Transforming Medical Outcomes Through Comparative Effectiveness Research

Health Industry Forum
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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

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A Possible Role of Real World Clinical Data and Registries in CER

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NCDR Registries

A generation of quality care

PINNACLE Registry™

ACTION Registry®-GWTG™

CathPCI Registry®

IMPACT Registry™

CARE Registry®

ICD Registry™

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NCDR®
National Cardiovascular Data 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

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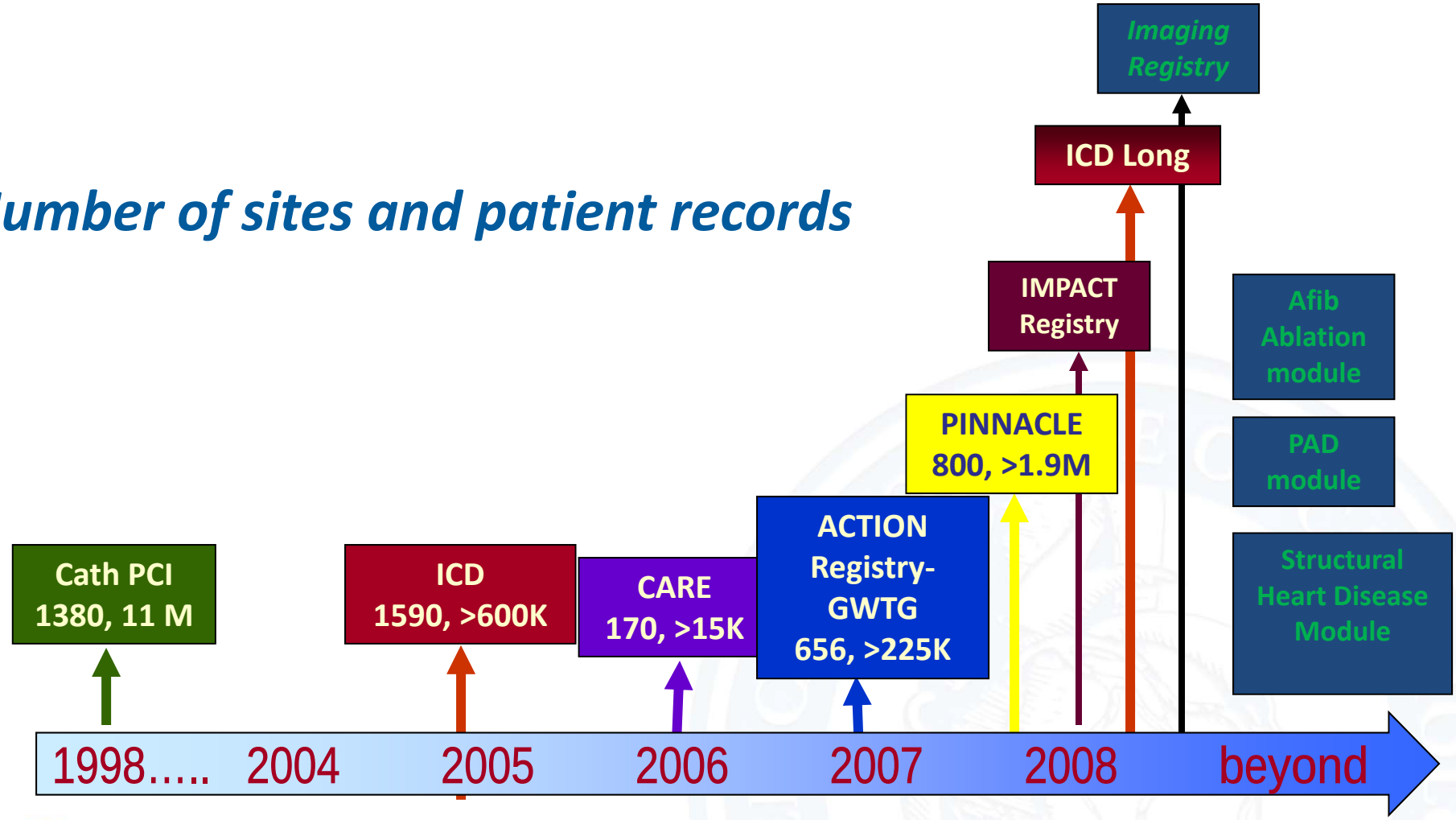
National CV Data Registry

