Secondary Uses of Data for Comparative Effectiveness Research

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Disclosure/Perspectives

- Training: Internist/Hematologist/Cancer Research
- Practice: Hematology and Medical Oncology; Population Medicine; EBM/CER/PCOR

Kaiser Permanente (past)

- Heme/Onc Practice
- EBM (Guidelines & Population Management)
- HIT (EMR, Pop’n Mgmt, Oncology Systems)

Lewin/Optum (current)

- Center for CER
  - Inventory of CER and PCOR (ASPE/HHS; AHRQ & NIH)
  - Multi-Payer Claims Database (HHS/ASPE)
  - Autism Registry (NIMH)
  - Geographic Variation (IOM)

Observations on the data and information infrastructure for cancer…

- This is a very complex area…
  - There is increasing certainty that there are workable and even elegant technical solutions
  - There is minimal agreement about how to scale solutions to a national level and/or sustain them over time

- Hypothesis: The current evolving national effort around comparative effectiveness research is a rich laboratory for exploring and refining effective and durable scaling and sustainability of the informatics support for cancer care and learning

Overview

- Comparative Effectiveness Research (CER) and *Patient Centered Outcomes Research* (PCOR)
- Secondary use of data
  - Examples
- Sustainability
  - Key issues
  - Conceptual framework

CER

Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings…

Federal Coordinating Council for
Comparative Effectiveness Research 2009

Medicare Modernization Act 2003; Section 1013 ($15-30M)
"Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings"

AHRQ Effective Health Care Program 2003-Present


U.S. Department of Health & Human Services

AHRQ Agency for Healthcare Research and Quality

Effective Health Care Program
Helping You Make Better Treatment Choices

What Is the Effective Health Care Program

ARRA 2009 ($1.1B)


INITIAL NATIONAL PRIORITIES FOR
COMPARATIVE EFFECTIVENESS RESEARCH

FEDERAL COORDINATING COUNCIL FOR
COMPARATIVE EFFECTIVENESS RESEARCH

REPORT TO
THE PRESIDENT
AND
THE CONGRESS

JUNE 30, 2009

ACA 2010


Subtitle D—Patient-Centered Outcomes Research

SEC. 6301. PATIENT-CENTERED OUTCOMES RESEARCH.

(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

"PART D—COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

"COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

"SEC. 1181. (a) DEFINITIONS.—In this section: 42 USC 1320e.

"(1) BOARD.—The term 'Board' means the Board of Governors established under subsection (f).

"(2) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH; RESEARCH.—

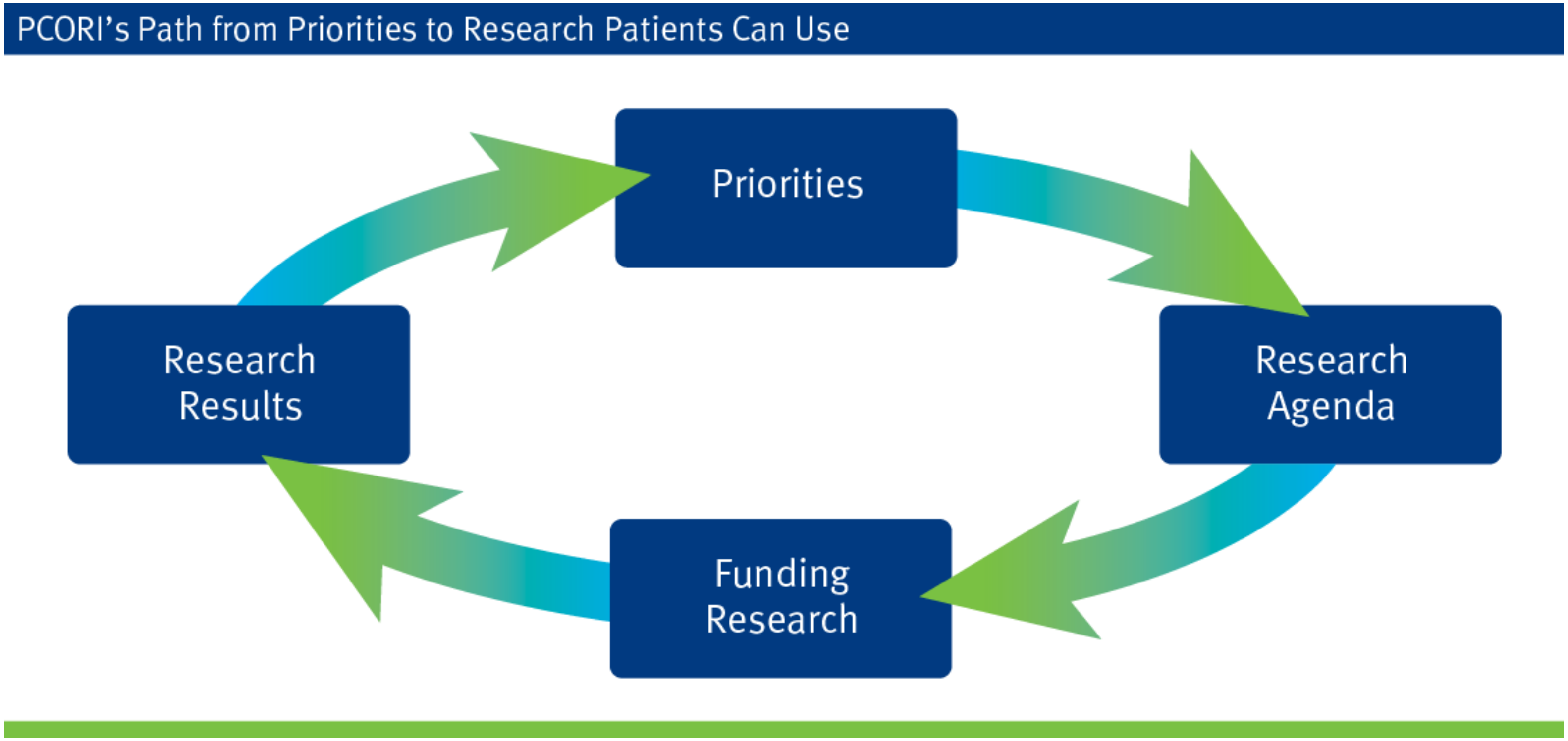
"(A) IN GENERAL.—The terms 'comparative clinical effectiveness research' and 'research' mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

