Defining Quality in the Cath Lab

Sridevi Pitta, MD, MBA, FSCAI

Jayant Bagai MD, FSCAI

Disclosures

- Pitta, Sridevi: No relevant relationships with commercial interests to disclose.
- Bagai, Jayant: No relevant relationships with commercial interests to disclose.

Quality as it relates to patient care

- Quality is a science that involves ensuring that appropriate structural and process elements are in place to achieve the best patient selection and the best patient outcomes

- Quality, at the patient level, ensures providing the right procedure to the right patient at the right time in the right way

Evaluation of quality in the Cath Lab

- Quality can be evaluated in three broad areas or "domains"

Structural Domain

- Refers to the context in which care is delivered (hospital, cardiac catheterization lab (CCL) and its human resources)

- Examples:
  - Hospital and CCL infrastructure
  - CCL Quality Improvement (QI) committee
  - Staff education, training and specialty certification
  - Institutional PCI volume

Process Domain

- Refers to the processes and procedures for delivering care

- Examples:
  - System-related (pre-procedure checklists, STEMI/hypothermia protocols, D2B time, patient turnaround, adequacy of ancillary services)
  - Patient care related (quality of angiograms, CCL documentation and reporting)
  - Guideline-related (dual antiplatelet therapy or DAPT, statin post MI, infection control, radiation safety, appropriateness use criteria or AUC)
  - Cost and utilization related (supplies, length of stay and readmission post PCI)

Outcome Domain

- Refers to the consequence of care delivered

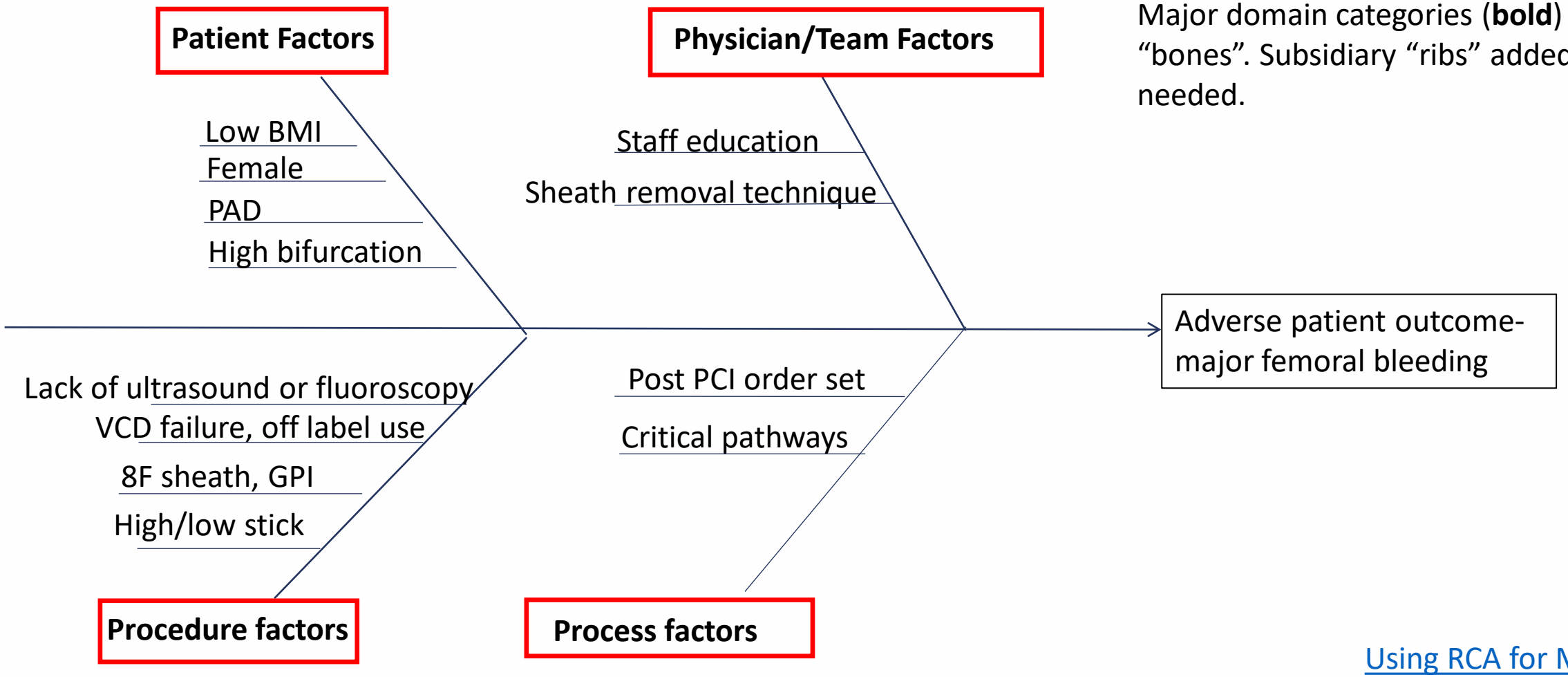
- Examples:
  - PCI risk-adjusted mortality
  - Morbidity due to radiation, contrast nephropathy, bleeding, stroke
  - Patient satisfaction

QI tools

Root Cause Analysis (RCA)

- Retrospective analysis which evaluates the cause of failure after the event has occurred
- Required by The Joint Commission (TJC) for sentinel events
- Typically represented by a cause and effect or “fishbone” or Ishikawa diagram
- Examples in CCL- analysis of medication or communication errors, adverse events discussed in Morbidity and Mortality Improvement (MM&I) conference, slow case turnover

Example of fish-bone diagram for MMI
Major domain categories (**bold**) are "bones". Subsidiary "ribs" added as needed.



Using RCA for MM&I

FOCUS-PDSA

- **F**ind a problem or process to improve
- **O**rganize a team
- **C**larify the current process
- **U**nderstand the process, variations and the root cause(s) of the problem
- **S**elect the improvement or intervention

- **P**lan
- **D**o
- **S**tudy
- **A**ct

PDSA

Plan

- Define the current situation and process
- Define specifically what you are trying to accomplish
- Obtain buy-in from key stakeholders and identify ways to counteract resistance to change
- Develop a plan to implement the improvement and how to test the change

Do

- Implement the plan
- Record any unexpected events and other observations

Study

- Monitor outcomes
- Determine if the interventions improved the process/problem
- Evaluate need for modifications to the approach and identify additional area for improvement

Act

- Decide if it is appropriate to implement the plan broadly, modify or discard it
- Determine if processes can be improved further.

Failure mode and effects analysis

- Prospective (analysis performed **before** event has taken place), unlike RCA which is retrospective
- Identifies probability, possible mode(s), timing and impact of failure
- Develops action plan to follow in case event occurs
- “Fish-bone” or Ishikawa diagram can be used during analysis

- Example in CCL- prevention of radiation induced skin damage

  - Recognize risk factors and probability for radiation induced injury (obesity, complex PCI, especially chronic total occlusion (CTO) PCI, prior radiation exposure/damage, faulty equipment)
  - Gain awareness of implications of radiation damage (skin ulceration, malignancy)
  - Develop **prospective** action plan if high radiation exposure were to occur (establish limits for hard stop, change to 7.5 fps during case, stage additional PCI, close follow-up of patient and reporting)

Total Quality Management

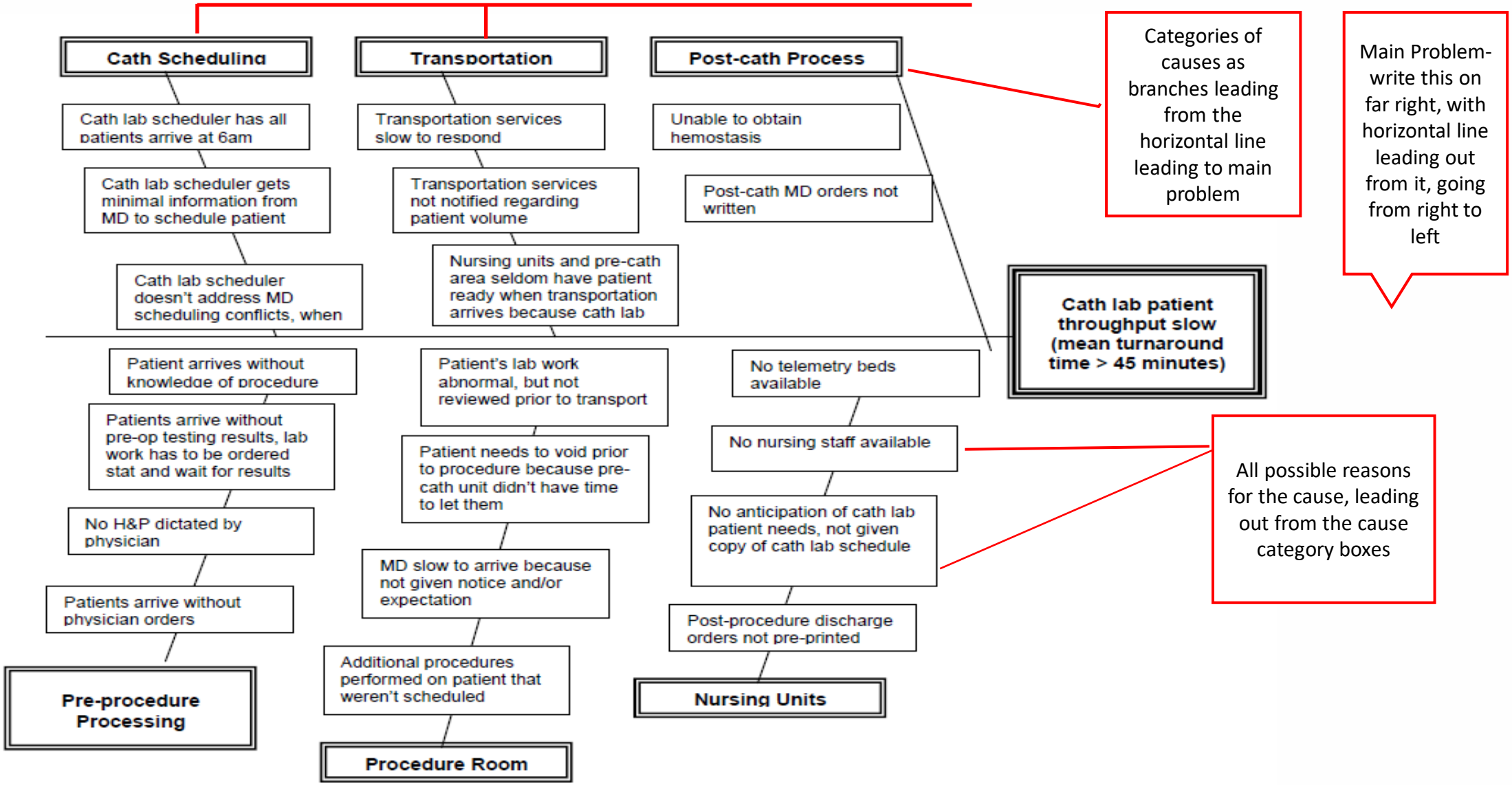
- Stresses importance of multidisciplinary or cross-organizational approach
- System wide emphasis on importance of quality, measurement, empowerment and continuous improvement
- Examples in CCL-
  - Development of multi-disciplinary team of nurses, physicians, NPs and pharmacists/pharmacy residents to ensure post PCI compliance with DAPT, statins and smoking cessation
  - Coordination of care with patient's primary care physician to ensure adequate follow-up post PCI and medication counselling

