Rapid-Learning Healthcare Systems

\textit{in silico} Research and “Best Practice” Adoption in Promoting Rapid Learning

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Rapid-Learning Healthcare Systems

- Produce optimal health and economic value for individuals, health systems, communities and populations

- Utilize 21st century technology infrastructure to close gaps in evidence base; variation as the problem, variation as a diagnostic tool in solution identification

  *In silico* research - utilize EHR’s, registries, claims databases to answering questions that are meaningful to clinicians and their patients/caregivers

- Ensure impact: dissemination, diffusion, uptake and incorporation into decision making
From evidence generation to clinical benefit

- 30% science: finding the “right things to do” (evidence generation)
  closing the “knowledge gap”

- 70% “sociology”: making the right information easy to access (dissemination/diffusion)
  closing the “knowing gap”

  making the right thing easy to do (implementation/uptake)

  closing the “knowing-doing gap”
From Rapid-Learning Systems to System

- Rapid-learning care systems with a research mission exist today – the “bright spots” (Kaiser Permanente, Geisinger, VHA, Mayo HMO Research Network etc); clinical and health services research, QI, rapid cycle improvement
- Large Health Plan claims databases; Medicare/Medicaid claims data; EHR’s; registries
- Future state: from “systems” to “system”; standardization of data vocabulary and data entry elements to allow comparability across databases;
- Advances in dissemination and implementation science to speed access to (and uptake of) best evidence at the point of care/point of decision-making
Public Investment in Evidence Generation and Use

- 2003 MMA - $75 million (authorized) for AHRQ Effective Healthcare Program → 1st major national investment in comparative effectiveness research (CER)

- ARRA funds - $1.1 billion for training, network development, CER infrastructure

- ONC *Meaningful Use* incentives/payments

- Center for Medicare and Medicaid Innovation pilots

- FDA Sentinel and Mini-Sentinel

- PCORI (Patient-Centered Outcomes Research Institute)
About PCORI

• Independent, non-profit institute created by Congress in 2010 in the ACA.

• Mission: to fund research that will provide patients, their caregivers and clinicians with the evidence-based information needed to make better-informed health care decisions.

• Commitment to continually seek input from patients and a broad range of stakeholders to guide its work.

• Board of Governors representing entire healthcare stakeholder community
PCORI’s Core Duties established in statute

Establish **research priorities**

Establish and carry out a **research agenda**

Develop and update **methodological standards**

**Disseminate** research findings

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**PCORI’s Path from Priorities to Research Patients Can Use**
CER vs PCOR: Patient-Centered Outcomes Research Defined

Patient-Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

“Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”

“What are my options and what are the potential benefits and harms of those options?”

“What can I do to improve the outcomes that are most important to me?”

“How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?”
Establishing PCORI’s First National Priorities for Research and Initial Research Agenda

- 9 criteria outlined by law
- 5 draft priorities proposed
- Corresponding agenda drafted
- Public input received and evaluated
- Priorities and agenda revised and approved
- First primary funding announcements issued

Timeline:
- Aug-Dec 2011
- Jan-May 2012
- May 2012
Criteria for Research Outlined by Law

- Impact on Health of Individuals and Populations
- Improvability through Research
- Inclusiveness of Different Populations
- Addresses Current Gaps in Knowledge/Variation in Care
- Impact on Health Care System Performance
- Potential to Influence Decision-Making
- Patient-Centeredness
- Rigorous Research Methods
- Efficient Use of Research Resources
National Priorities for Research

- Assessment of Prevention, Diagnosis, and Treatment Options
- Improving Healthcare Systems
- Communications and Dissemination Research
- Addressing Disparities
- Accelerating PCOR and Methodological Research
Outline of Research Agenda

- **Assessment, Prevention, Diagnosis, and Treatment Options**
  - Comparisons of alternative clinical options to support personalized decision-making and self-care
  - Identifying patient differences in response to therapy
  - Studies of patient preferences for various outcomes

- **Improving Healthcare Systems**
  - Comparing alternative strategies for workforce deployment
  - Improving support of patient self-management
  - Focusing on coordination of care for people with complex conditions

- **Communication & Dissemination Research**
  - Understanding and enhancing shared decision-making
  - Alternative strategies for dissemination/implementation of evidence, measuring impact and incorporation into practice
  - Exploring opportunities to improve patient health literacy

- **Addressing Disparities**
  - Understanding differences in effectiveness across groups
  - Understanding differences in preferences across groups
  - Reducing disparities through use of findings from PCOR

- **Accelerating PCOR and Methodological Research**
  - Improving study designs and analytic methods of PCOR
  - Building and improving clinical data networks
  - Methods for training researchers, patients to participate in

- Establishing methodology for the study of rare diseases
Assessment of Prevention, Diagnosis, and Treatment Options

- Comparisons of alternative clinical options to support personalized decision-making and self-care
- Identifying patient differences in response to therapy
- Studies of patient preferences for various outcomes

Improving Healthcare Systems

- Improving support of patient self-management
- Focusing on coordination of care for complex conditions and improving access to care
- Comparing alternative strategies for workforce deployment

Communication & Dissemination Research

- Understanding and enhancing shared decision-making
- Alternative strategies for dissemination of evidence, measuring impact, uptake and incorporation into practice
- Exploring opportunities to improve patient health literacy

Addressing Disparities

- Understanding differences in effectiveness across groups
- Understanding differences in preferences across groups
- Reducing disparities through use of findings from PCOR

Accelerating PCOR and Methodological Research
Unique Aspects of PCORI Funded Research:

