

Building a Multi-Purpose Network for Enhanced Use of Health Information

*Challenges to be addressed in order to
create a distributed network that can
be used for CER, safety, quality*

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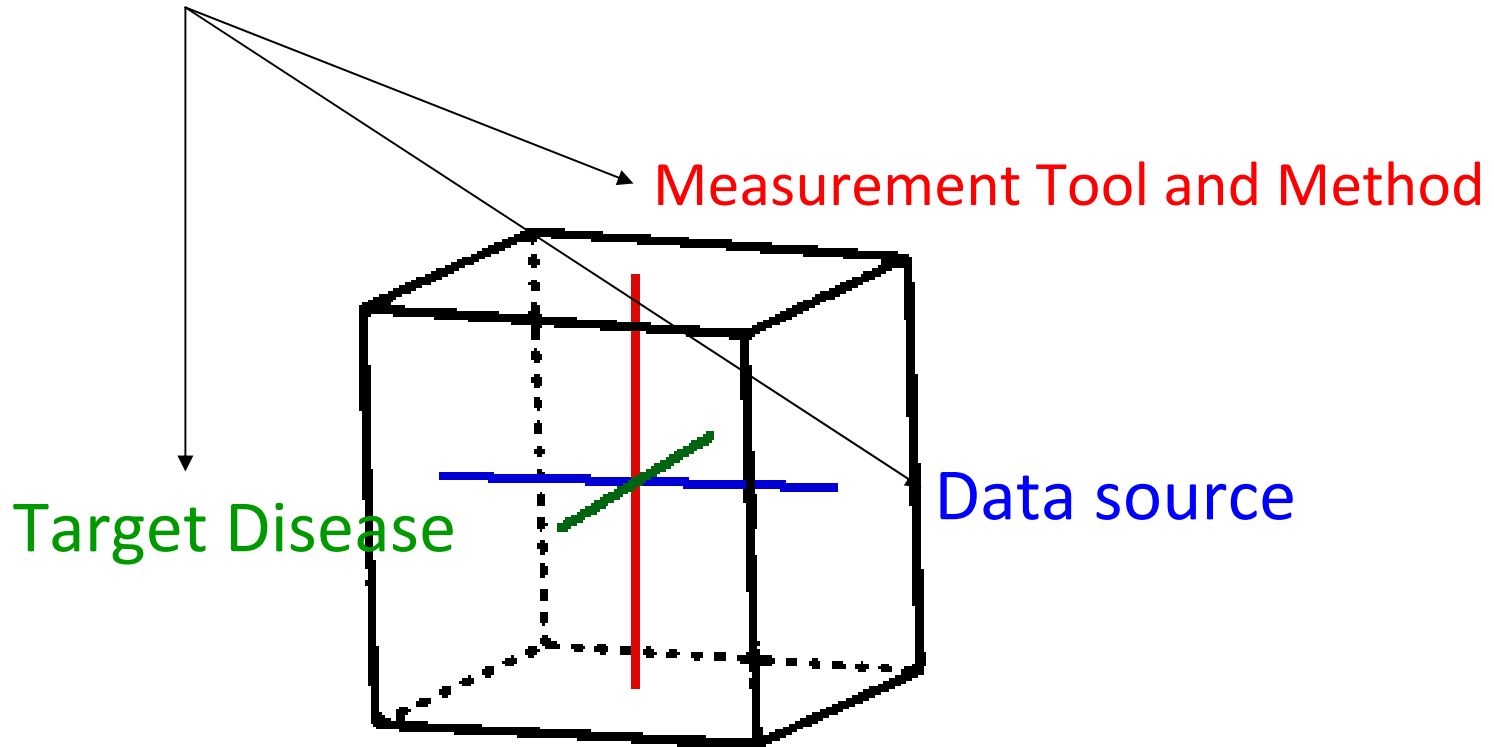
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Disclaimer

- This presentation and my comments are my own and do not necessarily represent those of my employer (J&J), the broader Industry, or other groups with whom I am affiliated (OMOP).
- However, much of my thinking recently has been shaped by my work with OMOP.

