCL directors, hospital administrators, interventionalists, nurses, technologists, advanced practice providers, SCAI QIT Champions
3 Domains

Structural Domain

Process Domain

Outcomes Domain
Structural Domain

QA Committee
- Hospital QA Committee 2-3 months
- CCL QA Committee 2-3 months

Credentialing Committee
- Initial Credentialing
- Recurrent Credentialing

Generate and Review Monthly-Quarterly-Annual Reports

Procedural Logs, Outcomes, and CME Requirements

Defining Quality in the Cath Lab
<table>
<thead>
<tr>
<th>Direct Patient Care</th>
<th>Systems Related</th>
<th>Guidelines Related</th>
<th>Cost &amp; Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of angiographic studies (peer review)</td>
<td>Pre-procedure checklists</td>
<td>Procedure indications</td>
<td>Availability and quality of supplies</td>
</tr>
<tr>
<td>Generation and completion of reports</td>
<td>Charting adequacy</td>
<td>Adjunctive medications</td>
<td>Staffing and personnel</td>
</tr>
<tr>
<td>Handling of complications</td>
<td>Response times in emergencies</td>
<td>Radiation and contrast safety</td>
<td>Length of Stay (LOS)</td>
</tr>
<tr>
<td></td>
<td>Ancillary services adequacy</td>
<td>Infection control</td>
<td>Impact on ancillary services</td>
</tr>
</tbody>
</table>
Outcomes Domain

Monitor outcomes

- Risk-adjusted mortality
- Procedure-related LOS, fluoro time
- Complications (30-day)

Data sharing & Reporting

- Aggregated and physician-specific data
- Cath lab statistics
- NCDR; state-mandated reporting

THE PURPOSE MUST BE QUALITY IMPROVEMENT
Resources & Support

- SCAI QI Committee Assistance: 
  Info@scai.org

- SCAI QIT Updates: 
  http://www.scai.org/QIT/default.aspx

- SCAI QIT Tip of the Month:  
  http://www.scai.org/QITTtip/default.aspx
Acknowledgments

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- SCAI QI Committee Chair/Vice-Chair: Sunil V. Rao, MD and Kalon K. Ho, MD
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- SCAI Staff: Joel C. Harder, MBA
Operator and Staff Requirements
Operator and Staff Requirements

- **Purpose**
  - To understand current operator and staff requirements for working in the CCL

- **Intended Audience**
  - CCL directors, hospital administrators, interventionalists, nurses, technologists, advanced practice providers, SCAI QIT Champions
Interventional cardiologists should be ACLS certified

AHA ACLS/BCLS Provider Course Completion is valid for 2 years

Up to 12 hours of CME credits

Includes:

- Computer-based lessons
- Completion of practice skills using a mannequin with a certified instructor
ABIM/AOA Certification in Interventional Cardiology is required for operators who completed fellowship training after 1993.

For ongoing re-certification via ABIM, Cardiovascular Diseases certification is recommended but no longer mandatory for Interventional boards.

Evolving certification boards, such as NBPAS, is also available.

Individuals should attain at least 30 hours of CME every 2 years. States or hospitals may have differing requirements.
Annual PCI caseload goal:
- **50** PCIs is recommended (averaged over two years)*
- **11** Primary PCIs for STEMI*

Institutional Measures of Proficiency
- CCL conferences (review complex cases, discuss new techniques or medication, stimulate dialogue and collaboration among peers)
- Participation in state or national outcomes database

Morbidity and Mortality (M&M) conferences

Peer review conferences of random case selection

*JACC 2013;62(4):357-96
Assuring Quality of CCL Staff

Challenges:

- Lack of expert consensus statements regarding qualifications
- No standardized examination to evaluate proficiency
- Lower volume facilities may face additional challenges with “on the job” training
Minimal Staff Certifications

- ACLS certification should be completed yearly

- All staff should have one of the following:
  - Nursing RN license
  - Radiation Technologist certification
  - Cardiovascular technologist professional training certificate
Cardiovascular Credentialing International

- Offers additional certification for CCL staff
- Similar process to ABIM certification including a standardized exam
- Cardiovascular invasive specialist, nursing or radiation technologist credentials are a prerequisite
- Also requires 2 years of CCL experience
- Recognized by SCAI
Staff Experience

- Nurses should have prior experience in a critical cardiac care unit, surgical unit, intensive care unit or an emergency department

- For all staff, a sufficient period of mentorship should precede independent work assignments
Competency Evaluation

- In house examination of expected knowledge base recommended for RNs and RTs
- A written and skills evaluation are recommended
- Prepared materials available
Skills Assessment Example

<table>
<thead>
<tr>
<th>Can Function Independently</th>
<th>Date</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room start up and rebooting sequence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile Tray set up and prep patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transducer set up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left heart cath assist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS valve case</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prep Arm case</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pericardiocentesis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>V-gram medrad set up and injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perform LV EF digital analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency pacemaker set up / insertion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Defibrillation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vagal Reaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sheath removal / Holding pressure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. What is the standard dilution for nitroglycerine?

2. Which of the following drugs do not need to be adjusted for renal dosing?
   a) Bivalirudin
   b) Heparin
   c) Low Molecular Weight Heparin
   d) Tirofiban

3. A patient is overly sedated and by physician assessment needs reversal of versed. What is the preferred agent and what is the initial dose?
Competency for High-Risk Patient Care

- For CCL performing PCI, additional mentorship may be necessary prior to taking call
- Additional training required for specific high-risk clinical situations:
  - Hemodynamic support devices
  - Patients under hypothermia protocols
  - Carotid interventions
  - Percutaneous valves and structural interventions
- CCL Emergency Preparedness Protocols
  - Drills should be performed at routine intervals in the CCL to practice response to these complications
Competency for High-Risk Patient Care

DRILLS

- Vascular Complications
- Acute Stroke
- Emergency Pacing
- VF/Cardiac Arrest
- Coronary Perforation
- Contrast Reaction
- Tamponade
- Sudden Cardiogenic Shock
Additional References

- ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures
  - JACC 2013;62(4):357-96

- SICP Position Papers and Guidelines
  - http://www.sicp.com/content/positionsissues

- Role and Expectations of the Cath Lab Manager
  - http://www.sicp.com/content/role-expectations-cardiac-catheterization-lab-managers

- Scope of practice statement – gives a comprehensive overview of expected skills and responsibilities for CCL staff
Resources & Support

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Continuous Quality Improvement (CQI)

- CQI should be an essential component of each PCI program\(^1,2\)

- CQI is an iterative method to evaluate operational approaches and remedy deficiencies

- Primary emphasis-
  - Evaluation of program structure, processes, outcomes of care
  - Evaluation of individual operator quality

5 elements of CQI program

1. Identification of quality indicators
2. Systematic data collection using standard definitions
3. Data analysis with benchmarking to determine areas for improvement
4. Development of plan to correct deficiencies
5. Systematic repeat data collection to determine effect of corrective action

CQI Committee

Composition
- Cardiac Cath Lab (CCL) Director
- CCL Administrative Director
- Interventional and Non-Interventional Cardiologists
- CCL administrator/manager and staff

Objectives
- Identification and monitoring of **PCI quality indicators**
- **Performance assessment** (for-cause review, random case review)
- **Serious adverse event review** (Morbidity and Mortality Conference)
Quality Indicators
Performance measures
- Process, structure, efficiency, or outcome measures
- Developed by ACC/AHA task force using defined criteria
- Suitable for public reporting and external comparisons
- Examples reported by NCDR CathPCI registry include risk-adjusted mortality, bleeding and discharge medications post-PCI

Quality metrics
- Support self assessment and quality improvement at the local (provider, hospital, and/or health care system) level
- Examples include completeness of documentation (cath/PCI indication, radiation and contrast) and angiographic quality

Bonow RO et al. ACC/AHA classification of care metrics. JACC. 2008 Dec 9;52(9):2113-7
NCDR
- QI resource developed by ACC in 1997
- Collects and reports data to measure and compare quality of cardiovascular care with help of registries

CathPCI registry
- Assesses characteristics, treatments and outcomes of patients undergoing diagnostic coronary angiography & PCI
- Measures adherence to guidelines, performance standards and appropriate use criteria for coronary revascularization
- SCAI partners with ACC for CathPCI registry

Link to NCDR CathPCI registry
Quality assessment is also important in diagnostic cardiac catheterization cases

Many facilities do not diagnostic cath data to NCDR due to logistic reasons such as case volume and cost of data abstraction

Internal review, self assessment and monitoring trends then becomes key to ensure quality documentation, reduction of access site complications, angiographic quality and tracking percentage of normal studies
Benchmarking

- A benchmark is a standard or point of reference against which things may be compared or assessed.

