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Cardiac Quality Development and Framework

Alda Osinaga, MD, MPH and Kimberly Cozzens, MA

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INTRODUCTIONS

Alda Osinaga, MD, MPH

Director of the Clinical Center and Chief Medical Officer,
Office of Health Services Quality and Analytics

Kimberly Cozzens, MA

Program Director, Cardiac Services Program
Research Assistant Professor, Health Policy Management & Behavior,
College of Integrated Health Sciences, University at Albany

Background: Diagnostic Catheterization and Percutaneous Coronary Intervention (PCI)



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UNDERSTANDING DIAGNOSTIC CATH AND PCI

Cardiac Catheterization: Is a general term for a procedure where a catheter (thin flexible tube) is inserted in a blood vessel in the arm or groin and passed to the heart to diagnose or treat heart disease.

| | Diagnostic Catheterization | Percutaneous Coronary Intervention (PCI) |
|----------|-------------------------------|--|
| Purpose: | <u>Diagnose</u> heart disease | <u>Treat</u> a specific kind of heart disease by opening narrowed or blocked coronary arteries |

UNDERSTANDING DIAGNOSTIC CATH AND PCI

| | Diagnostic Catheterization | Percutaneous Coronary Intervention (PCI) |
|-----------------------|---|--|
| Number of Hospitals | 85 hospitals 8 are “Diagnostic Only” – no PCI | 77 hospitals 37 with cardiac surgery onsite |
| Number of Procedures | 2018 Cath Survey* 102,740 diagnostic w/out PCI <u>+ 45,954 w/PCI</u> 148,694 Total Dx Cath | 51,933 discharges in 2024 PCIRS |
| NYS Clinical Registry | None | PCI Reporting System (PCIRS) |

*Annual Diagnostic Cath Survey has been discontinued. 2018 is the last complete data collection.



PCI VOLUME AND OUTCOMES

PCI Volume and In-Hospital Observed Mortality Rate (OMR) by Emergency Status, 2024 Discharges DRAFT

| Type of Case | N (%) | In-hospital OMR |
|------------------------|----------------|-----------------|
| Emergency ¹ | 8,417 (16.21) | 4.89% |
| Non-Emergency | 43,516 (83.79) | 0.35% |
| Total | 51,933 | 1.09% |

¹MI or Cardiac Arrest within 24 hours of PCI or Cardiogenic Shock at the time of PCI
Of note, there is substantial additional mortality after discharge but within 30-days of PCI.

LOW-RISK NON-EMERGENCY PCI

Society for Cardiovascular Angiography & Interventions (SCAI) Expert Consensus Statement on PCI Without Surgical Backup was used to identify a subset of the total PCI population that may be candidates for PCI in ambulatory surgery centers.

This excludes patients that:

- are not suitable for planned PCI
- have acute coronary syndromes (i.e. heart attack or unstable angina)
- have comorbidities that might require ancillary support
- have complex lesions that SCAI suggests to approach with caution

[SCAI Expert Consensus Statement on Percutaneous Coronary Intervention Without On-Site Surgical Backup - Journal of the Society for Cardiovascular Angiography & Interventions](#)

SCAI Expert Consensus Statement on Percutaneous Coronary Intervention Without On-Site Surgical Backup. Grines, Cindy L. et al. Journal of the Society for Cardiovascular Angiography & Interventions, Volume 2, Issue 2, 100560

LOW-RISK NON-EMERGENCY PCI

In 2022, there were 6,608 PCI patients that met these criteria

- 13.7% of the 48,115 total PCIs

These patients had very low rates of in-hospital death or complications.

- 1 death (0.02% observed mortality rate)
- 52 (0.79%) had a PCIRS reportable complication such as stroke, myocardial infarction, coronary occlusion or perforation, procedural related bleeding, or emergency cardiac surgery or PCI

59% were discharged the same day as their PCI

Cardiac Services Program Outcomes Assessment and Quality Improvement



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DATA COLLECTION

Percutaneous Coronary Interventions Reporting System (PCIRS) - est. 1991

Process:

- Clinical staff at the hospital complete a 2 – 3 page form for each PCI case
- Data collection includes:
 - patient demographics
 - clinical risk factors
 - cardiologist that performed the case
 - the areas in the heart that were treated and how they were treated
 - complications that the patient experienced during the hospital stay
- Data are submitted quarterly through a secure DOH data collection system
- Due date is 30-days after the end of the quarter

DATA VALIDATION

Completeness and accuracy of the data are assured through an extensive system of validation and auditing.

