SCAI Quality Improvement Toolkit

Working on QUALITY, One Cath Lab at a Time
SCAI promotes excellence in invasive and interventional cardiovascular medicine through physician education and representation, and the advancement of quality standards to enhance patient care.
Aims

- Develop QI programs in catheterization laboratories
- Maintain existing QI programs
- Allow labs to tailor QI programs to local environments
Outline

Defining Quality in the Cath Lab
Operator and Staff Requirements
Procedural Quality
  ◦ Benchmarking
  ◦ Key conferences
Cath Lab Best Practices
Facility and Environmental Issues
Care Coordination with Referring Physicians
Defining Quality in the Cath Lab

- Structural Domain
- Process Domain
- Outcomes Domain
Structural Domain

- Hospital and cath lab structure
  - Overall hospital QA committee that meets regularly
  - Cath lab QA committee that meets regularly

- Credentialing criteria
  - Initial + periodic re-credentialing
  - Credentialing committee

- CME requirements

- Monthly-Quarterly-Annual reports generated
Process Domain

- Monitoring specific patient-care processes.
  - Direct patient-care activities
  - System-related activities
  - Guidelines-related activities
  - Cost and utilization activities
Direct Patient Care
- Quality of angiographic studies (peer review).
- Generation and completion of reports.
- Handling of complications.
Process Domain (Continued)

- System Related
  - Pre-procedure checklists.
  - Transport/Lab results/Charting adequacy.
  - Response time in emergencies.
  - Ancillary services adequacy (anesthesia, respiratory, etc).
Guideline Related
- Procedure indications
- Adjunctive medications
- Radiation safety
- Contrast
  - Type and dose
  - Allergy (prevention, treatment)
- Infection control
Process Domain (Continued)

- Cost and Utilization
  - Availability and quality of supplies
  - Staffing and personnel
  - Length-of-stay
  - Impact on ancillary services
Outcomes Domain

- Monitoring of outcomes on a regular basis
  - Risk adjusted mortality
  - Procedure related LOS, Fluoro time, etc.
  - Complications (30 days).
- Data sharing and reporting
  - Aggregated data or physician-specific.
  - Cath lab statistics – posted/available
- The purpose must be quality improvement.
Operator and Staff Requirements
Interventional cardiologists should be ACLS certified.

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

Valid for 12 hours of CME

Includes:

- Computer-based lessons
- Completion of practice skills using a mannequin with a certified instructor.
Maintenance of Proficiency

- ABIM Interventional Cardiology certifying examination
- Individuals should attain at least 30 hours of continuing medical education (CME) every 2 years. States or hospitals may have differing requirements.
Maintenance of Proficiency (Continued)

- Annual caseload PCI goal of 75 procedures per year per operator is recommended
- Institutional Measures of Proficiency
  - Catheterization Laboratory conferences (review complex cases, discuss new techniques or medication, stimulate dialog and cooperation/collaboration among peers)
  - Participation in the state or national outcomes database
- Morbidity and Mortality conferences
- Peer review conferences of random case selection
Board Re-Certification

- Recommendations for interventional cardiologists
  - Internal medicine
  - Cardiovascular Diseases
  - Interventional Cardiology

- Recertification is recommended every 10 years
Board Re-Certification (Continued)

- Maintenance of certification (MOC) involves
  - Self-assessment in medical knowledge and practice improvement
  - Computer-based examination
  - Verification of credentials: remain licensed and in good standing

- Resources for MOC can be found at scai.org and cardiosource.com
Board Re-Certification Requirements

- For Interventional Cardiology MOC self-evaluation:
  - ACCF/SCAI Premier Interventional Cardiology Overview and Board Preparatory Course
  - ACCF/SCAI Interventional Cardiology Board Review Meeting on Demand (MOD)
- Documentation of performance as primary operator, co-operator or supervisor of at least 150 PCI cases during the two years prior to the expiration of the certificate
Assuring Quality of Catheterization Laboratory Staff

- Challenges:
  - Lack of consensus statements regarding qualifications
  - No standardized examination to evaluate proficiency
  - Lower volume facilities may face additional challenges with “on the job” training.
Minimal 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 cath lab staff. Similar process to ABIM certification including a standardized exam.
- Cardiovascular invasive specialist, nursing or radiation technologist credentials are a prerequisite.
- Also requires two years of catheterization laboratory experience.
- Recognized by SCAI
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

**Can Function Independently**

<table>
<thead>
<tr>
<th>Task</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>Percusurge set up</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>
Catheterization Laboratory RN Critical Knowledge Assessment

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?
For labs performing PCI, additional mentorship may be necessary prior to taking call

- Additional training and skills assessment may be needed for specific hi-risk clinical situations:
  - Hemodynamic support devices (impella, tandem heart, etc.)
  - Carotid interventions
  - Patients under hypothermia protocols
  - Percutaneous valves and structural interventions
Additional References

- SICP Position Papers and Guidelines
- Role and Expectations of the Cath Lab Manager
- Scope of practice statement – gives a comprehensive overview of expected skills and responsibilities for laboratory staff
- Orientation Standards – detailed checklist of needed training
Methods for Maintenance of Competency for Staff

- Yearly skills review with clearly defined standards and remedial process
- Requirements for annual continuing education
- Performance of mock patient care scenarios
  - Particularly valuable for low volume facilities and for skills specific to unstable patients such as STEMI, shock, etc.
- RCIS certification requirement
Procedural Quality
Benchmark — “something that serves as a standard by which others may be measured or judged”

Using external benchmarks allows you to see how your cath lab performs relative to:

- Absolute standards, for example,
  - Joint Commission Sentinel Events:
    - Wrong patient; wrong body part
    - Fluoroscopy dose >1,500 rads to a single field
- Other cath labs in your region, nation, and worldwide
Caveats About Benchmarks

- One size does not fit all!
  - Is your institution comparable to the benchmarked population?
  - Care must be individualized for each specific patient.
    - Example - Radiation safety: ALARA (as low as reasonably achievable) principle:
      - You should use as little radiation as possible
      - Use as much as necessary to get adequate images
      - Some patients are sicker and some cases more complex, so more fluoroscopy time and radiation will be necessary
“You can’t improve quality if you can’t measure it.”

The 1st step: Collect information on the things you need to measure quality

Collect information on every cath lab procedure using standardized definitions

- Preferred - Prospective data collection
- Retrospective chart reviews are acceptable
Use your spreadsheet to generate a histogram

**Median 9.85**

**75% percentile 3rd quartile 16.475**
Different cases would be expected to have different fluoro times! One size does not fit all!

* Coronary and graft angiography in patient with unknown graft anatomy
† Hemodynamic assessment: aortic stenosis+hypertrophic cardiomyopathy
General Principles of Quality Improvement

- Comparison to a benchmark will give you a sense of whether your typical results are similar to the comparison population

- Outlier values are opportunities to learn!
  - They might represent “bad” performance, or …
  - They might reflect unusual cases

- Can improve quality by …
  - Moving outliers closer to the median
  - Shifting the curve by improving performance on every case by a little bit
  - Reviewing unusual behavior, e.g., performing elective PCI on a lesion with 40-70% diameter stenosis without ischemia on non-invasive testing (and with FFR >0.8 if pressure wire performed)
Look at Data by Subgroups

- Compare “apples to apples”

- Divide your data into subgroups:
  - PCIs
    - Planned PCIs without diagnostic angiography vs. Ad hoc PCIs
    - STEMIs vs. all others
  - Diagnostic coronary angiography
    - Diagnostic coronary angiography only
    - Diagnostic coronary angiography with ad hoc PCI
    - Coronary angiography with adjunctive procedures (e.g., lower extremity angiography, RHC)
  - Special procedures without coronary angiography
    - RHC, IABP insertion, temporary RV pacing
    - Valvuloplasty
Fluoroscopy Time (minutes)

- A crude measure of radiation exposure
  - Doesn’t include exposure from “cine”
  - Doesn’t account for higher radiation doses per minute necessary for larger patients
  - Doesn’t account for collimation and protective filters

Current Benchmarks from CathPCI Registry:

<table>
<thead>
<tr>
<th>Cases</th>
<th>Mean</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic cath (with &amp; without PCI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without prior CABG</td>
<td>14.0</td>
<td>11.0</td>
</tr>
<tr>
<td>With prior CABG</td>
<td>10.3</td>
<td>15.3</td>
</tr>
<tr>
<td>With prior CABG</td>
<td>10.8</td>
<td>14.1</td>
</tr>
<tr>
<td>With prior CABG</td>
<td>13.2</td>
<td>18.8</td>
</tr>
<tr>
<td>PCI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without prior CABG: 1 lesion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without prior CABG: &gt;1 lesion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>With prior CABG: 1 lesion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>With prior CABG: &gt;1 lesion</td>
<td></td>
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</tbody>
</table>
Ideally adjust expected risk of death for each patient based on his/her severity of illness.

CathPCI Post-PCI Risk Adjusted Mortality (RAM):
- Median: 1.45%
- 10th percentile: 2.55%
- 25th percentile: 1.93%
- 90th percentile: 0.73%
- 75th percentile: 1.06%

Lower RAM is better!