Number of sites and patient records



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Participants, Patient Records, Manuscripts & Abstracts

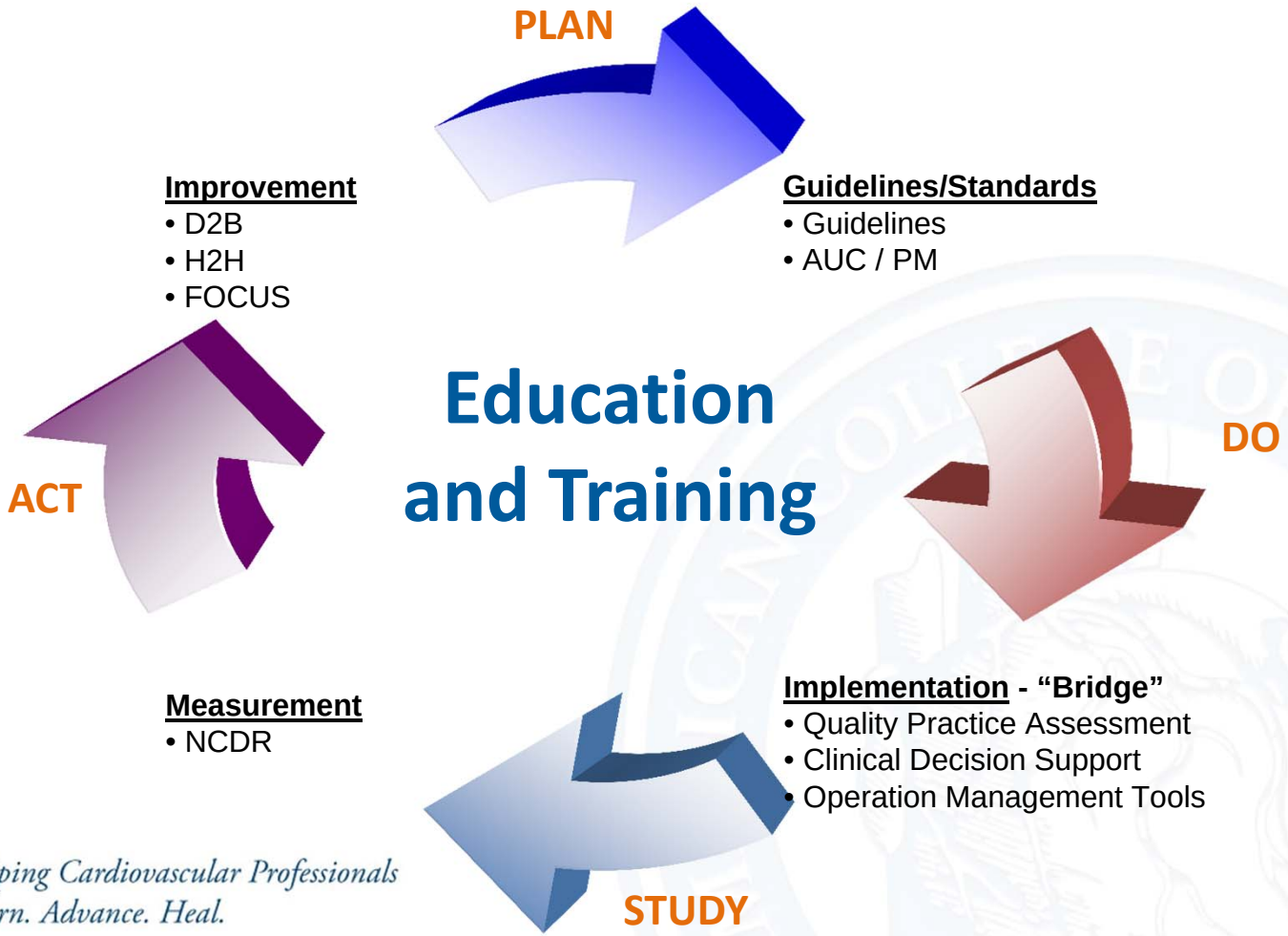
Name	# of Participants	# of Patient Records	# of Manuscripts & Abstracts
CathPCI	1380	14 million	61/142
ICD	1590	600,000	16/26
ACTION-GWTG	656	225,000	22/41
CARE	170	15,000	3/9
IMPACT	16 pilot sites	2000	1/2
PINNACLE	800	2,100,000	7/21