Lean production

- Focus on cost/value equation
- Aim is "doing better with less (cost)"
- Example in CCL-choosing lower cost equipment of equivalent efficacy and safety in cath lab inventory, after consultation with physicians and staff in cath lab

Case example of quality issue in CCL

- Physicians and CCL staff complain about the long turnaround between cases.
- CCL, holding room staff and physicians are blaming each other, contributing to stress and low morale
- RCA and PDSA techniques can be applied to resolve this issue


Cath Scheduling
Transportation
Post-cath Process
Cath lab scheduler has all patients arrive at 6am
Cath lab scheduler gets minimal information from MD to schedule patient
Cath lab scheduler doesn't address MD scheduling conflicts, when
Transportation services slow to respond
Transportation services not notified regarding patient volume
Nursing units and pre-cath area seldom have patient ready when transportation arrives because cath lab
Unable to obtain hemostasis
Post-cath MD orders not written
Cath lab patient throughput slow (mean turnaround time > 45 minutes)
Patient arrives without knowledge of procedure
Patients arrive without pre-op testing results, lab work has to be ordered stat and wait for results
No H&P dictated by physician
Patients arrive without physician orders
Pre-procedure Processing
Patient's lab work abnormal, but not reviewed prior to transport
Patient needs to void prior to procedure because pre-cath unit didn't have time to let them
MD slow to arrive because not given notice and/or expectation
Additional procedures performed on patient that weren't scheduled
Procedure Room
No telemetry beds available
No nursing staff available
No anticipation of cath lab patient needs, not given copy of cath lab schedule
Post-procedure discharge orders not pre-printed
Nursing Units
Categories of causes as branches leading from the horizontal line leading to main problem
Main Problem- write this on far right, with horizontal line leading out from it, going from right to left
All possible reasons for the cause, leading out from the cause category boxes

Using PDSA to resolve quality issues

- **Plan**: focus group consisting of holding room and CCL charge nurses, CCL Director, patient representative, bed manager and discharge coordinator
- **Do**: electronic charting, eliminate need to give report more than once, discharge patients from holding room in timely manner, physicians asked to place post-cath orders and speak with family immediately after case, use pre-procedure checklist to keep next patient ready
- **Study**: measure reduction in turn around time and obstacles to implementation of plan
- **Act**: Decision made to implement plan after significant reduction noted in turnaround

Question 1- A 67-year-old obese male with chronic kidney disease is scheduled for coronary angiography via the R radial artery for atypical chest pain. A 60-70% distal circumflex stenosis is noted, and a decision is made to perform PCI. The procedure is lengthy due to poor guide support, proximal tortuosity and poor quality images. 350 ml of contrast is used with a fluoroscopy time of 26 minutes and Air Kerma of 3.2 Gy. The patient is discharged the day following PCI and presents to an outside hospital 1 week later with severe renal failure. Quality assessment and improvement is required in which of the following domains

A. Structural domain

B. Process domain

C. Outcome domain

D. All three domains

Correct Answer: D

- Quality assessment in this case with an adverse patient outcome (contrast-induced acute kidney injury) should focus on all three domains. There is potential for quality improvement in the structural (outdated cath lab equipment with high x-ray output), process (non-utilization of appropriateness use criteria before performing PCI on a lesion with borderline angiographic severity with non-limiting symptoms and no functional testing) and outcome (education and close monitoring for radiation and contrast induced injury) domains.

Question 2- A 56-year-old diabetic male weighing 290 lbs. is scheduled for PCI on a chronically occluded left circumflex coronary artery. Dual injection is planned. The procedure is expected to be challenging due to presence of calcification, tortuosity and prior failed attempt. Which of the following QI tools can be used to improve patient outcomes?

A. Root cause analysis

B. Lean production

C. Failure mode and effects analysis

D. PDSA

Correct Answer: C

- This case is likely to be associated with high radiation dose delivered to the patient. By recognizing this before the case, efforts can be made prospectively to lower radiation dose by using a lower frame rate, fluoro save, last image hold, collimation, dose spreading, monitoring table height and using shallower working angles. A hard stop limit can be decided if the occlusion is not crossed by a wire. This is an example of failure mode and effects analysis. RCA is used to determine the cause of an event retrospectively (i.e. after its occurrence). Lean production is not a relevant tool in this case as it focuses on cutting cost and utilization. PDSA cycles are also applied retrospectively.

Question 3- You are concerned about quality issues in a case involving a 63 year old man who suffered a stroke surrounding PCI. The patient was restless on the cath lab table and required large doses of sedation. 4 hours after being transferred to the floor, a nurse discovered him to be unresponsive and not breathing. He was emergently intubated and treated for respiratory failure with CO2 retention. CT imaging 12 hours later showed a large MCA territory stroke. He was outside the window for reperfusion and sustained a severe neurological deficit. Which of the following quality issues does this event raise concern about?

A. Structural domain

B. Process domain

C. Both A and B

D. Neither A or B

Correct Answer: C

- This patient likely suffered a stroke during or soon after the procedure. Unfortunately due to the confounding effect of the sedation and CO2 retention, he was treated for respiratory failure. Inclusion of q 1 hour neurochecks in the order set with immediate notification of the procedural MD/Neurology for any mental status change post PCI as part of the post-PCI process/system of care could have resulted in earlier diagnosis of stroke and possible reperfusion with improved neurological outcome. In addition, improved staff education (structural domain) could have resulted in improved outcome as well.

Operator Staff and Training Requirements

Mazen Abu-Fadel, MD, FSCAI

Jayant Bagai, MD, FSCAI

Christine Gasperetti, MD, FSCAI

Disclosures:

- **Abu-Fadel, Mazen.** No relevant relationships with commercial interests to disclose.
- **Bagai, Jayant.** No relevant relationships with commercial interests to disclose.
- **Gasperetti, Christine.** Boston Scientific, PI. Abiomed, Honoraria.

Cath Lab Staff Required Qualifications

Type of Staff	Degrees	Experience	Training
Licensed Nurse	One or more of following- RN, APRN, BSN, NP-C, CNS, CVRN, CRN, RCIS	At least 6 months experience in critical care (ICU, ER, cath lab)	BLS and ACLS (PALS), ≥ 15 hours of documented accredited CE relevant to heart disease every 3 years, including 1 hour of radiation safety training every 3 years
Licensed Technologist	RCIS or RT (R) meeting either cardiac or cardiovascular interventional radiography qualification	≥ 1 year of full-time equivalent experience as CV cath technologist/specialist under direct supervision of personnel meeting pathway (as in column on left)	BLS, recommended ACLS (PALS), ≥ 15 hours of documented accredited CE relevant to heart disease every 3 years, including 1 hour of radiation safety training every 3 years

All staff must comply at all times with all federal, state and local laws and regulations, including but not limited to laws relating to licensed scope of practice, facility operations and billing requirements.

Core/Basic Competencies

- Nurse
  - Administering and monitoring conscious sedation
  - Assessment and monitoring clinical status of patient
  - Theoretical and practical knowledge of medications used in cath lab
  - Knowledge of radiation safety, infection control and hemodynamic support
  - Communicating with patient care team, patient and patient's family
- Technologist
  - Recording patient history and clinical data; recording physiological data
  - Patient positioning, selection of radiation exposure parameters, imaging and archival
  - Thorough understanding of equipment, supplies, troubleshooting
  - Assisting physician as scrub person; circulating and procuring supplies if needed

Cath Lab Manager Qualifications

Type of Staff	Degrees	Experience	Training
Cath Lab Manager	Appropriately credentialed technologist and/or nurse with RCIS certification	Minimum of 5 years experience (preferably in a cardiac catheterization lab) with strong leadership qualities.	BLS and ACLS (PALS), ≥ 15 hours of documented accredited CE relevant to heart disease every 3 years, including 1 hour of radiation safety training, every 3 years

Responsibilities of Cath Lab Manager

- Leadership through motivation, positive communication, team building and accountability
- Operations planning
- Maintaining safety and regulatory standards
- Quality monitoring and management
- Budgeting and resource allocation
- Personnel management

Responsibilities of Clinical Staff Leader (CSL)

- People management/leadership
  - Supervision of day to day performance
  - New staff coaching and assessment
  - Problem solving skills
- Communication
  - Feedback, performance improvement counseling
- Compliance and safety
  - Supports delivery of quality patient care
  - Monitors staff training and compliance
  - Implements area specific policies and guidelines
  - Manages PDSA cycles
  - Demonstrates clinical knowledge to coach staff
  - Identifies and addresses customer service issues
- Planning and organization
  - Resource management
  - Provides input for budget