<table>
<thead>
<tr>
<th>Cases</th>
<th>Observed Death Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic cath (excluding organ donors, PCI, CABG, other major surgery)</td>
<td>0.6%</td>
</tr>
<tr>
<td>PCI</td>
<td>1.39%</td>
</tr>
<tr>
<td>STEMI patients</td>
<td>5.38%</td>
</tr>
<tr>
<td>Patients without STEMI</td>
<td>0.65%</td>
</tr>
</tbody>
</table>
Thresholds for Concern

- Observed unadjusted event rate > the 10th percentile of event rate in the CathPCI Registry
- Post-PCI observed in-hospital all-cause mortality thresholds for concern:
  - All PCIs: 2.55%
  - PCIs for STEMI: 10.72%
  - PCIs for patients without STEMI: 1.62%
Vascular Complications

CathPCI Registry Definition:
- Bleeding event - Access site (hematomas, retroperitoneal bleed) and/or Major access site related injury (access site occlusion, peripheral embolization, dissection, pseudoaneurysm, AV fistulas)
- Requiring treatment
- Developing within 72 hours of the procedure
- Must be associated with a hemoglobin drop of >3 g/dL; transfusion of whole or packed red blood cells, or a procedural intervention/surgery at the bleeding site to reverse/stop or correct the bleeding

Current Benchmark rates:
- Diagnostic cath (with or without PCI)
  - Median: 0.2%
  - 10th percentile: 0.8%
  - 25th percentile: 0.5%
  - 90th percentile: 0.0%
  - 75th percentile: 0.0%
- PCI
  - Median: 1.2%
  - 10th percentile: 3.3%
  - 25th percentile: 1.9%
  - 90th percentile: 0.0%
  - 75th percentile: 0.6%
Other Metrics: CathPCI Registry Data

- Stents per PCI admission: mean 1.45
- No obstructive CAD (proportion of elective coronary angiograms without a major coronary artery with a stenosis ≥ 50%. (excludes patients with prior CABG, cardiac transplant donor, pre-op evaluation for non-cardiac surgery, need for valve surgery or ICDs)
  - Median: 44.1 %
  - 10th percentile: 55.4 %
  - 25th percentile: 49.8 %
  - 90th percentile: 32.1 %
  - 75th percentile: 38.9 %

- If > 50% of your diagnostic coronary angiograms do not have flow-limiting CAD, the non-invasive testing algorithm used to select patients for angiography should be re-evaluated.
What Are Key Conferences?

- **Invasive Cardiology Morbidity and Mortality (Cath Lab M&M)**
  - Separate from clinical cardiology M&M
  - *Open review and assessment* of cath lab complications and in-hospital events following invasive cardiovascular procedures

- **Invasive Case Review Conference (Angio Review)**
  - *Open review* of random sample of cases
  - Diagnostic and interventional cases

- **Catheterization Laboratory Educational Conference (Cath Conf)**
  - Regular, frequent, *formal educational events*
  - Focus on cath lab practice and issues

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Why Have Key Conferences?

- Essential to link your current practices to best practices
- Foster interdisciplinary collaboration, process improvement
- Helpful in maintaining CME
- Required by JCAHO
- Needed for Ongoing Professional Performance Evaluations (OPPEs), a JCAHO requirement to assess operator performance
- Required by ACGME if a fellowship training program
- Must be independent – no vendor sponsorship

2http://www.acgme.org/outcome/implement/complete_PBLIBooklet.pdf; accessed March 1, 2011
Why Have Cath Lab M&M?

- Essential to achieve meaningful practice improvement
- Opportunity to review adverse events with peers
- Opportunity for collaborative process improvement
- Engages multiple stakeholders: physicians, allied health, other disciplines
- Non-punitive: *the aim is process improvement*
Cath Lab M&M: How To Make It Happen

- Designate MD or an independent cath lab person to be responsible for identifying cases for review (Quality Officer)
  - Must develop system for unbiased incident reporting
  - Everyone is empowered to report: nurses, technicians, trainees, allied health staff, patients and families
- Meet at least quarterly, more often if possible
- Attendance by all cath lab staff mandatory
- Multidisciplinary: bring in all relevant care providers for specific complications
- Case presentations by fellow/resident if possible – N.B. written documents by responsible physician are discoverable if legal action
Case selection based on complications

- All deaths within 30 days of the procedure are reviewed at the next conference.
- All major complications, defined by ACCF/SCAI1,2 and/or state reporting requirements, are reviewed.
- Prospectively select other complications, aligned with process/quality improvement projects

**Responsible MD must be present when case reviewed.**

Keep sign in sheet, case review forms with response/action plans

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2. ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention J Am Coll Cardiol 2006;47:e1-e121
Why Have Angio Review?

- Assure indications for invasive procedures and intra-procedure decision-making conform to guidelines
- Permits learning from others’ routine cases, not just complication cases
- Independent criteria provide objective quality measures
  - ACCF/SCAI Cath Indications1
  - PCI Appropriateness Criteria2
- For questionable or inappropriate case selection or procedures this is the venue to discuss openly and develop collaborative action plan.
- Non-punitive: *the aim is process improvement*

1 A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Coronary Angiography) developed in collaboration with the Society for Cardiac Angiography and Interventions. Circulation, 1999; 99:2345-57
Angio Review: How To Make It Happen

- Designate responsible MD (Cath Lab Director) or cath lab manager, Quality Officer to select random cases for review.
- Cases presented by a fellow if possible
- Cases reviewed openly, in group, with discussion
- *Never review a case when responsible MD away*
- Keep track of progress (e.g., appropriate indication, number of “normal coronary” cases, use of FFR) and update the group on progress
Why Have Cath Conference?

- Provides for continued professional development
- Required by JCAHO
- Can help meet ACGME core curriculum requirements for fellows
- Venue for faculty and fellow development
Cath Conference: How To Make it Happen

- Designate responsible MD (e.g., Cath Lab Director, Fellowship Program Director)
- Regular event: hold each week, same time and place
- Use fellowship core curriculum to structure calendar of topics
- Run by fellows if possible
- Encourage attendance by non-cath lab MDs – especially cardiac surgeons – to inform all care providers, stimulate discussions
- Sign-in sheets for attendance.
- Consider CME credit application

¹For information, contact Accreditation Council for Continuing Medical Education: [www.accme.org](http://www.accme.org)
Summary

Key conferences required by JCAHO, facilitate practice improvements, continuing medical education, professional development

To be successful, they must be:

◦ Regular
◦ Inclusive
◦ Non-punitive
◦ Focused on practice improvement
Why Have A Process To Assess Performance Issues?

- Cath lab director ultimately answers for quality…
  - Physicians
  - Nurses
  - Technicians
  - Other allied health staff

- Mechanism for process improvement
- Quality remediation practices and policies, records reviewed by JCAHO
- Required by ACGME if a fellowship training program
- Robust policies important if legal action

...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 Quality Officer or Chief Medical Officer)
- Independent/objective benchmarking
  - NCDR™ CathPCI or CARE1
  - HealthGrades
- Public/aggregate performance reporting
- Private counseling of serious/persistent outliers
- Clear probation and termination policies

1For information, see https://www.ncdr.com/webncdr/DefaultCathPCI.aspx
Effective Remediation Begins With Clear Expectations

- Engage all team members in quality goals and expectations
- Clear definitions of “complications”
  - Definitions maintained by cath lab director, aligned with independent sources/references
  - NCDR™ CathPCI, JCAHO provide standards1,2
- Independent chart abstractors collect and collate complications information
- Clear definitions of “performance issues”

1 [http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX#1](http://www.ncdr.com/WebNCDR/ELEMENTS.ASPX#1); accessed 3/1/2011
Criteria for “performance issue” 1
- Admissions/procedures that raise questions of competence
- Patients with lengths of stay longer than other practitioners
- Patterns of unnecessary diagnostic testing/treatments
- Failure to follow clinical practice guidelines
- Frequent readmission → inadequate initial treatment
- Inadequacies identified during Ongoing Professional Performance Evaluations (OPPE)

Will trigger a Focused Professional Performance Evaluation (FPPE)

Ongoing Professional Practice Evaluation (OPPE)

- Ongoing assessment of MD competencies
- Conducted by: Cath lab director or Quality Officer
- JCAHO requirement
- Must be frequent i.e. more than once per year
- Cath labs select their own measurement criteria
  - Door to balloon time, hematomas, urgent CABG, readmissions, conference attendance, etc
- Information used to determine whether to renew, limit, or revoke privileges

1 [Link](http://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFAQId=76&StandardsFAQChapterId=25); accessed 3/1/2011
Focused Professional Practice Evaluation (FPPE)

- Process to evaluate and remediate an individual MD’s performance issue.
- JCAHO requirement
- Process must define four 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

Focused Professional Practice Evaluation (FPPE)

- Information may be collected for FPPE through:
  - Chart review
  - Direct observation
  - Monitoring of diagnostic and therapeutic techniques
  - Discussion with others involved in the care of patients (consultant physicians, nurses, assistants, administration personnel)

- Evaluation for new privileges: similar process

Summary

- Creating a culture of quality requires participation of entire healthcare team
- Suboptimal performance issues must be identified and remediated
- Clear policies and processes are essential
  - Written
  - Transparent and unbiased
  - Referenced to published standards
- OPPE required, useful quality tool
- FPPE required when/if performance issues arise
Cath Lab Best Practices
Pre-Procedural Best Practices

- Pre-cath H&P ≤ 4 weeks (outpatient) or 24 hrs (inpatient), with update by attending physician at time of procedure.

