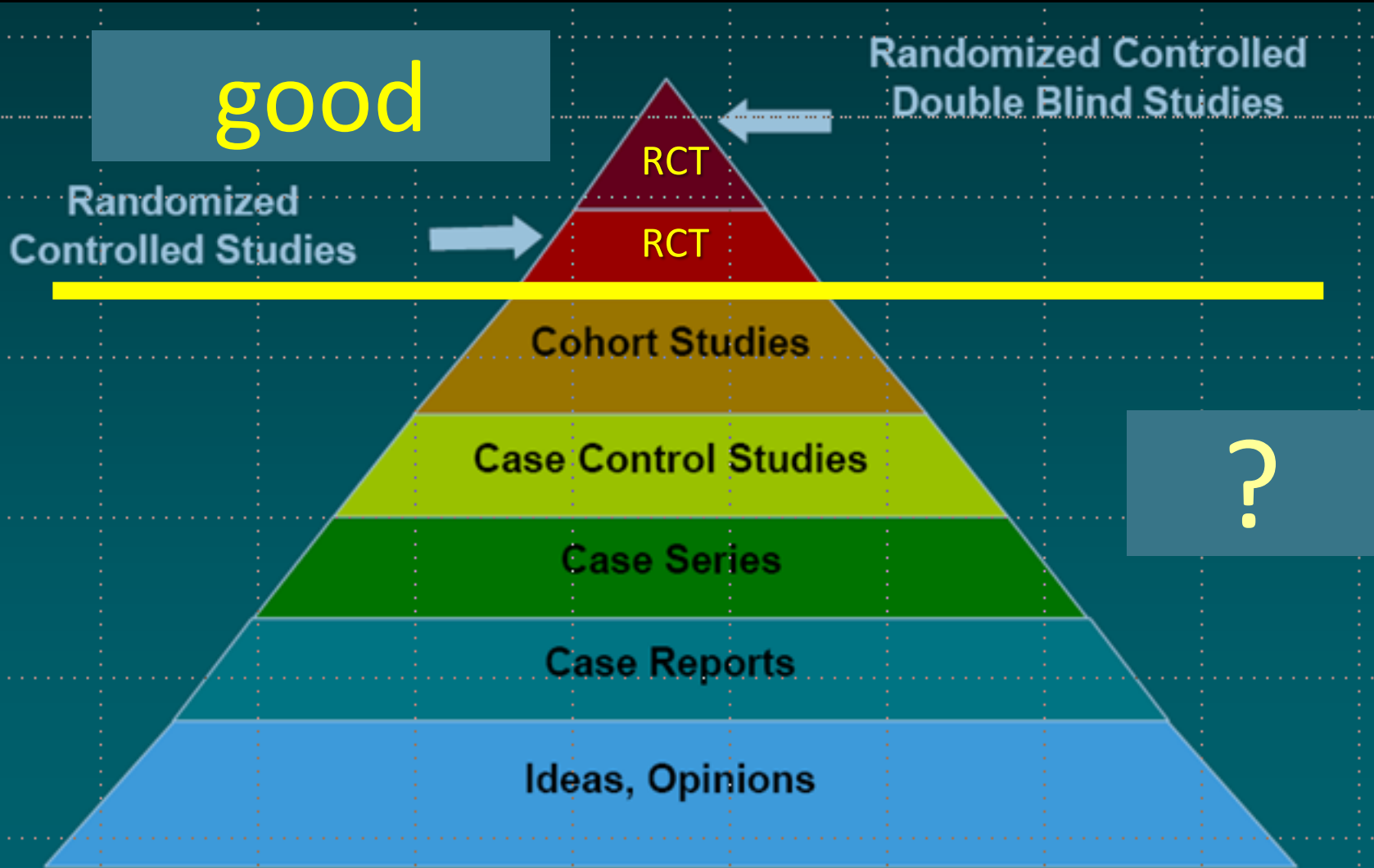


# Recognizing High-Quality Observational Studies of Comparative Effectiveness

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June 24, 2010

# Using Evidence to Support Decisions



# Observational Data

Information is needed about real-world practices and outcomes that result from that behavior or treatment

- What interventions are best?
- For whom?
- When?



# Guidelines for Quality – Observational Studies

- GRACE principles for observational studies of comparative effectiveness. Am J Man Care 2010;16(6):21-24
- ENcEPP Checklist for methodologic studies, 2010. [www.encepp.eu](http://www.encepp.eu)
- ISPOR Good Research Practices for CER I, II, III . Value in Health 2009; 1044-1072
- GPP: Guidelines for good pharmacoepidemiology practices Pharmacoepidemiology & Drug Safety 2008:17:200-208
- STROBE: Strengthening the Reporting of Observational Studies in Epidemiology, Epidemiology 2007;18(6): 805-835
- AHRQ REGISTRIES HANDBOOK: Gliklich RE, Dreyer NA, eds. : Registries for Evaluating Patient Outcomes: A User's Guide. Prepared by Outcome DEcide Center. AHRQ Publ. No. 07-EHC001-1. Rockville, MD. 2007. 2<sup>nd</sup> edition, in press, 2010.