- Comparison with benchmarks (benchmarking) allows for assessment of performance relative to other institutions.

- Benchmarking must be risk-adjusted for certain outcome measures to account for patient characteristics, complexity and type of procedures.

- NCDR provides quarterly risk-adjusted benchmark reports with performance measures and quality metrics to compare an institution's performance with other institutions and national experience.
Interpretation of NDCR reports

Interpreting Box and Whisker Plots

**Distribution of Hospital Performance**

- **10th Percentile**: If your hospital scores below the 10th percentile, the arrow will be on the left of this number.
- **25th Percentile**: 25% of the hospitals achieved “better” scores than the 25th percentile.
- **50th Percentile**: Middle of the distribution: Half of the hospitals data is above and half are below the median.
- **75th Percentile**: 75% of the hospitals achieved “better” scores than the 75th percentile.
- **90th Percentile**: 90% of the hospitals achieved “better” scores than the 90th percentile.

**Your Hospital Position**

Your ‘Hospital Position’ in relation to all other hospitals’ data.
Executive Summary
CathPCI Registry®
compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q3

Section I: PCI Performance Measures
Endorsed by the National Quality Forum and appropriate for public reporting

<table>
<thead>
<tr>
<th>PCI Performance Measures</th>
<th>10th percentile</th>
<th>90th percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI in-hospital risk adjusted mortality (all patients)</td>
<td>My Hospital</td>
<td>Vol Group R4Q</td>
</tr>
<tr>
<td>1.76</td>
<td>1.40</td>
<td>0.73</td>
</tr>
</tbody>
</table>

Your hospital’s PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1979]
# Executive Summary Metrics

<table>
<thead>
<tr>
<th>Metric Name</th>
<th>My Hospital 2018Q1</th>
<th>US 50th Pctl 2017Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI Performance Measures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - PCI in-hospital risk adjusted mortality (all patients)</td>
<td>3.36</td>
<td>2.03</td>
</tr>
<tr>
<td>38 - Composite: Discharge Medications in Eligible PCI Patients</td>
<td>99.2</td>
<td>96.9</td>
</tr>
<tr>
<td>40 - PCI In-Hospital Risk Standardized Bleeding (all patients)</td>
<td>2.95</td>
<td>2.81</td>
</tr>
<tr>
<td>PCI Process Metrics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 - Proportion of elective PCIs with prior positive stress or imaging study</td>
<td>38.89</td>
<td>66.91</td>
</tr>
<tr>
<td>3 - Median time to immediate PCI for STEMI patients (in minutes)</td>
<td>65</td>
<td>60</td>
</tr>
<tr>
<td>4 - Proportion of STEMI patients receiving immediate PCI w/in 90’</td>
<td>85.71</td>
<td>95.14</td>
</tr>
<tr>
<td>5 - Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.</td>
<td>88</td>
<td>75</td>
</tr>
<tr>
<td>6 - Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)</td>
<td>123</td>
<td>106</td>
</tr>
<tr>
<td>7 - Median fluoro time (in minutes)</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>8 - Proportion of patients with aspirin prescribed at discharge</td>
<td>100.0</td>
<td>99.3</td>
</tr>
<tr>
<td>9 - Proportion of patients with a P2Y12 inhibitor prescribed at discharge</td>
<td>99.8</td>
<td>99.8</td>
</tr>
<tr>
<td>10 - Statins prescribed at discharge</td>
<td>99.4</td>
<td>97.8</td>
</tr>
<tr>
<td>PCI Outcome Metrics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 - Emergency CABG post PCI</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>13 - Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>14 - Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>16 - Proportion of PCI procedures with post procedure stroke</td>
<td>0.10</td>
<td>0.16</td>
</tr>
<tr>
<td>17 - Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.</td>
<td>3.01</td>
<td>2.82</td>
</tr>
<tr>
<td>18 - PCI in-hospital risk adjusted mortality (patients with STEMI)</td>
<td>5.78</td>
<td>7.01</td>
</tr>
<tr>
<td>19 - PCI in-hospital risk adjusted mortality (STEMI patients excluded)</td>
<td>2.54</td>
<td>1.09</td>
</tr>
<tr>
<td>25 - Proportion of PCI procedures with transfusion of whole blood or RBCs</td>
<td>2.32</td>
<td>1.07</td>
</tr>
<tr>
<td>39 - PCI in-hospital risk adjusted acute kidney injury (all patients)</td>
<td>3.23</td>
<td>5.85</td>
</tr>
</tbody>
</table>
PCI Performance Measures

1. PCI in-hospital risk adjusted mortality (all patients)

38. Composite: Discharge Medications in Eligible PCI Patients

40. PCI In-Hospital Risk Standardized Bleeding (all patients)
Outlier values are opportunities to learn. They might represent:

- Actual poor performance
- Unusual cases
- Misinterpretation of physician documentation
- Incomplete data entry

Can improve quality by:

- Shifting the curve by improving performance on every case by a little bit
- Reviewing unusual behavior, e.g., performing elective PCI on intermediate lesion without documented ischemia
- Accurate, complete documentation and physician oversight to help data abstractors
Thresholds for Concern

- Hospital performance below the 25\textsuperscript{th} percentile of event rate for all US hospitals reporting to CathPCI Registry

Example

- Post-PCI Risk Adjusted Mortality (RAM)
  - 50th percentile or median: 1.83%
  - 10th percentile: 3.17%
  - 75th percentile: 1.37%
  - 25th percentile: 2.47%
  - 90th percentile: 1.01%

- Risk adjusted mortality > 2.47% suggests a consistent trend of poor outcome and needs to be immediately addressed

- After interventions are undertaken, look at change in outcome in the next quarter rather than wait for rolling four-quarter report
The CathPCI Registry was recently updated to version 5 (v.5). Data collection for v.5 started in July 2018

Key New Data Elements
- Details about the timing and type of mechanical support devices
- Cumulative air kerma as a patient radiation-exposure parameter
- Surgical turndown and patient refusal for surgery
- Frailty assessment
- Hypothermia details and timing
- Details of out-of-hospital cardiac arrest
- Assessment of fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR) in all scenarios to identify ischemia-producing lesions and to support AUC for PCI

SCAI Tip of the Month on CathPCI v.5
CathPCI v.5 form

www.SCAI.org/QIT
New CathPCI v.5 metrics and measures

- Median time to immediate PCI for STEMI in-house patients (in minutes)
- Proportion of procedures where all three radiation dose measurements were recorded
- Median post-procedure length of stay for PCI patients with uncomplicated STEMI (in days)
- Proportion of STEMI and NSTE/ACS patients with high-dose statin prescribed at discharge
- Proportion of PCI patients referred to Cardiac Rehabilitation at discharge
- Composite: Proportion of PCI patients with death, emergency/salvage CABG (post-PCI), stroke or repeat target segment revascularization (all patients)
New Dashboard Design CathPCI v.5

