

Unleashing the Power of Patient Registries through Harmonized Outcomes: *An Early Test of the Outcome Measure Framework in Atrial Fibrillation*

Prepared for the Concordium Challenge Workshop
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L&M POLICY RESEARCH, LLC





Disclaimer

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- The opinions expressed during this workshop are the panel members' own and do not reflect the views of the Department of Health and Human Services, its Agencies or of the United States government.



Panel Members

- Elise Berliner, PhD, Moderator
 - ▶ Director of the Technology Assessment Program, Center for Evidence and Practice Improvement, Agency for Healthcare Research & Quality (AHRQ)
- Richard Gliklich, MD
 - ▶ CEO, OM1
- Paul Wallace, MD
 - ▶ Senior Scholar, AcademyHealth
- Joseph Chin, MD, MS
 - ▶ Deputy Director, Coverage and Analysis Group, Center for Clinical Quality and Standards, Centers for Medicare and Medicaid Services (CMS)
- Lara Slattery, MHS
 - ▶ Team Leader, ACC Scientific Reporting, American College of Cardiology



Workshop Overview

- Welcome and Purpose
 - ▶ Definition and Context
 - ▶ Outcome Measure Framework (OMF) as tool for organizing and classifying information
 - ▶ Use Case Example: Atrial Fibrillation (AFib) Registries
- Panelist Perspectives
 - ▶ Development and use of harmonized outcome measures in registry context
- Panel and Audience Discussion
 - ▶ What level of harmonization is feasible?
 - ▶ Who should be involved in harmonization efforts?
 - ▶ How should harmonized measures be disseminated for use in new studies?



What Is a Patient Registry?

“an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure and that serves one or more pre-determined scientific, clinical, or policy purposes”

Gliklich R, Dreyer N, Leavy M, eds. Registries for Evaluating Patient Outcomes: A User's Guide. Third edition. Two volumes. (Prepared by the Outcome DEcide Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014. <http://www.effectivehealthcare.ahrq.gov/registries-guide-3.cfm>.



Background Context: Registries and Uses Have Evolved

- Patient registries have multiple purposes and use cases - natural history of a disease/condition; safety, effectiveness, and quality of treatments
- Uses have expanded to include:
 - ▶ Providing decision support at the point of care
 - ▶ Providing evidence for coverage and reimbursement
 - ▶ Combining data from multiple registries and data sources in order to leverage data for comparative effectiveness research on safety and effectiveness of alternative treatments and services



Background Context: Need for Harmonization

- However, usefulness (collection burden, comparison, aggregation, etc.) is limited by:
 - ▶ Variation in outcomes collected
 - ▶ Variation in how outcomes are defined
- Harmonization of outcome measures is required to increase utility of registries:
 - ▶ To compare and aggregate results between and among registries and clinical research
 - ▶ To facilitate performance and value-based measurement



Outcome Measure Framework:

A tool to organize and classify registry information

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Outcome Measure Framework

- **Goal:** Common, conceptual model for classifying the range of outcomes that are relevant to patients and providers across most conditions
- **Process:** Stakeholder-driven process incorporating iterative rounds of review and revision across multiple condition areas

Characteristics

Participant

Demographics
Genetics
Family/Participant/Social History
Functional/Performance Status
Health Behaviors
Environmental Exposures
Preferences for Care

Disease

Diagnosis
Risk Factors
Staging Systems
Genetics of Disease
Tissue or Infectious Agent
Biomarkers
Comorbidities/Symptoms
Assessment Scales
Physical Findings
Severity
Disease Understanding

Provider

Training/Experience
Geography
Practice Setting
Academic vs. Community

Treatment

Type

Surgical
Medical
Device
Alternative
Education

Intent

Palliative/Management vs.
Curative

Outcomes

Survival

Overall Mortality
Cause-Specific Mortality
Disease Free Survival
Other

Clinical Response

Recurrence/Exacerbation/Improvement/Progression/
Change in Status/Other

Events of Interest

Adverse
Events/Exacerbations/Complications
/Other

Patient Reported

Functioning
Quality of Life
Other

Resource Utilization

Inpatient Hospitalization/
Office Visits/ED Visits/
Productivity/
Additional
Treatments/Procedures/Direct
Cost/Other

Impact on Non-Participant
Experience of Care

OMF – Next Steps

- Critical next step to support harmonization:
 - ▶ Assess whether standardized libraries of definitions can be developed for a sample set of clinical areas
- Libraries will be housed in Outcome Measure Repository (OMR), a virtual location to facilitate use of harmonized outcome measures
- Questions to address:
 - ▶ Is it feasible to reach consensus on which outcomes to measure? To harmonize measure definitions?
 - ▶ What are the barriers? Do barriers differ across clinical areas?
 - ▶ How should harmonized measures be disseminated for maximum use?