Staff education and certification

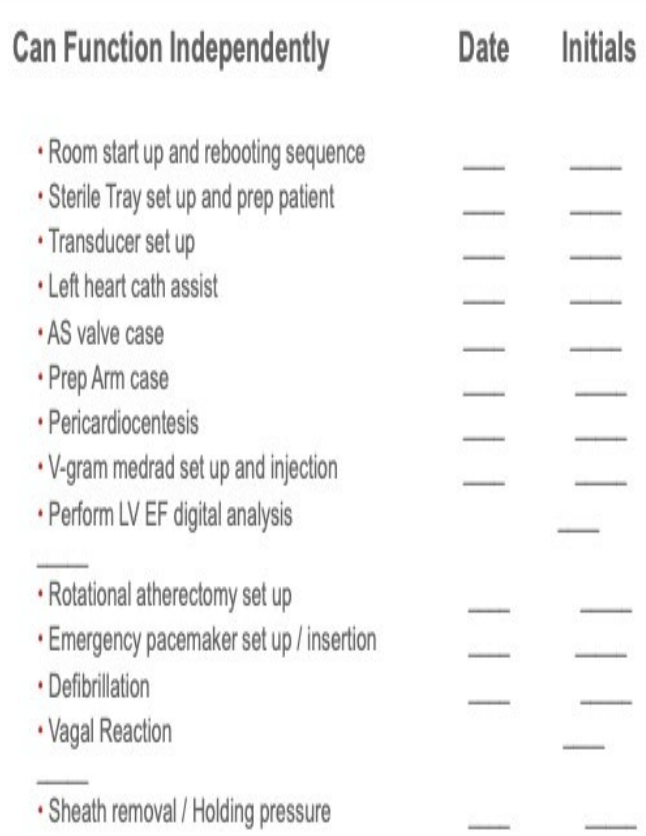
- Society of Invasive Cardiovascular Professionals (SICP)
  - Established in 1993, recommends educational curriculum for invasive Cardiovascular Technologists (CVT)
  - Now merged with Alliance of Cardiovascular Professionals (ACVP) professional society
  - 2015 Educational Guidelines for Invasive Cardiovascular Technology Personnel in the Cardiovascular Catheterization Laboratory

Staff credentialing

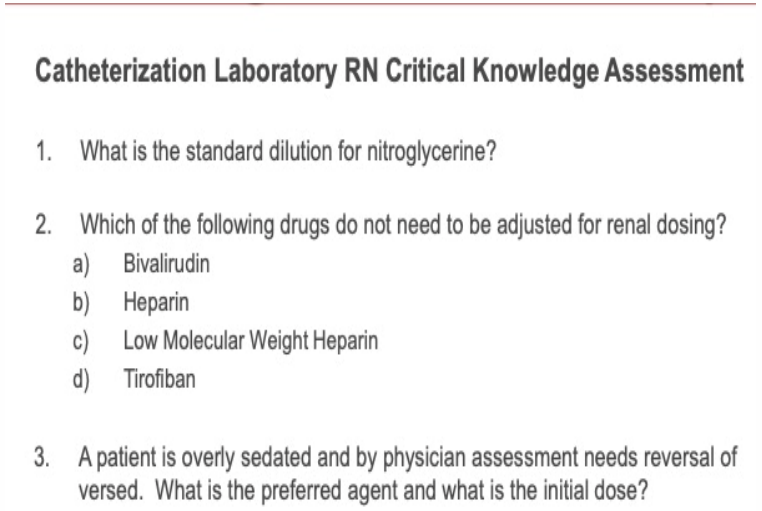
- Cardiovascular Credentialing International (CCI)
  - Credentialing organization for invasive CVTs, including both RN and RT(R) staff
  - Registered Cardiovascular Invasive Specialist (RCIS) Certification after passing exam; endorsed by ACC
  - SICP recommends at least one RCIS per cath lab
  - Requires renewal after 1 year; then every 3 years with fees and continuing education
  - RCIS examination overview
- Commission on Accreditation of Allied Health Education Programs (CAAHEP) and Joint Review Committee on Education in Cardiovascular Technology (JRC-CVT)
  - Develop accreditation standards and guidelines for post-secondary educational programs in invasive CVT
  - CAAHEP-accredited invasive cardiovascular program graduates eligible to sit for RCIS exam

Ongoing education, training and assessment

- Written and practical exam recommended; materials available from CCI and SCIP
- Additional training and skills assessment for complex procedures- coronary (CTO, atherectomy, high-risk PCI, mechanical circulatory support), endovascular (carotid, stroke, EVAR, TEVAR) and structural (TAVR, MitraClip, perivalvular leak closure, LAA occlusion, valve-in-valve and percutaneous MV replacement)
- Mentorship and cross-training
- Annual skills review with remedial process
- Continuing education credits, webcasts, conference attendance- concept of “lifelong learning”



Can Function Independently	Date	Initials
• Room start up and rebooting sequence	___	___
• Sterile Tray set up and prep patient	___	___
• Transducer set up	___	___
• Left heart cath assist	___	___
• AS valve case	___	___
• Prep Arm case	___	___
• Pericardiocentesis	___	___
• V-gram medrad set up and injection	___	___
• Perform LV EF digital analysis		___
___		
• Rotational atherectomy set up	___	___
• Emergency pacemaker set up / insertion	___	___
• Defibrillation	___	___
• Vagal Reaction		___
___		
• Sheath removal / Holding pressure	___	___



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?

Operator (MD) Requirements

- Successful completion of COCATS Level III training undertaken during a dedicated Interventional Cardiovascular (IC) training program
- ABIM certification in IC and maintenance of certification (MOC) are strongly recommended
- ABIM Recertification-traditional 10-year MOC exam or new 2-year knowledge check-in MOC exam
- Minimum volume of 50 PCIs per year, averaged over a 2-year period, to maintain competency
- 30 CME hours every 2 years

Harold JA et al. ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures

Operator PCI volume

- Operator volume is only one of several factors that should be considered when assessing an individual operator's competence
- Other factors to consider include (but are not limited to): performance of additional noncoronary cardiovascular interventional procedures, lifetime experience, ABIM certification in IC, attendance at educational symposiums, CME credits, and simulation courses
- Operators performing<50 PCIs/year should not be denied privileges or excluded from performing PCI based solely on their procedural volume
- Alternate pathways (independent institutional committee or an external review organization) to evaluate performance of low-volume (<50 PCIs annually) operators should be established and monitored

Qualifications of Cath Lab Director

- MD or DO with board certification in Cardiology/Interventional Cardiology (Adult or Pediatrics)
- Minimum 5 years of experience with strong leadership qualities
- BLS and ACLS certified
- Completion of radiation safety training
- Leadership, team management and communication skills

Responsibilities of Cath Lab Director

- Oversight, review and updates of cath lab policies and clinical practices
- Establishment and monitoring of QI programs and conferences (MMI, cath conference)
- Establish criteria for MD credentialing and recredentialing
- Periodic performance review (OPPE, FPPE), recommendations for renewal of privileges
- Review performance of trainees and staff and provide necessary training to personnel
- Ensure adequate resources and safe use of equipment; inventory decisions, procurement and budgeting
- Oversight of patient scheduling, referral services, post-procedure reporting and tracking of quality measures (including appropriate use and complications)
- Conflict resolution, team building

Daggubati et al. Chin Med J. 127. 1194-6

Question 1- During MM & I conference, questions were raised regarding the effect of PCI volume on quality of procedures. Which of the following is correct?

A. Many consider those with higher PCI volumes to be better operators. Because Dr. X is a high-volume operator, it can be assumed that there are no quality issues in his cases with adverse events.

B. Dr. Y performs 60 PCIs/year but his volume has lesser impact on patient given his lifetime experience of performing PCI with good outcomes and high institutional PCI volume.

C. During the past 10 years, overall PCI volume has diminished, with mean annual PCI volume of 59. Operators performing <25 cases/year are now considered to low-volume operators.

D. During the past 10 years, overall PCI volume has diminished, with mean annual PCI volume of 59. Operators performing > 400 cases/year are now considered to high-volume operators.

Answer: B

A 2013 ACCF/AHA/SCAI publication lowered the minimum annual PCI volume (averaged over 2 years) to 50. In addition, a significant interaction has been noted between operator and institutional PCI volume, with lower rates of in-hospital mortality and CABG in patients undergoing PCI by operators performing > 75 PCIs/year in hospitals performing > 400 PCIs/year . Answer A is incorrect-while high volumes are not discouraged, case volume is not a substitute for quality and appropriateness. Answer C is incorrect-operators performing <50 cases per year are considered to have low volumes. Answer D is incorrect-operators performing >100 cases per year (averaged over 2 years) are considered to have high volumes. Operators performing 50-100 cases per year are considered to have intermediate volume.

Harold JG et al. ACCF/AHA/SCAI 2013 update of the clinical competence statement on coronary artery interventional procedures. J Am Coll Cardiol. 2013;62:357–396.

Question 2- A study by Fanaroff et al assessing 4 million PCIs performed by >10,000 operators at >1500 centers confirmed that operators who continue to achieve higher volumes have been found to have lower mortalities. Which of the following is true?

A. There was no difference in risk-adjusted in-hospital mortality between low (< 50), intermediate (50-100) and high volume (> 100) operators
B. Operators with higher volumes were more likely to be found in the North and Midwest
C. Procedural success was similar for all operator volumes
D. PCIs performed by high-volume operators were more often in patients with STEMI than those performed by intermediate- or low-volume operators

Answer: B

In this study, operators in the western part of the U.S. had the lowest annual volumes, followed by operators from the South, Midwest, and North. Answer A is incorrect-adjusted risk of in-hospital mortality was higher for PCI procedures performed by low- and intermediate-volume operators compared with those performed by high-volume operators. Answer C is incorrect- while procedural success rates were > 92 % for all operators, success rate was highest (94.2% vs. 93.3% vs. 92.6%) and the risk of new in-patient dialysis was lowest for high-volume operators. Answer D is incorrect- PCIs performed by low-volume operators were more often in patients with STEMI/emergency PCIs than those performed by intermediate- or high-volume operators

Fanaroff AC et al. J Am Coll Cardiol. 2017 Jun 20;69(24):2913-2924.

Question 3- You are trying to hire a new nurse for the cath lab. One of the candidates has excellent recommendations and appears to be competent, friendly and dedicated. She has worked in same day surgery for 3 years. As the nurse manager, you should-

A. Hire her immediately
B. Inform her that she does not qualify as she does not have at least 6 months of critical care experience before working in the cath lab
C. Inform her that she will need a period of supervision and on the job training
D. Hire her if she has BLS, ACLS training

Answer: B

While good work ethic, personal attributes and required certification are important considerations for hiring new cath lab staff, critical care experience in the ICU for at least 6 months, and ideally 1 year are generally required before a nurse can work in the cath lab for the first time. This is due to the high complexity and rapid changes in patient's clinical status that can occur in the cath lab, which requires significant prior experience of assessing and managing critically ill patients.

Procedural Quality

Jayant Bagai MD, Christine Gasperetti MD, Cesar Jara MD, Faisal Latif MD, John Messenger MD, Sri Pitta MD, Bonnie Weiner MD.