"(B) MEDICAL TREATMENTS, SERVICES, AND ITEMS DESCRIBED.—The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

"(3) CONFLICT OF INTEREST.—The term 'conflict of interest' means an association, including a financial or personal association, that have the potential to bias or have the appearance

pcori

The **Patient-Centered Outcomes Research Institute (PCORI)** is an independent, non-profit health research organization. Its mission is to fund research that offers patients and caregivers the information they need to make important healthcare decisions.



PCORI's Path from Priorities to Research Patients Can Use

Priorities

Research Agenda

Funding Research

Research Results

Patient Centered Outcomes Research (PCOR) helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options.

This research answers patient-focused questions:

- "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?"
- "What are my options and what are the benefits and harms of those options?"
- "What can I do to improve the outcomes that are most important to me?"
- "How can the health care system improve my chances of achieving the outcomes I prefer?"

PCORI Draft Research Agenda

Priority	% Funding Allocation
Comparative Assessment of Options for Prevention, Diagnosis, and Treatment	‣ Approximately 40%
Improving Healthcare Systems	‣ Approximately 20%
Communication and Dissemination Research	‣ Approximately 10%
Addressing Disparities	‣ Approximately 10%
Accelerating PCOR and Methodological Research	‣ Approximately 20%

The Evolving Evidence Perspective…

Study Type	Methods	Data Source/Organization	Perspective
Expert Opinion	• Case Reports • Case Series	• Charts • Experience	Effect on Patients (N of 1)

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Study Type	Methods	Data Source/Organization	Perspective
Expert Opinion	- Case Reports - Case Series	- Charts - Experience	Effect on Patients (N of 1)
Evidence Based Medicine	- RCTs - Systematic Reviews - (Observation)	- **Trial Data & Databases** - **Meta-analysis** - Reports & Series	Population Efficacy (N of Many)

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Comparative Effectiveness Research	• RCTs • Systematic Reviews • Observation	• Trial Data & Databases • Meta-analysis • ***Large Pop'n Databases*** • Reports & Series	Population Effectiveness (N of Many)

The Evolving Evidence Perspective…

Study Type	Methods	Data Source/Organization	Perspective
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Comparative Effectiveness Research	• RCTs • Systematic Reviews • Observation	• Trial Data & Databases • Meta-analysis • ***Large Pop'n Databases*** • Reports & Series	Population Effectiveness (N of Many)
Patient Centered Outcomes Research	• RCTs • Systematic Reviews • ***Systematic Observation***	• Trial Data & Databases • Meta-analysis • Large Pop'n Databases • Reports & Series • ***Patient Generated Data***	Patient Effectiveness Many (N of 1)s

“Secondary Use” of Data

- “Reactive” Secondary Use
  - Insurance Claims
    - Single payer
    - Multiple payer
  - Clinical
    - Lab, radiology, pathology, …
    - EMR, Population Management…
- “Planned” Secondary Use
  - Structured data creation and capture
  - Expanded common data sets outside clinical trials
  - Common intervention protocols
- Patient related and ‘generated’ data
  - Expanded demographics (race, ethnicity, language, SES, …)
  - Functional status
  - Personal and family preferences and values
  - Genomics, etc…