Use Case: Atrial Fibrillation

Atrial Fibrillation Registries

- Over 40 patient registries related to AFib in Registry of Patient Registries (RoPR)*
- Used these criteria to narrow field:
 - ▶ Collecting at least some data in US
 - ▶ AFib is primary focus (rather than related condition)
- Yields 12 registries with varied purposes and measures
 - ▶ Includes subset of registries related to CMS Coverage with Evidence Decision (CED): focus on percutaneous left atrial appendage closure (LAA) registries
 - ▶ 26 measures across 12 registries, with no more than 5 registries collecting any single measure

* <https://patientregistry.ahrq.gov>

Example Registry Objectives

EXAMPLE 1: Cognitive Impairment in Atrial Fibrillation (NCT01816308)

- To compare the **incidence of new-onset cognitive impairments** and change in existing impairment status between AF patients undergoing either **catheter ablation** or remaining on **anti-arrhythmic drugs (AAD)**

EXAMPLE 2: AVIATOR 2 Registry (NCT02362659)

- To compare the **safety and efficacy of antithrombotic regimens** comprising one single antiplatelet agent plus an oral anti-thrombotic versus those consisting of DAPT alone or DAPT plus oral antithrombotic therapy

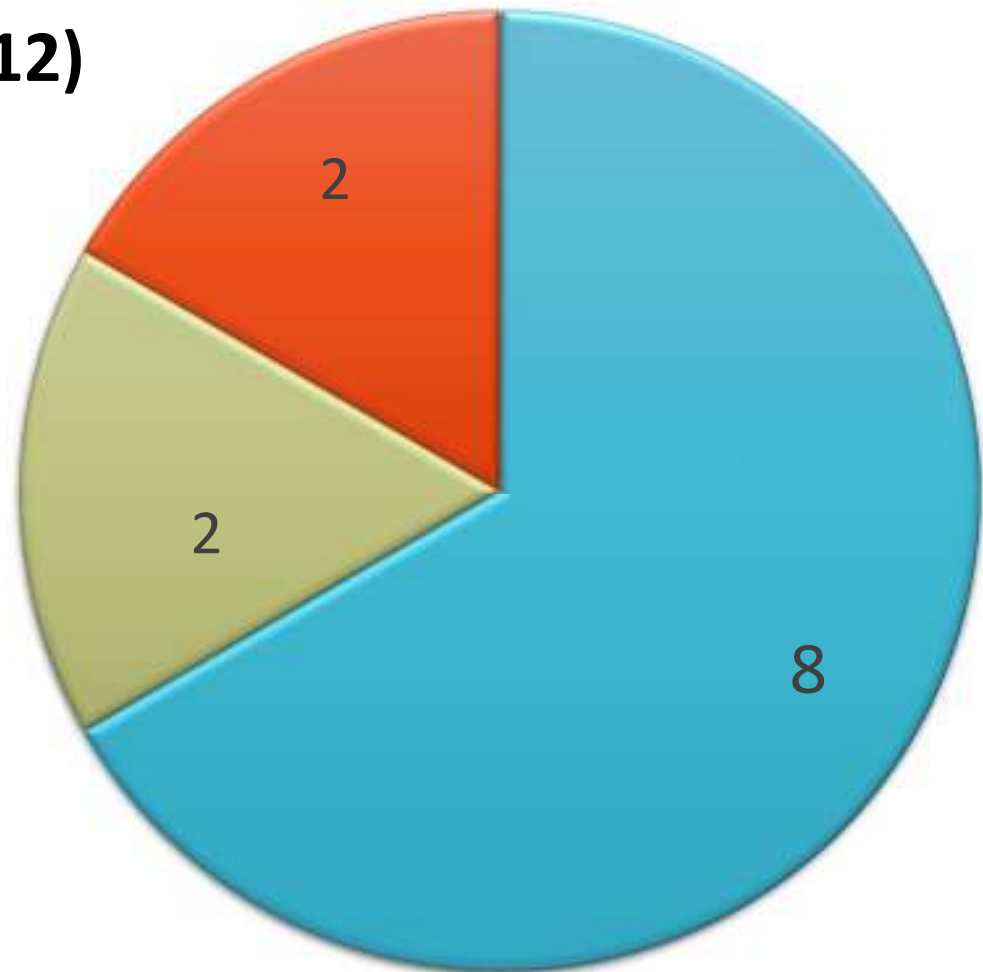
EXAMPLE 3: LAAO Registry (NCT02699957)

- To assess the **prevalence, demographics, management, and outcomes** of patients undergoing percutaneous and epicardial based **left atrial appendage occlusion procedures** to reduce the risk of stroke

