Oversight of Regulated Cardiac Services in Maryland
A Legislative Update

Mission: Lifeline State Meeting
STEMI Workshop
October 20, 2012
Modified from presentations presented by MHCC staff to legislators and the CAG earlier in 2012

- Current approaches to performance evaluation by MHCC
- Recent regulatory history
  - Cardiac surgery
  - Primary PCI
  - Non-primary PCI
- 2012 legislation – Implementation by MHCC
Current approaches to performance evaluation

**Hospital Performance Evaluation Guide**
http://mhcc.maryland.gov/consumerinfo/hospitalguide/index.htm

- In-place
  - 29 process of care measures including six for AMI and four for heart failure
  - Six outcome measures including 30-day mortality rate and standardized readmission for AMI and heart failure
  - Surgical Care Improvement Project – includes 10 measures including an infection prevention and a drug management measure for post-operative cardiac surgery patients

Coming soon to **HPEG**
- Reporting of selected surgical site infection rates, including CABG, based on NHSN reporting
- Reporting of risk-adjusted cardiac surgery and PCI mortality rates, based on NCDR reporting

Current approaches to performance evaluation

**Very limited use of performance evaluation in CON regulation and blunt measures**

- Volume requirements instituted for cardiac surgery in late 1990s – applied to last two CON approvals
- Volume requirements for PCI waiver programs and interventionalists practicing in waiver programs – 2006 to present
Hospitals Performing PCI Services
Primary (pPCI) and Non-Primary (npPCI)

- PCI services at non-cardiac surgery hospitals, have been regulated by MHCC (or its predecessor) since 1990.
  - 10 hospitals perform PCI by virtue of their status as cardiac surgery hospitals
  - 13 additional pPCI hospitals with no cardiac surgery on site added since 2006 through MHCC waivers
  - Of the 13 new sites, all perform pPCI; 8 also perform npPCI through MHCC research waivers (C-PORT E trials)
- About 12,000 PCIs performed in 2010, about 80% of all PCIs are performed at the 10 SOS hospitals.

Research trials have informed MHCC on appropriate use of PCI

Prior to 1996 PCI only performed at Cardiac SOS Hospitals

Research Activities

- pPCI performed at cardiac hospitals
- Research Activities commenced
- Research Activities concluded

MHCC Actions

- MHCC mandates primary PCI for selected hospitals
- MHCC approves research projects
- MHCC approves clinical trial

Notes: Collaborators: Patient Outcomes Research Trust (PORT) Combating the Patient Outcomes Research Trust (C-PORT)

Expected: MHCC to expand use of PCI in primary PCI hospitals

MHCC mandates primary PCI for selected hospitals
Hospitals with On-Site Cardiac Surgery

Certificate of Need is required for cardiac surgery.

- Except for cardiac surgery programs approved since 1997, cardiac surgery programs do not have to meet any ongoing performance requirements.
- Like non-SOS hospitals, cardiac surgery hospitals began reporting National Cardiac Disease Registry (NCDR) data to MHCC in July 2010.

Hospitals without On-Site Cardiac Surgery

In 2004 the Commission adopted two “waivers” from the policy requiring co-location of cardiac surgery and PCI:
- For hospitals to provide primary (emergency) angioplasty services.
- For specific Commission-approved PCI research projects

MHCC issued waivers to provide Primary PCI in 2006
- 13 hospitals operate Primary PCI under waiver status.
- Waivers renewed every two years
- Must meet ongoing volume and quality assessment standards.
- All 13 hospitals have been renewed for another 2 year cycle.