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



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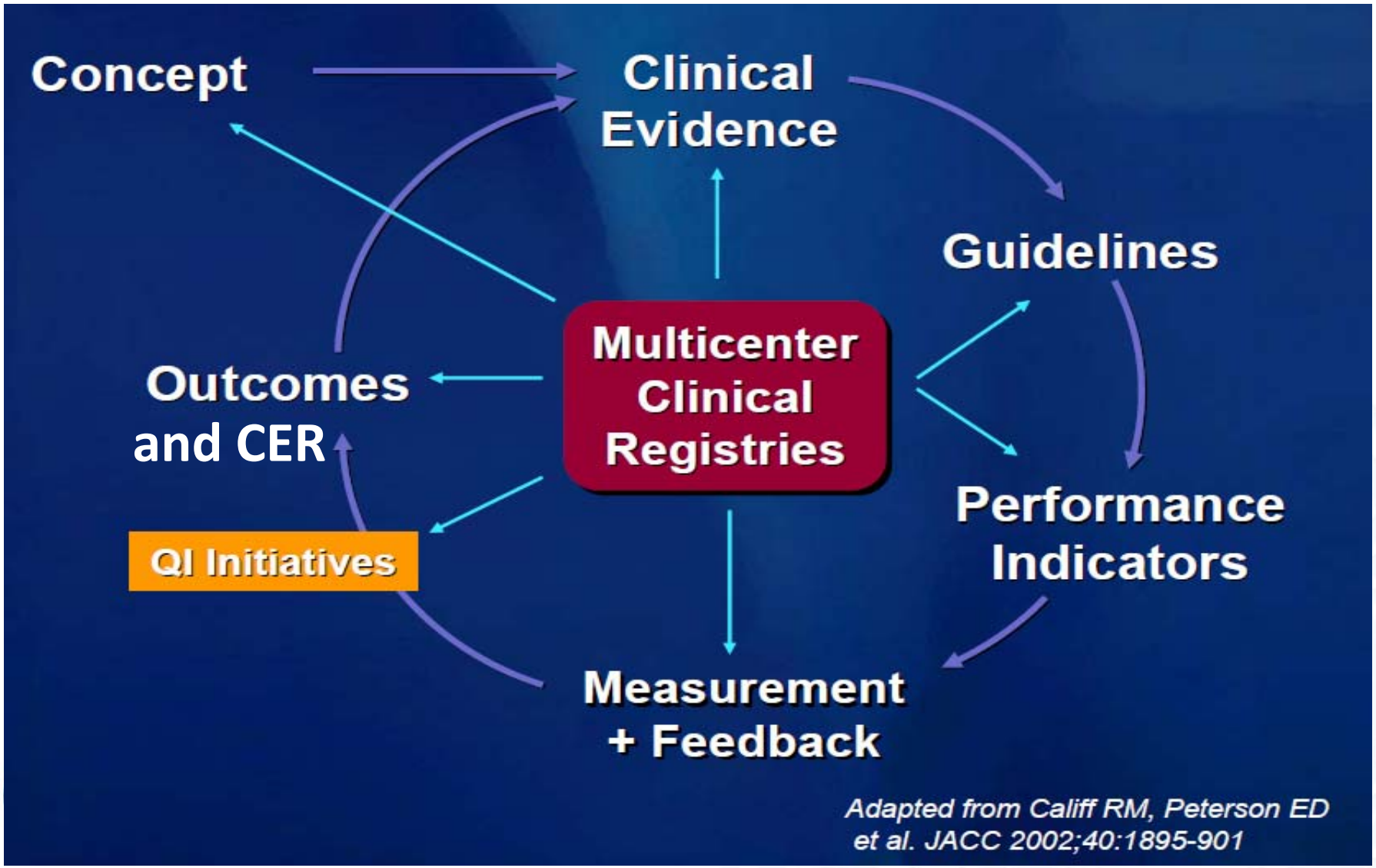
Registries for Evidence Development and Dissemination