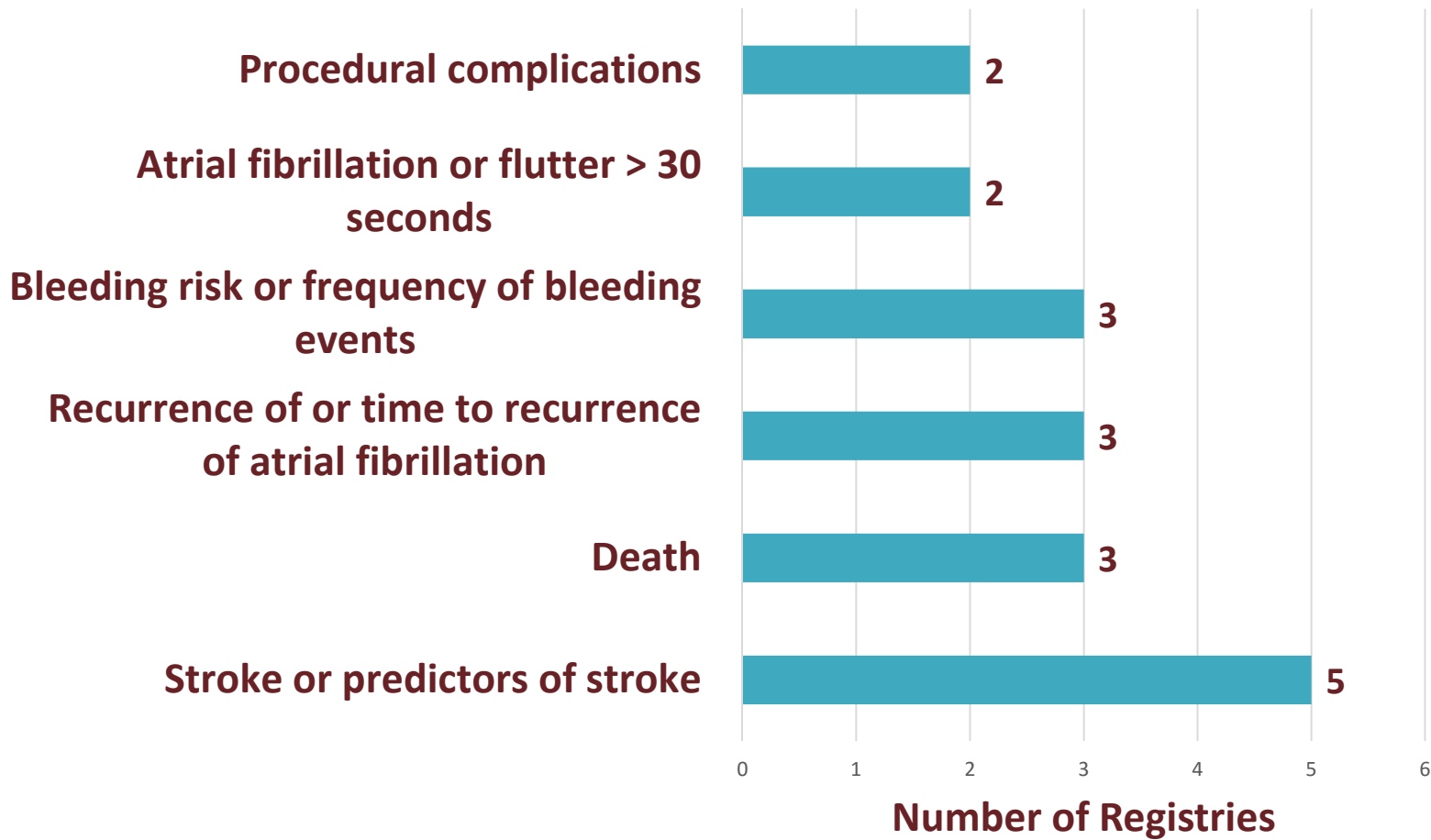
Varied Registry Objectives: Challenges for Collecting Common Data Elements

AFib Registries (n=12)

- Procedure
- Medical
- Medical/Procedure



Varied Registry Measures: Most Commonly Collected AFib Registry Measures



Other AFib Registry Measures

- Reason(s) for Warfarin discontinuation
- Change in INR values
- Improvement or no-worsening in MoCA score assessed at baseline and 2-year follow-up
- Association between social support and MoCA score
- Association between arrhythmia occurrence and MoCA score
- Comparison of QoL between baseline and post-ablation period
- Fluoroscopic usage
- Failure of the hybrid ablation procedure in patients with AFib
- Number of participants with adverse events

Definitions Vary Widely: Transient Ischemic Attack Examples

EXAMPLE 1: EWOLUTION (NCT01972282)

- **New** focal neurological deficit with **rapid symptom resolution** (usually 1-2h), **always within 24 hrs**, Neuroimaging without tissue injury

EXAMPLE 2: AVIATOR 2 Registry (NCT02362659)