# GRACE Initiative: Goal

GRACE: **Good ReseArch for Comparative Effectiveness**

To develop principles of good practices for observational studies of comparative effectiveness to enhance quality and facilitate use for decision-making by physicians, patients and payers



[www.graceprinciples.org](http://www.graceprinciples.org)

# GRACE: a Work in Progress

Built as a model for consensus

Principles posted online for public comment

Input and review from broad group of collaborators

Iterative postings/presentations/reviews/revisions

4th & most recent iteration – April, 2010

A living document

[www.graceprinciples.org](http://www.graceprinciples.org)

# GRACE Principles

## 1) Study plan

- Clinically relevant
- Disease/conditions, treatments, comparators, target pop'n
- Measures of effectiveness, safety and tolerability

## 2) Transparent analysis and reporting

- Data collection, including handling of missing data
- Comparison to patients with similar likelihood of treatment and benefit
- Consideration of alternative explanations

## 3) Validity of the interpretation

# 3) Validity of Results

## Hierarchy of evidence

[likelihood that data are confounded]

1. Determinants of use are not related to determinants of outcomes (e.g., treatment decisions driven by reimbursements, not patient characteristics)
2. No consistent determinants of treatment; determinants of treatments are largely known; or the risk of toxicity from treatment is unlikely to be related to the outcome(s) of interest
3. Confounding is likely to be present, but little relevant evidence is available



# GRACE Initiative

- Offers opportunities to further refine and extend principles and write publications

Dreyer NA, Schneeweiss S, McNeil B et al on Behalf of the Grace Initiative . Recognizing High-Quality Observational Studies of Comparative Effectiveness. Am J Managed Care Am J Man Care 2010;16(6):21-24

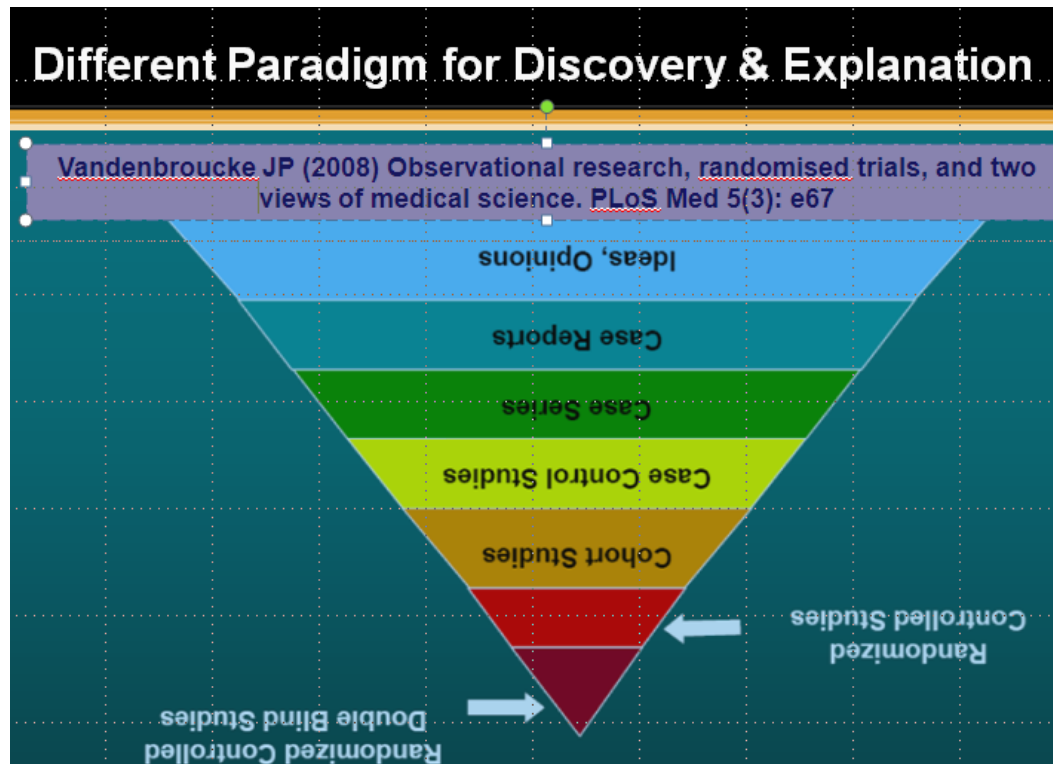
- Building a public library of case studies on observational studies that have been used for decision-making
- Multi-society support and endorsement



GRACE Principles are endorsed by  
the International Society of Pharmacoepidemiology

# Overview

Guidelines for good practice promote quality and better use of observational studies of comparative effectiveness



# Contact Information

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