“Reactive” Secondary Use: Optum Natural History of Disease (NHD) Model

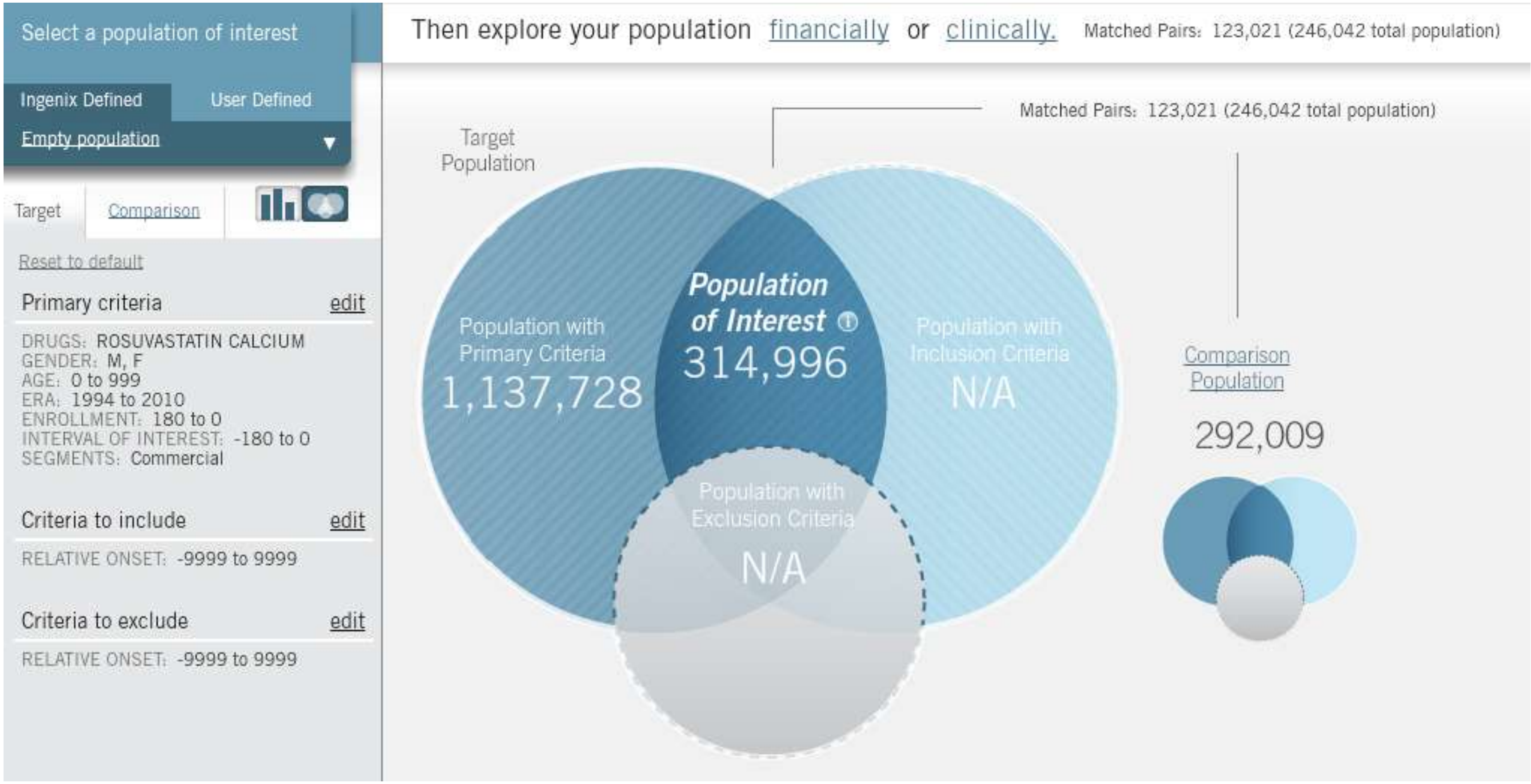
Challenge: Using claims…

- Define a disease protocol
- Find people who match the protocol
- Gather all their medical history
- Find control cohorts for each individual
- Find *their* history
- Compare clinical and financial attributes between the two groups in every conceivable way
- Do this in a minute or two…

“Big Data” and NHD

- Massively parallel database (Netezza)
- Optimized Data Storage structures
- User Interface for mix and match attributes
  - Medical Codes
  - Temporal requirements
  - Member demographics
- SQL based Real Time cohort matching
- Signal Visualizations

Matched sets



Then explore your population financially or clinically. Matched Pairs: 123,021 (246,042 total population)

Primary criteria edit

DRUGS: ROSUVASTATIN CALCIUM
GENDER: M, F
AGE: 0 to 999
ERA: 1994 to 2010
ENROLLMENT: 180 to 0
INTERVAL OF INTEREST: -180 to 0
SEGMENTS: Commercial