- **Sudden onset** of a focal neurologic deficit...from a **non-traumatic cause** and categorized as ischemic, hemorrhagic, or unspecified, as evidenced by neuroimaging or lumbar puncture **lasting less than 24 hours**

EXAMPLE 3: LAAO Registry (NCT02699957)

- An **acute** focal neurological event **lasting at least 5 minutes**



Panelist Perspectives:

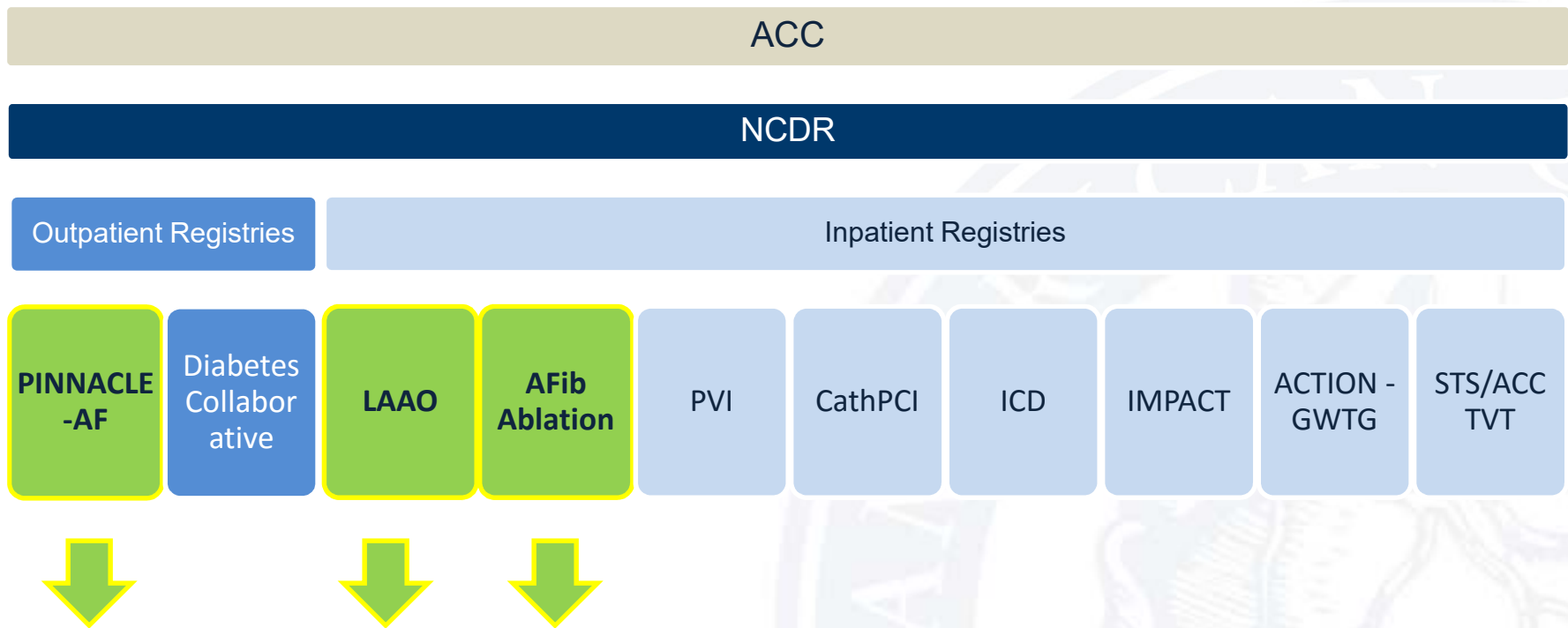
Challenges of Developing Registries
Big Data Approaches to Addressing Challenges
Use of Registry Data for Coverage Purposes



Challenges of Developing Registries

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With NCDR, data can monitor quality and utilization