PCI Performance Measures
38 - Composite: Guideline medications prescribed at discharge

98.4%
My Hospital R4Q Performance

Quality Metrics
4 - PCI within 90 minutes (patients with STEMI)

94.12%
My Hospital R4Q Performance
New v.5 Metrics

41 - Median time to PCI for in-house STEMI

Your hospital does not have metric value for this quarter

42 - Radiation Dose (PCI Procedures with or without DxCath)

97.4%

My Hospital R4Q Performance

10th 25th 50th 75th 90th
0.1 0.2 52.4 97.7 100

US Hospital R4Q Performance Distribution for 2018Q3

44 - Composite: Major adverse events (select PCI patients)

1.9%

My Hospital R4Q Performance

10th 25th 50th 75th 90th
4.4 3.2 2.2 1.2 0

US Hospital R4Q Performance Distribution for 2018Q3
New v.5 Metrics

45 - Cardiac rehabilitation referral

88.1%

My Hospital R4Q Performance

10th 25th 50th 75th 90th
2.6 39.2 80.3 95.9 99.4
US Hospital R4Q Performance Distribution for 2018Q3

46 - Median post-procedure length of stay (patients with uncomplicated STEM)

3 Day

My Hospital R4Q Performance

10th 25th 50th 75th 90th
2.7 2 1.6 1.6 1.5
US Hospital R4Q Performance Distribution for 2018Q3

47 - Radiation Dose (Diagnostic Cath Procedures without PCI)

96.1%

My Hospital R4Q Performance

10th 25th 50th 75th 90th
0 0.1 55.2 98.5 100
US Hospital R4Q Performance Distribution for 2018Q3

www.SCAI.org/QIT
Performance assessment
Why have performance review?

- CCL director ultimately answers for quality…
  - Physicians
  - Nurses
  - Technicians
  - Other allied health staff
- Mechanism for process improvement
- Quality remediation practices, policies, and records are reviewed by accrediting agencies such as The Joint Commission (TJC), ACE, DNV
- Required by ACGME if a fellowship training program
- Robust policies important to prevent legal action
- Adherence to policies should be ensured

...but everyone is responsible for quality
Effective Remediation Begins With Clear Expectations

- Fair and rational quality assessment policies
  - Transparent assessment processes
  - Independent adjudication process if necessary (e.g., review by outside entity)

- Independent/objective benchmarking
  - NCDR™ CathPCI Registry
  - HealthGrades

- Public/aggregate performance reporting

- Private counseling of serious/persistent outliers

- Clear probation and termination policies

- Delivery of quality care should be taken into account for recredentialling providers
Engage all team members in quality goals and expectations

Clear definitions of “complications”
- Definitions maintained by CCL director, aligned with independent sources/references
- NCDR CathPCI Registry, The Joint Commission provide standards

Independent chart abstractors collect information on post-discharge adverse events/readmissions

Clear definitions of “performance issues”

4 Ps essential to peer review process

Protection of Patients, Participants and Process
Ongoing Professional Practice Evaluation (OPPE)

- Ongoing assessment of MD competency and behavior
- Conducted by: CCL Director or Quality Officer
- The Joint Commission requirement
  - Must be frequent i.e. more than once per year
- Examples of criteria for evaluation- procedure outcome, morbidity and mortality data, length of stay, readmission
- Data sources- chart review, direct observation, discussion with peers
- Information used to determine whether to renew, limit, or revoke privileges
- Mechanism for evaluating performance of CCL Director
Performance Issues

Criteria for “performance issue”

- High rates of operator related adverse events identified on random case review that may raise signal of performance issues/ competence
- Patients with lengths of stay longer than other providers
- Patterns of unnecessary testing/treatments
- Failure to follow clinical practice guidelines
- Frequent readmission → inadequate initial treatment
- “Triggers”- sentinel events, infection rates

- The above will trigger a Focused Professional Performance Evaluation (FPPE)

TJC criteria for FPPE
Focused Professional Practice Evaluation (FPPE)

- Required to evaluate competence for all privileges for new applicants and all newly requested privileges for existing practitioners regardless of board certification/experience.

- Also performed when question arises regarding ability to provide safe, high-quality care.

- A corrective action plan is devised on the basis of a FPPE with need for follow-up regarding plan’s efficacy.

FPPE for new privileges
FPPE process design has 4 components:

1) Criteria for conducting an evaluation
2) Method of establishing a monitoring plan specific to the area of concern
3) Method of determining the duration of performance monitoring
4) Circumstances under which monitoring by an external source is required
Random case review

- Written policy detailing review process mandatory
- Cases and reviewers selected randomly by CCL Director or designate
- 5-10% of cases per operator (minimum 10/year)
- Diagnostic and PCI cases included

Following are evaluated-
- Appropriateness based on AUC\(^1\)
- Quality of the angiogram
- Intraprocedural decision making- conformity to guidelines
- Procedural complications- prevention and management
- Contrast and radiation use
- Overall procedural results and areas for improvement
- Procedural documentation\(^2\)

\(^{1}2017\) AUC for SIHD
\(^{2}2014\) structured reporting
Adverse event review
Cath lab M&M

- **Aim**
  - Quality improvement rather than punitive

- **Objective**
  - Open review and assessment of cath lab complications (both in-hospital and within 30 days) following invasive cardiovascular procedures by a formal phase of care (pre-procedure, intra-procedure, post-procedure) analysis to achieve consensus regarding preventability of event
Types of events suitable for M&M

- In-lab death or death within 30 days of procedure
- In-lab cardiac arrest
- Emergency CABG
- Stroke
- Unanticipated PCI (for vessel dissection during cath, stent thrombosis)
- Major vascular complications
- Serious anaphylactoid reaction
- Respiratory depression requiring reversal/intubation
- Medication error, verbal miscommunication, wrong patient/procedure
- Cases with excessive radiation (>5Gy) and excessive contrast/AKI
Suggested format for M&M

- Should occur at least quarterly
- Case MD should ideally be present
- Begins with announcement “M&M are medico-legally confidential. All the data and conclusions of this conference are not to be discussed outside of this conference except as part of a performance improvement project.”
- Case presentation, chronology of hospital course
- In-depth and evidence based hypothesis
  - Identify all major quality concerns
  - Identify major contributing causes of each quality concern
  - Individual (provider) issues
  - Process/ systems issues
- Propose solutions and process improvements
Resources & Support

- SCAI QI Committee Assistance: Info@scai.org
- SCAI QIT Updates: http://www.scai.org/QIT/default.aspx
- SCAI QIT Tip of the Month: http://www.scai.org/QITTtip/default.aspx
Cath Lab Best Practices
2016 Cath Lab Best Practices

Purpose
- SCAI continues to share best practices for pre-, intra-, and post-procedure patient evaluation and management
- This update of the 2012 Expert Consensus Statement includes new 2016 best practices on CCL governance
- 2016 Best Practices are supplemented by tools and checklists to assist providers in implementation

Intended Audience
- CCL directors, hospital administrators, interventionalists, nurses, technologists, advanced practice providers, primary care/referring physician, SCAI QIT Champions
The CCL is a unique environment distinct from operating rooms and therefore should have its own set of best practice guidelines.

The CCL is an area of high throughput and cares for patients with elective, urgent, and emergent presentations.