Criteria to include edit

RELATIVE ONSET: -9999 to 9999

Criteria to exclude edit

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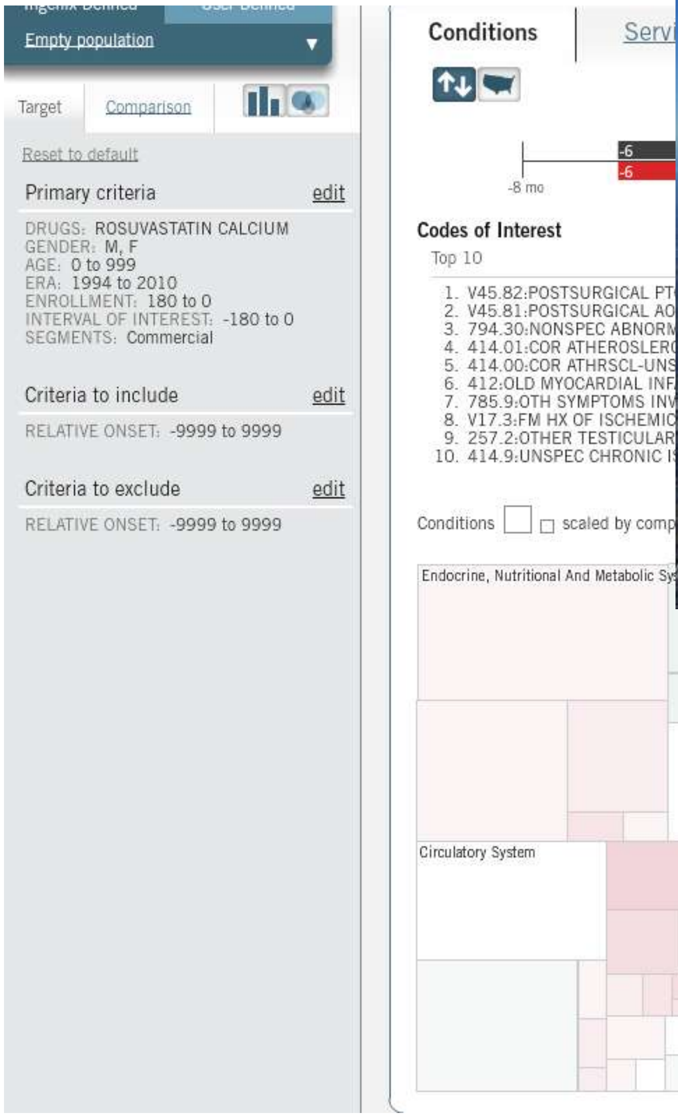
Matched Pairs: 123,021 (246,042 total population)

Pre exposure Dx comp



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Codes of Interest

Top 10

1. V45.82:POSTSURGICAL PT
2. V45.81:POSTSURGICAL AO
3. 794.30:NONSPEC ABNORM
4. 414.01:COR ATHEROSLERO
5. 414.00:COR ATHRSCL-UNS
6. 412:OLD MYOCARDIAL INF
7. 785.9:OTH SYMPTOMS INV
8. V17.3:FM HX OF ISCHEMIC
9. 257.2:OTHER TESTICULAR
10. 414.9:UNSPEC CHRONIC I

“Planned” Secondary Use: Optum Claims Linked Registries (CLRs)

A Registry for Healthcare Operations

- Initial Focus on Breast and Lung Cancer
- The registry is being created for healthcare operations purposes.
- All services provided by Optum in creation of the registry are conducted on behalf of the holder of the data.
- The holder of the data has sole discretion over the design of the registry, use of any PHI and whether to de-identify the data for healthcare operations and/or research purposes.

Linked Longitudinal Data

Claims Data

Member

- Plan characteristics
- Age
- Gender
- Dates of benefit eligibility

Pharmacy Claims

- Prescribing Physician
- Drug Dispensed NDC
- Quantity and Date
- Drug Strength
- Days Supply
- Patient/Plan Paid Amounts
- Standardized Costs

Physician & Facility Claims

- Physician or Facility Identifier
- Procedures (CPT-4, revenue codes, ICD9, J-codes for medications)
- Diagnosis (ICD-9-CM, DRG)
- Admission and Discharge Dates
- Dates and Places of Service
- Patient/Plan Paid Amounts
- Standardized Costs

Other Linkages

Linked Medical Records

- selected relevant clinical data
- Fill gap in claims:
- Identify patients from claims and add clinical data from medical record
- Baseline data and annual follow-up
- Periodically add new patients, and follow-up on existing patient