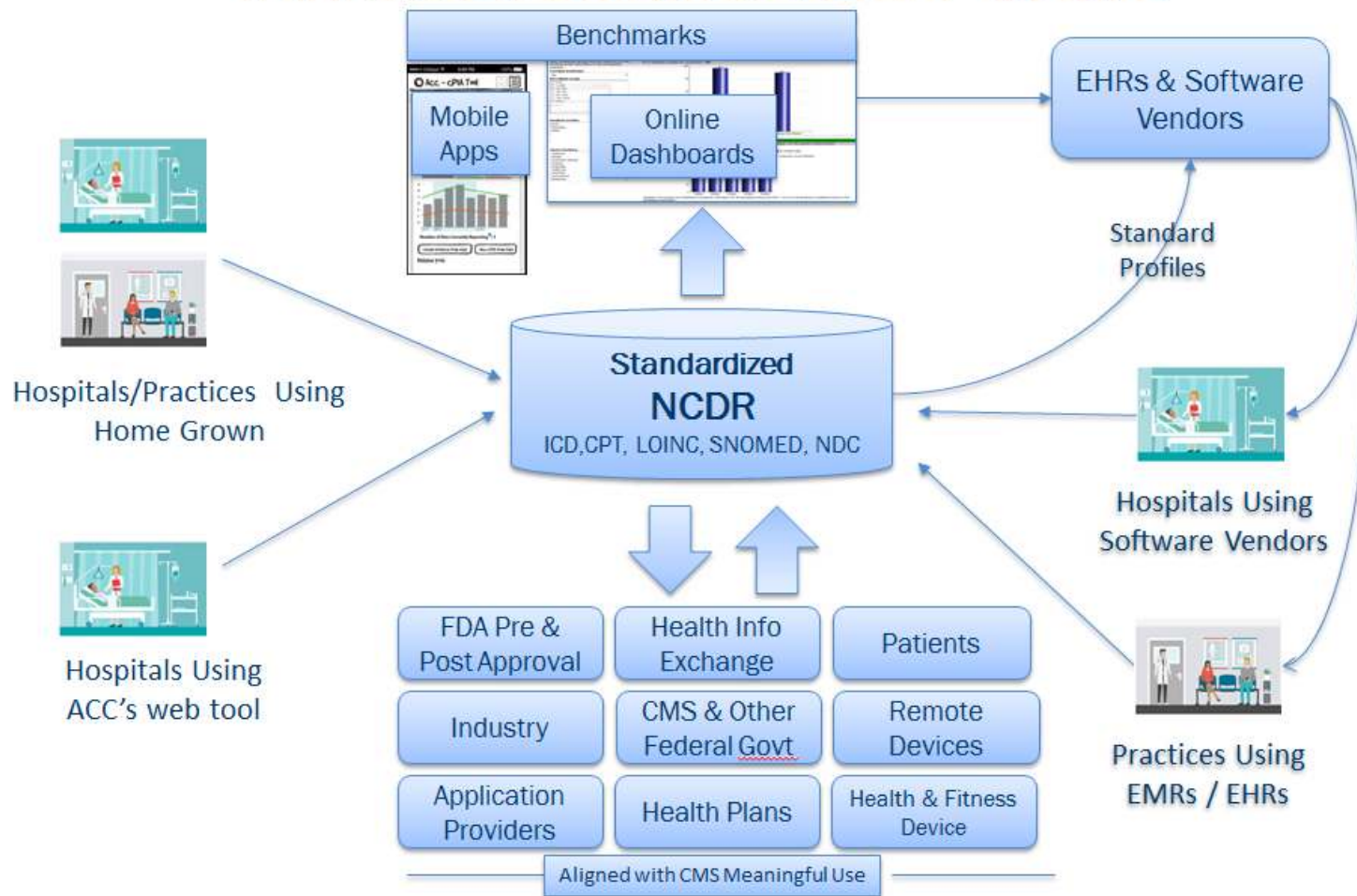
NCDR's new registries monitor key performance metrics in caring for atrial fibrillation, from