SCAI
Society for Cardiovascular Angiography & Interventions

Contents

- Continuous Quality Improvement (CQI)
- Quality Monitoring and Reporting (NCDR/CathPCI)
- Benchmarking
- Performance review

Continuous Quality Improvement (CQI)

- CQI is an iterative method to evaluate operational approaches and remedy deficiencies
- CQI should be an essential component of each PCI program
- Primary emphasis-
  - Evaluation of program structure, processes, outcomes of care
  - Evaluation of individual operator quality

SCAI standards for QI in Interventional Cardiology Part 1_Klein L et al
2011 ACCF/ACA/SCAI PCI guidelines

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

Klein LW et al. CCI. 2011;77(7):927-35

CQI Committee

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

- Objectives
  - **PCI quality indicators-** identification and monitoring
  - **Performance assessment** (for-cause review, random case review)
  - **Serious adverse event review** (Morbidity and Mortality Conference)

Quality Indicators

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

- **Performance measures**
  - Include process, structure, efficiency or outcome measures
  - Developed by ACC/AHA task force using defined criteria and some are endorsed by the NQF
  - **Suitable for external comparisons, public reporting and possibly pay-for-performance**
  - Examples include risk-adjusted mortality, bleeding and discharge medications post-PCI

2008 ACC/AHA classification of care metrics
2014 ACC/AHA performance measures for PCI
2017 STEMI and NSTEMI performance measures

Quality Monitoring and Reporting

- **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

Link to NCDR CathPCI registry

Quality assessment for diagnostic cardiac catheterization

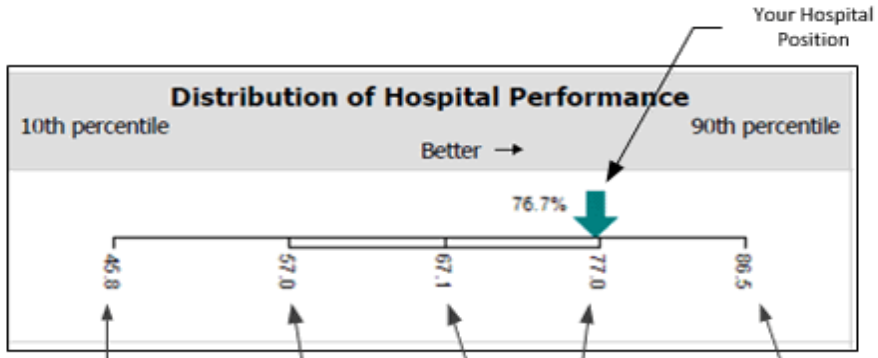
- Quality assessment is also important for diagnostic cardiac catheterization cases
- Many facilities do not report diagnostic cath data to NCDR due to logistic reasons such as case volume and cost of data abstraction
- Internal review, self assessment and monitoring trends then become key to ensure 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 to compare an institution and operator's performance with other institutions/operators

Interpretation of NDCR reports

Interpreting Box and Whisker Plots



10th Percentile
90% of the hospitals achieved "better" scores than the 10th percentile.

25th Percentile or 1st Quartile
75% of the hospitals achieved "better" scores than the 25th percentile.

50th Percentile or 2nd Quartile
Middle of the distribution: Half of the hospitals data is above and half are below the median.

75th Percentile or 3rd Quartile
25% of the hospitals achieved "better" scores than the 75th percentile.

90th Percentile
10% 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

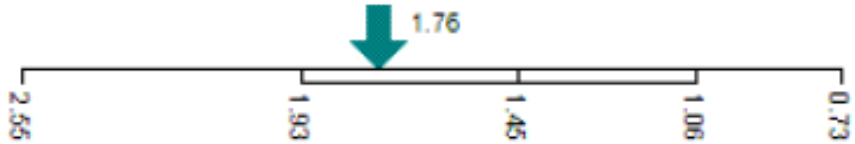
Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures		Distribution of Data
		10th percentile — Better → — 90th percentile
1	**PCI in-hospital risk adjusted mortality (all patients)**	

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
1.76		1.40	0.73

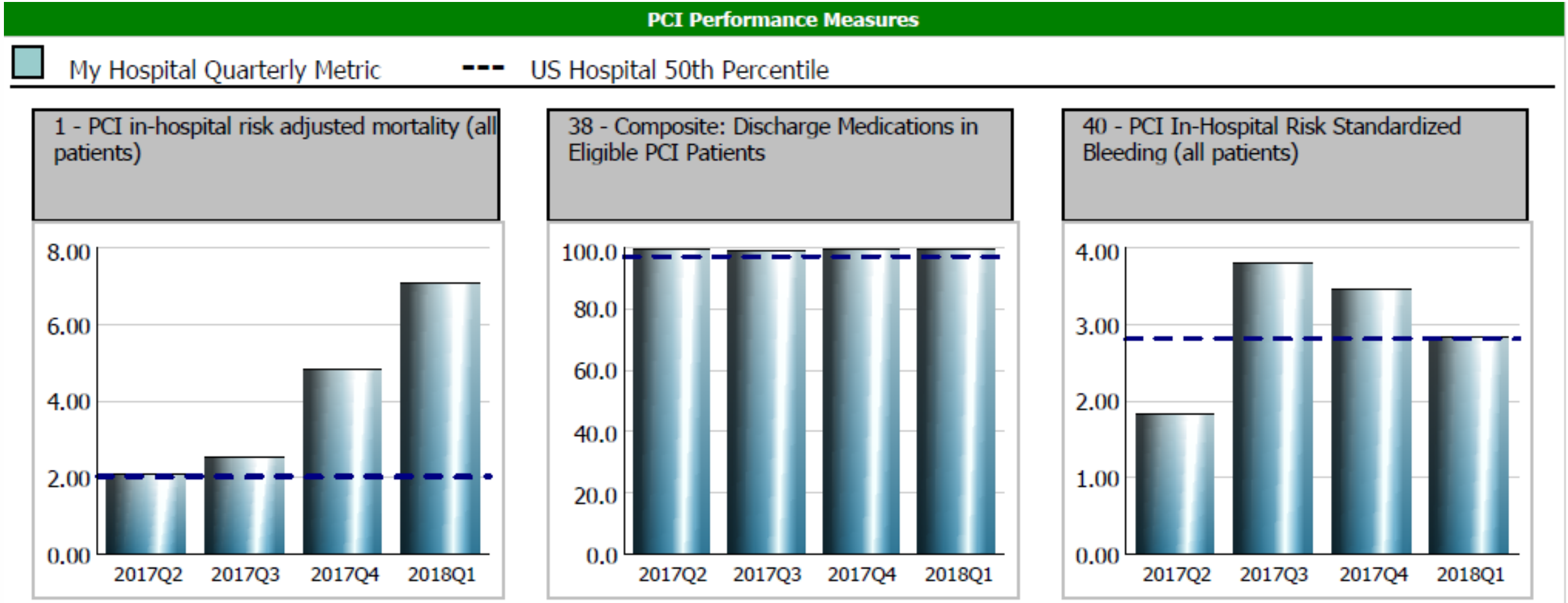
Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1979]



Sample Report from NCDR

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

Rolling 4 Quarter Reports



SCAI
Society for Cardiovascular Angiography & Interventions

Troubleshooting sub-optimal performance measures

- **Outlier values are opportunities to learn. They might represent:**
  - Actual poor performance
  - Unusual cases
  - Misinterpretation of physician documentation or incomplete documentation
  - Incomplete data entry by abstractors

- **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

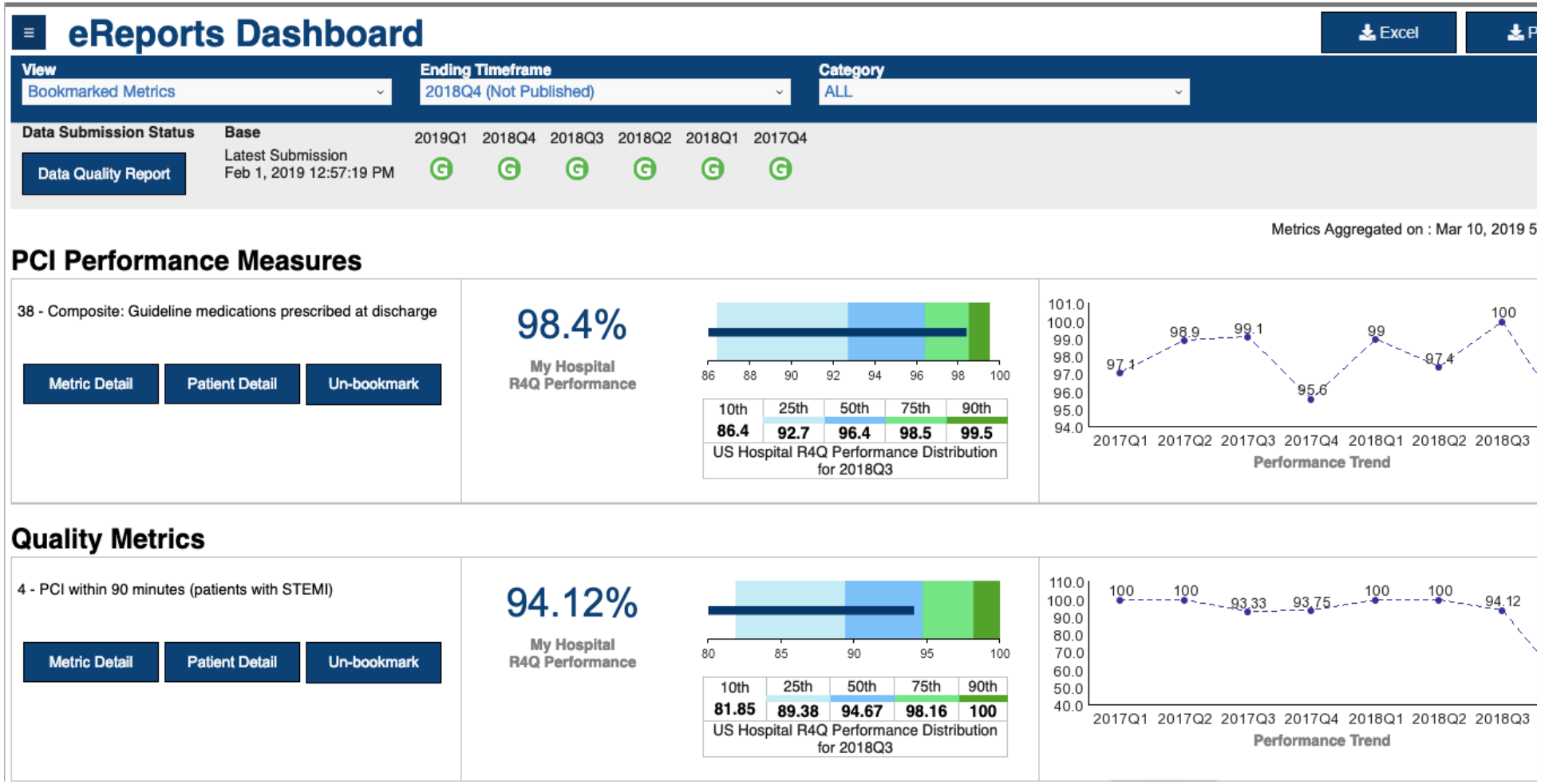
- Hospital performance below the 25th percentile of event rate for all US hospitals reporting to CathPCI Registry
- Example
  - Post-PCI Risk Adjusted All-Cause Mortality (RAM)
    - 50th percentile or median: 1.83%
    - 10th percentile: 3.17%
    - 25th percentile: 2.47%
    - 75th percentile: 1.37%
    - 90th percentile: 1.01%
- Important to look at quarterly trends, in addition to rolling quarters, to identify early changes that can be addressed proactively
- After interventions are undertaken, look at change in outcome in the next quarter
- "Topping out"- difference in performance between the 10th and 90th percentile is small (98% rate of aspirin prescription on discharge vs. 99%) and likely clinically insignificant