CCL physicians and staff should be properly trained and equipped to handle increasing patient complexity and emerging technology.
Outline

- Competence, Optimal CCL Team, & Maintenance of Qualifications
- Pre-Procedure
- Intra-Procedure
- Post-Procedure
- CCL Governance
Competence

- Physicians should maintain procedure-specific credentialing and privileging by their institution

- Technologists should obtain RCIS certification

- Nursing staff should ideally have a minimum of 1 year of critical care experience

- A procedure for recertification of privileges is required every 2 years by The Joint Commission (TJC)
  - Ongoing professional practice evaluation (OPPE) annually
  - Focused professional practice evaluation (FPPE) for newly hired operators or established operators requesting new procedures
Competence

- Institutional volume $\geq 200$ PCIs/year
- Operator volume $\geq 50$ PCIs/year (averaged over 2 years)
- Institutional volume $\geq 36$ Primary PCIs/year (STEMI)
- Operator volume $\geq 11$ Primary PCIs/year (STEMI)

*JACC 2013;62(4):357-96*
Competence

- Document and review case numbers, procedural outcomes, and risk-adjusted outcomes at least bi-annually

- Participate in national or regional quality improvement registry (such as NCDR)

- Hold at least quarterly meetings for Angio Review (Procedural Appropriateness), Cath Lab Conference, and M&M Conference
Maintenance of Qualifications

- ABIM/AOA Certification in Interventional Cardiology is required for operators completing training after 1993 and strongly recommended for all operators.

- NBPAS may be an alternative to ABIM/MOC.

- CME should be completed every 2 years.

- SCAI and ACC Membership is strongly encouraged.
Pre-Procedural Best Practices

- A pre-cath H&P should be completed within 30 days for outpatients or 24 hrs for inpatients

- A focused update should be performed by the attending physician within 24 hours prior to the procedure

- Incorporate use of SCAI AUC calculators
  - IPhone, Android, and Web-Based
  - [http://www.scaiaucapp.org/auc](http://www.scaiaucapp.org/auc)

- Utilize risk scores for predicting complications and document methods employed to reduce risk [www.scaipciriskapp.org](http://www.scaipciriskapp.org)
Pre-Procedural Best Practices

- **Informed Consent (IC)**
  - Obtain within 4 weeks (by physician or informed team member)
  - Present in native language and in lay man terms
  - Outline indications, risks, benefits, alternatives, and outcomes of the procedure
  - Discuss when witnessed by 3rd party, preferably a family member
  - Reaffirm on the day of the procedure

- **Sedation, Anesthesia and Analgesia Evaluation**
  - Physicians must be credentialed for conscious sedation
  - ASA and/or Mallampati classification should be established by the physician or designee (although no supportive data in the CCL)
  - NPO for 2 hrs (clear liquids) and 6 hours (solids)
  - Some institutions are not requiring NPO status given lack of supportive evidence\(^1\)

1. Anesthesiology 2011; 114:495–511
Pre-Procedural Best Practices

- **Medications**
  - Initiate antiplatelet therapy prior to the procedure when PCI is possible/likely
  - Review potential issues with long-term DAPT for these patients
  - Discontinue warfarin with goal INR <1.8 on day of procedure (consider radial access, especially for emergent cases)
  - Discontinue novel oral anticoagulants 1-2 days prior to procedure
  - Adjust insulin dosing for NPO status
  - Hold Metformin on day of procedure and restart a minimum of 48 hrs after procedure
Other considerations

- Hydrate patients at risk of CIN with Normal Saline
  - e.g. 1-1.5ml/kg/hr for 3-12 hrs before procedure and 6-24 hrs after

- N-acetyl cysteine is no longer recommended

- Document contrast reactions & pre-medicate for severe reactions
  - e.g. 50mg of oral prednisone 13, 7, and 1 hour prior to the procedure in addition to 50mg of oral diphenhydramine 1 hour before

- Shellfish allergy is not a predictor of contrast reactions and does not require pre-treatment
Labs and Other Studies

- Draw CBC and SMA within 4 weeks of procedure
- PT/INR is not required unless there is warfarin use, severe anemia, or liver disease
- Consider alternative options/cancellation of elective case if INR >1.8 (consider radial access, especially for emergent cases)
- Obtain baseline EKG
- A CXR is not routinely required
- Check B-HCG for women of childbearing age (<2 weeks)
# Pre-Procedural Checklist

## Table 1. Pre-Procedural Check List for Cardiac Catheterization

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>MRN:</th>
<th>Procedure Date:</th>
</tr>
</thead>
</table>

### Planned Procedure:
(circle all that apply)
- Diagnostic Cardiac Catheterization (L, R, simultaneous)
- Coronary Angiography
- Left Ventriculography
- Intravascular Imaging/Hemodynamic Assessment (IVUS, OCT, FFR)
- Possible PCI
- Planned PCI
- Other

### History and Physical Examination:

<table>
<thead>
<tr>
<th>Elective Outpatient Procedures: H&amp;P documented within 30 days?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Inpatient Procedures: H&amp;P documented within 24 hours of admission?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>History of prior PCI or CABG: If yes, report's obtained?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Stress test/ LVFS assessment: If yes, report's obtained?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### Candidacy for Drug Eluting Stent:

1. Major surgery in the past month or next year? Yes No
2. Is there any clinically overt or suspected bleeding? Yes No
3. Is patient on chronic anticoagulation (e.g., warfarin, TSOAC)? Yes No
4. Is there history of anticipated medication non-adherence? Yes No

### Allergies:

1. Contrast: Yes No If yes, was the patient pre-treated? Yes No
2. Aspirin: Yes No If yes, was the patient desensitized? Yes No
3. Heparin (HIT): Yes No If yes, consider alternative anti-thrombotic agents (DTI)
4. Latex: Yes No If yes, remove all latex products from procedural use

### Medications:

1. Did patient take aspirin within the past 24 hours? Yes No
2. Did patient take clopidogrel, prasugrel, or ticagrelor within the past 24 hours? Yes No
3. Did patient take metformin within the past 24 hours? Yes No
4. Did patient take amlodipine or other CCB? Yes No
5. Did patient receive LMWH within the past 12 hours? If yes, for LMWH, time of last dose
6. Did patient take anticoagulants and when was last dose?

### Informed Consent:

- Was informed consent obtained within 30 days? Yes No
- Is there a healthcare proxy? Yes No
- Is the patient DNR or DNOL? Yes No
- If yes, was it revoked for procedure? Yes No

### Sedation, Anesthesia, and Analgesia:

- Are ASA and Mallampati Class documented? Yes No
- Is there any contraindication to sedation present? Yes No

### Risk scores applied:

- Bleeding
- CIN
- Mortality

### Laboratories and Studies:

- CBC and renal profile within 30 days (prescription) or 24 hours (inpatient)
- Hgb ____________ GFR ____________
- Was ECG performed within 24 hours? Yes No
- PT/INR performed within 24 hours (for patients on warfarin)? Yes No
- INR ≤ 1.8? Yes No
- Urine/serum human chorionic gonadotropin (HCG) in woman of childbearing age? Yes No
- Does the patient require pre-procedure hydration? Yes No
- Preferred vascular access: R L TR TF
- Same Day Discharge candidate? Yes No
Patient Preparation in Procedure Room
- Review medical record and checklist
- Briefly re-confirm procedure and consent with patient

Sedation, Anesthesia and Documentation
- Consider conscious sedation for all patients (especially transradial procedures)
- Monitor for side effects and log doses of administered agents
- Keep reversal agents readily accessible
Intra-Procedure Best Practices

- **Universal Protocol and “Time Out”**
  - Routine site marking is not necessary in the CCL
  - Label table solutions in real-time (do not pre-label)

- “Time Out” Protocol
  - Perform prior to vascular access when all team members present
  - Check patient ID with double-identifiers
  - Ensure unanimous agreement as to the nature of the procedure

- Consider “Pre-PCI Timeout” for ad-hoc PCIs
**Table 2. Sample “Time Out” Pre-procedure Checklist**

All members of the procedural team must be present for the “Time Out.”

Time Out must take place immediately before vascular access is obtained.