office to hospital to home



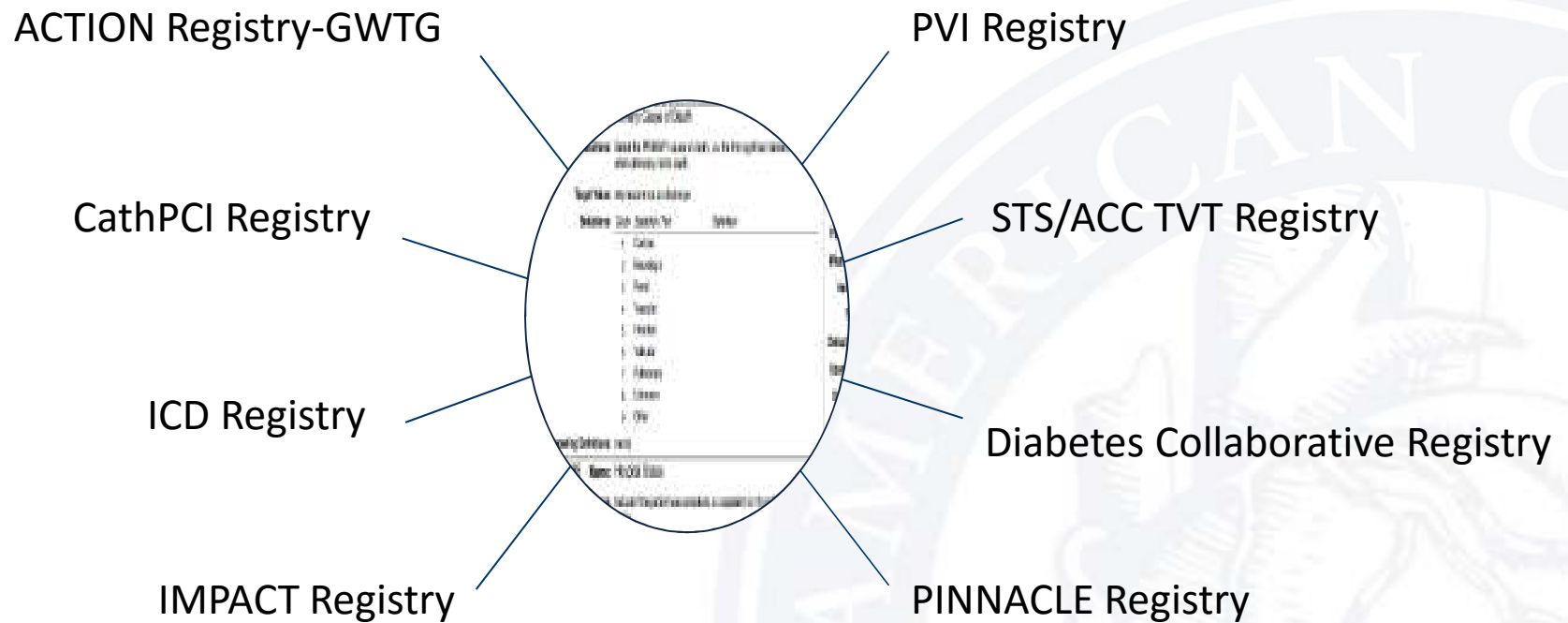
NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