The Axes of Benefit-Risk

By Perspective

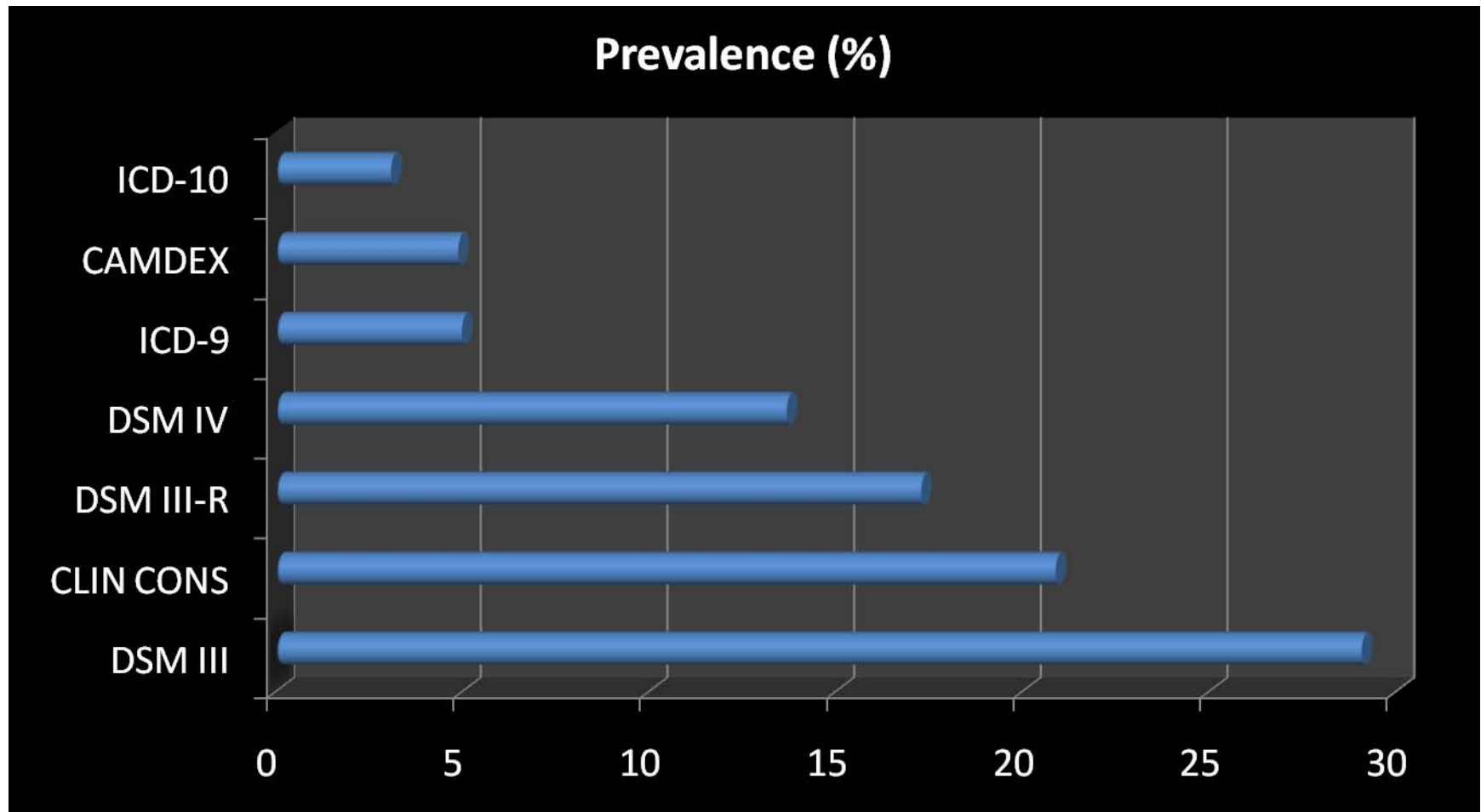


THE DATA

Quality, completeness, credibility, transparency

- ***Data are not scarce*** but studies of a drug are dependent on the number of folks on the drug
- How well are *Risks* and *Benefits* captured in these data?
- What are the issues in defining events, exposures, outcomes?
- Can all those with data be ‘transparent’ about the characteristics of their underlying databases?
 - ‘Business-sensitive’ and competition issues

An Example with Dementia Definitions



Created from Erkinjuntti T, Masbye T, Steenhuis R, Hachinski V: The effect of different diagnostic criteria on the prevalence of dementia. N Engl J Med 337:1667-1774, 1997

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THE EVIDENCE

- **What is the level of ‘evidence’ that is appropriate for a decision and at what point in time?**
 - One database, one evaluation study, at one point in time ?
 - Surveillance methods across multiple data sites?
 - What are the alternatives to the clinical trial?
- **What is the ultimate decision being informed?**
 - Labeling - Clinical Practice
 - Product approval - Reimbursement
 - Safety vs. effectiveness

WHO IS INVOLVED

- **Don't try this on your own:** No one stakeholder group has a monopoly on methods, data and/or insights
- **Conflicts of Interest**
 - financial
 - advocacy for a published position
 - those advocating use of a particular database
- **Transparency** in process of research and decision criteria is critical
- How will this effort be **funded**?

Bigger Concepts In Play

- **Longitudinal thinking**: these should be viewed as ongoing processes not singular studies
 - Can surveillance predict full study results?
- Tension between **CER and personalized** medicine
- Can we define a **process** with **meaningful measures for key decisions**?
- What is the **continuous learning** that we can employ so that the delivery system becomes the platform for insight?
 - Randomizing into the database
 - Need for continuous **training, education, and research**

What are the next steps?

- **Invest in the basic science behind the science**
 - Methods for effectiveness, risk, quality
 - Definitions of exposure, outcome
 - Summarizing and communicating results from across multiple sites
- **Standards in the data sources**, esp in EHR
 - Systematic capture of critical data elements
 - Dealing with missing data; linkage
 - Data quality, availability, definitions
- **Evidence standards**: should inform action
 - What constitutes actionable evidence?
 - Transparency in what those evidence standards are
- **Defining the process**
- **Governance and Funding Models**
- **Education and Training**

“It’s important to know
what you don’t know...

but could.”

- H. Guess