The physician taking ultimate responsibility for the procedure should lead the Time Out and ensure each of the following items is announced:

- Patient’s name and medical record number
- Procedure to be performed (e.g., left heart catheterization, coronary angiography, right heart catheterization)
- Confirm that the equipment needed is available or alternatives are available including intended stent type for PCI or cath-possible patients
- Patient’s allergies and premedication if appropriate (e.g., heparin-induced thrombocytopenia, contrast allergy)
- Special laboratory or medical conditions (e.g., INR, GFR)
- Confirm IC signed, witnessed and present
Infection Control

- Infectious complications are exceedingly rare
- Use electric clippers to shave/prep the femoral access site
- Scrub access sites with anti-microbial and chlorine based preps
- Use either traditional surgical scrub with water/soap or chlorhexidine/ethyl alcohol hand antiseptic solutions
- Wear hats/masks for every procedure involving device insertion
- Antibiotics are not recommended for routine cases
  - Consider antibiotics during insertion of vascular closure devices in high-risk patients (i.e. diabetics)
Intra-Procedure Best Practices

- **Radiation Exposure**
  - Goal: ALARA (As Low as Reasonably Achievable)
  - All: Wear lead aprons, thyroid shields, radiation badges, lead glasses (when close to radiation source)
  - Techs: Notify operator when approaching harmful thresholds

<table>
<thead>
<tr>
<th>Radiation Threshold</th>
<th>Action</th>
</tr>
</thead>
</table>
| 5 Gy                | *Patient Education  
                      *30-day phone call  
                      *Office visit if required |
| 10 Gy               | *Medical physicist should calculate peak skin dose  
                      *Skin examined at 2-4 wks |
| 15 Gy               | *TJC → hospital risk management/regulatory agencies should be contacted within 24 hrs |
Post-Procedure Best Practices

- **Access Site Management**
  - Perform femoral angiography (particularly before PCI or VCD)
  - Remove femoral sheath when ACT < 180 seconds (for heparin), after 2 hours (for bivalirudin, unless eGFR<30 in which case follow ACT), or after 8-12 hours (for LMWH)
  - Restrict ambulation for 2-6 hours after manual compression
  - Restrict ambulation for 1-4 hours after VCD
  - Use the patent hemostasis technique with immediate sheath removal after radial cases and keep the arm immobile for 2-4 hours

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Panchofy S et al. CCI 2008;72:335-40

Gupta S et al. Cardiac Intv Today May/June 2015
Post-Procedure Best Practices

- **Physician to Patient Communication**
  - Physician should discuss procedure results with patient and family
  - Delay discussions with patients until cognitive impairment due to sedation has resolved

- **Appropriate Attending to Referring Physician Handoff**
  - Formal handoffs (RN-to-RN and MD-to-MD) should be conducted
  - Ensure procedure note is available to receiving team and that formal procedure note is sent to all referring physicians
Post-Procedure Best Practices

- **Procedure Report**
  - Generate a formal procedure note immediately post-procedure and included in the chart prior to transferring to the next level of care.
  - Finalize the report within 24 hours.
  - At a minimum, a brief progress note with the following elements should be included in the chart prior to patient transfer:
    - Name of operator
    - Indication & Type of Procedure
    - Findings
    - Estimated blood loss
    - Specimens removed (if appropriate)
    - Complications
    - Post-procedure diagnosis
    - Recommendations

Cath Lab Best Practices
# Post-Procedural Best Practices

## Table 3. Recommended Elements of the Procedure Report

<table>
<thead>
<tr>
<th>Element</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient demographics</td>
<td>Age, gender, risk factors, medications</td>
</tr>
<tr>
<td>Primary operator and CCL team members</td>
<td>Primary and assisting physicians, fellows, nurses, technicians, anesthesiologists</td>
</tr>
<tr>
<td>Procedures performed</td>
<td>Right/Left heart catheterization, PCI</td>
</tr>
<tr>
<td>Indications</td>
<td>Clinical presentation, symptoms, exam findings, prior studies</td>
</tr>
<tr>
<td>Access site</td>
<td>Femoral, radial, brachial</td>
</tr>
<tr>
<td>Equipment</td>
<td>Sheaths, catheters, wires</td>
</tr>
<tr>
<td>Drugs and doses</td>
<td>Cardiac medications and sedation</td>
</tr>
<tr>
<td>Contrast data</td>
<td>Type and amount used</td>
</tr>
<tr>
<td>Radiation exposure</td>
<td>Dose</td>
</tr>
<tr>
<td>Complications</td>
<td>Clear description of complications, otherwise report “none”</td>
</tr>
<tr>
<td>Hemodynamics</td>
<td>Computer generated measurements must be verified by the operator: Initial and end aortic pressure, left ventricular systolic and end-diastolic pressure, valve gradients and areas, right sided chamber pressures, cardiac output, and shunt data</td>
</tr>
</tbody>
</table>

### Notes
- Left ventriculogram: Ejection fraction, wall motion abnormalities, valvular abnormalities
- Coronary angiography: Detailed anatomy, lesions, variants, size of vessels, collaterals
- Intervventional procedures: Procedure description including equipment, results and complications, TIMI flow pre- and post-PCI
- IVUS, OCT: Indication, artery segment evaluated, measurements performed, morphology and changes in management
- FFR: Indication, documentation of vasodilator used and route, location of lesion evaluated, results, interpretation
- Method of hemostasis: If vascular closure device (VCD), comment on whether or not device was successful
- Summary of findings, diagnosis, and follow-up: Management plan, admission or observation status, follow-up
- Communication: Report that results and complications were discussed with the patient and/or family, receiving team, consultants, and referring provider

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*a Adapted with modifications from the Accreditation of Cardiovascular Excellence Cath/PCI Standards 2015. Online at http://www.cvexcel.org.*

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[SCAI](www.SCAI.org/QIT)
Post-Procedure Best Practices

- **Appropriate Monitoring and Length of Stay (LOS)**
  - Patients should be monitored on a telemetry floor specializing in cardiac care
  - Check vital signs q15 min for the first 2 hours
  - Diagnostic LOS ranges from 2-6 hrs depending on access site used, patient ambulation, and well-being
  - Post-PCI LOS varies based on any complications, comorbidities, and need for further procedures, therapy, or testing
  - Low-risk patients after elective PCI can be considered for same-day discharge

Post-Procedure Best Practices

Medication Reconciliation

- The recommended duration of DAPT is per current guidelines, which is at least 6-12 months after 2nd generation DES and 1-12 months after BMS depending on whether the patient presented with an ACS.
- Pay careful attention to “triple therapy” and duration of each medication.
- Start novel oral anticoagulants the next day.
- Start warfarin immediately with a follow-up PT/INR within 1 week.
- Hold metformin for 48 hours.
- Start PPI for patients with prior history of GI bleed on DAPT and consider starting for all patients on triple therapy.

1. Levine GN et al, JACC 2011;58:e44-122
DES = 2nd generation DES

Levine GN et al, JACC 2016.
2016 ACC/AHA Focused Update on Duration of Dual Antiplatelet Therapy
Analysis of DAPT Study suggests that in patients treated for 1 year with DAPT and without significant bleeding or ischemic events, subsequent use of the “DAPT Score” can be helpful in assessing the benefit/risk ratio with prolonged DAPT.