- Informed Consent
  - Within 4 weeks by physician or informed member of team
  - Lay terms outlining indications, risks, benefits and alternatives; outcomes of the procedure must also be discussed
  - Witnessed by third party, preferably a family member
  - Re-affirm at least verbally within 24 hours of procedure

- Sedation, Anesthesia and Analgesia Evaluation
  - Usually conscious sedation, although sedation not required
  - Physicians must be credentialed for conscious sedation
  - ASA and/or Mallampati classification designation should be established by the physician or designee
Pre-Procedural Best Practices

- **Pre-Procedure Checklist**
  - CBC and SMA within 4 weeks (PT/INR not required unless on warfarin)
  - INR > 1.8 should consider alternative options or cancellation of elective cases
  - Hydration, if possible, for CRI (N-acetyl-cysteine not recommended)
  - Baseline EKG helpful, but CXR not routinely required
Fertile women must have Beta-HCG within 72 hours
Allergy documentation including contrast reaction and prior Heparin-Induced Thrombocytopenia (HIT)
NPO except medications for minimum 4 hours
Diabetics should have hypoglycemic medications and insulin regimens reviewed and adjusted
Outpatients should arrange for transport to home
Review previous procedure reports and films (CABG and/or PCI).
## Pre-Procedure Checklist

**Patient Name:** ____________________  **MRN:** ____________________  **Procedure Date:** ____________________

**Planned Procedure:**
- [ ] Diagnostic Cardiac Catheterization
- [ ] Diagnostic Cardiac Catheterization with possible PCI
- [ ] Percutaneous Coronary Intervention

**History and Physical Examination:**

<table>
<thead>
<tr>
<th>Item</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective Outpatient Procedures: H &amp; P documented within 2-4 weeks?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inpatient Procedures: H &amp; P documented within 24 hours of admission?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**History of prior PCI or CABG:**
- [ ] If yes, previous reports obtained?

**Candidacy for DES:**

1. Is the patient anemic?  
2. Major surgery in past month or in next year?  
3. Any clinically overt bleeding?  
4. Is patient on chronic anticoagulation (eg. warfarin, dabigatran)?  
5. History of medication non-adherence?

**Allergies:**

1. Iodine dye:  
2. Aspirin:  
3. Heparin (HIT):  
4. Latex:  
5. Multiple allergies:

- [ ] If yes, was the patient pre-treated?  
- [ ] If yes, does patient need desensitization?  
- [ ] If yes, consider alternative anti-thrombotic agents  
- [ ] If yes, remove all latex products from procedural use  
- [ ] If yes, consider prednisone pretreatment
## Pre-Procedure Checklist (Continued)

### Medications:
1. Did patient take aspirin within past 24 hrs?  
   - Yes □  No □
2. Did patient take clopidogrel within past 24 hrs?  
   - Yes □  No □
3. Did patient take metformin within past 24 hrs?  
   - Yes □  No □
4. Did patient take sildenafil (or equivalent) within past 24 hrs?  
   - Yes □  No □
5. Did patient receive LMWH within past 24 hrs?  
   - Yes □  No □
   - □ If yes for LMWH, time of last dose ______________________

### Informed Consent:
Was informed consent obtained within 2-4 weeks?  
- Yes □  No □

### Is there a healthcare proxy?  
- Yes □  No □

### Is the patient DNR or DNI?  
- Yes □  No □  □  Yes, but revoked for procedure

### Sedation, Anesthesia & Analgesia:
Are ASA and Mallampati Class documented?  
- Yes □  No □
Is there any contraindication to sedation present?  
- Yes □  No □

### Laboratories and Studies:
CBC and SMA performed within 2-4 weeks (outpatient) or 24 hours (inpatient)  
- Yes □  No □
PT/INR within 24 hours (for patients on warfarin)  
- Yes □  No □
Does the patient require pre-procedure hydration?  
- Yes □  No □
Procedural Best Practices (Continued)

- **Patient Preparation in Procedure Room**
  - Review medical record and checklist
  - Briefly re-confirm procedure and consent with patient

- **Sedation, Anesthesia Administration and Documentation**
  - Consider conscious sedation (nurse should be present)
  - All drugs recorded and signed by attending physician

- **Optimal Catheterization Laboratory Team**
  - Attending cardiologist and assistant/fellow in training.
  - One (1) monitoring and one (1) circulating nurse/tech
  - Consider anesthesiologist if deeper sedation is needed.
Procedural Best Practices (Continued)

- Infection Control in the Lab
  - Sterile clipping and prep over access site
  - Surgical scrub for all tableside personnel is recommended for first case, followed by self-drying solutions for subsequent cases
  - Hats and masks are optional for routine percutaneous procedures.
  - Antibiotic prophylaxis not indicated, although may be considered for high infection risk procedures or permanent implants

- Universal Protocol and “Time Out”
  - “Wrong Site” procedures are generally not a concern; therefore routine site marking is not necessary.
  - All solutions on the table must be labeled in real-time (not pre-labeled)
  - Documentation of verbal orders by technician or nurse and signed by MD
  - “Time Out” Protocol
    - Performed prior to vascular access, when all team members present
    - Check patient ID with double-identifiers
    - Unanimous agreement as to nature of procedure to be performed
Procedural Best Practices (Continued)

- **Physician to Patient Communication**
  - Physician should discuss with patient and family procedure results
  - Management plans should be discussed, including need for and duration of DAPT in those who receive a stent

- **Access Site Management**
  - For femoral access, sheath removal generally when ACT < 180 seconds (for heparin), after 2 hours (bivalirudin) or after 6-8 hours (LMWH)
  - For femoral closure devices, ambulation generally restricted for 1-4 hours
  - For radial access, sheath removed immediately after case

- **Monitoring and Length of Stay**
  - Telemetry monitoring in recovery or other unit specializing in cardiac care
  - Length of stay for diagnostic cases range 2-6 hours
  - Length of stay for PCI dependent on risk of complications, patient co-morbidities and need for further care
Discharge Instructions
- Physician or designee instructs on any physical activity limitations
- Discuss follow-up appointment (usually at 2-4 weeks)

Medication Reconciliation
- Medication reconciliation documented on discharge instructions (examples: DAPT, metformin and other oral hypoglycemic agents, warfarin)

Attending to Referring Physician Handoff
- Handoffs require appropriate documentation, including procedure performed, complications and post-procedural plan
- Formal procedure notes as well as, ideally, verbal communication to the referring physician are necessary (consider automated electronic servers)
Physician documentation is required or recommended at multiple steps:

- Update H&P at time of procedure (confirmation of ASA/Mallampati classification)
- Sign Informed Consent (IC) form
- Sign for all drugs delivered during procedure
- Sign for all verbal orders
- Sign procedure note with all findings and complications, including the plan of care
- Document discussion of findings with patient and family
- Document discussion and handoff to referring physician
Facility and Environmental Issues

- Infection Control
- Radiation Safety
- Operator and Staff Health – Ergonomics (Back Pain, Neck Pain, Etc.)
- Information Storage and Inventory
- Equipment Maintenance
All labs should have sterile/infection control protocols in place.

**Patient preparation**
- electric clippers for removal of hair
- antiseptic to the skin
- Sterile drapes.

**Operators:** appropriate hand washing, hospital-based scrub attire, sterile gown and gloves.

**Masks, eye shield and protective caps (optional)**

**Universal precautions should be followed**

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 laboratory 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 catheterization laboratory 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) \((K_a,r, \text{Gy})\) and/or air kerma area product \((P_{ka}, \text{Gycm}^2)\).
  - Peak skin dose \((P_{SD}, \text{Gy})\) should be included.

Survey for:

- Total air kerma at the interventional reference point \((K_a,r, ) \geq 5 \text{ Gy} \) or air kerma area product \((P_{ka}) = 500 \text{ Gycm}^2\) and/or fluoroscopy > 60 minutes.

Chambers et al. Radiation Safety program for the Cardiac Catheterization Laboratory. CCI 2011:
Facility and Environmental Issues

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** (\(PKA, \text{Gy cm}^2\)): 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
  - Joint Commission Sentinel event, >15 Gy.

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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.
Document radiation dose with Fluoroscopic Time, and interventional reference point (IRP) Cumulative Air Kerma, and/or Cumulative Kerma Area Product (CKAP, Gycm2) 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 is 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.
- Inventory of disposable supplies.
- Facilities performing PCIs must have an adequate inventory for the scope of services provided.
- Emergency management equipment.
- 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 and
    h) maximum table-top exposure rate
- 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.
A Quality Improvement program is essential for every cath lab

Important to understand how quality is defined and measured: Structure, Process, and Outcomes

Operator and Staff Proficiency is essential to assuring quality

Maintaining procedural quality involves peer review, benchmarking, and establishing key conferences
  - Benchmarking is facilitating by joining a national registry (NCDR CathPCI)

Creation of checklists and protocols can help maintain best practices

Facility and environmental issues are important for patient and employee safety as well as maintaining JCAHO standards
Acknowledgements

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  - Kirk Garratt, MD, FSCAI
  - Kalon Ho, MD, FSCAI
  - Srihari Naidu, MD, FSCAI
  - Steve Yakubov, MD, FSCAI

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  - Greg Dehmer, MD, FSCAI
  - Peter Duffy, MD, FSCAI
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  - Lloyd Klein, MD, FSCAI
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  - Ken Rosenfield, MD, FSCAI
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  - Bonnie Weiner, MD, FSCAI
  - Steve Yakubov, MD, FSCAI
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.
Appendix: Benchmarking Case Studies

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Director of Quality Assurance, Cardiovascular Division
Beth Israel Deaconess Medical Center
Boston, Massachusetts
Assistant Professor of Medicine
Harvard Medical School
Boston, Massachusetts

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“Benchmarking” Individual Patients

- What was the predicted post-PCI mortality for this specific patient?
- Two recent models using the CathPCI dataset
  - NCDR Risk Score Model
  - Massachusetts model (includes additional “compassionate use” variable for coma, ongoing CPR, need for hemodynamic support, or extreme anatomic risk)
# NCDR CathPCI Risk Score