This includes:

- Checking for inconsistencies in the data and fields that were not reported
- Comparing data reported to PCIRS to that reported to SPARCS
- Reviewing medical record documentation to assure risk factor accuracy
- Obtaining primary endpoints of in-hospital/30-day death and readmission from NYS Vital Statistics and SPARCS

FEEDBACK AND QUALITY IMPROVEMENT (QI)

Feedback Reports

Patient Profiles

STEMI Feedback Reports

Other periodic feedback, for example, Ad Hoc PCI reports

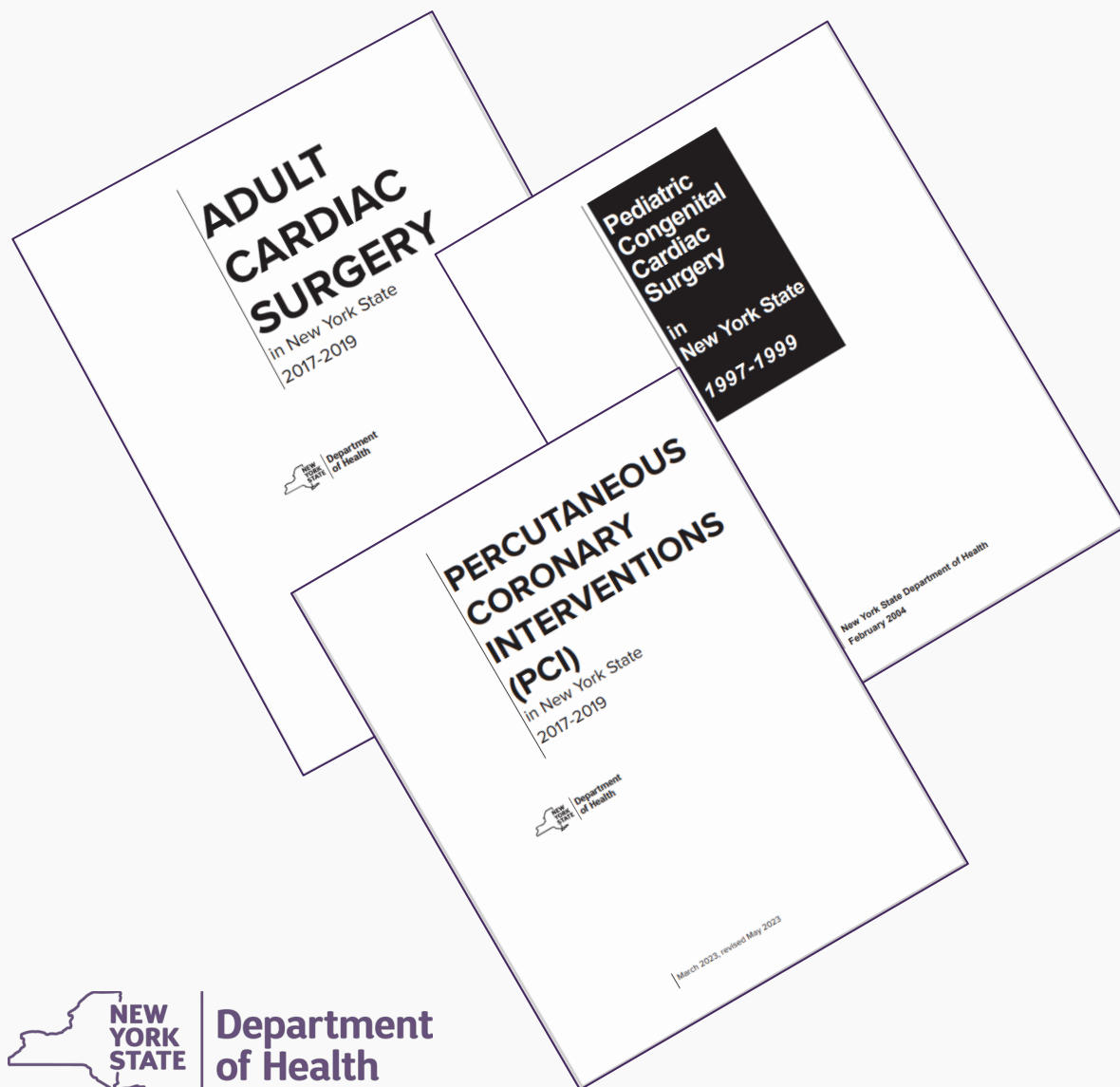
Alert Letters

- Semi-annual review of raw data
- Hospital CEO and Program Director notified when observed mortality rate is 2.5 times the NYS rate
- Hospital replies with description of QI processes and case-level details including internal review findings and medical record documentation
- Reviewed by Cardiac Advisory Committee (CAC) QI Subcommittee
- Post-review feedback provided to hospitals



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FEEDBACK AND OUTCOMES ASSESSMENT



Outcome reports with hospital and physician risk-adjusted mortality results are publicly available on the Department's website.