- A score of $\geq 2$ was associated with a favorable benefit/risk ratio for prolonged DAPT, while a score of $< 2$ was associated with an unfavorable benefit/risk ratio.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age $\geq 75$</td>
<td>-2</td>
</tr>
<tr>
<td>Age 65 - $&lt; 75$</td>
<td>-1</td>
</tr>
<tr>
<td>Age $&lt; 65$</td>
<td>0</td>
</tr>
<tr>
<td>Current cigarette smoker</td>
<td>1</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1</td>
</tr>
<tr>
<td>MI at presentation</td>
<td>1</td>
</tr>
<tr>
<td>Stent diameter $&lt; 3$mm</td>
<td>1</td>
</tr>
<tr>
<td>Paclitaxel-eluting stent</td>
<td>1</td>
</tr>
<tr>
<td>CHF or LVEF $&lt; 30%$</td>
<td>2</td>
</tr>
<tr>
<td>Saphenous vein graft PCI</td>
<td>2</td>
</tr>
</tbody>
</table>

Post-Procedure Best Practices

- **Discharge Instructions and Patient Information**
  - Stress DAPT duration and adherence
  - Provide stent card with device information and location
  - Counsel on physical activity limitations and driving restrictions

- **Appropriate Follow-up Evaluation**
  - CCL team member should contact all patients within 24-48 hrs to ensure no complications, reinforce med adherence, and to answer questions
  - Arrange serum Cr check within 3-5 days for those at risk of CIN
  - Provide clinic follow-up within 4 weeks of discharge or earlier if presence of baseline renal insufficiency, anemia, or procedural complications
  - Document evaluation of access site
  - Re-assess medication list and compliance
  - Address lifestyle modifications including need for cardiac rehab/smoking cessation
CCL Governance

- **Role of CCL Director, Manager, and Hospital Administration**
  - Collaboration between a physician director, non-physician manager, and hospital administration is important
  - A minimum of 10% effort is necessary for the CCL director
  - CCL director responsibilities – Administrative, QI, Academic

- **Management of Industry Presence**
  - Industry role should be consistent with policies set by the hospital and/or director
  - Hands-on equipment should only be present for defined educational purposes or device preparation
  - An industry rep presence without specific purpose is of uncertain appropriateness and may reasonably be prohibited
CCL Governance

- Cost Considerations
  - Goal is to provide highest value of care which translates to:
    - Appropriateness
    - Reducing complications
    - Judicious use of resources
  - Target CCL operating costs and/or costs of care outside the CCL
    - Negotiate lower device prices and volume-related discounts ("bulk purchase")
    - Use the most cost-effective device when there is clinical equipoise
    - Track physician-specific cost data (adjusted for case complexity)
    - Participate in hospital technology-assessment committees
    - Be aware of evolving strategies that lower cost (e.g. radial access, heparin)
CCL Governance

- Major Complication CCL Preparedness Protocols
  - Develop specific protocols for rare, but serious complications
  - Drills should be performed at routine intervals in the CCL to practice response to these complications

Vascular Complications
- Acute Stroke
- Emergency Pacing
- VF/Cardiac Arrest
- Coronary Perforation
- Contrast Reaction
- Tamponade
- Sudden Cardiogenic Shock
Patient Experience Optimization

- Patient experience/satisfaction impacts clinical outcome
- HCAHPS (http://www.hcahpsonline.org) → regulated by CMS
- Results are publically available at www.hospitalcompare.hhs.gov
- Not specific to CCL → all CCLs should consider developing and administering a unique survey for this purpose
- Implement techniques for enhancing patient satisfaction
<table>
<thead>
<tr>
<th>Pre-Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Prompt, easy scheduling for outpatients</td>
</tr>
<tr>
<td>- Minimize or eliminate NPO period before procedure (some institutions allow clear liquids until 2 hours before procedure, or no longer require NPO)</td>
</tr>
<tr>
<td>- All outpatient suite and CCL personnel introduce themselves by name</td>
</tr>
<tr>
<td>- Update patients when delays are anticipated</td>
</tr>
<tr>
<td>- Emphasize comfort and privacy, including of family members</td>
</tr>
<tr>
<td>- Respect confidentiality</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intra-Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Careful attention to adequate sedation and pain control during the procedure</td>
</tr>
<tr>
<td>- Time out with introduction of all team members to the patient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full explanation of results of procedure to patients and family when appropriate</td>
</tr>
<tr>
<td>Prompt food and drink when tolerated after procedure</td>
</tr>
<tr>
<td>Discuss follow-up plans, provide instructions for emergency help after discharge, and provide appointment before discharge</td>
</tr>
<tr>
<td>Follow-up call to answer questions and identify post-procedural problems</td>
</tr>
</tbody>
</table>
Resources & Support

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- SCAI QIT Updates: http://www.scai.org/QIT/default.aspx

- SCAI QIT Tip of the Month: http://www.scai.org/QITTip/default.aspx
Acknowledgments

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- SCAI QI Committee Chair/Vice-Chair: Sunil V. Rao, MD and Kalon K. Ho, MD

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- 2016 Cath Lab Best Practices Expert Consensus Statement: Srihari S. Naidu, MD; Herbert D. Aronow, MD; Lyndon C. Box, MD; Peter L. Duffy, MD; Daniel M. Kolansky, MD; Joel M. Kupfer, MD; Faisal Latif, MD; Suresh R. Mulukutla, MD; Sunil V. Rao, MD; Rajesh V. Swaminathan, MD; and James C. Blankenship, MD

- SCAI Staff: Joel C. Harder, MBA
Facility and Environmental Issues
Facility and Environmental Issues

Purpose
- To review the following facility/environmental issues related to daily CCL practice:
  - Infection Control
  - Radiation Safety
  - Equipment Maintenance
  - Information Storage and Inventory

Intended Audience
- CCL directors, hospital administrators, interventionalists, nurses, technologists, advanced practice providers, SCAI QIT Champions
Infection Control Overview

- All CCL should have sterile/infection control protocols in place
- Patient preparation
  - Electric clippers for removal of hair
  - Chlorhexidine-based prep to the skin
  - Sterile drapes
- Operators: appropriate hand washing, hospital-based scrub attire, sterile gown and gloves
- Masks, eye shield and protective caps (optional but required based on state/institutional policy)
- Universal precautions should be followed

Infection Control

Ancillary Personnel
- Wear scrub suits and gloves when within the sterile field. Cap, mask, eye protection are optional.

High Risk Patients (for staff exposure)
- Screening for blood borne pathogens is not routinely performed.
- Wearing two pairs of gloves reduces inner glove punctures by 60% (not proven to prevent transmission of hepatitis or HIV).
- Cap, mask, eye protection are encouraged.

Skin Puncture or Laceration
- Report immediately.
- Established protocol for the management of such event with CDC published guidelines available for guidance.

Vaccination
- Vaccination for Hepatitis B virus is encouraged.
Infection Control

- The CCL should be thoroughly cleaned once a day and spot-cleaned with trash removal between each case
- The ventilation system should provide at least 20 air exchange/hr and be cleaned monthly
- The doors to the CCL should be kept closed, except for essential personnel leaving or entering
- Equipment near the entry site, such as foot switches, should be covered
- Multi-dose vials should be avoided, unless used with an approved device to protect against backflow
- Blood-contaminated drapes, gowns, gloves, and sponges should be discarded in containers labeled as health care waste. Needles and blades should be placed in puncture-proof containers

Chambers CE et al. Infection control guidelines for the cath lab. CCI 2006;67:78-86
Radiation Safety

- Each facility must have a radiation safety program
- Documentation of radiation safety training must be provided
- Patient radiation dose must be monitored and recorded
  - Includes fluoroscopic time, total air kerma at the interventional reference point (IRP) ($K_{a,r}$, Gy) and/or air kerma area product ($P_{KA}$, Gy*cm2)
  - Peak skin dose (PSD, Gy) should be included
- Surveillance for:
  - Total air kerma at the interventional reference point ($K_{a,r}$) $\geq 5$ Gy or air kerma area product ($P_{KA}$)=$500$ Gy*cm2, and/or fluoroscopy $>60$ minutes

Chambers CE et al. Radiation Safety program for the Cardiac Catheterization Laboratory. CCI 2011;77(4):546-56.
Assessment of Patient Dose