## Table 4: NCDR CathPCI Risk Score System

<table>
<thead>
<tr>
<th>Variable</th>
<th>Scoring Response Categories</th>
<th>Total Points</th>
<th>Risk of In-Patient Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>&lt;60</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>≥60, &lt;70</td>
<td>4</td>
<td>0.1%</td>
</tr>
<tr>
<td></td>
<td>≥70, &lt;80</td>
<td>8</td>
<td>0.2%</td>
</tr>
<tr>
<td></td>
<td>≥80</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>No</td>
<td>0</td>
<td>0.1%</td>
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<tr>
<td></td>
<td>Yes</td>
<td>25</td>
<td>0.2%</td>
</tr>
<tr>
<td>Prior CHF</td>
<td>No</td>
<td>0</td>
<td>0.3%</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>5</td>
<td>0.6%</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>No</td>
<td>0</td>
<td>1.1%</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>5</td>
<td>2.0%</td>
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<tr>
<td>Chronic lung disease</td>
<td>No</td>
<td>0</td>
<td>3.6%</td>
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<tr>
<td></td>
<td>Yes</td>
<td>4</td>
<td>6.3%</td>
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<tr>
<td>GFR</td>
<td>&lt;30</td>
<td>18</td>
<td>10.9%</td>
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<tr>
<td></td>
<td>30–60</td>
<td>10</td>
<td>18.3%</td>
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<tr>
<td></td>
<td>60–90</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;90</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>NYHA functional class IV</td>
<td>No</td>
<td>0</td>
<td>29.0%</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>4</td>
<td>42.7%</td>
</tr>
<tr>
<td>PCI status (STEMI)</td>
<td>Elective</td>
<td>12</td>
<td>57.6%</td>
</tr>
<tr>
<td></td>
<td>Urgent</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Emergent</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Salvage</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>PCI status (no STEMI)</td>
<td>Elective</td>
<td>0</td>
<td>81.0%</td>
</tr>
<tr>
<td></td>
<td>Urgent</td>
<td>8</td>
<td>89.2%</td>
</tr>
<tr>
<td></td>
<td>Emergent</td>
<td>20</td>
<td>93.8%</td>
</tr>
<tr>
<td></td>
<td>Salvage</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>85</td>
<td>96.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>90</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>95</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>
Massachusetts Mortality Models

- Divided into 2 cohorts
  - STEMI within 1st 24 hours after arrival, or cardiogenic shock (SoS)
  - All others

- Available as
  - Web-based tools
  - Excel spreadsheets for download

- [http://www.massdac.org/riskcalc](http://www.massdac.org/riskcalc)
## 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>Distribution of Data</th>
<th>90th percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PCI in-hospital risk adjusted mortality (all patients)</strong></td>
<td>10th percentile</td>
<td>90th percentile</td>
</tr>
<tr>
<td>My Hospital 1.76</td>
<td>Better ←</td>
<td>Better ←</td>
</tr>
<tr>
<td>Vol Group R4Q 1.40</td>
<td>0.73</td>
<td>1.76</td>
</tr>
<tr>
<td>All Hosp 1.40</td>
<td>0.73</td>
<td>1.76</td>
</tr>
<tr>
<td><strong>PCI Outcome Metrics</strong></td>
<td>10th percentile</td>
<td>90th percentile</td>
</tr>
<tr>
<td><strong>Vascular access site injury requiring treatment or major bleeding</strong></td>
<td>10th percentile</td>
<td>90th percentile</td>
</tr>
<tr>
<td>My Hospital 1.2%</td>
<td>Better ←</td>
<td>Better ←</td>
</tr>
<tr>
<td>Vol Group R4Q 1.4%</td>
<td>0.0%</td>
<td>1.2%</td>
</tr>
<tr>
<td>All Hosp 1.4%</td>
<td>0.0%</td>
<td>1.2%</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]

Your hospital’s proportion of patients (excluding CABG or other surgery during same admission) with major access site related injury requiring treatment or major bleeding. [Detail Line:1818]
Interpreting CathPCI Registry Reports (Continued)

### PCI in-hospital risk adjusted mortality (all patients)

<table>
<thead>
<tr>
<th></th>
<th>My Hospital</th>
<th>Vol Group R4Q</th>
<th>All Hosp</th>
<th>90th Pctl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality Rate</td>
<td>1.76</td>
<td>1.40</td>
<td>0.73</td>
<td></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]

---

**Distribution of Data**

- **10th percentile**
- **25th percentile**
- **Median**
- **75th percentile**
- **90th percentile**

---

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Case Studies

Kirk N. Garratt MSc, MD, FACC, FSCAI

Director of Quality Assurance, Cardiovascular Intervention
Lenox Hill Heart and Vascular Institute of New York
New York, New York
Case Study #1: Managing Complications
72 Year Old Man with Intermittent Visual Changes

- History of prior carotid artery disease with similar symptoms
  - Left carotid endarterectomy 4 years ago
  - Right carotid stent placement 18 months ago

- Non-invasive carotid studies indicate severe stenosis of left carotid artery; right carotid patent

- Admitted for angiography, possible carotid artery stent placement
72 Year Old Man with Intermittent Visual Changes (Continued)

- Angiography of left carotid shows severe stenosis
- Right carotid not intubated/imaged
72 Year Old Man with Intermittent Visual Changes (Continued)

- Operator proceeds with carotid stent intervention; good result, no immediate complications
- Patient undergoes usual post-stent observation
72 Year Old Man with Intermittent Visual Changes (Continued)

- Normal neurologic exam at 2 hours
- Normal neurologic nursing checks q1h until 3am
- Sudden altered mental status, rapidly decaying to coma
- Urgent head CT
72 Year Old Man with Intermittent Visual Changes (Continued)

- Massive hemorrhagic stroke of right frontal lobe
- Urgent resuscitation stabilizes pt but prognosis grim
- Comfort care provided
- Death within 24 hours
What Is the Correct Course of Action?

- Immediate QA review and temporary suspension of operator clinical privileges
- Immediate QA review and initiation of operator FPPE
- Immediate QA review and listing for Morbidity and Mortality conference
- Immediate QA review and listing for Quality Assurance Angiography Review conference
What Is the Correct Course of Action? (Continued)

- Immediate QA review and temporary suspension of operator clinical privileges
- Immediate QA review and initiation of operator FPPE
- **Immediate QA review and listing for Morbidity and Mortality conference**
- Immediate QA review and listing for Quality Assurance Angiography Review conference
This patient had fatal intra-cranial bleed on the contra-lateral side to intervention. QA review within 24 hours is necessary, but unless there is a finding of a contributing mishap (e.g., dosing error in anticoagulants) no corrective action is indicated. FPPE is indicated if a pattern of inadequate performance. Practice suspension is considered only when there is clear malpractice or a pattern of inadequate performance despite corrective measures. QA Angio Review does not focus on complications.
Case Study #2: Catheterization Laboratory Conference
Which of the Following Would Be Least Appropriate for Cath Conference?

- Second year interventional fellow discussing his research project
- Senior faculty member discussing PCI of saphenous vein graft disease
- Invited speaker discussing how PACs can influence impact of healthcare reform on cath lab practices
- Invited speaker discussing the development and future of the market-leading DES
Which of the Following Would Be Least Appropriate for Cath Conference? (Continued)

- Second year interventional fellow discussing his research project
- Senior faculty member discussing PCI of saphenous vein graft disease
- Invited speaker discussing how PACs can influence impact of healthcare reform on cath lab practices
- **Invited speaker discussing the development and future of the market-leading DES**
Purposes of Cath Conference may include

- Education of staff on matters impacting invasive cardiology (including non-technical discussions such as healthcare reform)
- Inform staff regarding on-going projects, including research and process improvement projects
- Staff development, including senior members

Cath Conference should not be used as a venue for commercial product promotion, hence a lecture focusing on the development and success of the products of a single company is inappropriate.
Case Study #3: Quality Assurance Angiogram Review
Diagnostic catheter dissection of RCA ostium requiring placement of coronary stent
Intermediate lesion in mid-LAD, treated with DES after IVUS showed MLA 3.7mm²
Perforation of SVG lesion with 3.0mm balloon, treated successfully with 4.0mm covered stent
Patient with STEMI, 3VD, pLAD occlusion, CPR required, PCI successful but patient died of refractory heart failure within 36 hours
Which of the Following Would Be Best for QA Angio Review? (Continued)

- Diagnostic catheter dissection of RCA ostium requiring placement of coronary stent
- **Intermediate lesion in mid-LAD, treated with DES after IVUS showed MLA 3.7mm²**
- Perforation of SVG lesion with 3.0mm balloon, treated successfully with 4.0mm covered stent
- Patient with STEMI, 3VD, pLAD occlusion, CPR required, PCI successful but patient died of refractory heart failure within 36 hours
Quality Assurance Angiogram Review is intended to broaden the discussion about appropriateness of lab practice. While complications may be reviewed and discussed, they are not the focus of this conference. Discussion of common, borderline or indeterminate lesions, such as a mid-LAD stenosis falling near the threshold for treatment, can provide important opportunities for laboratory practice improvement conversations.
Case Study #4: Physician Performance
Dr. Smith is an interventional cardiologist in a 6 physician group practice working exclusively at General Hospital. He received ABIM Added Qualification Certification in Interventional Cardiology in 2002. He is credentialed at General Hospital to perform all common coronary interventional procedures. He has averaged 340 diagnostic catheterizations and 180 PCIs annually over the past 5 years, including 45 STEMI interventions per year.
Physician Performance (Continued)

An On-going Professional Performance Evaluation (OPPE) revealed:

