



Review of Cardiac Catheterization

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- The Bureau of Health Care Safety and Quality has conducted a review of issues related to Cardiac Catheterization (cardiac cath) and Percutaneous Coronary Interventions (PCI), commonly known as angioplasty.
- This presentation will update the PHC on the findings from our review and provide an overview of our next steps.



Cardiac Cath and PCI

- A cardiac catheterization (cardiac cath) is a procedure used to examine how well your heart is working. During a cardiac cath, a long thin tube called a catheter is inserted in a large blood vessel that leads to your heart.
- PCI is a treatment procedure that unblocks narrowed coronary arteries without performing surgery. It is generally completed after a cardiac catheterization.
- There are two types of PCIs:
 - 1) Emergency PCI, which is performed when a person has an emergency condition, such as a heart attack; and
 - 2) Non-emergency PCI, which is performed when person has been found to have a non-emergency condition that may be best addressed by performing a PCI.



- DPH:
 - Enforces regulations for surgery on site (SOS) hospitals to perform cardiac cath and administers special projects and waivers for non-SOS hospitals to perform PCI.
 - Receives feedback from the Invasive Cardiac Services Advisory Committee (ICSAC).
- ICSAC:
 - Established by regulation to “advise the Department on issues related to invasive diagnostic and therapeutic cardiac services licensed by the Department.” No further oversight role.
- Mass-DAC:
 - Hospitals are required under statute and regulation to submit patient-specific PCI and cardiac surgery outcome data to the Data Analysis Center (DAC).
 - This requirement applies to both SOS hospitals and those non-SOS hospitals approved to do PCI under special projects and waivers.



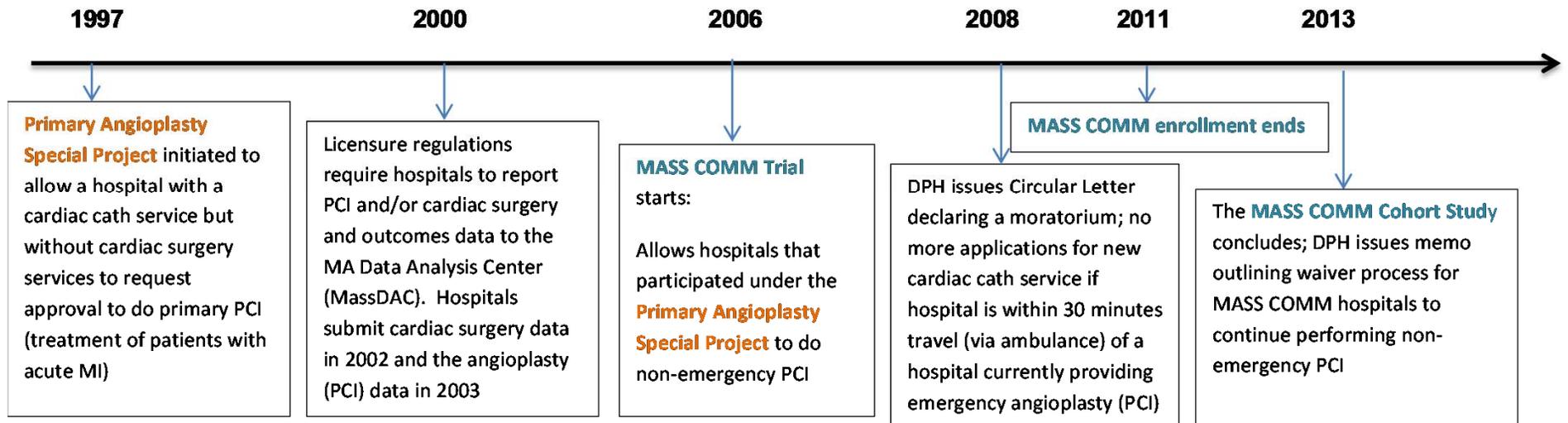
DoN and Licensure

- Prior to 1997, cardiac cath services were required to comply with the Determination of Need (DoN) process.
- In 1997, DPH adopted hospital licensure regulations that removed cardiac cath from the list of services that require DoN; this means that a hospital is licensed to perform cardiac cath and does not go through the DoN process.

Determination of Need	Licensing
Initial permitting	Ongoing monitoring of quality
Once implemented, no further review	Ongoing review and oversight



Background (1997 – 2013)





Background (2014 – Present)

July 2014



Circular Letter issued continuing the 2008 moratorium and adopting the April 2014 ICSAC recommendation that there was no demonstrable need for any additional emergency PCI or non-emergency PCI; any additional programs may have an adverse impact on the existing quality of PCI.

The circular also allowed hospitals that are part of an ACO to transfer an existing cardiac cath service to another hospital within the system and clarified the requirement to meet volume minimums for cardiac catheterization.

