TRUVEN HEALTH ANALYTICS

LESSONS LEARNED FROM MAJOR PUBLISHED CER STUDIES

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BACKGROUND

- Significant expansion of CER funding
  - PCORI and ARRA
- Indicates a national interest and investment in promoting the use of effective medicine to influence patterns of care
- Goal of better patient outcomes, reduced variation and perhaps reduced spending
- Return on this investment will be measured in part, by if, and how quickly, results from the research are translated into clinical practice patterns
- There is little analysis of the net effect of CER evidence on actual practice

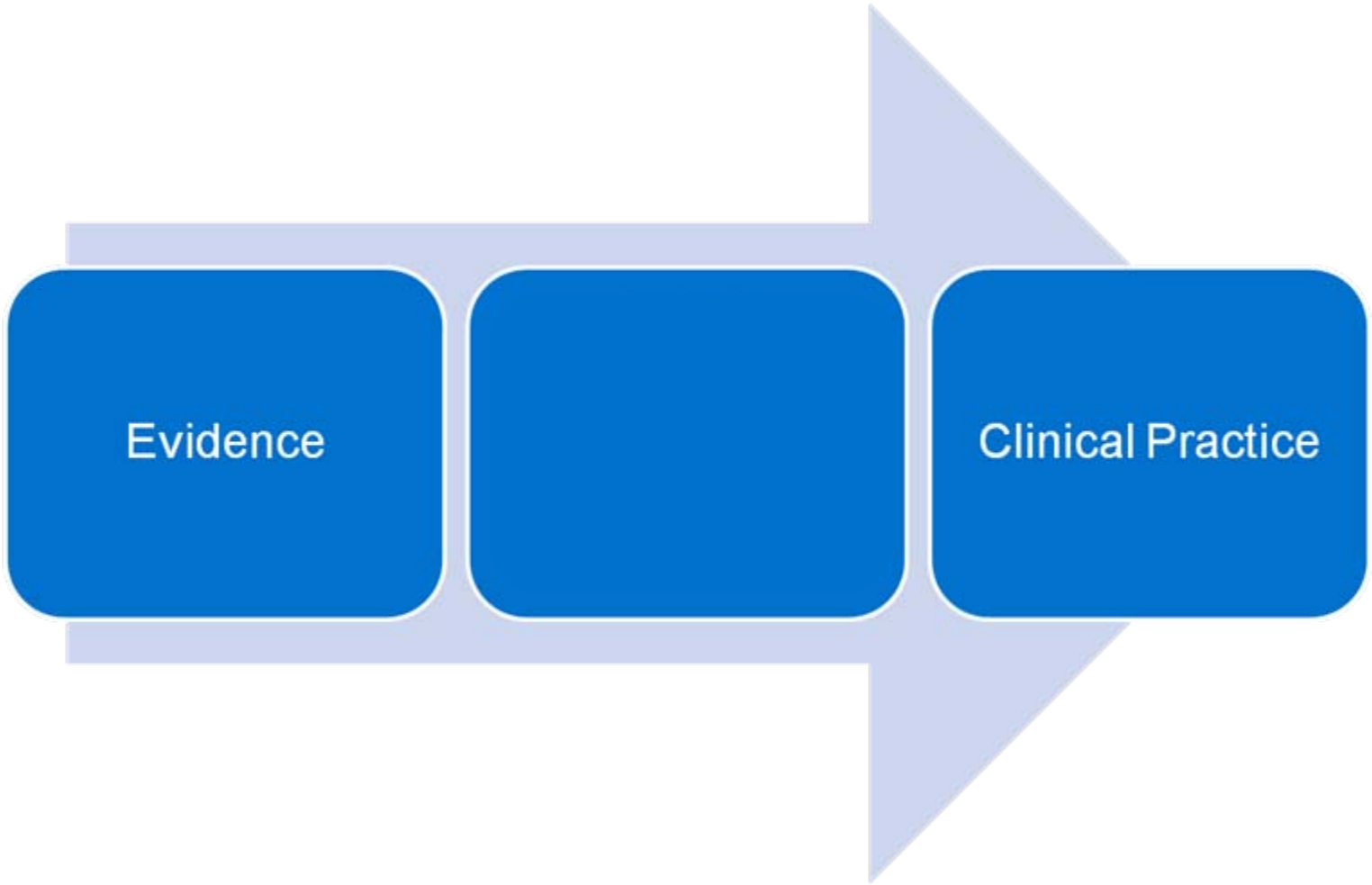
EXAMPLE
RESEARCH FINDINGS AND PRACTICE

- Estrogen Plus Progestin trial, a component of the Women's Health Initiative (Writing Group for the Women's Health Initiative Investigators, JAMA 2002).
- The associated health risks of combination hormone therapy among postmenopausal women outweighed the benefits.
  - Rates of coronary heart disease were observed to be higher among treated women, although rates of fractures were lower
  - The annualized rate of hormone therapy for postmenopausal women dropped from 90 million to 57 million prescriptions in the first 6 months of 2003 (Hersch, 2004).

STUDY OBJECTIVES

- We use a large, national administrative database to examine real-world utilization trends before and after publication of CER findings from four high-profile, government-funded CER studies published within the last decade.
- Analyze historical trends in utilization rates of procedures and treatments associated with widely-communicated CER evidence.
  - We do not attempt to trace a causal path between the releases of evidence and realized clinical practice
- Not normative or prescriptive

STUDY DESIGN



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METHODS: SELECTING CASE STUDIES

- Literature review
  - MEDLINE/PubMed, Congressional Budget Office publications, Agency for Healthcare Research and Quality CER studies
  - 23 studies

