RAPID
An Industry Perspective

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Open Science: What?

FRIED RICE

|	
Tom Moy Special	7.00
Pork	3.50
→ Chicken	3.70
Shrimp	5.00
BBQ Pork	6.75
Beef	6.75
→ Real Chicken	6.75
Meatless	3.70

Healthcare – Issues, challenges

- Increasing complexity of healthcare
  - New medical devices, technologies for improving health care, but with high levels of complexity and requiring changes
- Unjustified discrepancies in care patterns
  - The intensity of health-care services delivered for similar conditions varies significantly across geographic regions
- Importance of better value from health care
- Pressing need for evidence development
  - Comparative and longitudinal data is needed to determine the effectiveness and usefulness of new medical interventions, treatments, drugs, devices, and genetic information
- Promise of health information technology
  - Electronic medical record (EMR) & electronic health record (EHR) to improve the quality and efficiency of patient care, and reduce healthcare delivery costs
- New model of patient-provider partnership
  - More patient involvement needed
- Uncertainty exposed by the information environment
  - Information important to clinical decision making is often not available

High price of lack of medical evidence

- Priorities of healthcare system:
  - Identifying risk factors to reduce chronic diseases
  - Improving quality of health care
  - Reducing unnecessary spending
- High costs driven by a lack of info on the effectiveness of the different medical interventions
- Solutions:
    - o RCTs? – impractical
    - o Non-RCTs? – well-known limitations
    - o Systematic reviews? – some effects
  - Using data sets from EHRs, insurance claims, and other medical data – cost-effective and feasible but with some limitations
  - **Clinical Registries** – greater effects (patient-centered, evidence-based)

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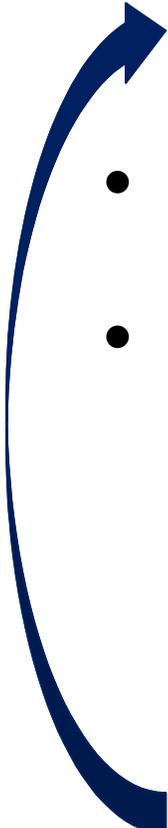
Other benefits of clinical registries

- Provide comprehensive performance information
- A platform for tracking new devices when they become used in routine clinical practice
- Support the need and rationale for future randomized trials (hypothesis, important questions, trial design)
- Could be a resource for future scientific discoveries (huge sample of well-characterized patients)
- Link with other administrative data sources (Medicare, private payers)

Registry example – Call to ACTION (Acute Coronary Treatment and Intervention Outcomes Network)

- Need for a national unified registry to track care and outcomes for patients with acute MI
- Launched in Jan 2007, led by AHA and ACC volunteers
- Dec 2008 – 344 US hospitals, 103,890 MI patients
- Important findings:
  - The reported comorbid illness and prior cardiac history proved characteristic of a high-risk cohort, particularly when compared to those patients enrolled in RCTs.
  - Innovative quality metrics

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Economic data as important as clinical data

- In most clinical trials, economic data are not collected
  - Efficacy
  - Safety
- With increasing health care costs – new data requirements
  - Effectiveness
    - An actual value of an innovation in daily practice
  - Cost-effectiveness
    - Effectiveness of the device/treatment and the savings relative to other devices/treatments

Health economic evaluation has become critical in health care decision-making

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Quality metrics

- Types of quality measures
  - Structure
  - Process
  - <u>Outcome</u> (mortality, morbidity, QoL)
  - Patient experience

THE PATH FROM RESEARCH TO FINALIZED QUALITY MEASURE

research

evidence base

clinical guidelines

standard of care

measure development

finalized quality measure

measure endorsement
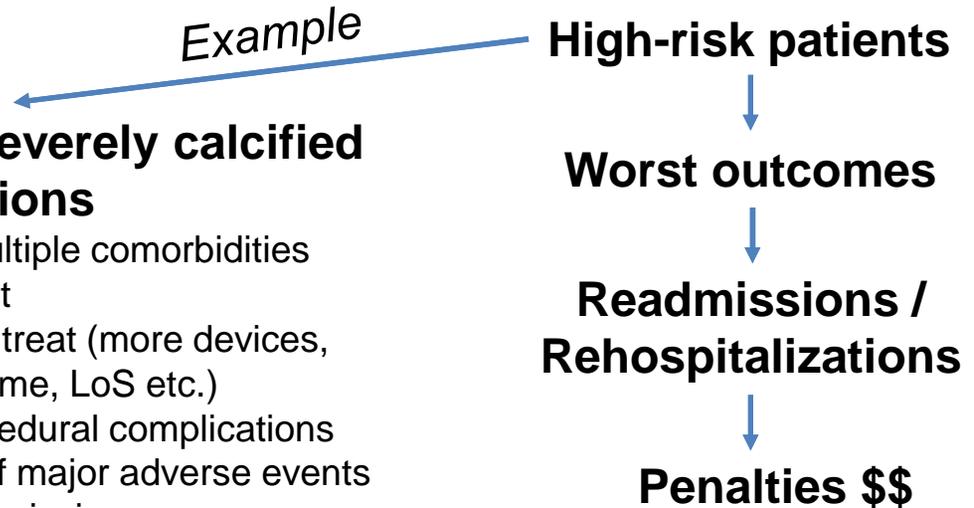
Example

High-risk patients

Patients with severely calcified lesions

- Sicker patients, multiple comorbidities
- Challenging to treat
- More expensive to treat (more devices, longer procedure time, LoS etc.)
- Higher rate of procedural complications
- Higher incidence of major adverse events
- Higher rate of readmission

Worst outcomes

Readmissions / Rehospitalizations

Penalties $$

Calcification is not a RAPID core data element

Shouldn't calcification be a risk-adjusted quality metric?

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Real-World Examples of How Industry May Benefit

Clinical and Economic Data Supports Procedures

Addresses FDA's focus areas

Safe, effective and patient-centric outcomes

Addresses CMS's focus areas

Reasonable and necessary

Patient Population Currently Treated Expands

Indications for Use for Technologies Expand

Practice Guidelines Updated to Reflect Real World Data

Cost of Healthcare Driven Down

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Thank you!