December 2014



Circular letter releases revised “Primary PCI Guidelines,” which were recommended by ICSAC at its September 4, 2014, meeting; these are a revision of the 2000 **Special Project Guidelines** and apply to the 11 non-SOS sites that applied prior to April 17, 2014, to perform emergency PCI.

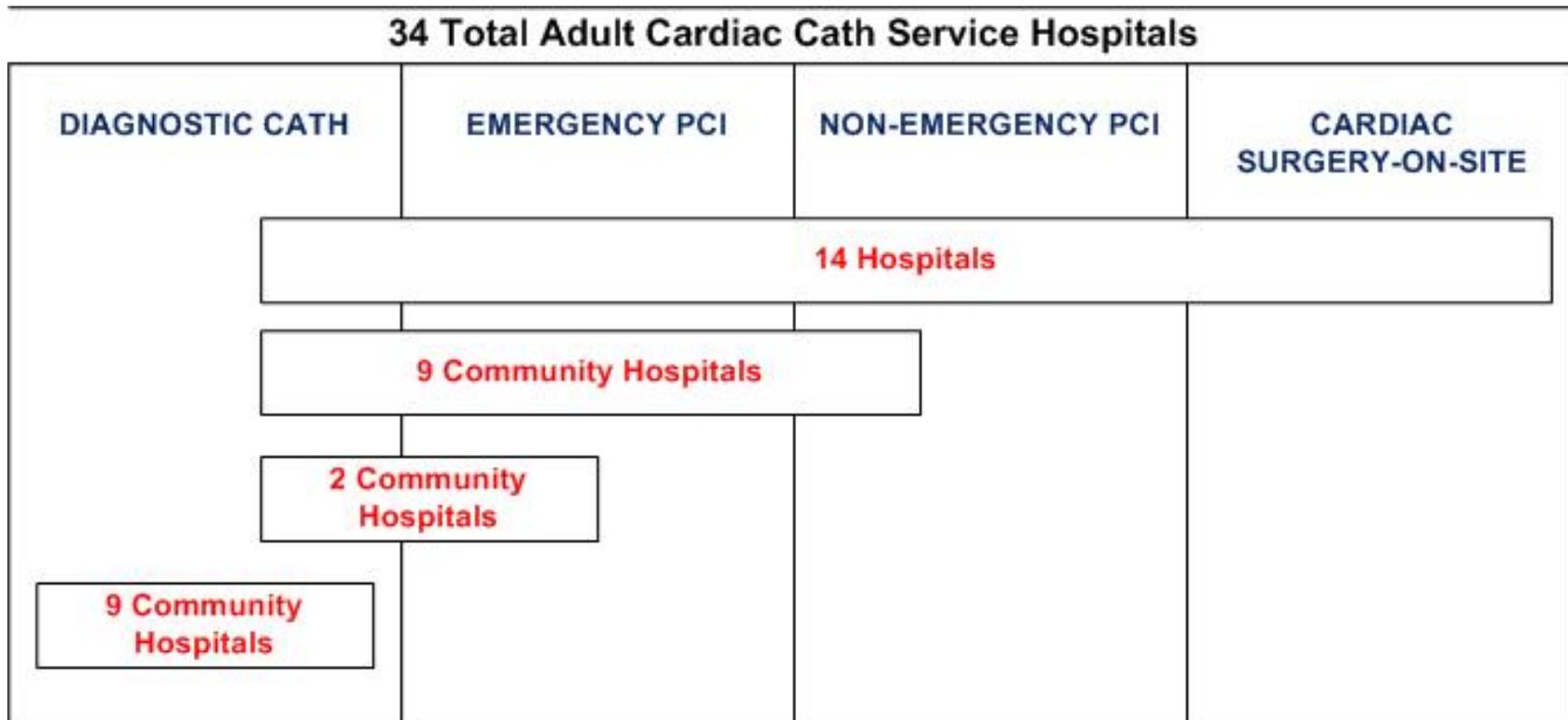
2015



**Current Cardiac Cath
Assessment**



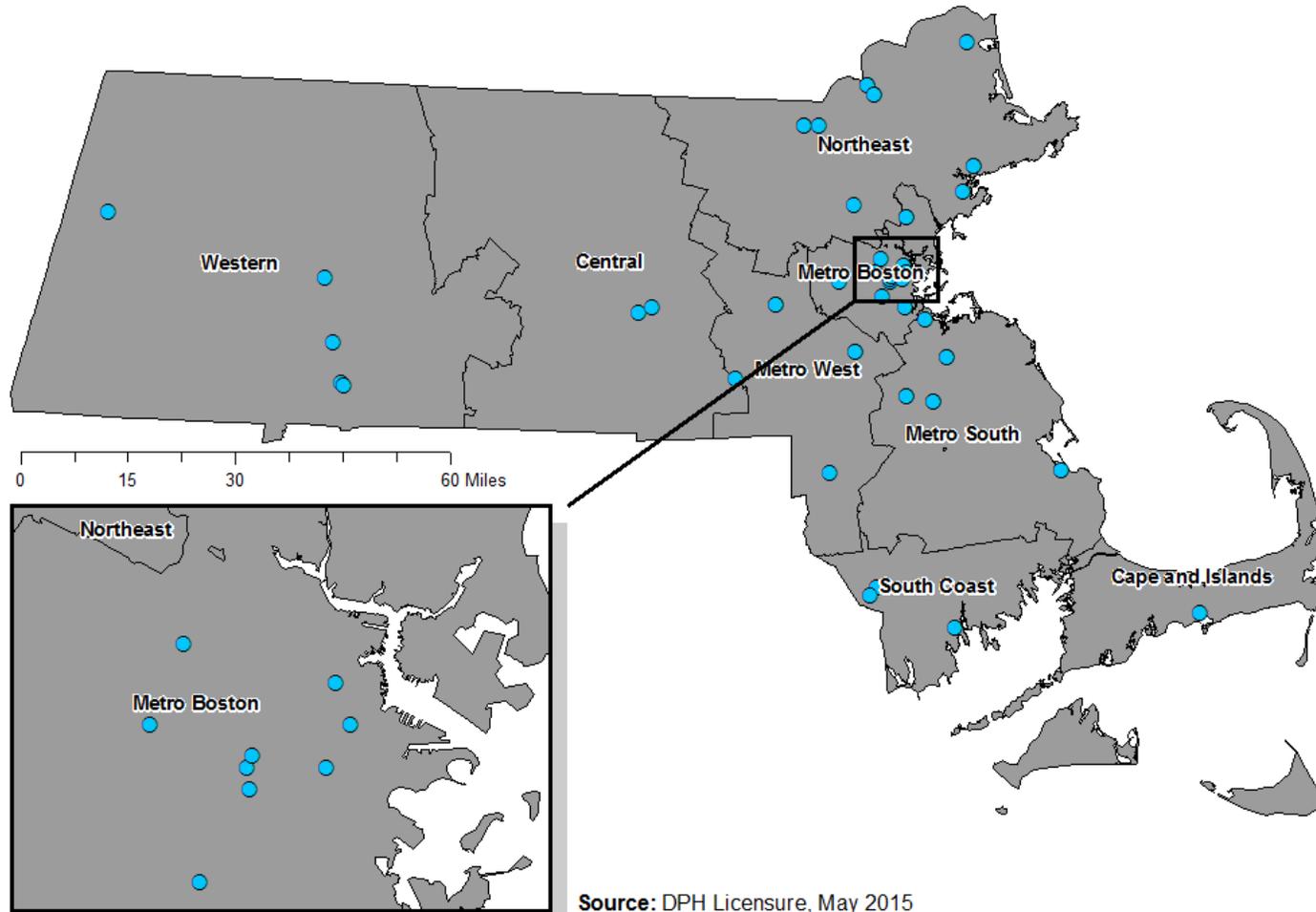
34 Adult Cardiac Cath Service Hospital Locations (cardiac cath + PCI [emergency and non-emergency]). Some hospitals do both emergency and non-emergency PCI.





Inventory

34 Adult Cardiac Catheterization Service Hospital Locations





- The review began in January 2015.
- It was an opportunity for the Department to review regulatory updates since 1997 in the field of cardiac cath and PCI.
- Comprehensive assessment included review of:
 - Current Massachusetts statutory and regulations requirements:
 - Statutory:
 - Data reporting.
 - Regulatory:
 - Volume minimums for facilities and physicians.
 - Compliance process for facilities that do not meet these minimums.
 - Licensure/eligibility process for hospitals to become approved to perform cardiac cath.
 - Additional data reporting that supports the statutory requirements.
 - Under the hospital licensure regulation, only hospitals with cardiac surgery on-site may perform emergency and non-emergency PCI.
 - The regulation allows the Department to administer special projects and waivers that have expanded the performance of emergency and non-emergency PCI by community hospitals.



- Comprehensive assessment included review of (cont.):
 - National Guidelines
 - The following organizations have stated standards for volume minimums: American College of Cardiology Foundation (ACCF), American Heart Association (AHA), and Society for Cardiovascular Angiography and Interventions (SCAI).
 - History of key initiatives and policy actions
 - Implementation of changes to PCI/cardiac cath policy. These changes have been communicated through circular letters and memorandums.
 - Actions in other states
 - Regulation of cardiac cath.
 - Volume minimums.
 - Enforcement/compliance.



Key Themes:

1. Regulations need to be updated and include appropriate engagement from stakeholders and experts as part of the process.
2. Data is available to utilize for decision making.



- Thank you for the opportunity to present this information today.
- Please direct any questions to:

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