CathPCI v.5

- The CathPCI Registry data collection form was updated to version 5 (v.5) in 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

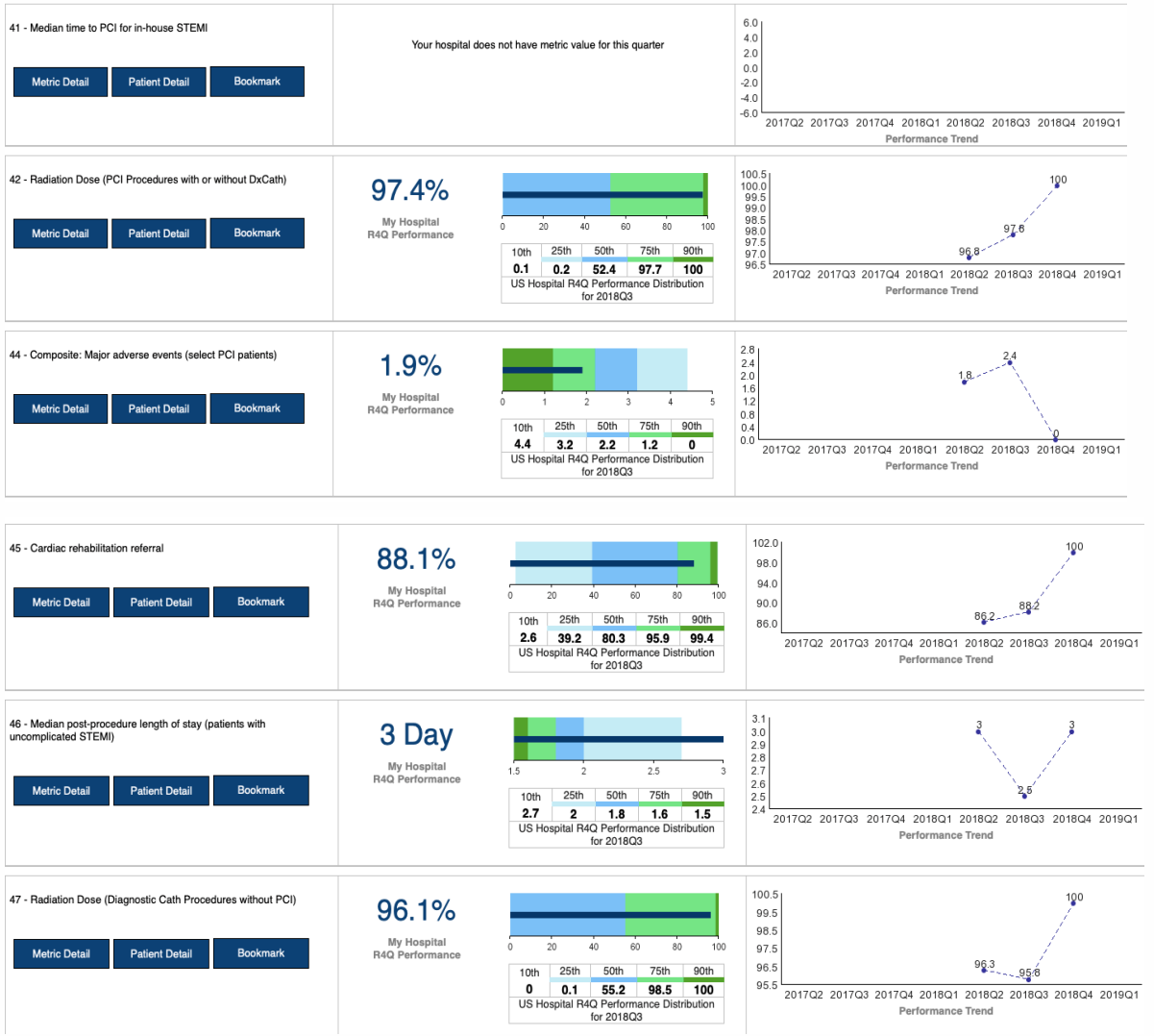
SCAI Tip of the Month on CathPCI v.5
CathPCI v.5 form
CathPCI data dictionary v5.0

New Dashboard Design CathPCI v.5



New CathPCI v.5 metrics and measures

- Median time to immediate PCI for in-house STEMI (in minutes)
- Proportion of PCI and diagnostic procedures in which all 3 radiation dose measurements were recorded
- Composite major adverse events post-PCI
- Proportion of PCI patients referred to cardiac rehabilitation at discharge
- Median post-procedure length of stay for PCI patients with uncomplicated STEMI (in days)
- Proportion of STEMI and NSTE-ACS patients prescribed high-dose statin at discharge



SCAI
Society for Cardiovascular Angiography & Interventions

Performance and peer review

- Purpose and importance
  - Mechanism for process improvement
  - Quality remediation policies and records are reviewed by accrediting agencies, such as The Joint Commission (TJC), Accreditation for Cardiovascular Excellence (ACE) and Det Norkse Veritas (DNV)
  - Required by ACGME, if site is a fellowship training program
  - Delivery of quality care may be taken into account for recredentialling providers

- Robust policies are important to prevent legal action

- Adherence to policies should be ensured

- 4 Ps essential to peer review process
  - **Protection** of **Patients**, **Participants** and **Process**

Key Principles

- Engage all team members in quality goals and expectations
- Fair, rational and transparent quality assessment policies
- Clear definitions of complications
  - Definitions aligned with independent sources/references
  - NCDR CathPCI Registry, The Joint Commission standards
  - Independent chart abstractors collect information on post-discharge adverse events/ readmissions
- Clear definitions of performance issues
- Independent adjudication process, if necessary (e.g., review by outside entity)
- Independent/objective benchmarking
  - NCDR™ CathPCI Registry
  - HealthGrades
  - Accreditation for Cardiovascular Excellence (ACE)
- Private counseling of serious/persistent outliers
- Clear probation and termination policies

Ongoing Professional Practice Evaluation (OPPE)	Focused Professional Practice Evaluation (FPPE)
Ongoing assessment of MD competency and behavior Conducted by CCL Director or Quality Officer Required by TJC[1] 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 There should be a mechanism for evaluating the performance of the CCL Director as well	Required to evaluate competence for all privileges for new providers and 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 TJC criteria for FPPE

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 (suggested minimum 10 cases/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, recognition and management
  - Contrast and radiation use
  - Overall procedural results and areas for improvement
  - Completeness and accuracy of cath report and procedural documentation[2]

[1]2017 AUC for SIHD
[2]2014 structured reporting

Cath lab Morbidity, Mortality and Improvement Conference (MM&I)

- **Aim-** quality improvement rather than punitive
- **Objective-** Open review and assessment of complications 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, acute stent thrombosis)
  - Major vascular complication
  - Serious anaphylactoid reaction
  - Respiratory depression due to sedation, requiring intubation
  - Serious medication error, wrong procedure
  - Cases with excessive radiation and/or contrast resulting in skin damage/acute kidney injury

Suggested format for MM&I

- Should occur at least quarterly
- Case MD should ideally be present
- Begins with announcement “MM& I 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 potentially resulting in adverse outcome
  - Identify potentially contributory structural and process issues
  - Root cause analysis identifying all major contributing causes using fish-bone diagram
- Assign level of care based on standardized grading criteria
- Propose solutions and process improvements

Question 1- Your CCL QI committee asks you to review the following NCDR data for your facility with regard to PCI in-hospital risk adjusted mortality.

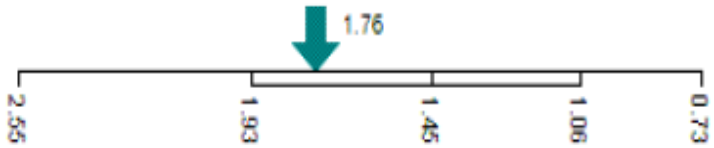
Executive Summary

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

PCI Performance Measures	Distribution of Data (10th percentile — Better → — 90th percentile)
1 **PCI in-hospital risk adjusted mortality (all patients)**	

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
1.76		1.40	0.73

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

(Question 1) Based on the metrics and benchmark presented, what will be your advice to the CCL QI committee?

a. Your facility's PCI in-hospital risk-adjusted mortality (RAM) is below the 25th percentile and the committee should immediately initiate a root-cause analysis.
b. Your facility's PCI in-hospital RAM is likely inaccurate, and you recommend looking at the observed mortality as a better indicator.
c. Your facility's PCI in-hospital RAM is below the 50th percentile; you recommend reviewing mortality cases from the last quarter to better understand the report.
d. Your facility's PCI in-hospital RAM is above the 50th percentile; you recommend to reviewing mortality cases from the last four quarters to better understand the report.
e. Your facility's PCI in-hospital RAM is above the 25th percentile, you recommend to move on with next item in agenda.

Correct answer- c

- Looking at the display graphic, the facility's 2010Q3 (third quarter of year 2010) RAM falls within the "brackets", which represent the 25th-75th percentile margins, but is closer to the 25th percentile, and corrective actions may need to be taken once more information is available about the specific cases (mortality is one of the metrics can be looked into detail because of the limited number of cases which need review, compared, for example, with radiation dosing that requires review of all cases). Answer **a** is therefore incorrect.
- Answer **b** is also incorrect, because the observed mortality does not take into account predicted mortality based on patient risk. On the other hand, the risk-adjusted mortality is the ratio of observed divided by expected mortality, and this ratio tends to decrease once severity of illness is included.
- Answer **d** is incorrect as the facility is below the 50th percentile- the middle bar of the bracket.
- Answer **e** is contrary to the basic principles of data analysis, benchmarking and instituting corrective actions.