METHODS: SELECTING CASE STUDIES

- Criteria
  - Reported between January 1, 2000 and December 31, 2009
  - Widely cited (ISI Web of Knowledge cites, Google Scholar)
  - Compared 2 or more treatments or diagnostic methods
  - Study design (experimental design, adequate sample size)
  - Clear findings (lack of ambiguity in implications)
  - Findings not reversed or contradicted by subsequent evidence
  - Excluded cost effectiveness

The main criteria for the case studies were: high profile study (published in a top tier journal as ranked by ISI Web of Knowledge) (ISI) and results c
(lack of ambiguity in the implications) and, finally, findings that were not reversed or contradicted by subsequent evidence. Cost-effectiveness studi

SELECTED CASE STUDIES

Case Study	Citation	Number of Citations	Journal Impact Factor
PROVE IT-TIMI 22	Cannon CP et al. Intensive Versus Moderate Lipid Lowering with Statins After Acute Coronary Syndromes. *N Engl J Med*. 2004 Apr 8;350(15):1495-1504.	ISI: 1,914 Google Scholar: 2,488	44.016 (2005)
MRI	Warner, E. et al. Surveillance of BRCA1 and BRCA2 Mutation Carriers with Magnetic Resonance Imaging, Ultrasound, Mammography, and Clinical Breast Examination. *JAMA.* 2004 Sept 15;292(11):1317-1325	ISI: 408 Google Scholar: 627	23.494 (2005)
SPORT	Weinstein JN, et al. Surgical vs nonoperative treatment for lumbar disk herniation: the Spine Patient Outcomes Research Trial (SPORT): a randomized trial. *JAMA.* 2006 Nov 22;296(20):2441-50.	ISI: 236 Google Scholar: 495	31.718 (2007)
COURAGE	Boden WE, et al. Optimal Medical Therapy With or Without PCI for Stable Coronary Disease. *N Engl J Med*. 2007 Apr 12;356(15):1503-16.	ISI: 900 Google Scholar: 1,342	50.017 (2008)

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SELECTED CASE STUDIES

- PROVE-IT (2004)
  - Medical therapies (statins)
- Mammography with MRI (2004)
  - Diagnostic screening procedures (MRI, ultrasound, mammography)
- SPORT (2006)
  - Diskectomy for low back pain
- COURAGE (2007)
  - Percutaneous coronary intervention (PCI)