Socio-economic Status *

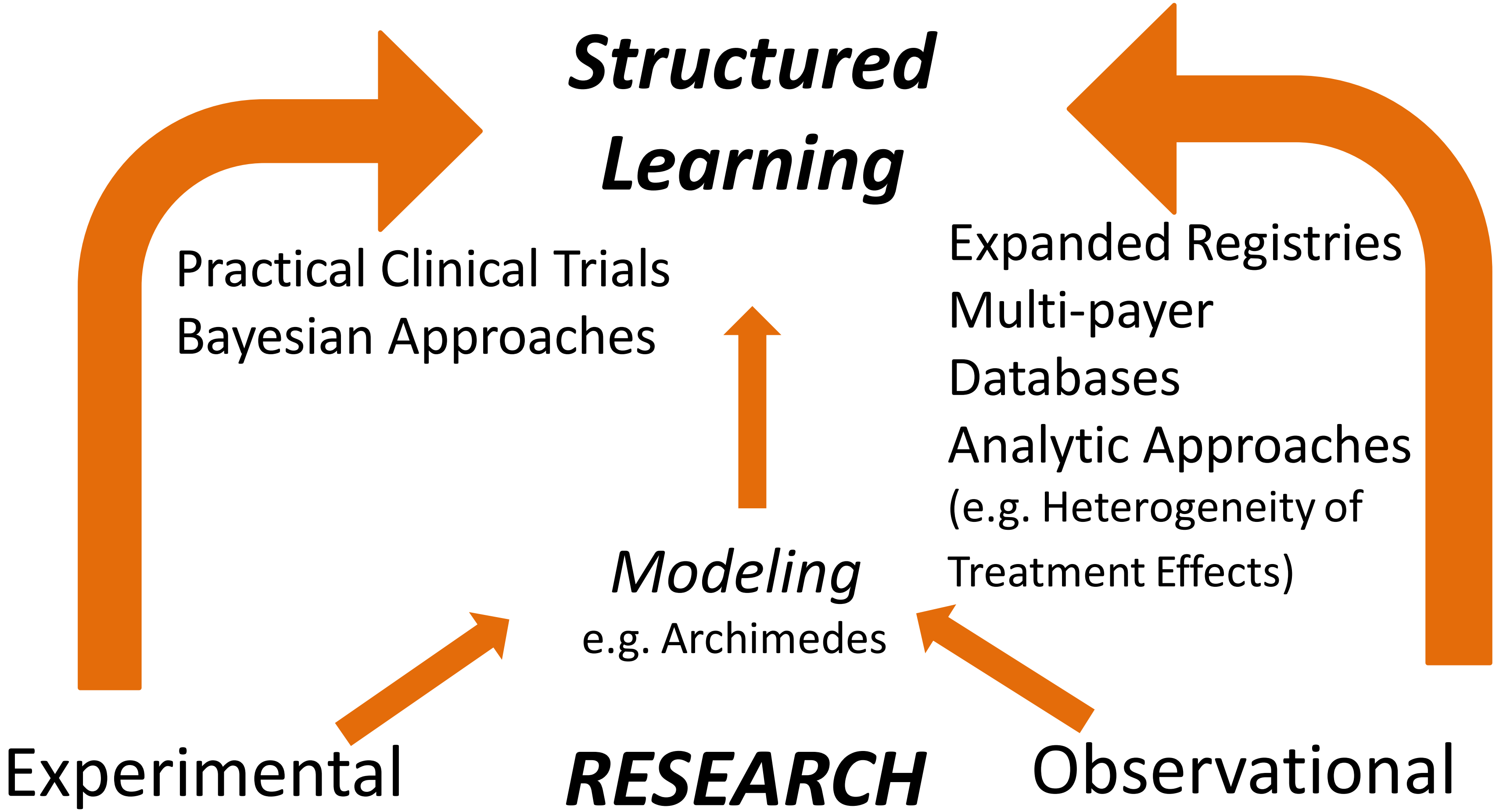
- Income
- Net Worth
- Education
- Race/ethnicity

*** Available for a subset of members.**

Date of Death

A few of the many applicable lines of research…

- **In both breast and lung cancer:**
  - How many patients have more than one line of therapy? What lines are used? Is there a relationship with survival rates?
  - How do survival and costs compare for advanced cancer patients who opt not to have therapy compared to those who are treated?
  - Can differences in costs and response rates for various lines of therapy be demonstrated?
  - What is the incidence of severe infusion reactions among treated patients? How are they managed and treated? How much do they cost?
  - How are chemotherapy regimens altered in response to adverse events (e.g., neutropenia, neuropathy)? Do dose delays or reductions follow?
- **Breast cancer:**
  - What are the treatment patterns among triple negative (HER2 under expressed, ER/PR negative) breast cancer patients? What are survival rates? Costs? Rates of disease progression?
- **Lung cancer:**
  - What are the treatment patterns among non-small cell lung cancer (NSCLC) patients? What are survival rates? Costs? Rates of disease progression?