- **Fluoroscopic Time** not a useful descriptor of patient dose
- **Total Air Kerma at the Interventional Reference Point** ($K_{a,r}[\text{Gy}]$): X-ray energy delivered to air 15cm from iso-center
  - Required since 2006 for patient dose burden for deterministic skin effects
- **Air Kerma Area Product** ($P_{KA, \text{Gy*cm}^2}$): also known as dose-area product (DAP) is the product of air kerma and x-ray field area. Estimates potential stochastic effects (radiation induced cancer)
- **Peak Skin Dose** ($PSD, \text{Gy}$): maximum dose received by any local area of patient skin
  - No established method to measure PSD
  - Can be estimated if air kerma and X-ray geometry are known
  - The Joint Commission Sentinel event is >15 Gy
Radiation Safety: Pre-Procedure

Assessment of Risk
- Consider the obese patient
- Complex PCI/CTO
- Repeat procedures within 30-60 days
- Other radiation-related procedures

Informed Consent
- Should include the following issues:
  - Procedures use ionizing radiation
  - Physicians will deliver the dose necessary for the procedure
  - Although both short- and long-term risk is present with radiation exposure, this rarely results in significant short or long term injury
  - In complex cases, local tissue damage to the skin or even underlying layers may occur that may require additional follow up and treatment
Post Procedure Issues

- Document radiation dose with Fluoroscopic Time, and interventional reference point (IRP) Cumulative Air Kerma, and/or Cumulative Kerma Area Product (CKAP, Gy*cm²) in procedure report
  - Especially if IRP Cumulative Air Kerma (CAKIRP) doses ≥5 Gy
- Follow up is required by thirty days for IRP Cumulative Air Kerma (CAKIRP) of 5-10 Gy. Phone calls with an office visit as needed
- For IRP Cumulative Air Kerma (CAKIRP) >10 Gy, health physics should perform a detailed analysis
  - An office visit at < 4 weeks is recommended for examination of these patients
  - Hospital risk management should be contacted within 24 hrs if a calculated peak skin dose > 15 Gy
- Adverse Tissue Effects are best assessed by history and physical exam
  - Biopsy – only for uncertain diagnosis
  - Wound from the biopsy may result in a secondary injury potentially more severe than the radiation injury
Cath Lab Equipment

- Imaging equipment and archival storage
- Multichannel physiologic monitoring (minimum of 2 pressure and 3 ECG channels) with real-time and archived physiologic, hemodynamic and rhythm monitoring
- Documenting of preventive maintenance and testing of laboratory equipment.
  - For radiographic systems this includes but is not limited to
    a) Image quality
    b) Dynamic range
    c) Modulation transfer function
    d) Fluoroscopic spatial resolution
    e) Fluoroscopic field of view size accuracy
    f) Low contrast resolution
    g) Record and fluoro mode automatic exposure control
    h) Maximum table-top exposure rate
Cath Lab Equipment Con’t

- Facilities performing PCIs must have an adequate inventory for the scope of services provided
- Inventory of disposable supplies
- Emergency management equipment
- Documentation of the safe operation of infrequently-used equipment
Information Storage and Inventory

- Should link reporting system with the hospital information system
- Linking inventory and billing creates a seamless interface to provide an accessible report, enhanced inventory management and can verify billing
- Compliance with the 1996 Health Insurance Portability and Accountability Act (HIPAA) is required
- Disaster recovery is essential to any archival storage system
Resources & Support

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- SCAI QIT Updates: http://www.scai.org/QIT/default.aspx
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- SCAI Staff: Joel C. Harder, MBA
Care Coordination with Referring Physicians
Purpose

- To provide education to the referring physician on common pre- and post-procedural issues in patients undergoing invasive/interventional CCL procedures
- To foster a collaborative effort regarding our mutual patients in the important area of aftercare

Intended Audience

- Primary Care/Referring physicians, interventionalists, nurses, advanced practice providers, SCAI QIT Champions
Class I indications are to assess risk of CI-AKI before PCI, provide adequate hydration, and minimize volume of contrast media
- QxMD.com Contrast Nephrology Post PCI Calculator
- PCI Risk Assessment Tool
- Contrast volume (CV) > 3.7 x CrCl is predictive of AKI
- N-acetyl-L-cysteine (mucomyst) is not useful
- Metformin: discontinue 24 hrs prior, check Cr 48 hrs after prior to restarting
- ACE-I: May need to be held in patients with low CrCl/GFR
Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate steroid and antihistamine prophylaxis before repeat contrast administration.

- **Example**: Oral Prednisone 50mg at 13, 7, and 1 hr prior with 50mg of oral diphenhydramine 1 hr prior to the procedure.

- **Shellfish allergy** is not a predictor of contrast reactions and **does not** require pre-treatment.
Assessing Bleeding Risk

- All patients should be evaluated for risk of bleeding before PCI
  - **SCAI PCI Risk Assessment Tool**
  - **Cath PCI: Bleeding Model (Risk Adjusted) Specifications/Testing Overview**
- Coumadin held; INR should be < 1.8
- Dabigatran/rivaroxaban/edoxaban/apixaban held 1-2 days prior; dependent on GFR
- UFH/LMWH bridging likely necessary in patients with mechanical prosthetic valves
- **WOEST**: Triple therapy vs. clopidogrel/warfarin (no ASA) after PCI with need for ongoing anticoagulation (AF, mech. valve)*
  - Bleeding complications on “triple therapy” = 44.9% vs. 19.4% for “double-therapy”
  - No increase in rate of thrombotic events in “double therapy” group
  - Less all-cause mortality in “double therapy” group

*Lancet 2013;381:1107-15
Aspirin dosing
- 81mg daily after PCI, range is 75-100mg

P2Y12 Inhibitor and duration (with ASA)
- BMS or DES during PCI for ACS: DAPT should be given for at least 12 months (options include: clopidogrel 75 mg qd, prasugrel 10 mg qd, or ticagrelor 90 mg bid)
- 2nd gen DES for a non–ACS indication: clopidogrel 75 mg qd should be given for at least 6 months if patients are not at high risk of bleeding
- BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month

Earlier Discontinuation reasonable in patients treated with DAPT after 2nd gen DES who develop a high risk of bleeding (e.g., treatment with oral anticoagulant therapy), at high risk of severe bleeding complication (e.g., major intracranial surgery), or develop significant overt bleeding; discontinuation of P2Y12 inhibitor therapy after 3 months for SIHD or after 6 months for ACS may be reasonable.

Levine GN et al, JACC 2016.
2016 ACC/AHA Focused Update on Duration of Dual Antiplatelet Therapy
DES = 2nd generation DES

Levine GN et al, JACC 2016.
2016 ACC/AHA Focused Update on Duration of Dual Antiplatelet Therapy
**Bleeding vs. Ischemic Risk**

<table>
<thead>
<tr>
<th>Increased Ischemic Risk/Risk of Stent Thrombosis (may favor longer duration DAPT)</th>
<th>Increased Bleeding Risk (may favor shorter duration DAPT)</th>
</tr>
</thead>
</table>
| **Increased Ischemic Risk** | • History of prior bleeding  
• Oral anticoagulant therapy  
• Female sex  
• Advanced age  
• Low body weight  
• CKD  
• Diabetes mellitus  
• Anemia  
• Chronic steroid or NSAID therapy |
| • Advanced age  
• ACS presentation  
• Multiple prior MI  
• Extensive CAD  
• Diabetes mellitus  
• CKD  | |
| **Increased Risk of Stent Thrombosis** | |
| • ACS presentation  
• Diabetes mellitus  
• Left ventricular ejection fraction <40%  
• First generation drug-eluting stent  
• Stent under-sizing or under-deployment  
• Small stent diameter or greater stent length  
• Bifurcation stents  
• In-stent restenosis | |

Levine GN et al, JACC 2016.  
2016 ACC/AHA Focused Update on Duration of Dual Antiplatelet Therapy
Analysis of DAPT Study suggests that in patients treated for 1 year with DAPT and without significant bleeding or ischemic events, subsequent use of the “DAPT Score” can be helpful in assessing the benefit/risk ratio with prolonged DAPT.