<https://www.health.ny.gov/statistics/diseases/cardiovascular/>

Just prior to publication, a notification is sent to the CEO of all high-outlier hospitals.

Historical Example: Waiver for PCI without Onsite Cardiac Surgery



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PCI WAIVER PROGRAM 2000 - 2009

Pre-2000

PCI only with cardiac surgery onsite*

2000- 2008

Time-limited waivers:
Emergency then Elective Cases

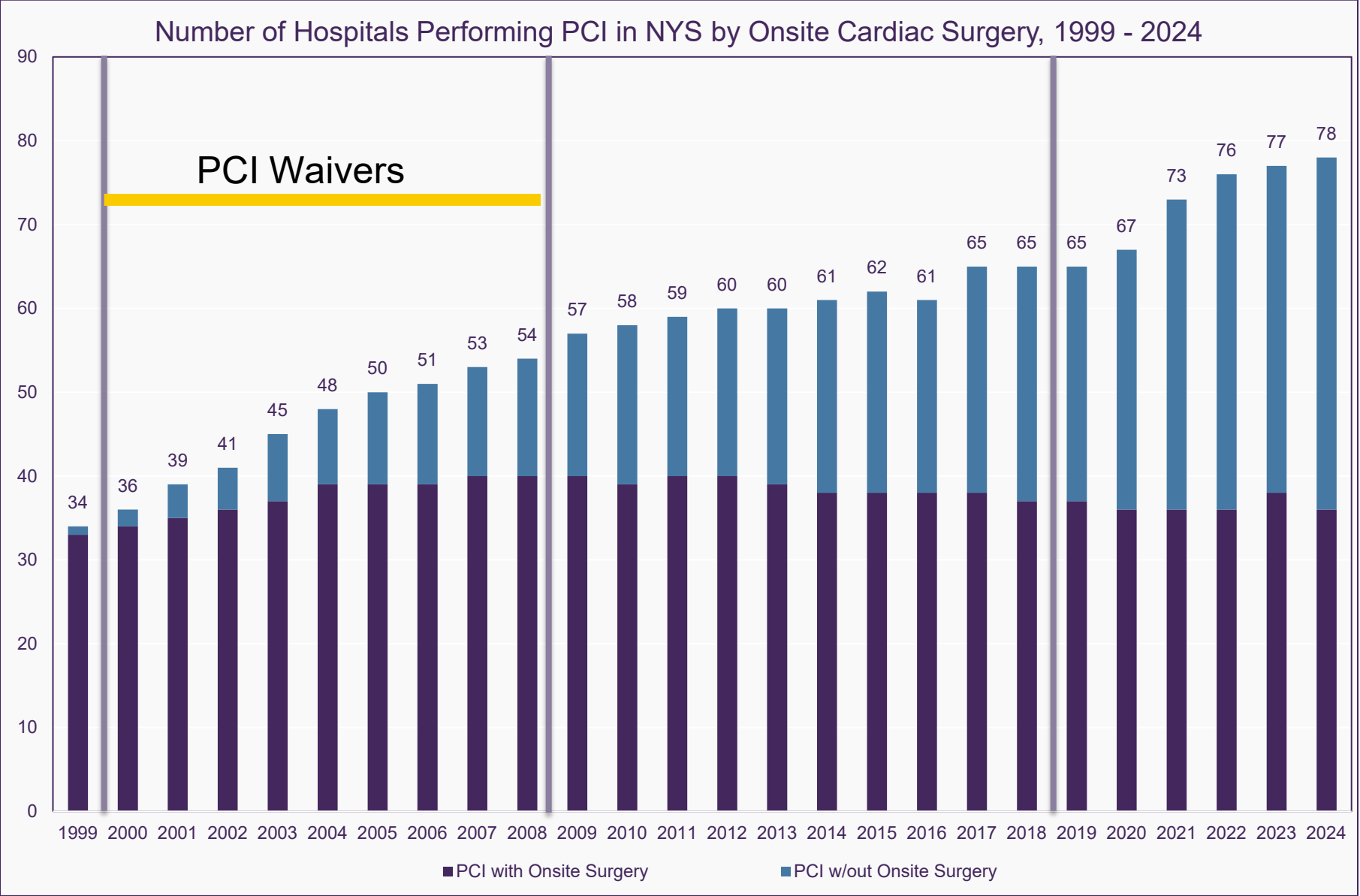
2009

PCI at Non-SOS in regulations

2019

Certificate of Need process modified

* 1 Hospital shared cardiac surgery with adjacent hospital



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PRIMARY PCI WAIVER PROGRAM – HISTORICAL EXAMPLE

The Department initiated a process to allow hospitals without on-site cardiac surgery to seek a waiver for provision of Primary PCI.