Structured Learning

Practical Clinical Trials
Bayesian Approaches

Expanded Registries
Multi-payer Databases
Analytic Approaches
(e.g. Heterogeneity of Treatment Effects)

Modeling
e.g. Archimedes

Experimental

RESEARCH

Observational

National ‘Secondary Use’ of Data Efforts to Support CER, PCOR and Related Research

- The HMO Research Network
- AHRQ (AcademyHealth): The Electronic Data Methods Forum
- Sentinel (FDA)
- Health Care Cost Institute (HCCI)
- PACES (FDA)
- Multi-Payer Claims Database (ASPE/HHS)
- Registry for Autism Spectrum Disorders (NIMH)
- Others…

Resources for Increasingly Structured Learning …Examples with a Lewin/Optum Role

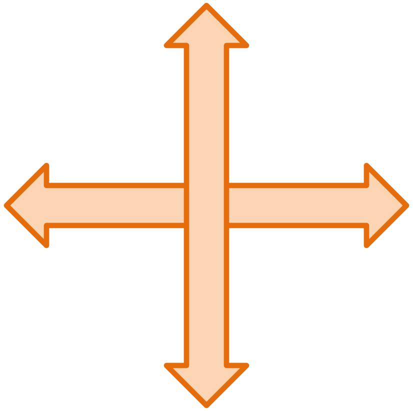
Multi-Payer Claims Database (ASPE/HHS)

- Build a database to include multiple data partners (public and private) <u>for CER</u>
  - CMS (MediCare and MediCaid)
  - Commercial Plan
  - Others – possibly state All Payer Databases
- Design to allow <u>both</u> distributed and aggregated analyses
- Beta-test for application to CER
- Develop a strategy for longer term sustainability

Registry of Individuals with Autism Spectrum Disorders (NIMH)

- Develop an advisory group including patients and families
- Build a registry from commercial claims that includes the individuals of interest plus their families
- Validate the registry through chart review
- Test hypotheses about etiology and health services use by patients *and families*
- Examine options for sustainability