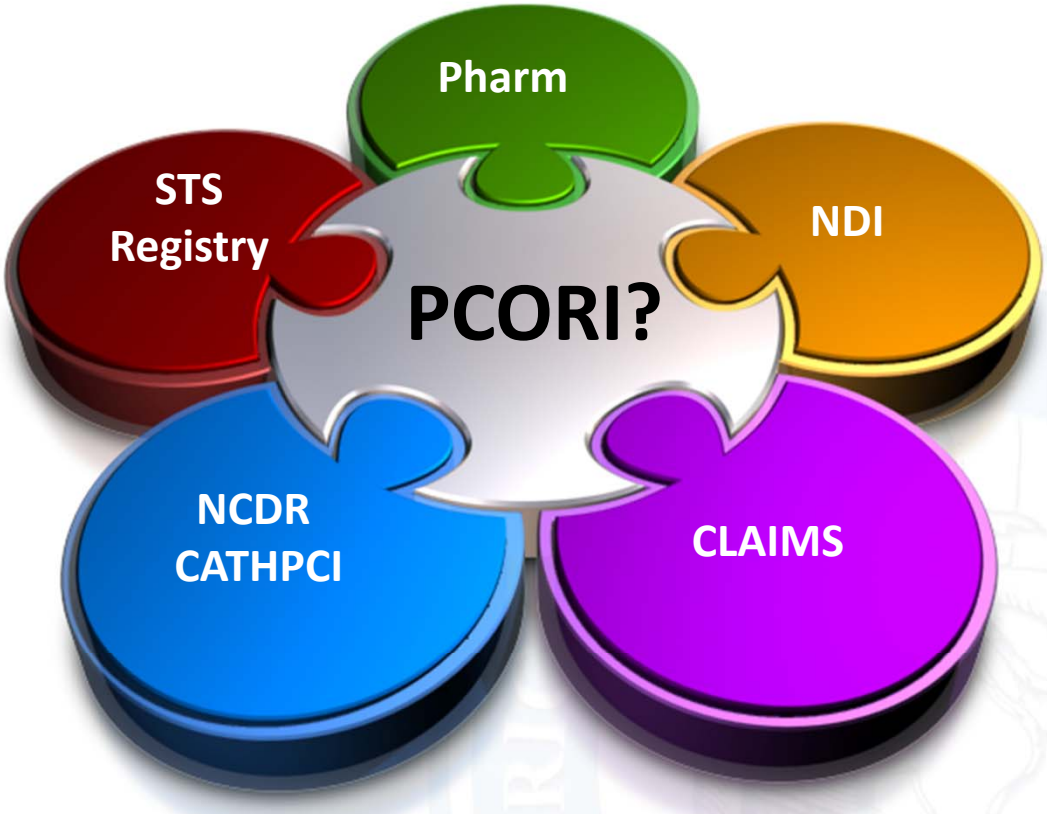


The NCDR® and CER

- **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



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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

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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