Beginning in 2008 MHCC granted research waivers to 8 non-SOS hospitals to participate in a research study investigating safety of non-primary PCI performed in hospitals without SOS.
- Hospitals must meet ongoing volume and quality assessment standards and participate in the C-PORT E research study.
- Hospitals are meeting requirements of the C-PORT E study

Non SOS Hospitals report NCDR results to MHCC
Maryland Hospitals performing PCI services

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Perform Cardiac Surgery &amp; PCI</th>
<th>Subject to Ongoing Review on Surgical Volume</th>
<th>Perform Elective PCI Under Research Waiver</th>
<th>Perform Emergency PCI Under Waiver</th>
<th>Subject to Ongoing Review on PCI Waiver Standards</th>
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Anne Arundel Medical Center (Anne Arundel County)    | n/a                          | √                                         | √                                        | √                                 | √                                             |
Baltimore Washington Medical Center (Anne Arundel County) | n/a                          | √                                         | √                                        | √                                 | √                                             |
Carroll Hospital Center (Carroll County)             | n/a                          | √                                         | √                                        | √                                 | √                                             |
Franklin Square Hospital Center (Baltimore County)   | n/a                          | √                                         | √                                        | √                                 | √                                             |
Frederick Memorial Hospital (Frederick County)       | n/a                          | √                                         | √                                        | √                                 | √                                             |
Holy Cross Hospital (Montgomery County)              | n/a                          | √                                         | √                                        | √                                 | √                                             |
Howard County General Hospital (Howard County)       | n/a                          | √                                         | √                                        | √                                 | √                                             |
Johns Hopkins Bayview Medical Center (Baltimore City) | n/a                          | √                                         | √                                        | √                                 | √                                             |
Meritus Medical Center (Washington County)           | n/a                          | √                                         | √                                        | √                                 | √                                             |
Saint Agnes Hospital (Baltimore City)                | n/a                          | √                                         | √                                        | √                                 | √                                             |
Shady Grove Adventist Hospital (Montgomery County)   | n/a                          | √                                         | √                                        | √                                 | √                                             |
Southern Maryland Hospital Center (Prince George's County) | n/a                          | √                                         | √                                        | √                                 | √                                             |
Upper Chesapeake Medical Center (Harford County)     | n/a                          | √                                         | √                                        | √                                 | √                                             |

Requirements for the Primary PCI Program

- **Institutional Resources**
  - 24/7 operation of Catheterization Lab
  - 24/7 nursing and technical staffing for catheterization lab and coronary care unit services
  - Provide primary angioplasty as soon as possible and not to exceed 90 minutes from patient arrival for 75% of appropriate patients
  - Formal, written agreement for patient transfer with SOS hospital
  - Formal, written agreement with advanced cardiac life support EMS provider

- **Physician Resources**
  - ACC/AHA criteria for competency of 75+ total angioplasty cases per year
  - Physicians who have taken leave of absence (leave of < 1 year) and whose volume is <75 for the 12-month period that includes the absence, may perform 10 proctored cases to resume PCI procedures.
  - New physicians (out fellowship < 3 years) complete a minimum of 50 acute MIs or 10 proctored cases before performing primary PCI alone
  - Participation in on-call schedule

- **Angioplasty Center Program Standards**
  - Development program (standards, staff training, logistics plan, and quality and error management program)
  - Hospital leadership participates in the program

- **Volume-Quality Relationship for Primary Angioplasty**
  - Minimum of 36 (rural areas) and optimally 49 (metropolitan areas) cases

- **On-Going Quality Assessment**
  - Develop uniform data set to be collected and analyzed from all hospitals in Maryland offering primary angioplasty services. Participate in ACCF ACTION and CathPCI Registries.
Maryland Environment

- Concern about appropriate use of PCI.
  - Consumer confusion about the benefit of the service
  - Continuing worry about potential provider misconduct
  - MHCC authority to provide oversight under current law is uneven
- Conclusion of C-PORT E research trial creates uncertainty in the health care community about npPCI programs.
- In 2011, General Assembly passed HB 1182
  - Prohibits a hospital from establishing a non-primary PCI program unless the hospital was operating a PCI program on January 1, 2011, through:
    - (1) A certificate of need for an open heart surgery program; or
    - (2) A non–primary research waiver in good standing from certificate of need and State Health Plan requirements, issued by the Maryland Health Care Commission.
  - The law required the Maryland Health Care Commission to:
    - (1) Develop recommendations for statutory changes needed to provide appropriate oversight of PCI services; and
    - (2) Report its recommendations to the Governor and, in accordance with § 2–1246 of the State Government Article, the General Assembly.