Sustainability…



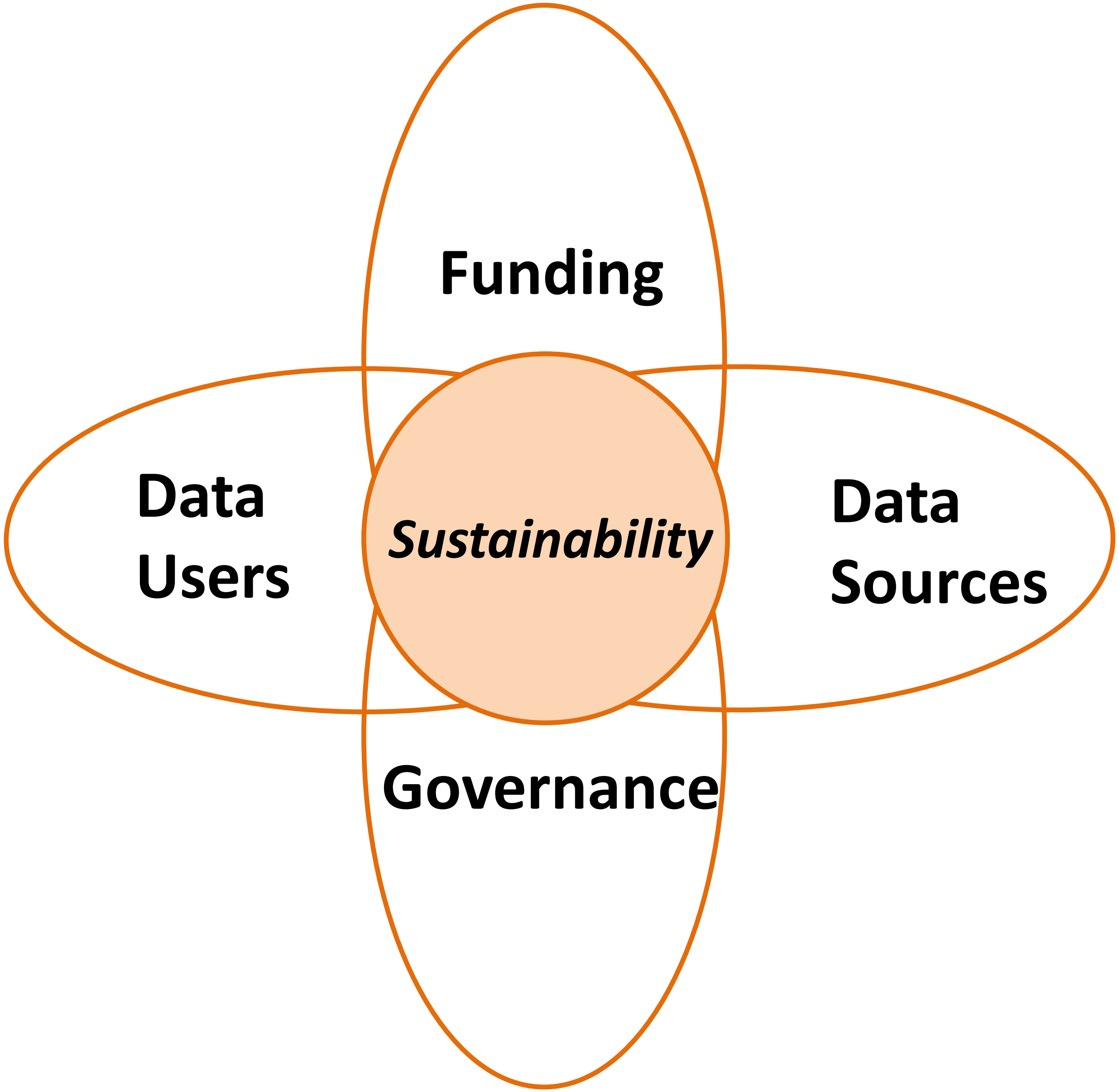
Funding

Data Users

Data Sources

Governance

A Framework for Sustainability…



Funding

Data
Users

Sustainability

Data
Sources

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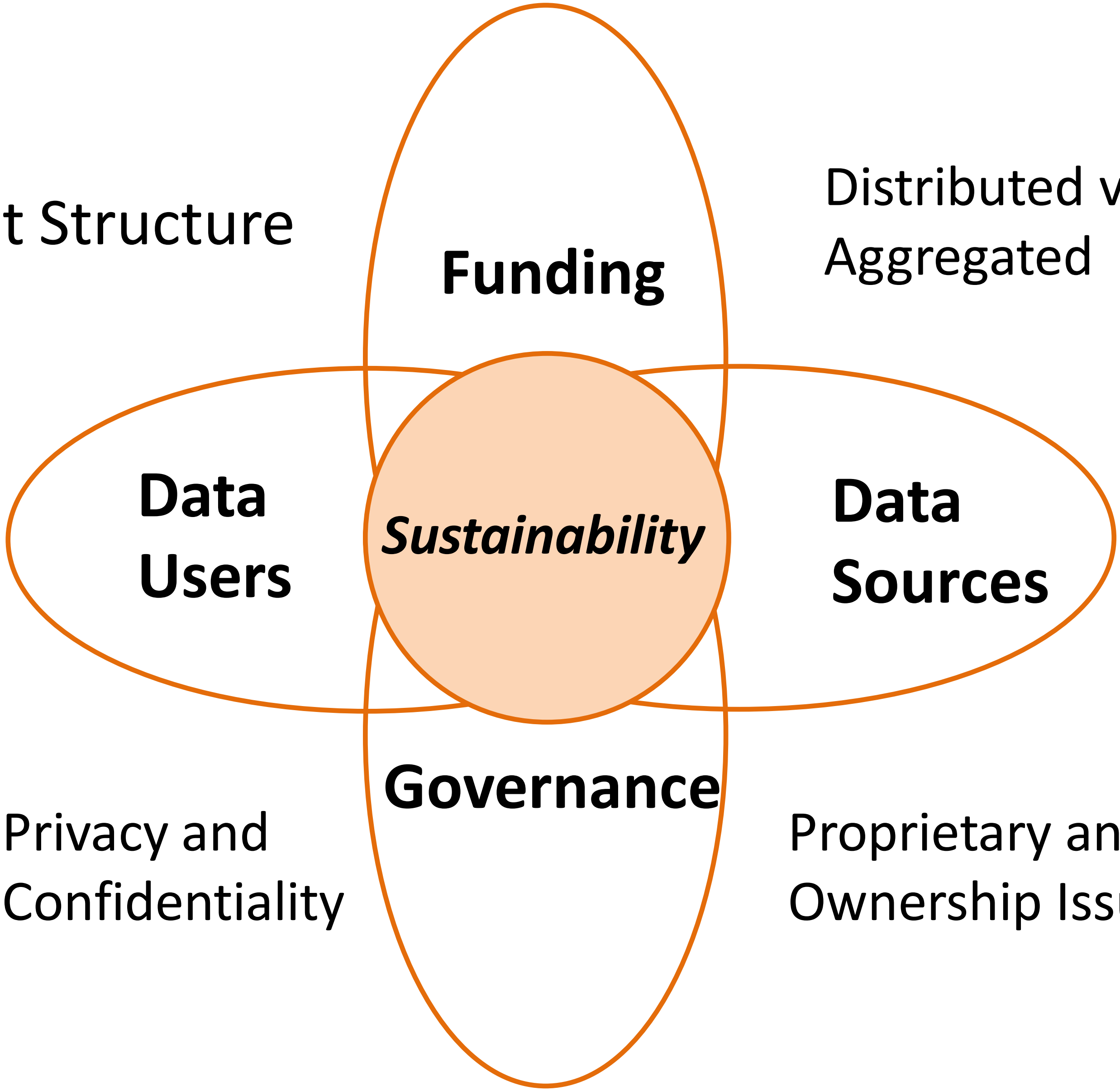
A Framework for Sustainability…