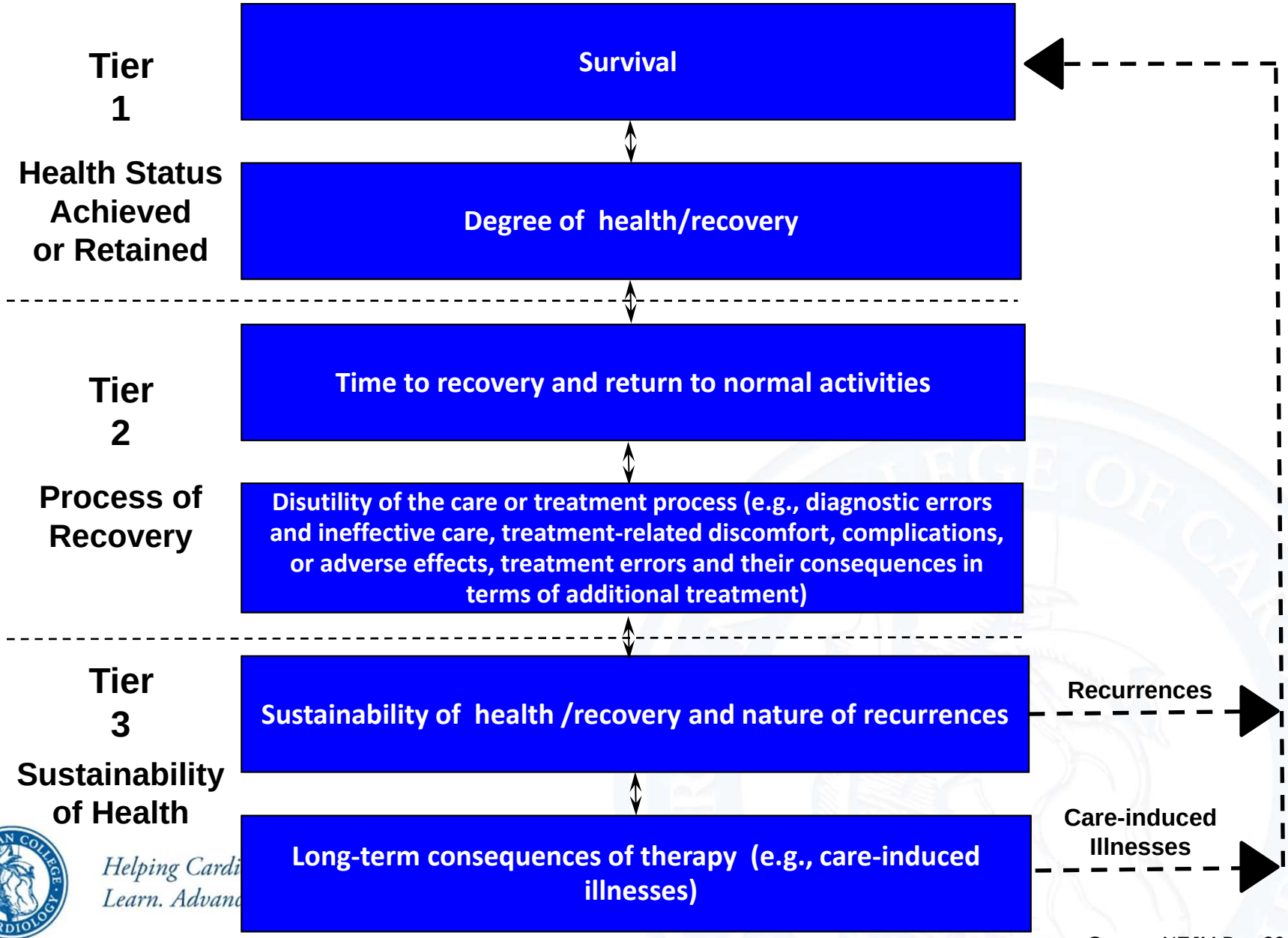
Principles of Value-Based Health Care Delivery

- 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



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

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