The road forward is dependent upon data alignment...

An Interconnected Future



...which requires internal data harmonization and governance



...and leverage existing standards to



- Facilitate Adoption
- Reduce Time-to-market
- Eliminate Data Mapping



NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

...and is a transparent part of data workflow design

an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information

- international
- standards-based
- addresses specific clinical needs
- support of optimal patient care

IHE Integrating the Healthcare Enterprise



NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY



“Big Data” Approaches

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... THE POWER OF REGISTRIES...

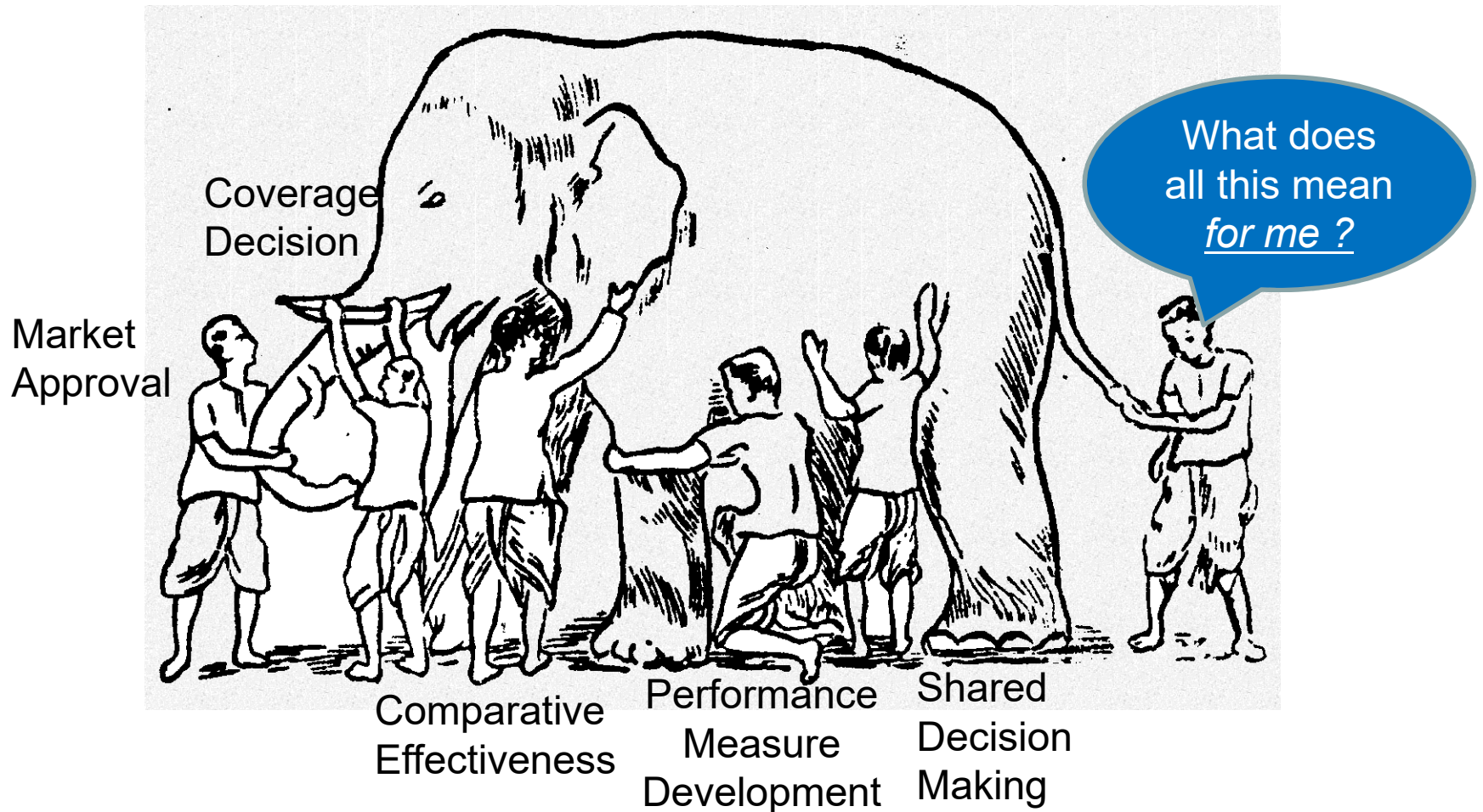
Paul Wallace MD

Paul.Wallace@academyhealth.org

Perspective...

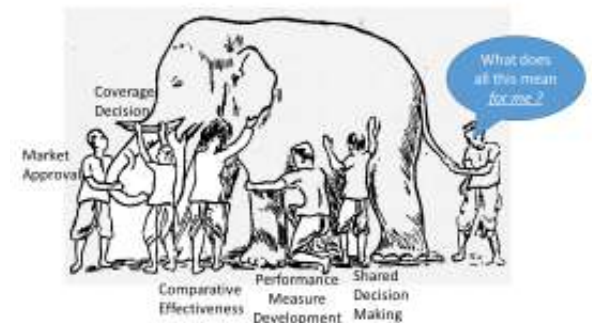
- I'm a doc and my wife is a nurse
- Kaiser Permanente
 - Practice (Hematology/Oncology)
 - Populations (Care Management and HIT)
 - Patient and care giver
- United Health Group
 - The Lewin Group(Consulting)
 - OptumLabs (Big data research and innovation)
- Health Services Research
 - AcademyHealth
 - Recent Projects- Commonwealth Fund, AHRQ, Medtronics

Use cases...



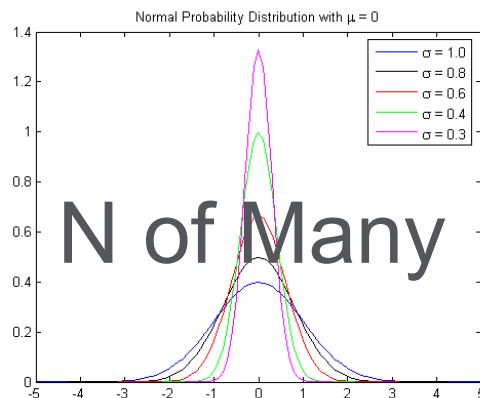
How might Registries help...

- Known knowns
 - Create focus on relevant data (~ design and build data marts)
 - Yield lots of information (vs. Babel)
 - Require lots of work (and maintenance)
- Known unknowns (aka Research Opportunities)
 - Appropriate variation – identification and bounding
 - *Intra*-use case
 - *Inter*- use case
 - Implications of abundant data
 - Efficient secondary use
 - Observational methods
 - Moving from efficacy to effectiveness
 - Potential vs. threat of machine learning
 - Application to complex patients (e.g. co-morbidity)
 - Complexity as a reflection of increasing rarity
 - Personalization
- *Standards problem vs. a computing challenge?*



Moving to the Patient as the Focus

- The complex patient and their caregiver as an ‘N of 1’:
 - Approaching the complex patient as being increasingly rare (an ‘N of 1’)
 - Building dynamic comparison populations of many (N of 1)s (rather than N’s of many)
 - Identify characteristics of providers obtaining better results and determine what resource mix they are using relative to peers
 - Personalized decision support and performance management



