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# Adult Elective Percutaneous Coronary Interventions in Hospitals without On-site Cardiac Surgery

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State of Washington

Department of Health

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# Scope of Work

- Report of findings and recommendations concerning the circumstances under which adult elective percutaneous coronary interventions should be allowed in State of Washington hospitals that do not provide on-site cardiac surgery

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# Methodology

- Extensive literature search
- Direct communications with nationally respected interventional cardiologists
- Interviewed select Washington hospitals currently performing elective PCIs and hospitals interested in starting programs
- Other State Regulations and guidelines

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# Level of Evidence

- The weight of evidence for all publications reviewed and cited were graded as A, B, or C. The basis for the assigned grades are detailed as follows:
  - **Level of Evidence A:** Data derived from multiple well powered prospective randomized clinical trials or meta-analyses.
  - **Level of Evidence B:** Data derived from a single randomized trial or nonrandomized studies including retrospective and registry reviews.
  - **Level of Evidence C;** Only consensus opinion of experts, case studies, or standard of care.

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# Elective PCIs in Hospitals without On-site Cardiac Surgery

- National professional societies state “elective PCI should not be performed at institutions that do not provide on-site cardiac surgery.”
- In spite of this in 2006 elective PCI without on-site surgery is being performed in the USA in nearly 180 hospitals in 27 different states.

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# Current Evidence does not support Elective PCI in hospitals without on-site cardiac surgery

- Not a single well powered, multiple site prospective, randomized study comparing elective PCI with and without on-site cardiac surgery
- A number of non-Gold Standard, Level of Evidence B studies
- Absence of justification to change policy and practice

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## Communities with Diminished Access to Interventional Cardiology

- New elective PCI program may be developed when a community lacks access to elective PCI.
- No documented prolonged waiting time for elective PCI in State of Washington
- May be diminished access for uninsured and in select communities but this needs to be studied and documented

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## Communities with Diminished Access to Interventional Cardiology

- Programs that focus on the care of the underserved and uninsured may need to be provided with priority consideration for developing new interventional cardiology programs.

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# Considerations for initiating new PCI without on-site cardiac surgery

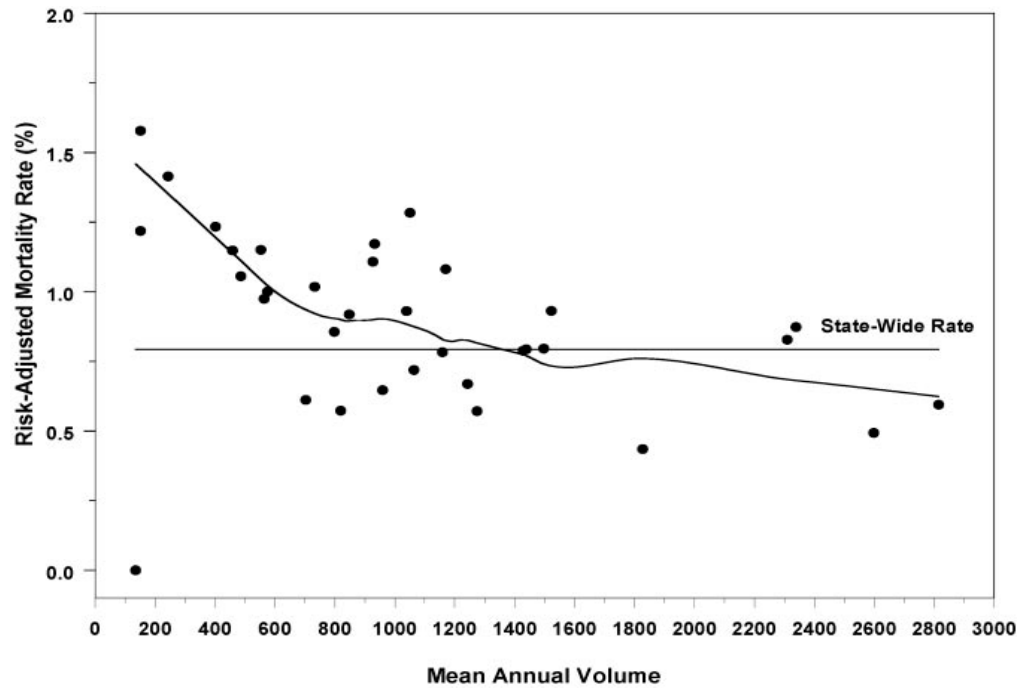
- Unmet PCI Need
- Program and Operator Volumes
- Impact on Existing PCI Programs
- Patient, Lesion, Device Selection
- Impact on Training Programs