DATA SOURCE

- Truven Health MarketScan Commercial Claims and Encounters (Commercial) and MarketScan Medicare Supplemental and Coordination of Benefits (Medicare Supplemental) Databases
  - January 1, 2003 to June 30, 2010
- Includes the enrollment, inpatient, outpatient, and outpatient pharmacy claims experience of tens of millions of individuals under age 65 across the nation with employer-sponsored insurance annually.
- Represents several million Medicare-eligible individuals with employer-sponsored Medicare Supplemental insurance annually

METHODS

- Calculated the quarterly utilization rates of each procedure (by calendar quarter)
- Replicated (as well as possible using claims data) the inclusion and exclusion criteria used in each clinical trial for patient selection
  - Nosologist
  - Clinician expert in clinical coding
  - Clinician reviewers
- Focus on patients highly similar to those included in the trial

RESULTS

- A consistent cohort of 66 data contributors (large firms and insurers) contributing data throughout the entire study period (2003 to Q2 2010)
  - Represented approximately 7 million enrollees each year

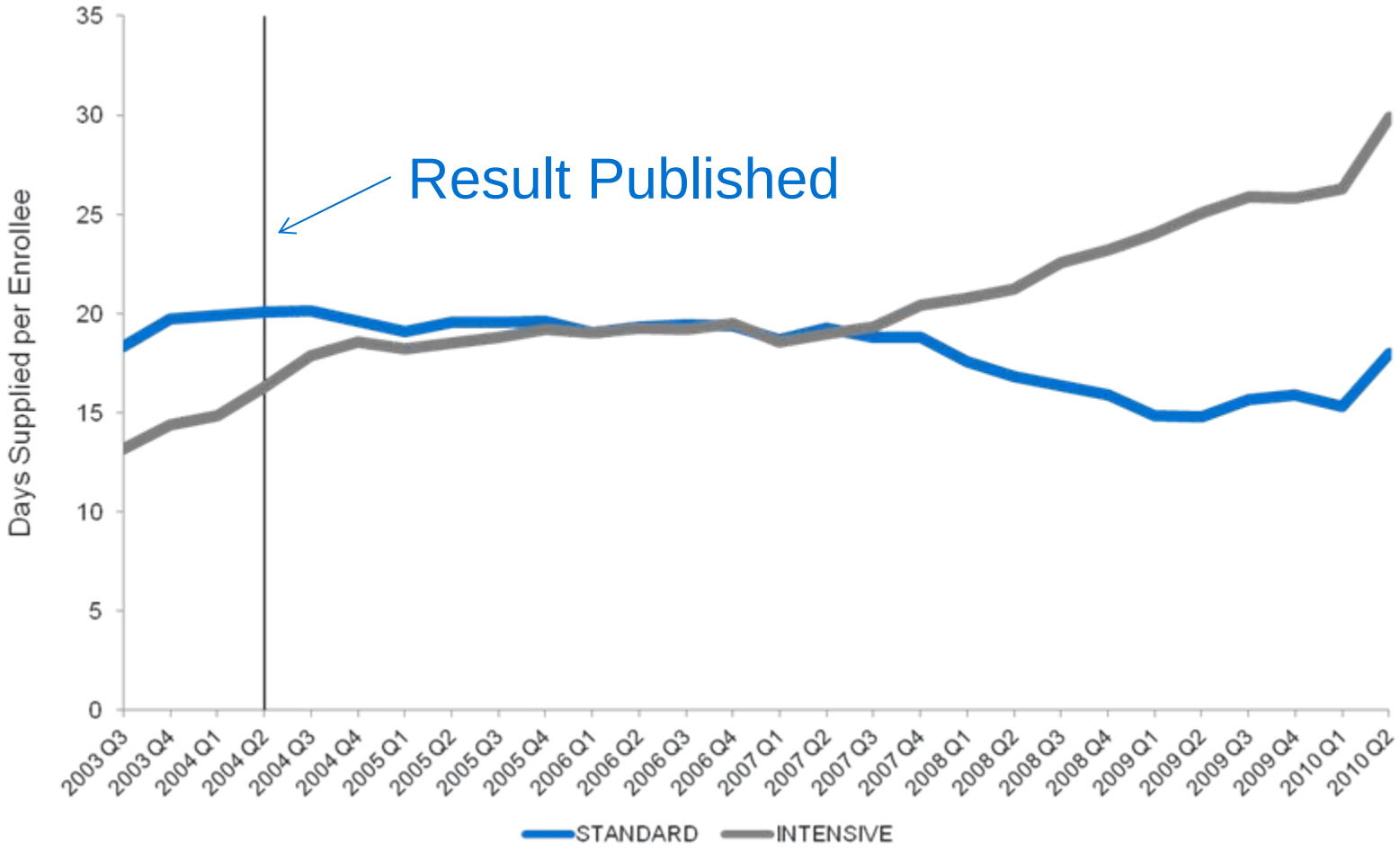
Age Group	Percentage
0-17 years	13.7%
18-34 years	22.7%
35-44 years	17.7%
45-54 years	20.2%
55-64 years	17.9%
65 and older	7.8%