- Door to balloon time average: 78 ± 23 min
- Unadjusted mortality: 3.1%
- Vascular access complication requiring transfusion or surgery: 5.6%
- Attendance at required departmental meetings: 34%
You are Chair of Cardiology. You should advise Dr. Smith that:

- He must lower his mortality rate or he will be placed on FPPE
- He must reduce his access complication rate or he will be placed on FPPE
- He must attend at least 50% of required conferences or he will be placed on FPPE
- He will undergo FPPE to assess several areas of his performance
You are Chair of Cardiology. You should advise Dr. Smith that:

- He must lower his mortality rate or he will be placed on FPPE.
- He must reduce his access complication rate or he will be placed on FPPE.
- **He must attend at least 50% of required conferences or he will be placed on FPPE.**
- He will undergo FPPE to assess several areas of his performance.
Dr. Smith is a high-volume operator with a large proportion of STEMI patients (25%). Unadjusted mortality of 3.1% and vascular complications of 5.6% for this patient population are not unexpected or unreasonable. However, attendance at mandatory conferences is a JCAHO requirement – his failure to attend can affect the practice and the hospital. Persistent failure may trigger a FPPE with clearly delineated corrective actions. The minimum attendance figure is determined by the Departmental Chair, but is typically $\geq 50\%$. 
Care Coordination with Referring Physicians
The Cath Lab Patient: Periprocedural Issues for the Referring Physician

- Henry S. Jennings III MD, FSCAI, FACC
  Vanderbilt University Medical Center
- Suresh R. Mulukutla MD, FSCAI, FACC
  University of Pittsburgh Medical Center
- Sunil V. Rao MD, FSCAI, FACC
  Duke University Medical Center
Care Coordination with Referring Physicians

Presentation Objectives

- To **provide education to the referring** physician on common pre- and post-procedural issues in patients undergoing invasive/interventional cardiac catheterization lab procedures
- To **heighten awareness** among referring physicians of the most recent **Guidelines** and **Appropriate Use Criteria** regarding diagnostic and interventional cardiac cath lab patients
- To **foster a collaborative effort** regarding our mutual patients in the important area of aftercare
- To **highlight what SCAI is actively doing** in the quality arena: SCAI-QIT Quality Champions

www.SCAI.org/QIT
What is SCAI-QIT?
Quality Improvement Toolkit Initiative

- Initiated late 2010 to bolster quality efforts in the cardiac cath lab environment
- SCAI Quality Committee oversight
- **SCAI-QIT Physician Champions**: currently more than 300 worldwide
- Series of SCAI-QIT Modules/Webinars: total of seven to date mid-2013

Care Coordination with Referring Physicians
The Recent SCAI-QIT Modules

- **SCAI-QIT:** Appropriate Use Criteria for Diagnostic Cath
- **SCAI-QIT:** What the Cath Lab Standards Update Has to Offer for Quality Improvement
- **SCAI-QIT:** Navigating the New Revascularization Appropriate Use Criteria
- **SCAI-QIT:** Navigating the Revised Guidelines to PCI
- **SCAI-QIT:** Defining Quality in the Cath Lab and Facility and Environmental Controls
- **SCAI-QIT:** Operator and Staff Requirements
- **SCAI-QIT:** Procedural Quality and Cath Lab Best Practices
Outline for this Presentation

- Appropriate Use Criteria/AUC Coronary Revascularization Overview/Elements
- Appropriate Use Criteria/AUC Diagnostic Cardiac Catheterization Overview/Elements
- Management Prior to and After Patient Referral to the Cardiac Cath Lab
- Dual Anti-Platelet Therapy/DAPT after PCI/Coronary Stenting
- Access Site Complications/Management
- Optimum Medical Therapy/OMT after PCI
- Diagnostic Testing after PCI
Outline for this Presentation

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- Access Site Complications/Management
- Optimum Medical Therapy/OMT after PCI
- Diagnostic Testing after PCI
Clinical Practice Guidelines: The Timeline

- **30 years ago:** Physicians relied upon experience and intuition to guide patient care.

- **20 years ago:** ACC/AHA/SCAI efforts began to provide Guidelines/standards of care
  - Rely on evidence-based care/randomized trials
  - If no evidence available, expert opinion
  - Generally speaking, ignore costs

- **Today:** Appropriate Use Criteria (AUC)
  - A supplement to ACC/AHA/SCAI guidelines
  - Designed to improve efficient use of medical resources, to monitor utilization, to improve patient care and health outcomes

Nat Rev Cardiol 2011;8(10)
Approximately 600,000 PCIs are performed in the US each year, at a cost that exceeds $12 billion.

Regional utilization variance has been noted by CMS.

Patients who undergo PCI are exposed to risks of peri-procedural complications and long-term bleeding and stent thrombosis.

Given the cost and invasiveness of PCI, determining the extent to which PCI procedures are performed for appropriate and inappropriate indications could identify procedural overuse and areas for quality improvement and cost savings.
AUC Coronary Revascularization

Background

- Intended to assist patients and clinicians
- Not intended to diminish the difficulty or uncertainty of clinical decision making
- Cannot act as substitutes for sound clinical judgment and practice experience
- Allow assessment of utilization patterns for a test or procedure, including across providers
AUC Methodology: RAND Appropriateness Method (Modified Delphi Process)

- Panel of 17 experts from various disciplines in cardiovascular disease; included noninvasive cardiologists, cardiac surgeons, others
- Limited number of most common clinical scenarios (>4,000 possible, 180 considered)
- First round voting with no group interaction
- Second round voting after review of first round data and discussion
- Scores from 1-9 generated for each indication
AUC Coronary Revascularization Prototypical Patient Scenarios

180 clinical scenarios involved different combinations of:

- **Clinical Presentation**
  - ACS, Stable CAD, prior CABG

- **Symptom severity**
  - CCS angina class

- **Ischemia severity**
  - Low, intermediate, high on noninvasive functional testing

- **High risk clinical features**
  - Left ventricular dysfunction, ventricular arrhythmia

- **Intensity of anti-ischemic medical therapy**

- **Extent of coronary anatomical findings on angiography**
  - Significant 1-, 2-, 3-vessel coronary artery disease with or without disease of proximal LAD, LM or bypass graft
Appropriateness Criteria: 2009 Methodology

- **Scores 7-9: Appropriate**, revascularization likely to improve health outcomes or survival
- **Scores 4-6: Uncertain**, likelihood that revascularization would improve health outcomes or survival was considered uncertain
- **Scores 1-3: Inappropriate**, revascularization unlikely to improve health outcomes or survival

*Health outcomes: symptoms, functional status, and/or quality of life*

AUC Coronary Revascularization: The Key Variables Gradient

- STEMI
- CCS Class IV
- High Risk
- Max
- LM + 3v CAD

Clinical Presentation
Severity of Angina
Ischemia Tests/Prognostic Factors
Medical Therapy
Anatomic Disease

Stable Angina
ASx, CCS Class I
None, Low Risk
None
No Sig. CAD

* CHF, DM, Low LVEF

Patel, et al. JACC 2009; 53:530-553
AUC Classification PCI Example

<table>
<thead>
<tr>
<th>Indication</th>
<th>Appropriate Use Score (1-9)</th>
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<tbody>
<tr>
<td></td>
<td>CCS Angina Class</td>
</tr>
<tr>
<td>14.</td>
<td>One- or 2-vessel CAD without involvement of proximal LAD</td>
</tr>
<tr>
<td></td>
<td>Low-risk findings on noninvasive testing</td>
</tr>
<tr>
<td></td>
<td>Receiving no or minimal anti-ischemic medical therapy</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>15.</td>
<td>One- or 2-vessel CAD without involvement of proximal LAD</td>
</tr>
<tr>
<td></td>
<td>Low-risk findings on noninvasive testing</td>
</tr>
<tr>
<td></td>
<td>Receiving a course of maximal anti-ischemic medical therapy</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td>One- or 2-vessel CAD without involvement of proximal LAD</td>
</tr>
<tr>
<td></td>
<td>Intermediate-risk findings on noninvasive testing</td>
</tr>
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<td>Receiving no or minimal anti-ischemic medical therapy</td>
</tr>
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<td>17.</td>
<td>One- or 2-vessel CAD without involvement of proximal LAD</td>
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<td>Intermediate-risk findings on noninvasive testing</td>
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<tr>
<td></td>
<td>Receiving a course of maximal anti-ischemic medical therapy</td>
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<td>18.</td>
<td>One- or 2-vessel CAD without involvement of proximal LAD</td>
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<td>High-risk findings on noninvasive testing</td>
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<td>19.</td>
<td>One- or 2-vessel CAD without involvement of proximal LAD</td>
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<td></td>
<td>High-risk findings on noninvasive testing</td>
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<tr>
<td></td>
<td>Receiving a course of maximal anti-ischemic medical therapy</td>
</tr>
<tr>
<td></td>
<td></td>
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</tbody>
</table>
# AUC PCI Chart Example

<table>
<thead>
<tr>
<th>Intermediate Risk Findings on Noninvasive Study</th>
<th>CCS Class I or II Angina</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms Med. Rx</td>
<td>Stress Test Med. Rx</td>
</tr>
<tr>
<td>Class III or IV/Max Rx</td>
<td>A</td>
</tr>
<tr>
<td>Class I or II/Max Rx</td>
<td>A</td>
</tr>
<tr>
<td>Asymptomatic</td>
<td>U</td>
</tr>
<tr>
<td>Class III or IV/No/min Rx</td>
<td>U</td>
</tr>
<tr>
<td>Class I or II/No/min Rx</td>
<td>U</td>
</tr>
<tr>
<td>Asymptomatic No/min Rx</td>
<td>I</td>
</tr>
</tbody>
</table>

| Coronary Anatomy                               | CTO of 1 vz.; no other disease |
|                                                | 1-2 vz. disease; no Prox. LAD  |
|                                                | 1 vz. disease; Prox. LAD       |
|                                                | 2 vz. disease; Prox. LAD       |
|                                                | 3 vz. disease; no Left Main    |

| Coronary Anatomy                               | CTO of 1 vz.; no other disease |
|                                                | 1-2 vz. disease; no Prox. LAD  |
|                                                | 1 vz. disease; Prox. LAD       |
|                                                | 2 vz. disease; Prox. LAD       |
|                                                | 3 vz. disease; no Left Main    |