N of 1



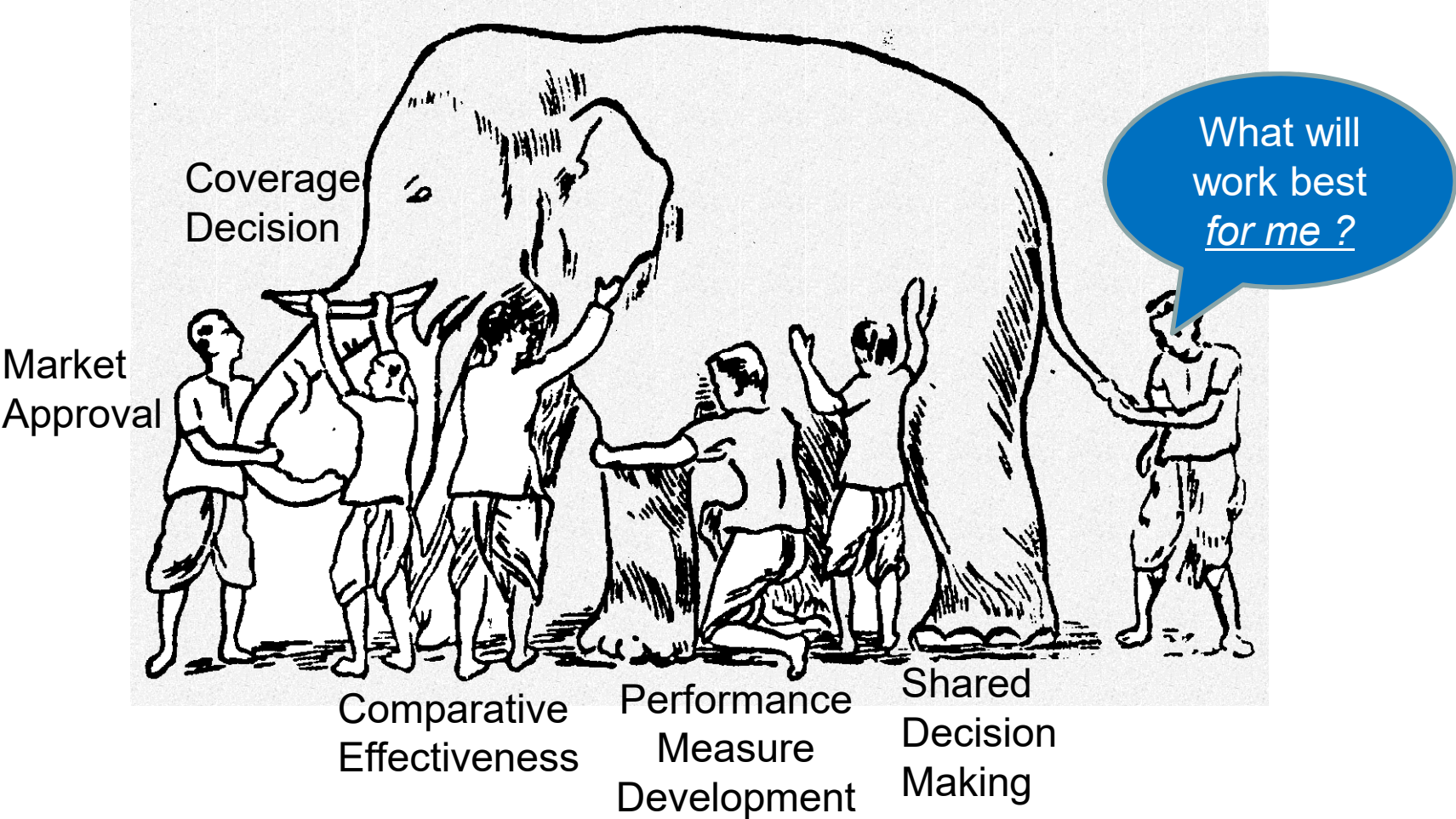
*Many
N's of 1*

Patient centered and personalized



When a patient like me sees a doctor like you in a community like ours, what works best for me?

The patient as the path to parsimony...





Registries and Coverage Decisions

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Perspective

Joseph Chin, MD MS

Deputy Director, Coverage and Analysis Group / CMS

Concordium, 09/12/2016

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Medicare Coverage with Evidence Development (CED)

- CED is a mechanism for Medicare to cover items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data.
- Established for a particular item or service through a national coverage determination (NCD).
- Allows earlier beneficiary access to innovative technology while generating evidence specific to the Medicare population.

Percutaneous Left Atrial Appendage Closure Registry Requirement

- A prospective, national, audited registry that:
 - 1) consecutively enrolls LAAC patients, and,
 - 2) tracks the following annual outcomes for each patient for a period of at least 4 years from the time of the LAAC:
 - Operator-specific complications
 - Device-specific complications including device thrombosis
 - Stroke, adjudicated, by type
 - Transient Ischemic Attack (TIA)
 - Systemic embolism
 - Death
 - Major bleeding, by site and severity

Percutaneous Left Atrial Appendage Closure Registry Requirement

- How do the outcomes listed above compare to outcomes in the pivotal clinical trials in the short term (≤ 12 months) and in the long term (≥ 4 years)?
 - What is the long term (≥ 4 year) durability of the device?
 - What are the short term (≤ 12 months) and the long term (≥ 4 years) device-specific complications including device thromboses?
-
- To appropriately address some of these questions, Medicare claims or other outside data may be necessary.



Open Discussion

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Open Discussion with Audience

- Where do we go from here?
 - ▶ What level of harmonization is feasible?
 - ▶ What level of harmonization is valuable?
 - ▶ Who should be involved in harmonization efforts?
 - ▶ How should harmonized measures be disseminated for use in new studies?