Region	Percentage
Northeast	15.6%
North Central	23.3%
South	21.2%
West	39.3%
Unknown	.6%

PROVE-IT (NEJM 2004, n= 86,080)

- Patients who obtained intensive lipid lowering statin therapy had a lower risk of death or cardiovascular events than those on a standard statin regimen.
- Hypothesis: After the release of CER evidence from the PROVE-IT trial, prescription utilization rates would increase for patients on intensive statin therapy and decrease for patients with standard statin therapy.

RESULTS: PROVE-IT



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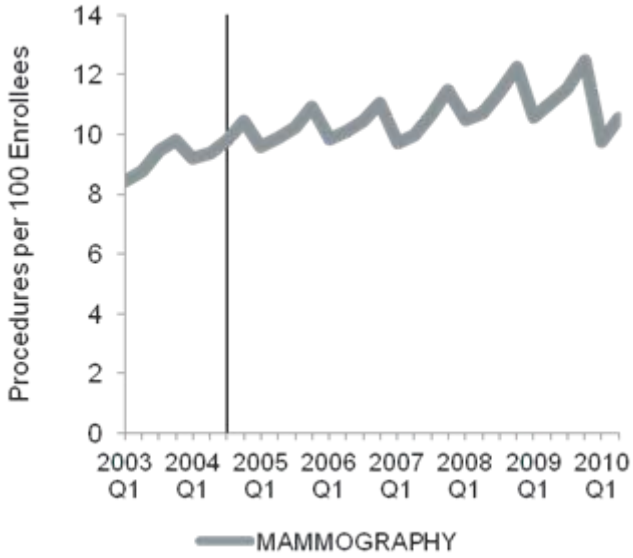
MRI (JAMA 2004, n=5,159,253)

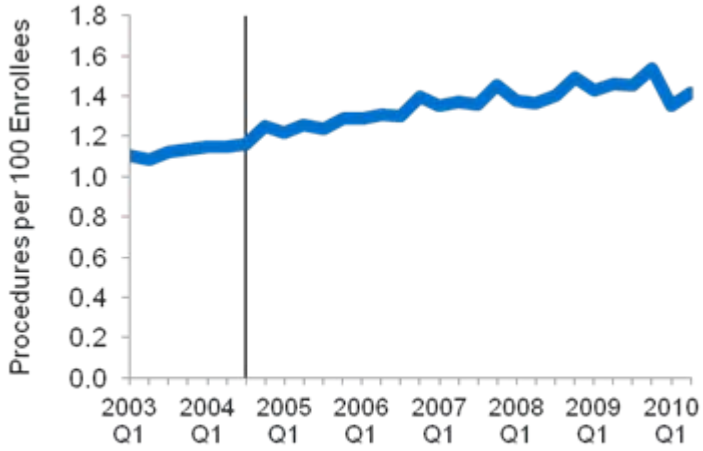
- The sensitivity of MRI to detect breast cancer was higher than all other procedures and 77% of all cancers detected were found by MRI compared to 36% by mammography, 33% by ultrasound and 9.1% by clinical breast exam.
- Hypothesis: Based on the results from this trial, we expected that MRI utilization rates among women would increase following publication of CER evidence.