**Figure 3.** Appropriate Use Ratings by Intermediate-Risk Findings on Noninvasive Imaging Study and CCS Class I or II Angina (Patients Without Prior Bypass Surgery)

Patel, et al. JACC 2012; 59:
Maximal Anti-Ischemic Medical Therapy: the use of at least 2 classes of therapies to reduce anginal symptoms

Risk of Findings on Noninvasive Testing:
- **Low-Risk** (<1% annual cardiac mortality)
- **Intermediate-Risk** (1-3% annual cardiac mortality)
- **High-Risk** (>3% annual cardiac mortality)

Patel, et al. JACC 2012; 59:
Classification of Chest Pain

Typical Angina (Definite):
- Substernal chest pain or discomfort
- Provoked by exertion or emotional stress
- Relieved by rest and/or nitroglycerin

Atypical Angina (Probable):
- Lacks one of the characteristics of definite or typical angina

Nonanginal Chest Pain:
- Meets one or none of the typical angina characteristics

Patel, et al. JACC 2012; 59:
Canadian Cardiovascular Society (CCS) Classification of Angina Pectoris

- **CCS I:** Ordinary physical activity does not cause angina, such as walking, climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.
- **CCS II:** Slight limitation of ordinary activity. Angina occurs on walking more than 2 blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal condition.

Patel, et al. JACC 2012; 59:
Canadian Cardiovascular Society (CCS) Classification of Angina Pectoris

- **CCS III**: Marked limitations of ordinary physical activity. Angina occurs on walking one or two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace.

- **CCS IV**: Inability to carry on any physical activity without discomfort—anginal symptoms may be present at rest.

Patel, et al. JACC 2012; 59:
In general, coronary revascularization for patients with acute coronary syndromes and combinations of significant symptoms and/or ischemia was felt to be appropriate.

Revascularization of asymptomatic patients or patients with low-risk findings on noninvasive testing and minimal medical therapy were viewed less favorably.
AUC PCI 2012: Caveats

- All physicians/facilities will not have 100% of their revascularization procedures deemed appropriate.
- May be clinical situations in which a use of coronary revascularization for an indication considered to be appropriate does not always represent reasonable practice, such that the benefit of the procedure does not outweigh the risks.
- Rating of scenario as inappropriate or uncertain should not preclude a provider from performing revascularization procedures when there are patient- and condition-specific data to support that decision.

Patel, et al. JACC 2012; 59:
Uncertainty about “Uncertain”

When a procedure is classified as “Uncertain” it generally means one of two things:

1. There **was not enough clinical information** in the scenario.
2. There is **not a substantial literature base** upon which to make a firm recommendation.
Uncertainty about “Uncertain”

There was not enough clinical information in the scenario.

What we need from the referring physician:

- *Specifics about the outside stress test
- *Specifics about medical therapy and the character and severity of angina
Adjunctive Diagnostic Devices to Evaluate Lesion Severity

- FFR, IVUS, and OCT evaluation has not yet been incorporated into defining appropriateness of PCI. This may change in next guideline update.
- However, FFR, IVUS, and OCT should be utilized to evaluate moderate lesions defined as lesion severity of 40-70% to justify intervention.
- Clearly document the use of FFR, IVUS, and OCT.
<table>
<thead>
<tr>
<th>Recommendation</th>
<th>COR</th>
<th>LOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>FFR to assess angiographic intermediate coronary lesions and to guide</td>
<td>IIA</td>
<td>A</td>
</tr>
<tr>
<td>revascularization decisions in patients with SIHD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IVUS for the assessment of angiographically indeterminate left main CAD</td>
<td>IIA</td>
<td>B</td>
</tr>
<tr>
<td>IVUS after cardiac transplantation</td>
<td>IIA</td>
<td>B</td>
</tr>
<tr>
<td>IVUS to determine the mechanism of stent restenosis</td>
<td>IIA</td>
<td>C</td>
</tr>
<tr>
<td>IVUS for the assessment of non-left main angiographically intermediate</td>
<td>IIIB</td>
<td>B</td>
</tr>
<tr>
<td>stenoses</td>
<td></td>
<td></td>
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<tr>
<td>IVUS for guidance of coronary stent implantation</td>
<td>IIIB</td>
<td>B</td>
</tr>
<tr>
<td>IVUS to determine the mechanism of stent thrombosis</td>
<td>IIIB</td>
<td>C</td>
</tr>
<tr>
<td>IVUS for routine lesion assessment when revascularization is not being</td>
<td>III</td>
<td>C</td>
</tr>
<tr>
<td>contemplated</td>
<td>No Benefit</td>
<td></td>
</tr>
<tr>
<td>Optical coherence tomography</td>
<td>No Recommendations</td>
<td></td>
</tr>
</tbody>
</table>
What is the NCDR CathPCI Registry?

- NCDR CathPCI is a registry of diagnostic cardiac catheterization and PCI data; more than 1000 US sites
- Provides reports containing practice patterns, demographics, and outcomes of diagnostic procedures and therapies
- Quarterly reports to institutions that are provider-specific; many parameters besides AUC data (fluoroscopy time, D2B, % normal cath rate, etc)
- Supported by ACCF and SCAI, among others
- Implemented the Appropriate Use Criteria 2009
# NCDR/CathPCI Registry Reporting An Example: Stress Test Level of Detail

**CathPCI Registry**

**NCDR® CathPCI Registry® v4.4**
Diagnostic Catheterization and Percutaneous Coronary Intervention Registry

<table>
<thead>
<tr>
<th>Stress or Imaging Studies Performed</th>
<th>No</th>
<th>Yes</th>
<th>Risk/Extent Of Ischemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Exercise Stress Test</td>
<td>O</td>
<td>O</td>
<td>If Positive, O Low, O High, O Intermediate, O Unavailable</td>
</tr>
<tr>
<td>Stress Echocardiogram</td>
<td>O</td>
<td>O</td>
<td>If Positive, O Low, O High, O Intermediate, O Unavailable</td>
</tr>
<tr>
<td>Stress Testing w/SPECT MPI</td>
<td>O</td>
<td>O</td>
<td>If Positive, O Low, O High, O Intermediate, O Unavailable</td>
</tr>
<tr>
<td>Stress Testing w/CMR</td>
<td>O</td>
<td>O</td>
<td>If Positive, O Low, O High, O Intermediate, O Unavailable</td>
</tr>
<tr>
<td>Cardiac CTA</td>
<td>O</td>
<td>O</td>
<td>If Yes, No disease, O 1VD, O Unavailable</td>
</tr>
<tr>
<td>Coronary Calcium Score</td>
<td>O</td>
<td>O</td>
<td>If Yes, Calcium Score 6251</td>
</tr>
</tbody>
</table>
AUC PCI: The JAMA Article & The NCDR Data 2009-2010

Appropriateness of Percutaneous Coronary Intervention

Paul S. Chan, MD, MSc
Manesh R. Patel, MD
Lloyd W. Klein, MD
Ronald J. Krone, MD
Gregory J. Dehmer, MD
Kevin Kennedy, MS
Brahmaje K. Nallamothu, MD, MPH
W. Douglas Weaver, MD
Frederick A. Masonidi, MD, MSPH
John S. Rumansfeld, MD, PhD
Ralph G. Brindis, MD, MPH
John A. Spertus, MD, MPH

A

PRXIMATELY 600,000 PERCU
teaneous coronary inter
entions (PCIs) are per
formed in the United States

Context Despite the widespread use of percutaneous coronary intervention (PCI), the appropriateness of these procedures in contemporary practice is unknown.

Objective To assess the appropriateness of PCI in the United States.

Design, Setting, and Patients Multicenter, prospective study of patients within the National Cardiovascular Data Registry undergoing PCI between July 1, 2009, and September 30, 2010, at 1091 US hospitals. The appropriateness of PCI was adjudicated using the appropriate use criteria for coronary revascularization. Results were stratified by whether the procedure was performed for an acute (ST-segment elevation myocardial infarction, non–ST-segment elevation myocardial infarction, or unstable angina with high-risk features) or nonacute indication.

Main Outcome Measures Proportion of acute and nonacute PCIs classified as appropriate, uncertain, or inappropriate; extent of hospital-level variation in inappropriate procedures.

Results Of 500,154 PCIs, 355,417 (71.1%) were for acute indications (ST-segment elevation myocardial infarction, 103,245 (20.6%); non–ST-segment elevation myocardial infarction, 105,708 (21.1%); high-risk unstable angina, 146,464 (29.3%), and 144,737 (28.9%) for nonacute indications. For acute indications, 350,469 PCIs (98.6%) were classified as appropriate, 1055 (0.3%) as uncertain, and 3893 (1.1%) as inappropriate. For nonacute indications, 72,911 PCIs (50.4%) were classified as appropriate, 54,988 (38.0%) as uncertain, and 16,838 (11.6%) as inappropriate. The majority of inappropriate PCIs for nonacute indications were
NCDR / Inappropriate Revascularization

ACUTE PCIs: 1.1%
NON-ACUTE PCIs: 11.6%

CathPCI Registry

www.SCAI.org/QIT
NCDR: What are the Most Frequent “Inappropriates”?  