Question 2-Your CCL QI committee is trying to determine the cause for an unexpectedly high PCI in-hospital risk-adjusted mortality (RAM). Which of the following are possible explanations?

a. Your facility's PCI in-hospital RAM is accurate. A new operator had had a higher than expected PCI mortality; a focused professional practice evaluation (FPPE) should be considered.
b. Your facility's PCI in-hospital RAM is inaccurate. The cath lab data abstractor was away for a month and a substitute abstractor was entering data in his absence.
c. Your facility's PCI in-hospital RAM is accurate, however there was an unusual number of extremely ill patients that render the RAM formula less precise.
d. Your facility's PCI in-hospital is RAM is inaccurate; there was incomplete and missing data entry by some physicians.
e. All of the above

Correct answer- e

- This question highlights the need for quarterly review of data outliers with the cath lab quality team and accurate capture of risk to ensure valid comparisons against benchmarks.
- Option **a** represents the effect on an outlier on a quality metric. Recognition and appropriate corrective action is required in this case.
- Option **b** emphasizes the importance of accurate data entry by a data abstractor who is very familiar with the facility and its health professionals and electronic medical record (EMR).
- Option **c** is a sobering reminder that RAM formulas sometimes do not reflect the actual expected mortality in high acuity cases. Some facilities can have RAM < 50^{th} percentile and still be providing above average care to a higher proportion of very sick patients, whereas other facilities can have > 50^{th} percentile RAM due to avoidance of high acuity cases.
- Option **d** is probably the most common reason for inaccurate RAM, specially when the EMR does not allow direct data element collection (requiring data abstractors to review consultations, progress notes, operative reports, etc, looking for data elements which accurately reflect acuity and complexity of treated patients).

Question 3-Regarding professional practice evaluation, which statement is FALSE?

a. OPPE is periodic assessment of physician competency and behavior with defined areas of assessment and evaluation.
b. In the peer review process, the CCL QI committee must behave equitably and transparently to ensure fairness to the operator, quality for the patient, and credibility for the committee.
c. FPPE is performed regularly for every physician, with clear criteria for evaluation and use of an external source if required.
d. Random case review should evaluate quality indicators such as procedure appropriateness, quality of angiogram, decision making process, radiation and contrast use, documentation and complication prevention and management.
e. High rates of adverse events identified in random reviews, longer length of stays, pattern of unnecessary procedures or sentinel events can trigger a FPPE.

Correct answer-c

- Ongoing professional practice evaluation (OPPE) is performed for every physician, including the medical director of CCL, with clear criteria for evaluation, transparency and independent objective benchmarking. This is different from a focused professional practice evaluation (FPPE), which is triggered for high rates of adverse events identified in random reviews, longer length of stays, pattern of unnecessary procedures or sentinel events. It is also performed for new providers and when a provider wishes to add new privileges. A FPPE must have clear criteria for evaluation, monitoring plan, duration of supervision of performance and external reviewers used if required. There should be clearly defined and objective medical staff bylaws and CCL policy regarding how this information can be used to renew, limit, or revoke privileges.
- Options **b** and **d** summarize the non-punitive and fair aspect of peer review (Protection of Patients, Participants and Process) and elements included in random case review, respectively.

Question 4-Regarding Cath Lab MM&I, which statement is FALSE?

a. It is a non-punitive and confidential review and assessment of 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.
b. Should be performed at least quarterly and physician involved in case should ideally be present.
c. It is an open forum, and participants are encouraged to discuss details and findings with others to improve outcomes and prevent future complications.
d. Types of events suitable for an M&M conference include serious medication error, excessive radiation or contrast leading to patient risk or harm.
e. The purpose of MM&I is non-punitive quality improvement, with a proposed plan for improvement to prevent future similar adverse events.

Correct answer-c

- Adverse event review or MM&I conferences are commonly used during medical training as an educational tool. There may be a misconception that their purpose is to target or blame the individuals involved in a case. Instead, MM&I is non-punitive and meant to improve care through a systematic analysis of the procedure (pre, intra and post). There should be a clear performance plan for improvement or policy changes with follow up to determine the effectiveness of the plan. It is not an “open forum”; rather it is strictly confidential. The data and conclusions of this conference are not to be discussed outside of this conference, except as part of a performance improvement project.

Question 5- Your CCL QI committee reviews the last quarter NCDR report and there is a significant increase in the risk adjusted bleeding of PCI cases as well as an increase in the proportion of acute kidney injury (AKI). Which of the following represents a quality metric as opposed to a performance measure regarding these data analysis?

a. Percentage use of ultrasound to get vascular access.
b. Percentage of radial cases in the cath lab.
c. Percentage of proper documentation of BMI and eGFR.
d. Percentage of use of evidence-based hydration protocol .
e. All of the above.

Correct answer-e

- While the importance of performance measures and quality metrics is known, the difference between them is sometimes not quite clear. Both are measurements or metrics; however only performance measures are suitable for public reporting, external comparisons, and possibly pay-for performance programs. Risk adjusted bleeding risk and rates of AKI are both performance measures. All the options mentioned in the question, however, are quality metrics that can be used internally at the local level for self-assessment and improve quality. Eventually some of these can become performance measures. For instance, radial access has been shown to lower major bleeding, vascular complications, acute kidney injury and mortality, and in the future, may be included as a performance measure.

Facility and Environmental Issues

Tami Atkinson, MD, FSCAI
Jayant Bagai, MD, FSCAI
Huu Tam D. Truong, MD, FSCAI

Disclosures

- **Atkinson, Tami.** No relevant relationships with commercial interests to disclose.
- **Bagai, Jayant.** No relevant relationships with commercial interests to disclose.
- **Tam Truong, Huu.** No relevant relationships with commercial interests to disclose.

Facility and Environmental Issues

Purpose

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

Intended Audience

- CCL directors, hospital administrators, interventionalists, nurses, technologists, advanced practice providers, SCAI QIT Champions

Infection Control

- **All CCL and hybrid operating rooms should have sterility/infection control protocols in place**
- **Universal precautions should be followed**
- **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 and follow institutional guidelines
  - CDC has published guidelines for management of occupational exposure
- **Vaccination**
  - Vaccination against Hepatitis B is encouraged for all CCL employees

Chambers, CE et al. CCI 2006;67:78-86

Infection Control

Room Type	Ventilation Requirements	Patient Preparation	Operators	Ancillary Personnel	Procedure Environment
Cardiac Cath Lab / Hybrid OR	• Positive-pressure room • Air exchange >15-20 per hour	• Electric clippers for hair removal • Chlorhexidine prep to skin • Sterile drapes	• Hand washing or sanitizer • Hospital based scrub attire • Sterile gowns & gloves ***Masks, eye shield and protective caps (optional but may be required per state/institutional policy)	• Hospital based scrub attire • Cap • Gloves when in contact with sterile field • Mask, eye protection are optional	• Keep doors to CCL closed, except to allow passage of patients, equipment and essential personnel • Equipment near catheter entry site should be covered • Equipment near sterile field should have sterile covers
Hybrid OR specific (Must meet local OR guidelines)	• Positive-pressure room • Air exchange >20-25 per hour	Same as above	• Masks, eye shield and protective caps required	Same as above	• Same as above

Chambers, CE et al. CCI 2006;67:78-86

Infection Control

- **Cleaning**:
  - The CCL should be thoroughly cleaned once a day and spot-cleaned with trash removal between cases
  - Blood-contaminated drapes, gowns, gloves, and sponges should be discarded in containers labeled as healthcare waste
  - Sharps should be placed in puncture-proof containers
  - Consider scheduling cases with high infectious risk at the end of the day, followed by terminal clean (example- C. difficile, MRSA, VRE, patients with droplet precautions)
- **Multi-dose vials:**
  - Should be avoided, unless used with an approved device to protect against backflow

Radiation Safety

Summary of radiation doses and units			
Absorbed dose (Deterministic effect)	Amount of radiation energy absorbed by tissue per mass of tissue. Skin typically receives the highest absorbed dose.	Peak skin dose (PSD) is the absorbed dose at the skin location that has received the highest dose. This quantity is used to predict a skin injury. Not usually measured; can be estimated if needed.	Unit: Gray (Gy) 1 Gy= 1 Joule of radiation energy absorbed per unit tissue.
Effective dose (Stochastic effect)	Calculated by adding the mean dose absorbed by organ multiplied by a weighting factor for that organ (highest for bone marrow, lung, stomach, breast; least for skin).	Approximate measure of potential harm from cancer. Takes into account susceptibility of different tissues.	Unit: Sievert (Sv) Effective dose of cardiac cath is 2-16 mSv compared with 0.02 mSv for chest x-ray.
Air kerma (Ak) or Reference Ak or $K_{a,r}$	Energy per unit mass absorbed by air at assumed location of skin.	Cumulative Ak is displayed on monitor- meant to estimate patient skin dose. Non-stationary position of X-ray tube will over-estimate and lower table position will under-estimate patient dose.	Unit: milli Gray (mGy)
KERMA-area product (KAP) or Dose-area product (DAP) or P_{KA}	Total energy absorbed across entire exposed skin/incident on the patient.	Product of Ak and cross-section area of X-ray beam. Used to estimate stochastic risk such as radiation induced cancer to patient and staff.	Units: $Gy.cm^2$, $cGy.cm^2$, $mGy.cm^2$

Radiation Safety

- **Follow the principle of ALARA (as low as reasonably achievable)**
- **Each facility must have a radiation safety program**
- **Staff radiation safety training and its documentation are essential**
- **Patient radiation dose must be monitored and recorded**
  - Includes fluoroscopy time, total air kerma at the interventional reference point (IRP) ($K_{a,r}$, Gy) and air kerma area product (PKA, Gy*cm2)
- **Document substantial radiation dose level (SRDL) as shown on right**

Dose metric	First notification	Subsequent notifications (increments)	SRDL
$D_{skin,max}$ [a]	2 Gy	0.5 Gy	3 Gy
$K_{a,r}$ [b]	3 Gy	1 Gy	5 Gy [b]
P_{KA} [c]	300 Gy cm^{-2d}	100 Gy cm^{-2d}	500 Gy cm^{-2d}
Fluoroscopy time	30 min	15 min	60 min

NCRP (2010) National Council on Radiation Protection and Measurements. Radiation Dose Management for Fluoroscopically Guided Interventonal Medical Procedures, NCRP Report No. 168 (National Council on Radiation Protection and Measurements, Bethesda, Maryland).