- A score of $\geq 2$ was associated with a favorable benefit/risk ratio for prolonged DAPT, while a score of $< 2$ was associated with an unfavorable benefit/risk ratio.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age $\geq 75$</td>
<td>-2</td>
</tr>
<tr>
<td>Age 65 - &lt;75</td>
<td>-1</td>
</tr>
<tr>
<td>Age &lt;65</td>
<td>0</td>
</tr>
<tr>
<td>Current cigarette smoker</td>
<td>1</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1</td>
</tr>
<tr>
<td>MI at presentation</td>
<td>1</td>
</tr>
<tr>
<td>Stent diameter $&lt; 3\text{mm}$</td>
<td>1</td>
</tr>
<tr>
<td>Paclitaxel-eluting stent</td>
<td>1</td>
</tr>
<tr>
<td>CHF or LVEF $&lt; 30%$</td>
<td>2</td>
</tr>
<tr>
<td>Saphenous vein graft PCI</td>
<td>2</td>
</tr>
</tbody>
</table>

Triple Therapy

- Assess ischemic and bleeding risks using validated risk predictors (e.g., CHA2DS2-VASc, HAS-BLED)

- Keep triple therapy duration **as short as possible**; dual therapy only (oral anticoagulant and clopidogrel) may be considered in select patients

- Consider a target **INR of 2.0-2.5** when warfarin is used

- **Clopidogrel** is the P2Y12 inhibitor of choice

- Use low-dose (≤100 mg daily) aspirin

- PPIs should be used in patients with a history of gastrointestinal bleeding and are reasonable to use in patients with increased risk of gastrointestinal bleeding
Newer Antiplatelet Agents

- **Prasugrel**: contraindicated in patients with prior stroke; caution in patients \( \geq 75 \text{ years} \) old and low body weight \(<60\text{kg}\) (consider lower dose prasugrel 5mg daily instead of 10mg daily)

- **Ticagrelor**: must use with aspirin dose \(<100\text{mg daily}\)

- **Cangrelor**: An IV P2Y12 inhibitor for adjunct use during PCI. An oral P2Y12 inhibitor loading dose must be given immediately after discontinuation\(^*\) to maintain inhibition for chronic treatment

\(^*\) Ticagrelor can be given during or immediately after discontinuing cangrelor infusion
PPIs and Antiplatelet Therapy

- **PPI should be used in patients with history of prior GI bleeding who require DAPT**

- **PPI use is reasonable in patients with increased risk of gastrointestinal bleeding** (advanced age, concomitant use of warfarin, steroids, nonsteroidal anti-inflammatory drugs, H. pylori infection, etc.) who require DAPT

- **Routine use of a PPI is not recommended** for patients at low risk of gastrointestinal bleeding, who have much less potential to benefit from prophylactic therapy
Pharmacodynamic effect and clinical efficacy of clopidogrel and prasugrel with or without a proton-pump inhibitor: an analysis of two randomised trials

Findings do not support the need to avoid concomitant use of PPIs for gastric protection in patients receiving thienopyridine therapy who are at increased risk for GI bleeding.
Although Pantoprazole is a weaker inhibitor of CYP2C19, no independent association was found in TRITON-TIMI 38 between use of these drugs and the risk of MI or the composite of CV death, MI, or stroke.
Provided reassurance that there is no clinically relevant CV interaction between PPI’s and clopidogrel

Called into question the utility of platelet reactivity assays

Worries About Using Plavix With Heartburn Pills May Be Overblown

By RON WINSLOW

Worries over the risk of combining the blockbuster blood thinner Plavix with certain heartburn pills may be overblown, a new study suggests.

Bhatt DL et al. NEJM 2010;363:1909-17
Peri-procedural DAPT: Recommendations

For **elective** procedures, **await completion of DAPT**
- 1 month minimum for BMS
- 6 months minimum for 2\textsuperscript{nd} gen DES. Consider 3-6 months if delayed surgery risk >> stent thrombosis risk

For **emergent or urgent surgeries**, discuss with surgeon to consider if willing to operate on DAPT. If the bleeding risk is significant, then:
- Stop antiplatelet agent for as short a period as is reasonable
- ASA 81 mg daily peri-procedurally
- Restart antiplatelet agent as soon as possible post procedure

**No proven benefit to “bridging”** with either IIb/IIa inhibitors or unfractionated heparin/LMWH

DAPT*: Elective Noncardiac Surgery

*2nd generation DES

Levine GN et al, JACC 2016.
2016 ACC/AHA Focused Update on Duration of Dual Antiplatelet Therapy
DAPT Duration Debate

- Prolongation of DAPT necessitates a fundamental tradeoff between ↓ ischemic risk and ↑ bleeding risk
- Decisions about duration of DAPT require a thoughtful assessment of the benefit/risk ratio, integration of study data, and consideration of patient preference, interventionalist, and referring provider
- In studies of prolonged DAPT after DES implantation or after MI, duration of therapy was limited to several years. Thus, in patients for whom the benefit/risk ratio favors prolonged therapy, the true optimal duration of therapy is unknown

Levine GN et al, JACC 2016.
2016 ACC/AHA Focused Update on Duration of Dual Antiplatelet Therapy
Access Site Management

- Femoral
  - manual compression
  - vascular closure device (faster hemostasis and earlier ambulation but no different than manual compression at reducing access site complications)

- Radial
  - Lower rates of access-site bleeding
  - Shorter length of stay and lower hospital costs
  - Increased patient comfort and faster ambulation

Pseudoaneurysms

- A contained arterial rupture with arterial communication
- Incidence: <2% (diagnostic) and 2-6% (PCI)
- Manifests as pain in the groin and a pulsatile mass
- Definitive test is duplex ultrasound and treatment usually can be performed by US-guided compression or thrombin injection. Small PSAs (<3cm) may close spontaneously

CT image demonstrating a thin-necked femoral pseudoaneurysm (PSA); ultrasound image showing “to and fro” flow of blood before and after thrombin injection
Arteriovenous fistula

- Anomalous direct connection between artery and vein resulting in shunting of blood
- May present with palpable thrill or audible bruit and rarely, ischemia beyond the lesion
- Severe untreated lesions may lead to high-output cardiac failure
- Diagnosis made with duplex imaging
- If symptomatic or severe in degree vascular surgery consultation and repair is warranted
Radial Access Site Issues

- Radial artery occlusion is the most frequent complication (~3-10%)
  - Majority of occlusions are asymptomatic and recanalize approximately 50% of the time
  - Symptomatic occlusions are uncommon but clinical sequelae are exceedingly rare with dual circulation
  - Most common complaint is pain/discomfort in affected forearm which may be treated with supportive therapy
    - NSAIDs
    - Warm soaks
Cardiac rehabilitation should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted.

In patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.

Routine, periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.
Nuclear MPI, echocardiography, or CMR with either exercise or pharmacological stress can be useful for follow-up assessment at 2-year or longer intervals in patients with stable ischemic heart disease (SIHD) with prior evidence of silent ischemia or who are at high risk for a recurrent cardiac event and a) are unable to exercise to an adequate workload, b) have an uninterpretable EKG, or c) have a history of incomplete coronary revascularization.

Nuclear MPI, echocardiography, or CMR, with either exercise or pharmacological stress or CTA, is not recommended for follow-up assessment in patients with SIHD, if performed more frequently than at: (a) 5-year intervals after CABG or (b) 2-year intervals after PCI.

Fihn SD et al., JACC 2012
Ferromagnetism is the issue

None of the currently or previously utilized coronary stents approved by FDA are significantly ferromagnetic

Device manufacturer caveats

Levine et al, Circulation. 2007;116:2878-2891
Resources & Support

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