- One- or two-vessel CAD, no proximal LAD involvement, no prior CABG, CCS class I or II, low-risk stress test, no/minimal anti-ischemic therapy (39.6%)  
- One- or two-vessel CAD, no proximal LAD involvement, no prior CABG, asymptomatic, intermediate-risk stress test, no/minimal anti-ischemic therapy (24.5%)  
- One- or two-vessel CAD, no proximal LAD involvement, no prior CABG, asymptomatic, low-risk stress test, no/minimal anti-ischemic therapy (18.3%)
The AUC Revascularization App

Fill out patient information and click apply to see results

Ischemic Symptoms (More Details In Section 3 Below)
- CCS II (Slight limitation of ordinary activity)
- Anti-Ischemic Medical Therapy:
  - Minimal Therapy (1 class of medications)

Non-invasive Test Results (More Details In Section 4 Below)
- Prior CABG
  - No Previous CABG

AUC Definitions
- Clinical Judgement
- Section 3 - Details On Ischemic Symptoms
- Section 4 - Details On Non-invasive Test Results
- What are Indications?
### Revascularization AUC Data Reporting Sheet

**Patient Information**
- CCS II (Slight limitation of ordinary activity)
- Minimal Therapy (1 class of medications)
- Intermediate-risk stress test findings: cardiac mortality 1-3%/year
- No Previous CABS

**CTO of 1 vessel, no other CAD**
- V: Indication: 26, Score: 4

**1-2V CAD, no prox LAD CAD**
- V: Indication: 16, Score: 5

**1V CAD with prox LAD CAD**
- V: Indication: 32, Score: 6

**2V-CAD with prox LAD CAD**
- A: Indication: 38, Score: 7
- A: CABG: Indication: 62; Score: 8
- A: PCI: Indication: 62; Score: 7

**3V-CAD without LMCA CAD**
- A: Indication: 44; Score: 7
  - Abnormal LV systolic function
    - A: Indication: 48; Score: 9
  - Low CAD burden (i.e., 3 focal stenoses, low SYNTAX score)
    - A: CABG: Indication: 63; Score: 9
    - A: PCI: Indication: 63; Score: 7
  - Intermediate-high CAD burden (i.e., multiple diffuse lesions, presence of CTO, or high SYNTAX score)
    - A: CABG: Indication: 64; Score: 9
    - A: PCI: Indication: 64; Score: 4

**LMCA-CAD**
- A: Indication: 49; Score: 9

**Compiled By:**
- Date/Time: 
- Signature: 

**Operating Physician:**
- Operating Physician Comments:
- Date/Time: 
- Signature: 

**Confirming Physician / Intervventionalist:**
Outline for this Presentation

- Appropriate Use Criteria/AUC Coronary Revascularization Overview/Elements
- Appropriate Use Criteria/AUC Diagnostic Cardiac Catheterization Overview/Elements
- Management Prior to and After Patient Referral to the Cardiac Cath Lab
- Dual Anti-Platelet Therapy/DAPT after PCI/Coronary Stenting
- Access Site Complications/Management
- Optimum Medical Therapy/OMT after PCI
- Diagnostic Testing after PCI
AUC Diagnostic Cardiac Cath Categories

- Suspected CAD: No prior noninvasive imaging
- Suspected CAD: Prior noninvasive imaging
- Patients with known prior obstructive CAD
- Evaluation of arrhythmias
- Pre-operative coronary evaluation
- Evaluation of valvular heart disease
- Evaluation of pericardial diseases
- Evaluation of cardiomyopathies
- Evaluation of pulmonary hypertension
The Important Ones for the Primary Care Physician

- Suspected CAD: No prior noninvasive imaging
- Suspected CAD: Prior noninvasive imaging
- Patients with known prior obstructive CAD
- Evaluation of arrhythmias
- Pre-operative coronary evaluation
- Evaluation of valvular heart disease
- Evaluation of pericardial diseases
- Evaluation of cardiomyopathies
- Evaluation of pulmonary hypertension
Suspected CAD: No Prior Noninvasive Stress Imaging

<table>
<thead>
<tr>
<th>Risk Assessment</th>
<th>Low</th>
<th>Intermediate</th>
<th>High</th>
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</thead>
<tbody>
<tr>
<td>Asymptomatic Global CAD Risk</td>
<td>I</td>
<td>I</td>
<td>U</td>
</tr>
<tr>
<td>Symptomatic Pretest Probability</td>
<td>I</td>
<td>U</td>
<td>A</td>
</tr>
</tbody>
</table>
Suspected CAD: Prior Noninvasive Stress Testing

Stress Imaging (ECG Stress Test or Stress Test with Imaging)

- Low Risk Findings
  - Asymptomatic: Inappropriate
  - Symptomatic: Uncertain

- Intermediate Risk Findings
  - Asymptomatic: Uncertain
  - Symptomatic: Uncertain

- High Risk Findings
  - Appropriate

- Discordant or Equivocal/Uninterpretable Findings
  - Asymptomatic: Uncertain
  - Symptomatic: Appropriate

www.SCAI.org/QIT
Patients With Known Obstructive CAD

Known Obstructive CAD

- Asymptomatic/controlled symptoms or unchanged findings
  - Post revascularization
    - Unprotected prior left main PCI?
      - No
        - Inappropriate
      - Yes
        - Inappropriate
  - Medically managed
    - Noninvasive findings?
      - Yes
        - Low risk
        - Intermediate risk
        - High risk
        - Uncertain
      - No
        - Appropriate
Preoperative Coronary Evaluation: Patients With No Prior Noninvasive Stress Testing
Diagnostic Catheterization AUC: General Conclusions for the PCP

- Assists us in determining need for right/left heart cath and coronary angiography in your patients
- Asymptomatic patients should generally not go directly to cath lab
- Stable pre-operative patients should rarely go directly to cath lab
- High probability CAD patients may go directly to diagnostic cath/coronary angiography, dependent on case specifics
Outline for this Presentation

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Patients should be assessed for risk of contrast-induced AKI before PCI.

Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration.

In patients with CKD (Crcl <60 mL/min), the volume of contrast media should be minimized.
Contrast-Induced Acute Kidney Injury

Administration of **N-acetyl-L-cysteine** is **not useful** for the prevention of contrast-induced AKI.

*Additional points:*
- **Metformin**: Discontinue 24 hours prior, check serum creatinine 48 hours after prior to restart
- **ACEI**: May need to be held in patients with low creatinine clearance/GFR
Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate steroid and antihistamine prophylaxis before repeat contrast administration.

In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial.
Administration of a high-dose statin is reasonable before PCI to reduce the risk of peri-procedural MI.

- Statin-naive patients:
  - I IIa IIb III

- Patients on chronic statin therapy:
  - I IIa IIb III

Administration of a high-dose statin is reasonable before PCI to reduce the risk of peri-procedural MI.
All patients should be evaluated for risk of bleeding before PCI.

*Additional points:
- Coumadin held; INR should be < 1.6
- Dabigatran/rivaroxaban held several days prior; dependent on GFR
- Unfractionated/low molecular weight heparin bridging likely necessary in patients with mechanical prosthetic valves
- Acknowledge significant bleeding risk of “triple therapy”
WOEST Trial: ESC 2012

- Compared DAPT + anti-thrombotic (warfarin) for PCI/stent patients with need for ongoing anticoagulation (AF, mechanical valve, other) vs warfarin and clopidogrel alone (no ASA)
- Bleeding complications on “triple therapy” = 44.9%
- No significant difference in CV major endpoints that included stent thrombosis, MI, death
- Major reduction in bleeding complications in pts not taking ASA
- No confirmatory study/change in guidelines at this point
Outline for this Presentation

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- Diagnostic Testing after PCI
Frequent Questions from the PCP About DAPT

- What about the newer agents prasugrel and ticagrelor, and is generic clopidogrel OK to use?
- Should I stop my patient’s proton pump inhibitor if they are taking clopidogrel?
- What do I do with my patient’s anti-platelet therapy during non-cardiac surgery?
- Does my patient benefit from DAPT > 1 year?
- What about that “black boxed” warning the FDA placed on the clopidogrel insert? Is my patient a “poor metabolizer”?
- What are “The Basics” about DAPT post-PCI?...
Patients already taking daily aspirin therapy should take 81 to 325 mg prior to PCI.

Patients not on aspirin therapy should be given nonenteric aspirin 325 mg prior to PCI.

After PCI, aspirin should be continued indefinitely.
The duration of **P2Y12 inhibitor therapy** after stent implantation should generally be as follows:

- In patients receiving a **stent (BMS or DES) during PCI for ACS**, P2Y12 inhibitor therapy should be given for at least 12 months. Options include: clopidogrel 75 mg daily, prasugrel 10 mg daily, and ticagrelor 90 mg twice daily.

- In patients receiving a **DES for a non–ACS indication**, clopidogrel 75 mg daily should be given for **at least 12 months** if patients are not at high risk of bleeding.

- In patients receiving a **BMS for a non-ACS indication**, clopidogrel should be given for a **minimum of 1 month and ideally up to 12 months** (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks).
After PCI, it is reasonable to use 81 mg per day of aspirin in preference to higher maintenance doses.

If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of P2Y12 inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 months) of P2Y12 inhibitor therapy is reasonable.
Some Aspirin Issues....

- True ASA allergy vs. “allergy”/GI intolerance
- ASA “resistance” vs. noncompliance
- ASA desensitization feasible for the truly allergic
- Specific ASA dosage to be used varies depending on the clinical context and additional antiplatelet therapy
PCI with coronary stenting (BMS or DES) should not be performed if the patient is not likely to be able to tolerate and comply with DAPT for the appropriate duration of treatment based on the type of stent implanted.