Cost Structure

Funding

Distributed vs.
Aggregated

**Data
Users**

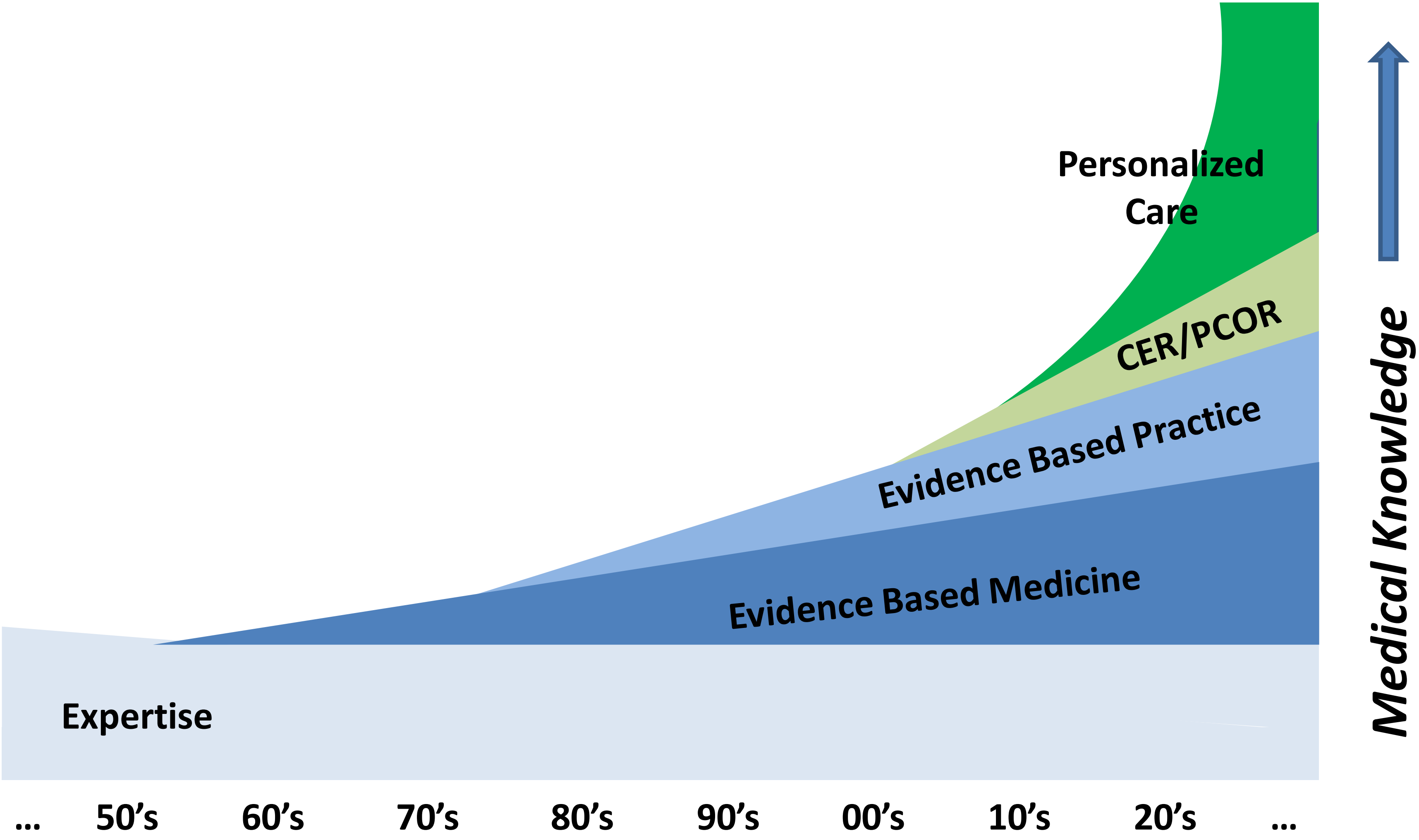
Sustainability

**Data
Sources**

Governance

Privacy and
Confidentiality

Proprietary and
Ownership Issues


Personalized Care
CER/PCOR
Evidence Based Practice
Evidence Based Medicine
Expertise
Medical Knowledge
…
50's
60's
70's
80's
90's
00's
10's
20's
…

Thanks…

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