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# Volume Related Standards

- **PCI programs in hospitals with and without on-site cardiac surgery should have minimum annual PCI volumes of >300 and optimal annual volumes of >400.**
- **Operators should have minimum annual PCI volumes of >75 and an optimal annual volume of 100 including a minimum of 11 annual primary PCIs and an optimal volume of 18 primary PCIs.**
- **New programs and operators should achieve the minimum annual volumes within 2 years.**

Mean annual hospital PCI volume  
and risk-adjusted in-hospital mortality  
rate in New York State, 1998 to 2000.



*Circulation*. 2005;112:1171-1179.

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# Patient, Lesion and Device Selection

- High risk patients are at risk for complications during elective PCI.
- High lesions are at risk for procedure failure and complications
- Atheroablative devices (directional, rotational, laser) have higher complications rates

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## Impact on Existing Elective PCI Programs of New Programs

- 40% of existing elective PCI programs in Washington could fall below minimum or optimal volume standards if new programs started in same service area
- Recruitment of interventionalists and qualified cath lab techs and nurses could be compromised (esp. in rural and micro-urban areas)
- There will be a fiscal impact

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# Impact on Cardiology Training Programs

- U of Washington has the only Cardiology and Interventional Cardiology Fellowship programs in NW USA
- Current program PCI volumes at the U of Wash hospital and its affiliates barely meet ACGME requirements
- Real risk that new elective PCI programs will negatively impact on U of Wash Cardiology and IC training programs

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# Impact on Existing Elective PCI Programs

- Projected impact of new programs on existing programs could be offset by increases in the prevalence of CAD
- Advances in diagnostic and therapeutic modalities may decrease indication for angiograms and PCIs

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## Minimum Criteria for the Performance of Elective PCI without On-site Cardiac Surgery

- Documented unmet need
- No impact on compliance with volume standards at existing programs
- Ability to staff PCI program without jeopardizing existing PCI programs
- Participation in well powered randomized study comparing elective PCIs with and without on-site cardiac surgery

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## Minimum Criteria for Performance of Elective PCI without On-site Cardiac Surgery

- No impact on Cardiology and IC training programs at the University of Washington
- Achieve minimum PCI volume >300 by year 2 (seek optimal volume >400 by year 3)
- Adequate # of fully equipped cardiac cath labs staffed by qualified, experienced techs/RNs
- Experienced Board Certified Interventionalist who meet annual/lifetime PCI volumes and national outcome standards

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## Minimum Criteria for Performance of Elective PCI without On-site Cardiac Surgery

- Only low risk patients with low risk lesions – if 2 year risk-adjusted outcomes meet national benchmark standards may expand to low risk patients with high risk lesions
- No atheroablative devices (directional, rotational, laser) or other aggressive interventions
- Provide Primary PCI services

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## Minimum Criteria for Performance of Elective PCI without On-site Cardiac Surgery

- Formal agreement with backup hospital and cardiac surgeons
- Acceptance of urgent and emergency transfers based only on medical condition
- Expedited emergency transportation with arrival in OR <60-90 minutes
- Emergency transport staff ACLS certified , competent in cardiac monitoring and use of IABP

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## Minimum Criteria for Performance of Elective PCI without On-site Cardiac Surgery

- Ongoing QI evaluation of elective PCI outcomes and complications, compliance with patient/lesion selection guidelines, comparison with national benchmarks, review of all emergency transfers for CABG, and formalized case reviews
- Participation in national PCI database (ACC-NCDR)

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# Regionalized Primary PCI Centers

- DOH should evaluate the benefits to the State of Washington of establishing designated Primary PCI Centers at hospitals with on-site cardiac surgery to which patients with AMI and Acute Coronary Syndromes would be directly transported
- Potential quality and outcome improvements and cost savings