Additional consideration:

Patient treatment compliance tools: SCAI Quality Committee actively evaluating
What about the newer agents prasugrel and ticagrelor, and is generic clopidogrel OK to use?
Oral Antiplatelet Therapy
Newer P2Y12 Receptor Blockers

- Ticlopidine: TTP risk, little used at present
- Clopidogrel: now generic and cost reduced; bioavailability issues/contaminants may be important but unknown; most studies done with original brand
- **Prasugrel**: contraindications include prior CVA; caution in age >75yo, weight <60kg
- **Ticagrelor**: ASA dose < 100mg
- Future agents: cangrelor, elinogrel, PAR-1 inhibitors
Should I stop my patient’s proton pump inhibitor if they are taking clopidogrel?
Proton pump inhibitors and Clopidogrel: The FDA Black Boxed Warning 2009

- Nov. 17, 2009 – FDA alert: “New data show that when clopidogrel and omeprazole are taken together, the effectiveness of clopidogrel is reduced. Patients at risk for heart attacks or strokes who use clopidogrel to prevent blood clots will not get the full effect of this medicine if they are taking omeprazole.”
The Issue: Clopidogrel & PPI’s

- PPIs are potent inhibitors of CYP2C19.
- Does co-administration of clopidogrel and PPIs lead to adverse patient outcomes?
- What effect will omeprazole have on clopidogrel metabolism in a patient with CYP2C19 *2/*2?
The COGENT Trial: Implications

- Provided reassurance that there is no clinically relevant CV interaction between PPI’s and clopidogrel.
- Called into question the utility of platelet reactivity assays.

**THE WALL STREET JOURNAL**

**HEALTH INDUSTRY | OCTOBER 7, 2010**

**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.
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.
What do I do with this patient’s anti-platelet therapy during non-cardiac surgery?

Two big considerations....
Peri-operative Stent Thrombosis: Risk Factors

- Timing: 6 weeks BMS, 12 months DES
- Advanced age
- Diabetes mellitus
- Renal dysfunction
- Low LVEF
- ACS @ presentation
- Stenting of long/multiple lesions
- Bifurcational and ostial lesions
- Suboptimal stent deployment/apposition
- Overlapping stents

Circulation 2007, 116:e378-e382
# Bleeding Risk of Procedures

## Low Bleeding Risk
- Dermatologic
- Anterior eye chamber
  - Cataract extraction
- Oral surgery/extractions
- EGD
- Colonoscopy without polypectomy

## Moderate Bleeding Risk
- Orthopedic surgery
- Abdominal procedures
- Thoracic procedures
- Urologic procedures
- Vascular procedures
Bleeding Risk of Procedures

- Intracranial
- Spinal column/neuraxis
- Specific procedures with high expected bleeding
  - Highly vascular tumors
  - Liver surgery/partial hepatectomy
- ?TURP
Peri-procedural DAPT: Recommendations

- For elective procedures, await completion of DAPT.
  - 1 month minimum for BMS.
  - 1 year for DES.

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

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

Grines. JACC. 2007;49:734-9
Does this patient benefit from prolonged dual antiplatelet therapy > 1 yr?

The Answer: No data to necessarily support DAPT > 12 months for low anatomic and clinical risk patients; definitive answer not available
DAPT Frequent Question

- What about that “black boxed” warning the FDA placed on the clopidogrel insert? Is my patient a “poor metabolizer”?
Patients with CYP2C19 *2,*3 alleles metabolize clopidogrel poorly and are at higher risk for adverse events following PCI.

Inform health care professionals of tests available to identify genetic differences in CYP2C19 function.

Consider alternative antiplatelet strategies for clopidogrel in poor metabolizers.

FDA did NOT recommend routine genetic screening.
Clopidogrel Metabolism

- Clopidogrel must be metabolized to be active
- CYP2C19 is one of the factors of concern
- CYP2C19 variants exist
- Homozygotes for the *2/*2 allele for CYP2C19 is an "at risk" category
- Heterozygote clinical implications are still unclear

Genetic testing might be considered to identify whether a patient at high risk for poor clinical outcomes is predisposed to inadequate platelet inhibition with clopidogrel.

When a patient predisposed to inadequate platelet inhibition with clopidogrel is identified by genetic testing, treatment with an alternate P2Y12 inhibitor (e.g., prasugrel or ticagrelor) might be considered.

The routine clinical use of genetic testing to screen clopidogrel-treated patients undergoing PCI is not recommended.
Platelet function testing may be considered in patients at high risk for poor clinical outcomes.

In clopidogrel-treated patients with high platelet reactivity, alternative agents such as prasugrel or ticagrelor might be considered.

The routine clinical use of platelet function testing to screen clopidogrel-treated patients undergoing PCI is not recommended.
Outline for this Presentation

- Appropriate Use Criteria/AUC Coronary Revascularization Overview/Elements
- Appropriate Use Criteria/AUC Diagnostic Cardiac Catheterization Overview/Elements
- Management Prior to and After Patient Referral to the Cardiac Cath Lab
- Dual Anti-Platelet Therapy/DAPT after PCI/Coronary Stenting
- Access Site Complications/Management
- Optimum Medical Therapy/OMT after PCI
- Diagnostic Testing after PCI
Access Site Management Issues

- **Femoral**
  - Hematoma vs. Pseudoaneurysm
  - AV fistula
  - Infection
  - Limb ischemia
    * Differential: cholesterol embolism syndrome

- **Radial**
  - Sterile local proliferation reaction

- **Vascular Closure Devices**
  - Temporal limitation on repeat access
Access Site Management Issues

Pseudoaneurysm Risk Factors

- Antiplatelet agents
- Anticoagulation
- Large sheath size > 8F
- Age > 65 years
- Obesity
- Poor post-procedural compression
- Hemodialysis
- Simultaneous artery/vein catheterization
- Hypertension
- Peripheral arterial disease
- Complex interventions
- Low or high puncture sites
Access Site Management Issues
Pseudoaneurysm Treatment

- PTFE covered stent in femoral artery to exclude pseudoaneurysm
- Ultrasound probe compression
- **Ultrasound-guided thrombin injection** *
- Open vascular surgical repair/ligation
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OMT/Secondary prevention: ACC/AHA/SCAI Class I Recommendations

1. **Tobacco Cessation**
2. **BP Control:** < 140/90 or < 130/80 if DM or CKD.
3. **Lipid Management:** LDL < 100, if trig > 200, non-HDL should be < 130 mg/dl.
4. **Physical Activity:** 30 min. at least 5 days / week.
5. **Weight Management:** BMI 18.5-24.9 kg/m2. Waist circumference: Men < 40 in, Women < 35 in.
6. **DM Management:** HbA1c < 7%.
7. **Aspirin:** ASA 162-325 mg / day x 1 m post BMS, 3 mo post SES, 6 mo post PES, then ASA 75-162 mg / day.

King et al. JACC 2008. 51: p. 172-209
OMT/Secondary prevention: ACC/AHA/SCAI Class I Recommendations

8. **Clopidogrel:**
   - DES → Clopidogrel 75 mg / day x 12 m.
   - BMS → Clopidogrel 75 mg / day x 1 m minimum and ideally up to 12 m. Minimum of 2 wks if increased bleeding risk.

9. **Warfarin:** INR 2-3 for AF / flutter.
   - If warfarin, clopidogrel, and ASA required, then INR of 2-2.5, ASA 75-81 mg, and clopidogrel 75 mg / day
OMT/Secondary prevention: ACC/AHA/SCAI Class I Recommendations

10. **ACE-I:** Use if
   - LVEF < 40%
   - HTN, DM, or CKD.

11. **ARB:** use if intolerant of ACE-I plus
   - CHF or LVEF < 40% or if HTN is present.

12. **Aldosterone blockade:** use if post-MI on an ACE-I and B-blocker, LVEF < 40% and have DM or CHF

13. **Beta blockers:** Use if pt has had an MI, ACS, or LV dysfunction.

14. **Annual Influenza Vaccination**
Medically-supervised exercise programs (cardiac rehabilitation) **should be recommended** to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted.
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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
What About CTA Usefulness After Stenting?

- Anatomic information alone; no physiologic data
- Pre-existing stents (especially with extensive calcification) significantly limit assessment of luminal narrowing of the involved vessel segment
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.

Possible additional considerations:
- Unprotected LMCA stent
- “Last remaining vessel” stent
- Silent ischemia/SCD as initial presentation
Other SCAI Quality Activities

- Accreditation for Cardiovascular Excellence/ACE certification
- Current AUC App for coronary revascularization
- Future AUC App for diagnostic catheterization
- Regional SCAI-QIT sponsored educational sessions for referring physicians
- “Choosing Wisely” effort

**BREAKING NEWS:** SCAI-QIT AUC App Now Available
Coronary revascularization appropriate use criteria (AUC) are now just a click away with the new SCAI Quality Improvement Toolkit (SCAI-QIT) AUC and Guidelines App. ACCESS THE ONLINE APP NOW! >

www.SCAI.org/QIT
The ABIM Foundation’s “Choosing Wisely” Initiative

- Cooperative effort of ABIM with multiple subspecialty societies, including ACP and AAFP
- ACC and SCAI, in addition to many other subspecialty organizations, partnering in these efforts as well
- List of five commonly used, but not always necessary, tests and procedures
- SCAI recommendations at www.scai.org
Questions/Answers

Let's Get to Work on QUALITY, One Cath Lab at a Time.