RESULTS: UTILIZATION

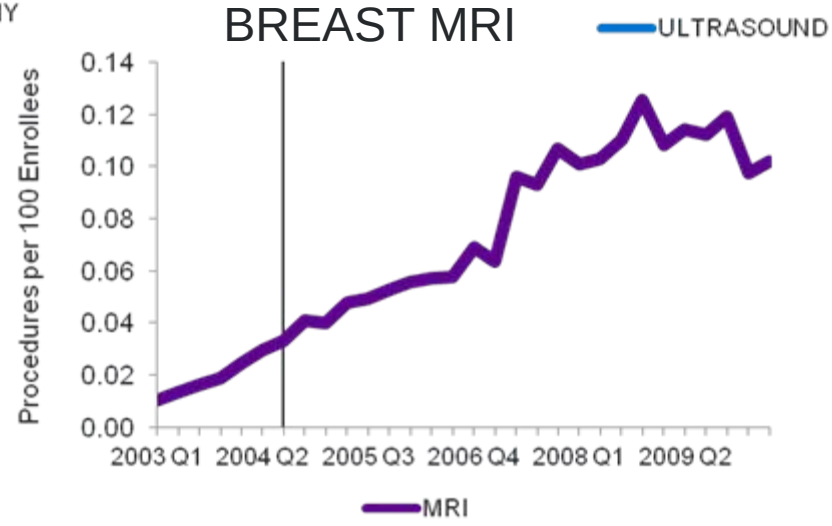
MAMMOGRAM



ULTRASOUND



BREAST MRI



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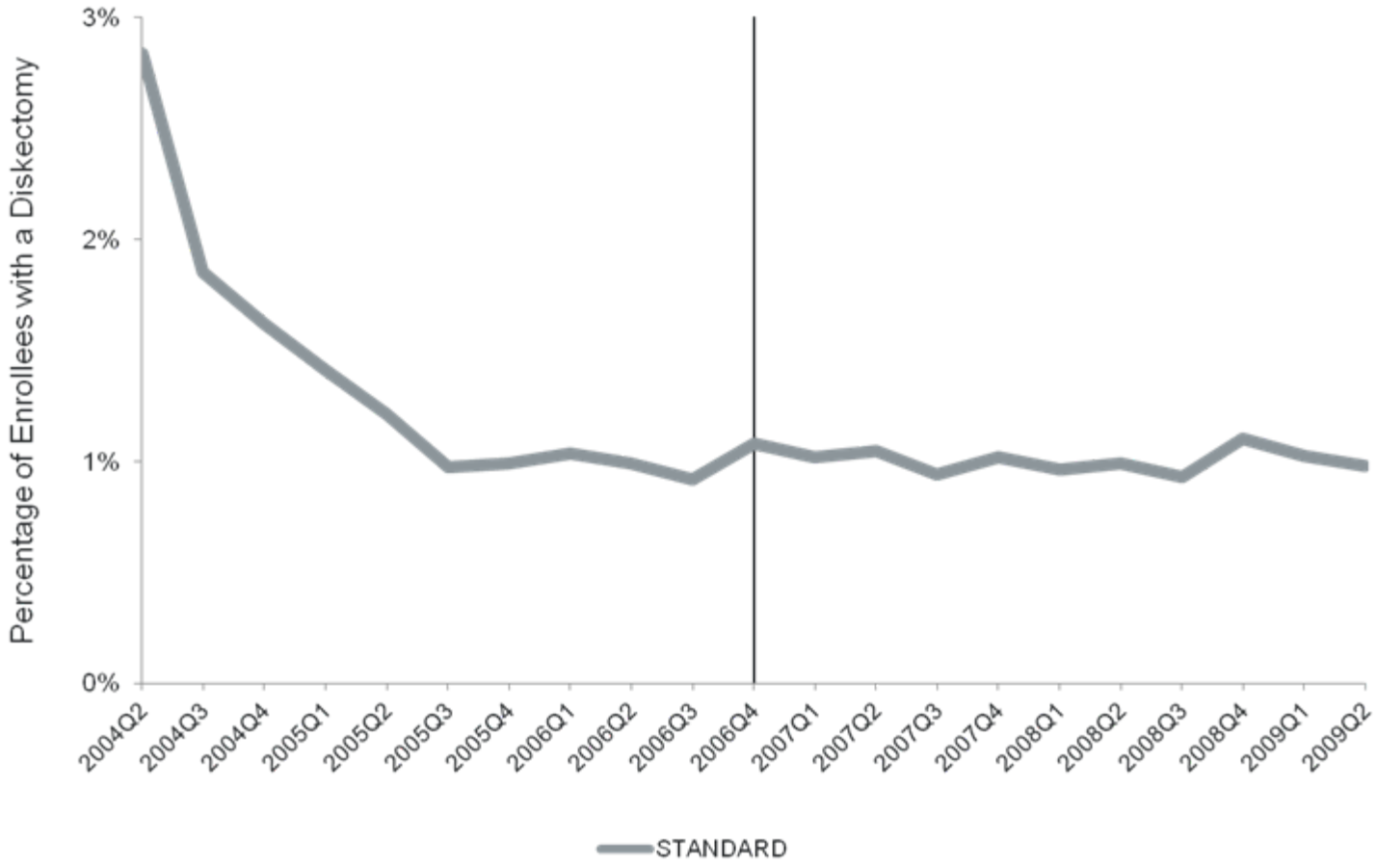
SPORT (JAMA 2006, n=298,780)