• **Required elements in all PCORI applications:**
  - Patient & Stakeholder Engagement Plan from design of the research question through dissemination
  - *Dissemination and Implementation Assessment*
  - Reproducible and Transparent Research Plan
  - Meets PCORI Criteria Outlined by Statute
  - References Methodology Standards
  - User-friendly announcements to encourage broader range of applicants: interest in supporting development of network of partnerships between traditional and non-traditional investigators, community-based participatory research proposals
From the PCORI Funding Announcement Guidelines

• 2.4 Research Plan: Section 4. Dissemination and Implementation Assessment (2 pages)

• PCORI is interested in funding studies with a high likelihood that results will be disseminated and incorporated into practice, if study findings warrant. To that end, it is important that key stakeholders are engaged early and throughout the research process, and that potential facilitators and barriers to dissemination and incorporation into practice are assessed and anticipated. The dissemination assessment should include:
Dissemination Assessment Should Include:

• Identify **key stakeholders** for whom the results of the research will be relevant (who)

• Describe **at what points** in the research process key stakeholders will be engaged – from early planning through and including results communication (when)

• Describe how you will engage stakeholders at each point, including sharing and discussing study results (how)

• How will you develop a **governance plan** for the project: roles and responsibilities of researchers and stakeholders, rules for decision making, conflict resolution

• How will you **allocate and share resources** with stakeholders

• Asses potential **facilitators and barriers to dissemination and implementation** of study results, & incorporation into practice
And, for more information on PCORI, research priorities and agenda, report of the PCORI Methodology Committee, and funding announcements

www.pcori.org
Kaiser Permanente: 50 year investment in data capture

- Integrated (financing and delivery) group-model healthcare delivery system
- 8.7 million enrollees in 8 states and the District of Columbia; 6.6 million enrollees in California, average tenure of 14 years enrollment – large, diverse, stable population
- Detailed, complete clinical and administrative databases; no “carveouts”; >97% capture of prescription drug info (70 million prescriptions in 2011) for 25 years
- Unique identifier (MRN) across time, databases
- Enrollee data geocoded to US census block data
- Self-reported race/ethnicity data on almost 90% of membership
KP Databases

- Fully deployed EMR (KPHealthConnect, EPIC platform) in 2009 for ambulatory care, inpatient in process in 36 KP-owned and operated hospitals

- Complete outpatient capture of dx, tx, procedures, lab, x-ray and clinical measures (BP, BMI, smoking status etc) for >15 years, pre-EMR

- Hospital discharge data: complete capture of hospital discharge data in 36 KP-owned and operated hospitals (90%), and claims data from non-KP hospitals (10%)

- Growing importance, and role, of registries in answering clinically important questions, and the need for methodologic advances in observational *in silico* research to fully exploit the value of registries and database research
Registries in QI and *in silico* Research

- “..organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by ..disease, condition or exposure, and that serves one or more predetermined scientific, clinical or policy purposes.” (AHRQ:2007, Rpt #07-EHC001-1)

- Foundation for research, comparative effectiveness research, as well as quality improvement - with direct feedback, at a provider level, into care delivery system

- TJRR (Total Joint Replacement Registry) est 2001; largest in the US: 95% capture of hips/knees of 400 participating KP orthopedic surgeons (95,331 knee replacements, 53,015 hips); voluntary participation

- Identify and track device utilization; patient and device outcomes; develop risk calculators for poor outcomes; manage recalls/advisories; adverse event surveillance
Registries in QI and *in silico* Research

- ACL reconstruction 2005; total shoulder 2006; hip fx and spine 2009; cardiac ICD and pacemakers 2000; bariatric surgery 2006

- Patient safety: identification of early failures; recalls/advisories; risk factors associated with outcomes of interest; patient-specific risk calculator; infection and adverse event surveillance; patient reported outcomes

- Quality improvement: hospital and surgeon-specific outcomes profiles; rapid feedback to surgeon community re needed changes in practice

- Evidence base for development of device formulary, based on performance of devices over time
Examples of non-surgical registries

- **Population/ Registries Size**
- HTN 575,000
- Diabetes Management 221,000
- Preventing Heart Attacks and Strokes Everyday (PHASE) 205,000
- Multi-fit (cardiac rehab) 10,000
- Asthma (adult and pedi) 162,000 Osteoporosis –
- Osteoporosis – screening 240,000; post fx 1500
- Hepatoma ~30,000
- Heart Failure 41,000
- Tobacco Cessation ~340,000
- Breast Cancer Screening ~530,000
- Breast Cancer Survivors – Adherence to AET ~6,500
- Colorectal Cancer Screening ~837,000
Learnings from > a decade of registry experience

• Clinician commitment to complete and accurate data capture contingent on:
  
  > organized with clinician input to make data entry as easy as possible, eliminate need for “double entry”
  
  > organized to answer real-world concerns of patients and clinicians, and answer clinically important questions
  
  > direct feedback loop into clinical practice, quality improvement
  
  > clinician and site-specific feedback/profiles used for QI purposes: “P4P” = pride for performance; culture of mutual accountability for the quality, safety and effectiveness of care
Key Messages

• Growing bipartisan and multistakeholder consensus on the need for a transformed, accountable learning healthcare system, which can rapidly improve the quality, consistency and value of care delivered, everywhere

• Substantial public and private investments in data infrastructure, data capture and research infrastructure – and methodologic research – essential to closing “knowledge gap”

• Advances in dissemination and implementation science essential to closing the “knowing gap”, and the “knowing doing gap” – and to move from “learning systems” to a “learning system”
Questions?