



Advancing Quality And Safety In Health Care

Steven D. Pearson, MD, MSc, FRCP
Senior Fellow

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Goal #1

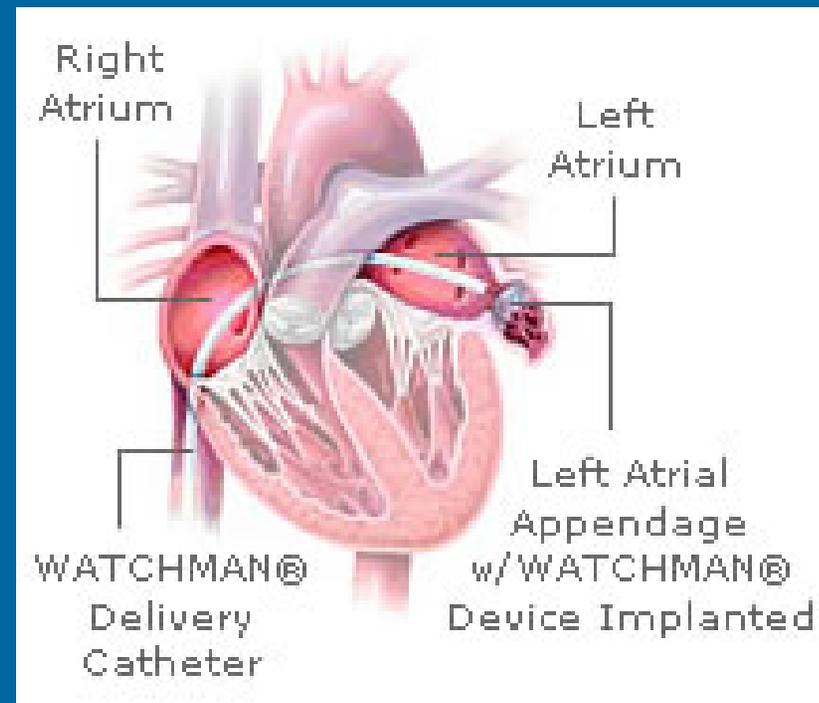
Assessing Safety and Quality

Support innovation by determining what procedures and technologies are safe and most effective

Recommendations:

- Establish a national entity to evaluate new and existing health care treatments and technologies
 - Reinforce FDA's capacity to assess long-term safety and effectiveness of new drugs
 - Strengthen FDA's review of certain devices and capacity to track device safety
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The Challenges





Comparative Clinical and Cost-Effectiveness

- Studies and systematic reviews rarely conclusive
 - CATIE trial, Women's Health Initiative
 - AHRQ review of treatment for prostate CA

 - We need to bring together all benefits, harms, patient values and show how they relate

 - Put all these together with downstream system effects

 - What to do about costs?
 - Not that easy to let others plug in costs
 - But what would we do with cost information anyway?
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Supporting Innovation and Value

- Value-based decision-making
 - Watchman® vs. usual medical care
 - Watchman® vs. competing device
 - Watchman® vs. Watchman-II

 - Comparative Clinical and Cost-Effectiveness
 - Better evidence = better care for individuals
 - Sends clear signals to manufacturers
 - Encourages dialogue over best use of health care resources
 - Higher quality, more affordable = innovation and value
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Comparative Effectiveness Board



Oversight

CEB

- Prioritize Topics for Research/Assessment
- Allocate Funds
- Review Research/Assessment for Validity, Reliability, Scope and Applicability
- No Authority for Coverage Decisions/Negotiate Prices

Intersecting Activities

Review Evidence of Clinical Effectiveness

Establish Methodological Standards

Assess Clinical Effectiveness and Value

Conduct studies of Comparative Effectiveness

Dissemination