- The SPORT trial was designed to assess whether standard open diskectomy was more effective than usual care among patients with intervertebral disk herniation.
  - Intent-to-treat analysis did not find statistically significant differences in pain reduction or physical function, but found differences in measures of sciatica severity and self-reported improvement. However, nonadherence to the assigned treatment was high
  - Larger beneficial effects from surgery were seen for the as-treated analysis.
- Hypothesis: Based on the findings, we expected that standard open diskectomy utilization rates per capita would increase within our study cohort.

RESULTS: SPORT



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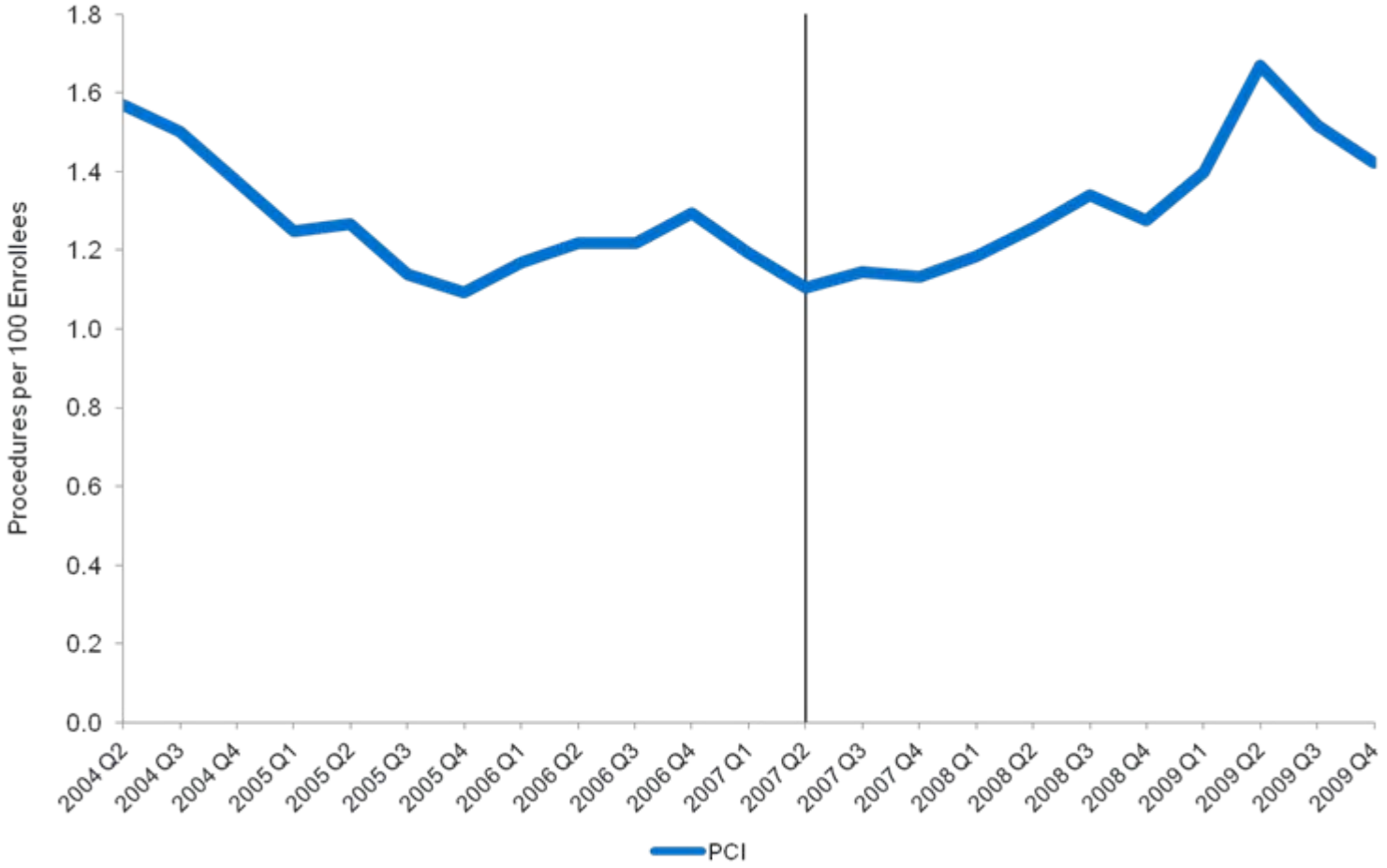