Primary PCI is PCI as primary reperfusion strategy for ST-segment Elevation Myocardial Infarction (STEMI) – a specific kind of heart attack where rapid treatment is shown to improve outcomes.

The Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Registry was central in the development of the waiver process as well as implementation and program monitoring.

PRIMARY PCI WAIVER PROGRAM – HISTORICAL EXAMPLE

Waiver Development Process

A Cardiac Advisory Committee Workgroup was convened to develop recommendations and guidelines.

The workgroup:

- Reviewed recent studies, discussed models and approaches in other areas of the country, and discussed proposed American College of Cardiology guidelines.
- Recommended 6-month time-limited waivers to allow **Primary PCI** at hospitals where specific criteria were met.
- Developed patient selection criteria, implementation requirements, and monitoring plan.

PRIMARY PCI WAIVER PROGRAM – HISTORICAL EXAMPLE

Waiver Application Review Criteria

Hospital must demonstrate:

- Existing diagnostic catheterization program with:
 - good results
 - annual volume at least 400 cases
 - At least 3 years of experience
- Appropriate equipment
- Administrative support including agreement to report data
- Sufficient anticipated volume (based on number of STEMI cases previously treated)
- Plan for Primary PCI as routine/preferred intervention for STEMI 24/7

PRIMARY PCI WAIVER PROGRAM – HISTORICAL EXAMPLE

Waiver Application Review Criteria (continued)

- Plan for immediate surgical back-up
 - Maximum transport time of 1 hour
- Affiliation agreement with high-volume / high-quality Surgery-On-Site hospital to include:
 - Clinical credentialing and training
 - Quality reviews
 - Transfer agreement
- Physician experience / volume requirements
- Agreement to participate in the C-PORT Registry and associated required training

PRIMARY PCI WAIVER PROGRAM – HISTORICAL EXAMPLE

Waiver Implementation Process

- Waiver requests reviewed by DOH staff and clinical consultants (CAC members and consultants)
 - If waiver application criteria were determined to be met, the hospital could proceed to C-PORT enrollment
- Hospitals participated in a 2-6 month C-PORT development and training protocol before initiation of PCI program
- Once all criteria were met, DOH issued a 6-month time limited waiver for provision of primary PCI
- Outcomes for the first 10 Primary PCI patients were reviewed by C-PORT
 - If first 10 cases performed had acceptable results, unrestricted recruitment allowed.

PRIMARY PCI WAIVER PROGRAM – HISTORICAL EXAMPLE

Program Monitoring – Quality Indicators

Processes

- Door to balloon time
- Door to thrombolytic time
- Institutional volume

Outcomes

- Death
- Myocardial infarction
- Stroke
- Significant bleeding

Adverse outcomes reported to C-PORT within 72 hours.

Data from C-PORT and PCI Reporting System reviewed by DOH and CAC consultants at six-month intervals.

PRIMARY PCI WAIVER PROGRAM – HISTORICAL EXAMPLE

Termination - At the discretion of the NYS Department of Health, based on recommendations from the expert panel (CAC consultants) or the C-PORT Project Chairperson

Reasons for Termination

- Inadequate volume
- Unsuccessful start-up
- Inadequate data set completion
- Inappropriate recruitment
- Data misrepresentation or falsification
- Violation of C-PORT publication policy
- Violations of standards of care
- Unacceptable trends in process or outcomes indicators

Things to Consider for Cardiac Catheterization in ASCs



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CASE SELECTION

- Who are the appropriate candidates for catheterization in ASCs? Will need to consider:
 - Type of procedure and approach
 - Patient risk factors / comorbidities
 - Type of lesion
 - Post-procedure - care and access to further medical care

PROGRAM REQUIREMENTS

What will be required of ASCs in terms of:

- Experience of interventional cardiologists
- Equipment
- Staffing
- Volume thresholds – for physicians and centers
- Transfer agreements and transfer time/distance to hospital with surgical backup
- Surgical consultation
- Data reporting
- Quality assurance – QI activities, monitoring, case review, credentialing

MONITORING

What will be monitored and how? Consider:

- Outcomes
- Adherence to patient selection criteria
- Adherence to program requirements
- Volume



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