[a] $D_{skin,max}$ is peak skin dose, requiring calculations by physicist.

[b] $K_{a,r}$ is total air kerma at the reference point.

[c] P_{KA} is air kerma-area product.

[d] Assuming a 100 cm^2 field at the patient's skin. For other field sizes, the P_{KA} values should be adjusted proportionally to the actual procedural field size (e.g., for a field size of 50 cm^2, the SRDL value for P_{KA} would be 250 Gy cm^{-2}).

Chambers CE, et al. CCI 2011;77:546-56

Radiation Safety

Methods to lower patient dose	Methods to lower operator dose	Methods to lower both patient and operator dose
• Raise table height • "Spread the dose" by moving tube • Avoid high magnification (changing from 22 cm to 17 cm doubles dose rate) • Keep patient's arms away from x-ray tube • Limit beam-on time especially in obese patients • Establish "hard-stops" for elective complex PCI (e.g. CTO)	• Wear adequate protective garments (lead apron and leaded glasses) • Increase distance from x-ray tube (dose rate is proportional to the inverse of the square of the distance from the source) • Use under and over-table shielding against scatter • Lower the detector as close to patient as possible • Use robotic PCI if available	• Limit beam-on time (do not step on pedal unless looking at screen, • Use "virtual" collimation, • Last-image hold • Only "tap" on fluoro pedal if needed • Keep detector close to patient • Minimize steep angles • Limit cine- use fluoro save/store • Use lower frame rate (7.5 fps) and "Eco" dose setting • Use collimation • Keep arms/hand out of beam

Radiation Safety

Post procedure monitoring and documentation	
AK 5-10 Gy (DAP > 500 Gy.cm^2)	• Patients should be educated regarding potential skin changes and call the Interventionalist if seen. • Patients should be contacted at 30 days. • Phone calls may be sufficient if $A_{k,r} < 10$ Gy, with an office visit if questions arise or adverse skin effect suspected.
AK > 10 Gy (DAP > 1,000 Gy.cm^2)	• Qualified physicist should promptly perform a detailed analysis to calculate PSD. • Patient should return for an office visit at 2-4 weeks with examination for possible skin effects.
PSD > 15 Gy	• Hospital risk management should be contacted within 24 hours with appropriate notification to the regulatory agencies. • This exposure represents a Joint Commission Sentinel Event.

Chambers CE, et al. CCI 2011;77:546-56

Essential Cath Lab Equipment

- Imaging equipment and archival storage system
- Multichannel physiologic monitoring (minimum of 2 pressure & 3 ECG channels) with real-time and archived physiologic, hemodynamic and rhythm monitoring
- X-ray system with periodic and documented preventive maintenance
  - Includes image quality, dynamic range, modulation transfer function, fluoroscopic spatial resolution, field of view size accuracy, low contrast resolution, automatic exposure control and maximum table-top exposure rate
- Adequate inventory for the scope of services provided
  - Disposable supplies
  - Equipment for management of complications and emergencies
- Daily checks and quality control to be performed (see table on right)

Cath Lab Daily Checklist
Emergency Equipment
Code Cart Checked
Temporary pacemaker & defibrillator tested
Pericardiocentesis tray in room
Check IABP & Impella consoles/catheters
Covered stents, coils, etc.
Quality Control Daily Check
ACT machine & blood gas analyzers
X-ray System
System turns on
Cine and fluoroscopy work
Table moves
Hemodynamic system turns on

Information Storage and Inventory

- Reporting system should be linked with 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
- Image Storage
  - Compliance with HIPAA requirements include minimum of 6 years of storage, but requirements vary by state
    - https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/pprequirements.pdf?language=es
  - Link to state requirements
    - https://www.healthit.gov/sites/default/files/appa7-1.pdf

Question 1- You are performing PCI on a complex left main bifurcation lesion with a planned two-stent technique. You reviewed the diagnostic images and the view that best delineates the bifurcation is LAO 40, caudal 35. You wish to attain optimal results, while following the principle of ALARA (as low as achievable). Which of the following strategies would result in *higher* radiation dose?

A. Collimate to the region of the bifurcation.

B. Raise the table as high as possible and lower the image detector as low as possible.

C. Change the field of view from 20 cm (8 inches) to 16 cm (6 inches).

D. Use intracoronary imaging to aid in stent sizing and post-stent deployment assessment.

E. Wire the vessels and perform pre-dilation at shallow angles and move to steep LAO-caudal for stent deployment.

Answer: C

- Changing the field of view (FOV) from 20 cm to 16 cm (higher magnification) will significantly increase the radiation dose. With modern imaging systems, diagnostic image quality is often achieved at 25 cm (10 in) FOV so higher magnification than 20 cm is rarely needed. All the other choices are best practices to reduce radiation doses to the patient and operator.

Question 2- You are a high-volume operator and have received several letters from the radiation safety officer regarding your high monthly dose. Your standard practice includes using 7.5 frame/s fluoro acquisition, 25 cm (10 inch) field of view, collimation, frequent fluoro save and collimation, keeping the table at elbow height and positioning the image detector close to the patient. Which of the following is likely to reduce your recorded badge dose?

A. Change from a two-piece lead to a one piece lead apron.

B. Use a RADPAD ® scatter shield

C. Use very brief cine to store images of balloon and stent deployments.

D. Change field of view to 20 cm (8 inches).

E. Use digital subtraction angiography for femoral angiograms instead of fluoro save.

Answer: B

- This operator is already using best practices to reduce radiation dose but still has high operator dose due to high-volume.
- Using a RADPAD scatter shielding has been shown to significantly reduce operator dose in randomized controlled trial (ref: Vlastra W et al. *Circ Cardiovasc Interv.* 2017;10:e006058.)
- Choice A – the badge is worn outside the lead so this would not change the recorded dose. Also, the difference between a two-piece vs one-piece lead apron is mainly preference. The absolute thickness of the lead equivalent is typically the same.
- Choice C – brief cine to store images is a older practice that's highly discouraged, less radiation is delivered using fluoro save.
- Choice D - increasing the magnification and will increase the dose.
- Choice E – using DSA will use deliver significantly higher dose.

Question 3- You are advancing a TAVR delivery system and wish to see both the tip of the wire in the left ventricle and the valve as it traverses from the abdominal aorta to the aortic root. Which of the following is the best strategy to optimize this process and minimize radiation?

A. Use standard coronary acquisition settings and pan the table as you advance the delivery system.
B. Change the acquisition from 7.5 to 15 frames/second.
C. Drop the table height.
D. Change the field of view to a lower magnification setting.
E. Raise the image detector.

Answer: D

- By lowering the magnification, the operator can see the wire tip and the valve at the same time without needing to pan the table. This will also lower the radiation dose.
- All the other choices would increase the radiation dose unnecessarily.

Question 4- You are hired as a new director of a cath lab. You have run into several instances in which emergency equipment, such as temporary pacemakers, malfunction when they are needed. Which of the following is the appropriate strategy?

A. Purchase new equipment.

B. Assign the cath lab manager to perform a daily checklist including emergent equipment and report to you if there are issues.

C. Hire a new cath lab manager.

D. File an incident report.

E. Accept that these are expected events.

Answer: B

- Performing a daily checklist is a quality assurance practice to ensure critical equipment are functional.

Question 5- Your vascular surgery colleague notified you that he has performed a second incision and drainage for femoral access infection post cardiac catheterization in a month. Which of the following is **unlikely** to improve this problem in the future?

A. Use vascular closure device instead of manual compression.

B. Use electric clippers for hair removal instead of a razor.

C. Use chlorhexidine-based prep.

D. Instruct the technologist to prep the site at the location of the puncture first and move to the periphery with an ever-widening circular motion.

E. Use universal precautions for all cases.

Answer: A

- Using vascular closure device does not reduce infection but is associated with higher rate of infection. (Noori VJ, Eldrup-Jørgensen J. *J Vasc Surg*. 2018 Sep;68(3):887-899.)
- All the other choices are best practices to reduce access site infection.

Care Coordination

Craig Beavers, MD, FSCAI
Jayant Bagai, MD, FSCAI

Disclosures

- **Beavers, Craig** No relevant relationships with commercial interests to disclose.
- **Bagai, Jayant** No relevant relationships with commercial interests to disclose.

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 procedures in the cardiac cath lab
- **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

Objectives

- Discuss risk factors for contrast nephropathy following cardiac catheterization
- Describe current recommendations on duration of withholding anticoagulation prior to cardiac catheterization
- Summarize current recommendations on duration of dual antiplatelet therapy after percutaneous coronary intervention (PCI)
- Manage patients who require both oral anticoagulation and dual antiplatelet therapy post-PCI

Contrast-induced acute kidney injury (CI-AKI)

- Identify patients at increased risk for CI-AKI using Mehran Score
- Assess appropriateness of cardiac cath in patients at high risk, i.e. Mehran score > 10 (example- age > 75 + diabetes + anemia + eGFR 40-60= Mehran score 11)
- Hold ACE inhibitor, NSAID and diuretic 24-48 hour pre-cath in patients with renal insufficiency/ increased risk of CI-AKI
- Hold metformin 24 hours pre- and resume 48 hours post cardiac cath (check Cr prior to restarting if pre-existing renal insufficiency)
- N-acetyl-L-cysteine (mucomyst) is no longer recommended

Recommended durations for withholding DOACs

Drug	Cr Cl (ml/min)	Hold time for low bleeding risk (diagnostic cardiac cath via radial access)	Hold time for uncertain, moderate or high bleeding risk (diagnostic cardiac cath via femoral access, any PCI)
Apixaban or Rivaroxaban	> 30	≥ 24 hours	48 hours
	15-29	≥ 36 hours	No data, consider holding ≥ 72 hours
	< 15	No data, consider holding ≥ 48 hours	
Dabigatran	> 80	≥ 24 hours	≥ 48 hours
	50-79	≥ 36 hours	≥ 72 hours
	30-49	≥ 48 hours	≥ 96 hours
	15-29	≥ 72 hours	≥ 120 hours
	< 15	No data, consider holding ≥ 96 h	No data

Hold warfarin 5 days prior to cardiac cath aiming for INR < 1.7 on day of procedure