COURAGE (NEJM 2007, n=342,630)

- The COURAGE trial, implemented among patients with stable coronary artery disease, was designed to determine whether percutaneous coronary intervention (PCI) with optimal medical therapy (OMT) decreased the risk of death, nonfatal myocardial infarction (MI) or other major cardiovascular events compared to patients treated with OMT.
  - PCI with OMT did not reduce the risk of these study outcomes compared to OMT alone.
- Hypothesis: We expected that PCI utilization rates would not change or would decrease after the release of the CER evidence in the study cohorts.

RESULTS: COURAGE



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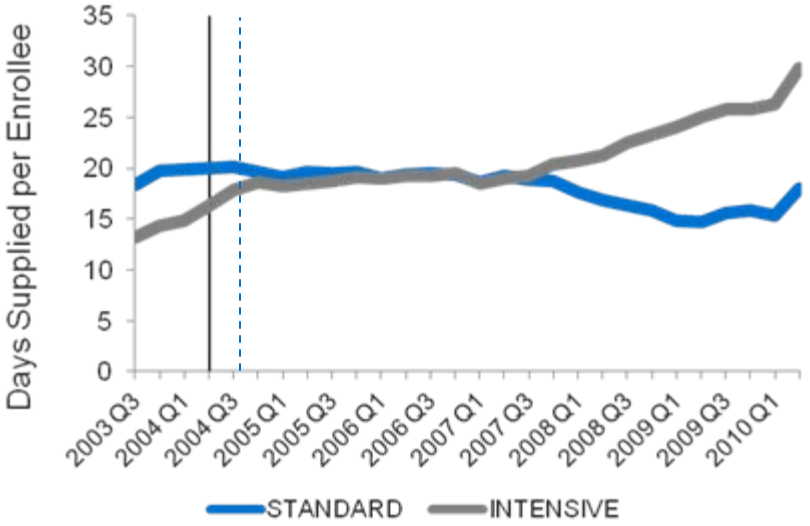
CONCLUSIONS