Technical Advisory Group Process

- The Technical Advisory Group (TAG) held 4 meetings in the fall of 2011; time was reserved for public comment at each meeting.
- TAG recommendations were incorporated into MHCC Report.
- MHCC submitted report to the General Assembly and the Governor in December 2011.
2012 Legislative Activity

- House Bill 1141 included recommendations from the 2011 MHCC Report on PCI.
- General Assembly passed HB1141
- Governor signed the bill on May 2, 2012.
- The statute took effect July 1, 2012.

MHCC Endorsed Statutory Changes (HB1141)

- PCI will be identified in the law as a specialized service regulated by MHCC.
  - PCI oversight will be separate from oversight of cardiac surgery under Maryland law.
  - MHCC oversight of PCI will be consistent across all hospitals (regardless of SOS).

- Authority to perform PCI will be transformed from the waiver process to a certificate process – i.e., Certificate of Conformance and Certificate of Continuing Performance (aka exemption from CON).
  - Certificate of Conformance- Initial application process, hospitals would demonstrate capabilities to perform PCI, meet minimum standards, and conform to requirement in the State Health Plan. No interested party status.
  - Certificate of Ongoing Performance- Hospitals subject to meeting minimum standards.

- MHCC should have authority to establish consistent standards for cardiac surgery hospital.
- MHCC should have authority to share information with other appropriate state agencies, to investigate quality or utilization of care in regulated facilities.
MHCC Endorsed Statutory Changes (continued)

• **How will the certificate process work?**

  – Hospitals with existing Primary PCI waivers will be required to maintain the standards in Certificate of Ongoing Performance.
  – Hospitals seeking to perform npPCI, including current npPCI waiver hospitals, would apply for a Certificate of Conformance and Certificate of Ongoing Performance.
    • Certificate of Conformance could consider capabilities of existing programs.
    • Hospitals that currently are not performing PCI could apply to perform PCI.
  – Hospitals with existing cardiac programs would be required to maintain standards in Certificate of Ongoing Performance.
  – All hospitals would maintain compliance with ongoing minimum standards. The consequences of failing to comply could result in loss of authority to perform PCI.

Timeline of Implementation

• **December 2012:** Review the eight Elective (Non-Primary) PCI Follow-on Registry programs for continuing compliance with state’s conditions; determine whether each program continues to have authority to provide PCI.

• **Throughout 2013:**
  – Analyze input from Clinical Advisory Group and develop recommendations on appropriate standards.
  – Report recommendations to the Governor and the Senate Finance Committee and House Health and Government Operations Committee.
  – Post recommendations and report for 60-day review and comment period.
  – Adopt regulations to implement recommendations.

• **December 1, 2013:** Report final recommendations.
Clinical Advisory Group for PCI and Cardiac Surgery

- MHCC has appointed a 27-member Clinical Advisory Group (CAG)
- Six meetings of the CAG have been scheduled through early 2013
- Based on recent clinical research findings and guidelines, the CAG will advise MHCC on appropriate standards for establishment and ongoing performance review of cardiac surgery and PCI programs

Co-Chairs:
- David O. Williams, Cardiac Interventionalist, Harvard Medical School, Brigham & Women's Hospital;
- Loren Hiratzka, Cardiothoracic Surgeon, University of Cincinnati College of Medicine, Tri-Health

CAG Composition

Substantial expertise in cardiovascular guideline development.
Clinical expertise of professional associations represented, including
- American College of Cardiology, National and State chapter
- Society of Thoracic Surgeons (STS)
- Society for Cardiovascular Angiography & Interventions (SCAI)
- MedChi – The Maryland Medical Society
- American Heart Association

- Participation of Maryland hospitals with and without PCI, cardiac surgery

- C-PORT E Study Principal Investigator – Thomas Aversano

- Five members also serve on MHCC Cardiac Data Advisory Committee
Questions?

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