Tomaselli GF et al. JACC. 2017;70(24):3042-3067
Zukkoor, Choudhury Pre-procedural DOAC guidance

Elective Percutaneous Coronary Intervention or Acute Coronary Syndrome and Need for Anticoagulation

Concern about thrombotic risk prevailing (PCI for acute coronary syndrome, complex PCI, h/o stent thrombosis, high DAPT score)	Concerns about high bleeding risk prevailing (HAS-BLED score ≥3)	Average thrombotic and bleeding risk (PCI for stable CAD)
Triple therapy (oral anticoagulant + aspirin 81mg + clopidogrel) x 1 month	Dual therapy (clopidogrel + oral anticoagulant) x 6 months	Dual therapy (clopidogrel + oral anticoagulant) x 6 months
Dual therapy (oral anticoagulant plus clopidogrel) for additional 11 months		
Oral anticoagulant alone after 12 months	Oral anticoagulant alone after 6 months	Oral anticoagulant + 81 mg aspirin after 6 months
		Oral anticoagulant alone after 12 month

DOAC preferred over warfarin. Do not use prasugrel as component of triple therapy

Dual Antiplatelet Therapy (DAPT) Duration

Stable Coronary Artery Disease	High Bleeding Risk	1 month of DAPT at minimum, ideally up to 3 months
	Low Bleeding Risk	3-6 months of DAPT at minimum, consider longer if high thrombotic risk
Non-ST Segment Elevation MI	High Bleeding Risk, Low Thrombotic Risk	6 months of DAPT at minimum
	Low Bleeding Risk, High Thrombotic Risk	12 months of DAPT at minimum
	High Bleeding Risk, High Thrombotic risk	3 months DAPT with aspirin + ticagrelor followed by 9 months ticagrelor alone*
ST Segment Elevation MI	High Bleeding Risk	6 months of DAPT at minimum of , ideally up to 12 months
	Low Bleeding Risk	12 months of DAPT at minimum

*Angiolillo DJ, et al. Ticagrelor With Aspirin or Alone in High-Risk Patients After Coronary Intervention TWILIGHT. JACC 2020

Use of prolonged DAPT therapy > 12 months

- In patients with ACS treated with PCI, who have tolerated DAPT without bleeding complication for 12 months, and who are not at high bleeding risk (prior bleeding on DAPT, coagulopathy, oral anticoagulant use) continuation of DAPT for > 12 months may be reasonable (Class IIB recommendation)

- DAPT score ≥ 2- **favorable** risk-benefit ratio for prolonged DAPT
- DAPT score < 2- **unfavorable** risk-benefit ratio for prolonged DAPT

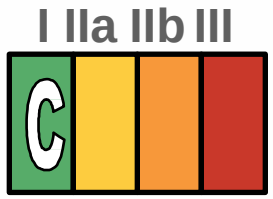
Components of DAPT score

Variable	Points
Age ≥ 75	-2
Age 65 to < 75	-1
Age < 65	0
Current smoker	1
Diabetes	1
MI at presentation	1
Prior PCI or MI	1
Stent diameter < 3 mm	1
Paclitaxel eluting stent	1
CHF or LVEF < 30%	2
PCI of bypass graft	2

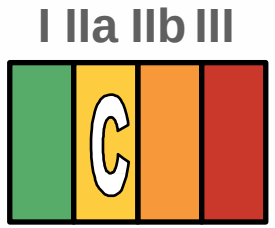
Interruption of DAPT for surgery

- P2Y12 inhibitors (clopidogrel, prasugrel, ticagrelor) can be interrupted for surgery **after 6 months** of therapy post-PCI
- Interruption of P2Y12 inhibitors for elective surgery can be considered **after 3 months and before 6 months** of therapy post-PCI, if risk of bleeding during surgery > risk of stent thrombosis
- Low dose aspirin should be continued in peri-operative period (i.e. patient should not suddenly stop all antiplatelet therapy)
- The timing of restarting clopidogrel, prasugrel or ticagrelor depends on risk of surgical bleeding
- There are emerging data suggesting safety of 1 month DAPT after PCI with drug eluting stents (DES) for stable CAD and 6 months DAPT after PCI with DES for ACS

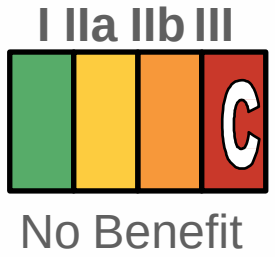
Proton Pump Inhibitors (PPIs) and Antiplatelet Therapy



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) 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

Question 1- A 64-year-old woman (68kg) is scheduled for diagnostic left heart catheterization via radial artery . Her CHA2DS2VASc is 3 (diabetes, female) and she takes apixaban 5mg twice daily (CrCL 100mL/min, SCr 1.0mg/dL)). Which of the following is the recommended duration for holding anticoagulation based on ACC guidelines?

a. Stop apixaban 48 hours prior to procedure
b. Stop apixaban 24 hours prior to procedure
c. Stop apixaban 12 hours prior to procedure
d. Stop apixaban 12 hours prior to procedure and administer andexanet alfa

Correct Answer: B

- Diagnostic coronary angiography via radial access is considered to have a low risk of bleeding, and therefore holding apixaban for 24 hours prior to the procedure is supported 2017 ACC expert consensus decision pathway for periprocedural management
- It is important to be aware that patients may require femoral access for coronary angiography in the event of failure of radial access.
- Femoral access carries a moderate to high risk of bleeding and requires a 48 hour hold in patients with normal renal function.
- The same applies to patients who may need PCI as opposed to just diagnostic angiography.

Question 2- A 45-year-old patient underwent PCI and DES placement in the mid right coronary artery for stable angina. She is placed on clopidogrel 75mg daily and aspirin 81mg daily. The patient is considered to have both low thrombotic and bleeding risk. Which duration best represents the recommended duration of DAPT based on current guidelines?

a. 1 month.
b. 3 months.
c. 6 months.
d. 12 months

Correct Answer: C

- Given the patient's low bleeding risk, low thrombotic risk and stenting for an elective procedure, the minimum recommended duration of therapy based on the 2016 ACC/AHA focused update on duration of DAPT is 6 months (Answer C).
- If her bleeding risk were higher, a shorter DAPT duration of 3 months may be reasonable.
- Had the PCI been performed due to ACS, the recommended duration would have been 12 months for both a DES and bare metal stent (BMS).
- A 1 month duration of DAPT is recommended if the patient had received a BMS for stable angina.

Question 3- Which of the following is the most appropriate recommendation prior to elective coronary angiography in an anemic patient with abnormal renal function?

a. Administer N-acetyl-L-cysteine prior to and after catheterization
b. Administer sodium bicarbonate prior to catheterization
c. Hold metformin 24 hours pre- and 48 hours post-catheterization
d. Administer 1 unit of packed red blood cells

Correct Answer: C

- Holding metformin for 24 hours before and 48 hours after exposure to iodinated contrast is recommended due to the potential for lactic acidosis in the event of severe renal failure due to CI-AKI.
- Several well-designed clinical trials have yet to elucidate the benefit of N-acetyl-L-cysteine nor sodium bicarbonate in prevention of contrast induced nephropathy (Answers a and b are incorrect).
- There has been no data routinely providing packed red blood cells prevents CKI (Answer d is incorrect).

Question 4- A 70-year-old patient with DM and prior MI who underwent PCI with DES placement for ACS angina 18 months ago wants you to refill his prescription for clopidogrel. He also takes daily low dose aspirin. He informs you that he was told by his Cardiologist that he need to take clopidogrel "for the rest of his life". What is current evidence regarding prolonged DAPT beyond the recommended 12 months in ACS patients?

a. Current guidelines do not support DAPT beyond 12 months under any scenario
b. Current guidelines state that continuation of DAPT beyond 12 months may be reasonable in patients who have not experienced bleeding on DAPT and are low risk for bleeding
c. Long term DAPT is not associated with increased risk of bleeding
d. Prolonged DAPT should be considered in patients with a DAPT score < 2

Correct answer: B

- Prolongation of DAPT beyond 12 months can be considered in patients who are at low risk of bleeding and have not experienced bleeding while on DAPT. Answer a is therefore incorrect.
- On the basis of studies of DAPT in post-MI patients, extended DAPT for approximately 18 to 36 months leads to an absolute decrease in ischemic complications of ~1-3% and an absolute increase in bleeding complications of ~1%. (Answer c is therefore incorrect.) Currently there is no data to support “lifelong” DAPT in such patients.
- The DAPT score is a useful tool to determine the risk-benefit of extended DAPT. Patients who are younger (< 65 years), and increased ischemic risk (history of MI, diabetes, CHF, CABG) with a DAPT score $\geq$ 2 have a favorable risk-benefit ratio for prolonged DAPT. (Answer d is therefore incorrect.)

Question 5- A 70-year-old patient with a CHA_2DS_2-VASc score = 4, HAS-BLED score = 3 on long-term anticoagulation for atrial fibrillation (AF) undergoes PCI with a DES for ACS. What is the recommended combination of antiplatelet and anticoagulant therapy?

a. Aspirin+ clopidogrel + warfarin x 12 months
b. Apixaban + clopidogrel x 6 months, followed by apixaban + aspirin x 6 months
c. Aspirin + clopidogrel + Warfarin x 6 months
d. Aspirin + prasugrel + apixaban x 6 months, then apixaban + aspirin x 6 months

Correct answer- b

- This patient has both high ischemic (stroke and MI) and bleeding risk. In the AUGUSTUS trial, patients with AF and recent ACS or PCI for stable angina treated with a **$P2Y_{12}$inhibitor (clopidogrel in > 90%) + apixaban** without aspirin for 6 months resulted in less bleeding (7.3%) and fewer hospitalizations, without significant differences in the incidence of ischemic events, than a combination of **P2Y12 inhibitor (usually clopidogrel) + warfarin + aspirin** for 6 months (bleeding rate 18.7%). The combination of apixaban + clopidogrel was also associated with less bleeding compared with warfarin + clopidogrel. Answer b is therefore correct and Answer c is incorrect.
- Triple therapy with aspirin + clopidogrel + warfarin x 12 months is associated with a very high risk (44% in the WOEST trial) of bleeding and not recommended in this patient with high risk of bleeding at baseline. (Answer a is therefore incorrect)
- Prasugrel should not be used as a component of “triple therapy” due to high risk of bleeding. Answer d is therefore incorrect.

Lopez et al. NEJM. 2019;380:1509-24
Dewilde WJ et al. Lancet. 2013;381(9872):1107-15