The Heated Debate Continues: PCI without Surgical Back-up in 2013 - Perspectives from the Ohio ACC

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Introduction to Ohio Hospital Regulations

- Ohio is the **only** state that does not license hospitals, however…
- Ohio does have regulatory authority over several service lines
  - Cardiac surgery
  - Cardiac catheterization labs
  - Transplantation
  - Maternity units and newborn care
Current Ohio Revised Code: Cath Lab, 3701-84-30

- (C) A provider of cardiac catheterization services may perform high-risk and therapeutic percutaneous coronary interventions (PCI), including percutaneous transluminal coronary angioplasty (PTCA), only if:
  - (1) An on-site adult open heart surgery service is available within the same hospital as the cardiac catheterization laboratory and is immediately accessible from the cardiac catheterization laboratory by gurney; and
  - (2) An experienced cardiovascular surgical team is readily available in less than sixty minutes on a twenty-four hour basis in the event that emergency open heart surgery is required.

Several Problems with Ohio Law:

- C-PORT Waiver sites: now that C-PORT is over, what should be done with these?
- Is state law outdated?
  - MASS COMM, C-PORT

Aversano et al. Outcomes of hospitals with or without On-Site Cardiac Surgery. NEJM 2012;366:1792-1802.
Jacobs AK et al. Nonemergency PCI at hospitals with or without on-site cardiac surgery. NEJM 2013;368:1498-1508.
ODH Interventional Cardiology Advisory Group

Stakeholders
• Ohio ACC
• Mission Lifeline
• C-Port Waiver Hospitals
• Ohio Hospital Association
• Ohio ACP: Greg Rouan
• Case Western: Dan Simon
• CT Surgery: Anthony DeRiso
• Cleveland Clinic: Joseph Cacchione

Favoring Expansion
• STEMI PCI saves lives
  – Expand STEMI PCI sites
  • Not financially viable to expand without revenue from elective PCI
• Too expensive for Cardiac Surgery
• PCI w/ out back-up on site is safe
C-PORT:

- No difference in 9-month mortality
- Higher revascularization in hospital without onsite back-up
  - 6.5 vs. 5.4%, P=0.01
- More expensive
- Conclusion: PCI without onsite back-up was not inferior to PCI with onsite back-up

Opposing Expansion

- Most areas of Ohio adequately covered by established sites with onsite surgery
- Shift of volume to low volume hospitals and doctors worsens outcomes at all centers
- Oversight low at low volume centers
  - No surgeon
  - Too few for effective peer review
Access to PPCI in Columbus

Legend
- C-Port Participating Hospital
- NonPCI Capable Hospital
- PCI Capable Hospital (SOS)

Ohio ACC Board of Trustees

- Ohio divided into 6 districts
- Two or more representatives from each district representing community and academic practices
- Review and address state issues
- Take issues from Ohio to National ACC
Ohio ACC Board of Trustees

- **District One**: Dan Cantillon, Michael Deucher, Sanjay Gandhi, Tom Lassar
- **District Two**: William Colyer, David Meier
- **District Three**: Joseph Restivo, Kevin Silver
- **District Four**: Subha Raman, David Richards
- **District Five**: John Lynch, Jacob Gibson
- **District Six**: John Jeffries, Puvi Seshiah
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- **Pediatric**: Timothy Hoffman
- **Surgery**: Michael Firstenberg
- **CCA**: Ann Broz
- **Practice Manager**: Elizabeth Smotherman

Ohio ACC Positions

1. Quality patient care, not economics, should be the determining factor in the decision to permit PCI at sites without surgical backup.
   - Unanimous agreement.
2. Standards should be enforced.
   – Unanimous agreement

3. Ohio ACC endorses the 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update, included in attachment B.
   – 22 in favor. 1 opposed
4. Ohio ACC strongly believes that sites performing PCI without backup must report data to a single quality database. The American College of Cardiology’s NCDR registry should be considered strongly, given the long history and large experience.
– Unanimous agreement

5. Data monitoring, from reviewers external to and independent of the doctor, hospital, or healthcare system, is essential for insuring reliable and meaningful data.
– Unanimous agreement
6. Ohio ACC opposes allowing sites to perform PCI without surgical backup if they are within a reasonable distance (30-60 miles) of an established PCI site that has surgical backup.
   – Unanimous agreement

7. Enhancing STEMI care, with coordination of transfer of care from EMS directly to STEMI centers, should be a focus of Ohio Department of Health. Currently EMS providers in several areas of the state are coordinating care with local and regional STEMI centers. These efforts should be broadened statewide to provide all Ohioans access to high quality care.
   – Unanimous agreement
The Trustees acknowledged that PCI sites without backup may improve cardiovascular care in limited areas of the state that are geographically isolated...however, the potential to:

- **Incentivize increased numbers of procedures to allow hospitals and physicians to maintain volume standards,**
- **Move cases from well-established high quality sites to lower quality sites,**
- **Failure to disclose to patients that option for care at sites with surgical backup during informed consent.**

**Conclusion**

- Cardiovascular care, including STEMI PCI, takes place in a *social framework that includes state agencies*. Ohio ACC actively participates to represent our patients, our physicians, and our allied health providers.
References

- Aversano et al. Outcomes of hospitals with or without On-Site Cardiac Surgery. NEJM 2012;366:1792-1802.
- Jacobs AK et al. Nonemergency PCI at hospitals with or without on-site cardiac surgery. NEJM 2013;368:1498-1508.