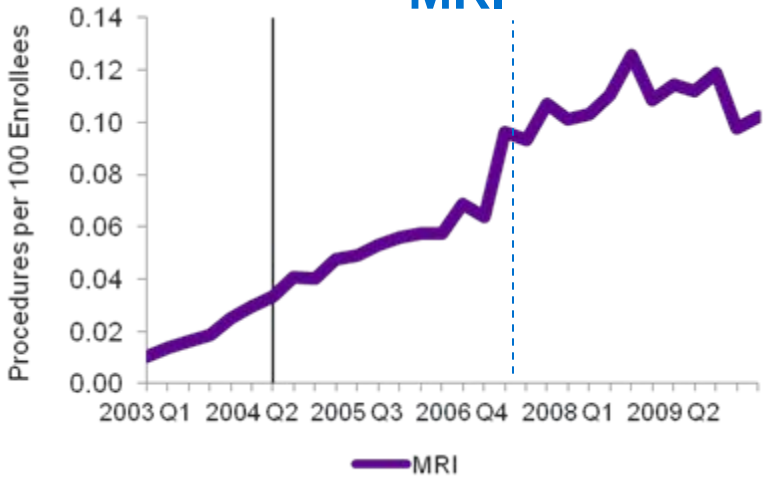
- Did not find an association between the release of evidence and a change in practice in the subsequent year
- PROVE-IT and Mammography with MRI – hypothesized changes began prior to the release of evidence
- COURAGE – We hypothesized PCI rates would decrease or not change, and they gradually increased
- SPORT – We hypothesized an increase, and diskectomy rates did not change

Role of Clinical Guidelines?

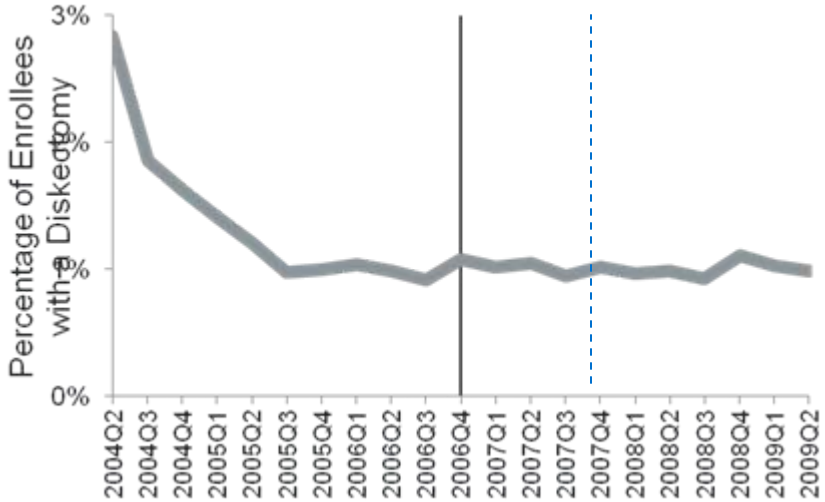
PROVE-IT



MRI



SPORT



| Result Published
¦ Guideline Published

Note: COURAGE Guideline published 2011

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DISCUSSION

- The greatest value of CER comes with development of evidence that is translated and implemented in practice
- Change is related to multiple factors: evidence, publication of clinical care guidelines, dissemination
- Publication of CER information is necessary but not sufficient to result in adoption
- One study may not be sufficient, multiple studies should be funded to inform/enact change

DISCUSSION

- Dissemination of new evidence may be cumulative, particularly when the evidence is conflicting with current practice (Haas)
- Change following study results is slow
  - Publication of results from studies also takes time
- Clarity and strength of research findings is critical
- Future research is needed to explore whether CER leads or lags change (or both)