Transforming Medical Outcomes Through Comparative Effectiveness Research

Health Industry Forum
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Jack Lewin, MD, FACC
CEO
The American College of Cardiology
The Conflicts Around CER

• Trusting clinical objectivity of CER?
• Quality vs. cost effectiveness?
• Who can be trusted to do CER reliably?
• Using CER for coverage decisions?
• Who should pay for CER?
• Impact of PCORI
Who We Are…

The ACC is the world’s primary professional organization for cardiologists, their patients and their advocates

- Over 40,000 professional members
  - 26k FACC cardiologists
  - 5k international FACCs
  - 5k nurse, PA, PharmD clinicians
  - 4k Fellows in Training

- Journal of the American College of Cardiology (JACC) most widely published global CV journal
- Over 17 million registry patient records
- Over 100 million patient encounters per year
- Rapidly expanding our research capacities
A Possible Role of Real World Clinical Data and Registries in CER
NCDR Registries
A generation of quality care

PINNACLE Registry™
ACTION Registry®-GWTG™
CathPCI Registry®
IMPACT Registry™
CARE Registry®
ICD Registry™
That was then...

- Launched 1997
- 1 registry
- Focused on quality patient care

This is now...

- More than 2,500 hospitals and 800 practices
- Health plans and government regulator adoption
- Industry uses for market research, clinical research, and to support best practice treatments
- FDA uses NCDR data for post market assessment
- CMS requires NCDR data for coverage with evidence development (CED)

This is our future...

- One holistic registry with multi-specialty interoperability
- International expansion
- Platform for clinical trials and CER
- More post market assessment studies
- Implement physician reports to support MOC and MOL
- EHR Integration
National CV Data Registry

Number of sites and patient records

- Cath PCI 1380, 11 M
- ICD 1590, >600K
- CARE 170, >15K
- ACTION Registry-GWTG 656, >225K
- PINNACLE 800, >1.9M
- Impact Registry
- ICD Long
- Imaging Registry
- Afib Ablation module
- PAD module
- Structural Heart Disease Module

Helping Cardiovascular Professionals
<table>
<thead>
<tr>
<th>Name</th>
<th># of Participants</th>
<th># of Patient Records</th>
<th># of Manuscripts &amp; Abstracts</th>
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</thead>
<tbody>
<tr>
<td>CathPCI</td>
<td>1380</td>
<td>14 million</td>
<td>61/142</td>
</tr>
<tr>
<td>ICD</td>
<td>1590</td>
<td>600,000</td>
<td>16/26</td>
</tr>
<tr>
<td>ACTION-GWTG</td>
<td>656</td>
<td>225,000</td>
<td>22/41</td>
</tr>
<tr>
<td>CARE</td>
<td>170</td>
<td>15,000</td>
<td>3/9</td>
</tr>
<tr>
<td>IMPACT</td>
<td>16 pilot sites</td>
<td>2000</td>
<td>1/2</td>
</tr>
<tr>
<td>PINNACLE</td>
<td>800</td>
<td>2,100,000</td>
<td>7/21</td>
</tr>
</tbody>
</table>
Multispecialty Representation

- SCAI
- HRS
- STS
- Emergency Physicians
- Neurology
- Neurosurgery
- Pediatrics
- AHA
ACC Quality Approach
An end-to-end system that translates science into practice while reducing cost

PLAN

Guidelines/Standards
• Guidelines
• AUC / PM

DO

Implementation - “Bridge”
• Quality Practice Assessment
• Clinical Decision Support
• Operation Management Tools

STUDY

Measurement
• NCDR

ACT

Improvemen
• D2B
• H2H
• FOCUS

Education and Training

Helping Cardiovascular Professionals
Registries for Evidence Development and Dissemination

Adapted from Califf RM, Peterson ED et al. JACC 2002;40:1895-901
The NCDR® and CER

• **Stimulus for new evidence development**
  – High scientific rigor
  – Advantage of ethnicity, gender and age diversity
  – CER priorities require multi-stakeholder inputs

• **More cost effective approaches to CER development**
  – Quality of care vs. cost reduction?
  – RCTs as Gold Standard; but, new opportunities using real world clinical data for CER
  – Significant increase in speed evaluating increasing numbers of clinical questions
The D2B Quality Alliance: A Case Study in Success
National Data Repository for Comparative Effectiveness Research
CER and Registries

Opportunity for Coverage with Evidence Development (CED)

- Offers the "carrots" and "sticks" for registry participation
- Realizes opportunities to assess new technology or pharmacology applications in real world applications (non-RCT and off label uses)

Percutaneous Aortic Valves
Atrial Fibrillation Ablation
New CV Imaging Technologies
Influence of NCDR® Research

• Public Policy
• Quality Improvement: Guideline Adherence
  – Reducing door to balloon times
  – Clinical indications & outcomes
• Quality Improvement: Translational Research
• Post-Market Surveillance
  – Adverse events in closure devices
• New technologies and effectiveness
  – Diffusion of new technology
The PINNACLE Registry

- First office-based QI program in U.S.
- Data collection system
- Assessments and continuous feedback
- Clinical decision support tools
- Opportunity for recognition
- EHR interoperable module
- FIG system integrator
- Contribution to CER
Accelerating Improvement in Clinical Practice with CER

- Using registries and CDS to accelerate translation of CER and science into care
- Using registries and CDR to accelerate the collection of clinical data and data points needed for CER
- Incorporating shared decision making related to CER findings into clinical practice
- The contribution of CER to improve value
- Building trust by keeping CER development and cost/coverage decisions parallel but separated
Bumps on the Road Ahead

- An abundance of clinical uncertainties
- Limited resources for clinical research
- A growing crisis in health care cost increases
- Difficulties in consistent translation of science to the point of care
- Societal concerns about the purposes of CER
- Sorting out the critical needs for both quality and cost effectiveness
Opportunities
Principles of Value-Based Health Care Delivery

- The overarching goal in health care must be **value for patients**, not access, cost containment, convenience, or customer service.

  \[
  \text{Value} = \frac{\text{Health outcomes}}{\text{Costs of delivering the outcomes}}
  \]

- Outcomes are the **full set of health results for a patient’s condition** over the care cycle.
- Costs are the **total costs of care for a patient’s condition** over the care cycle.
The Outcome Measures Hierarchy

Tier 1
Health Status Achieved or Retained

Tier 2
Process of Recovery

Tier 3
Sustainability of Health

- Survival
- Degree of health/recovery
- Time to recovery and return to normal activities
- Disutility of the care or treatment process (e.g., diagnostic errors and ineffective care, treatment-related discomfort, complications, or adverse effects, treatment errors and their consequences in terms of additional treatment)
- Sustainability of health/recovery and nature of recurrences
- Long-term consequences of therapy (e.g., care-induced illnesses)

Source: NEJM Dec 2010
Moving from Cutting Care to Improving Care

- PCORI and professional society partnerships
- Transparency in both quality and cost effectiveness processes
- The path toward a sustainable, high-performing health care system for the US
- The critical need for CER and research funding
- The uses of registries and real world data in the future of CER