Clinically Relevant Complex
Systematic Reviews (CRCSR's) & the
Next Challenges in Comparative
Effectiveness Research & Analysis

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UCLA Center for Maximizing Outcomes and Research on Effectiveness (C-MORE)



The two principal challenges in Comparative Effectiveness Research & Analysis for the next decade

Comparative Effectiveness Research (CER) and analysis entails:

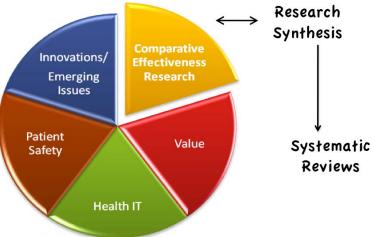
"...the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care...".

The purpose of CER is:

"...to assist consumers, clinicians, purchasers, and policy makers to **make informed decisions** that will improve health care at both the individual and population levels...".

(The Institute of Medicine, 2009)

AHRQ Portfolios







CER Funding as of 2009

Table 2: Estimated CER Grant/Study Counts FY 2006 - FY 20091

Agency	CER Grants/Studies FY2006-FY 2009 (YTD)								
AHRQ	144								
\mathbf{DoD}	25								
VHA	96								
NIH^2	463								
0.7									

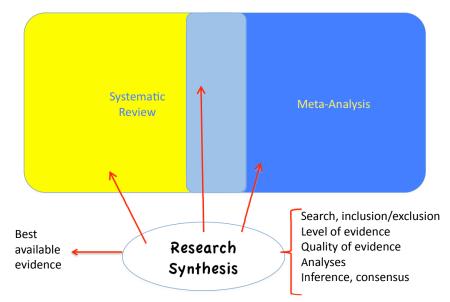
¹As of June 2009, based on review of agency/department websites and agency/department generated lists

NOTE: Roughly 86% of the CER studies across agencies focus on at least one priority disease/condition, among which leading are mental health disorders, substance abuse, cardiovascular disease, and diabetes

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²NIH is in process of cataloging CER. This primarily represents FY 2008.

The Process of Generating & Synthesizing Research Evidence & how to quantify it and how to operationalize it

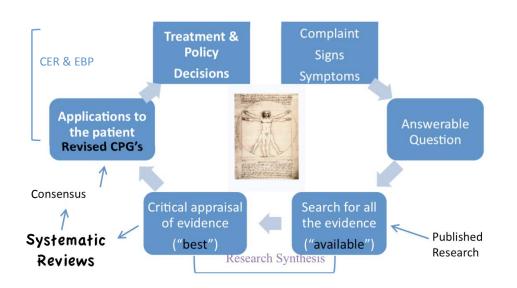


From Systematic Reviews (SR's) to Clinically Relevant Complex Systematic Reviews (CRCSR's)

SR's & CRCSR's in Effectiveness vs. Efficacy Decisions

CER Agenda for the Next Decade

Systematic Reviews (SR's) = Reports on Research Synthesis



The body of research is evaluated for: the level of evidence (what was done)





the quality of evidence (<u>how</u> it was done: based on common criteria of methodology,

design, data analysis)

R-Wong 2006 R-AMSTAR 2010 Ex-GRADE 2011

Bridging the Gap between Acceptable sampling & Clinical Relevance



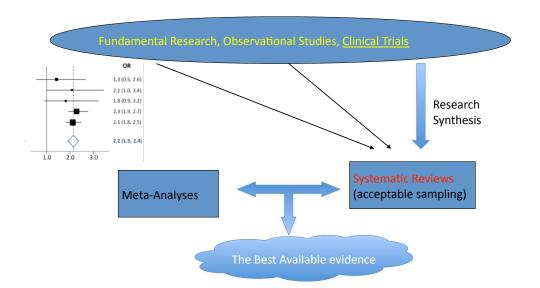
PICO	Paper	R-AMSTAR*	%ile	Rank ^b
PTSD	1	32.50	83	В
	2	33.00	85	В
	3	32.50	83	В
	+	39.00	100	— A
	5	32.00	82	В
	6	25.50	65	D
	7	33.00	85	В
	8	29.50	76	С
	9	30.00	77	С
	5	35.00	100	A
	11	30.00	77	С

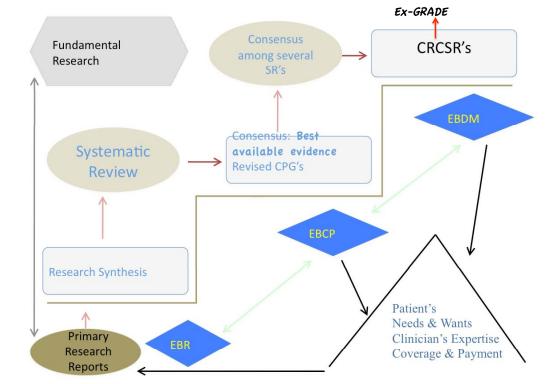
Reports	1	2	3	4	5	6	7	8	9	10	11	Total
1	4.00	1.00	4.00	2.00	3.50	3.50	3.50	3.50	1.00	1.00	1.00	28.00
2	3.50	2.50	4.00	4.00	3.50	4.00	3.50	2.50	3.50	1.50	1.00	33.50
3	4.00	4.00	3.50	4.00	1.50	2.50	3.50	3.50	2.50	1.50	1.00	31.50
4	4.00	2.00	4.00	4.00	2.00	4.00	3.50	3.00	3.50	1.00	1.00	32.00
5	3.50	4.00	4.00	3.00	2.50	4.00	4.00	4.00	2.50	1.00	2.50	35.00
Mean	3.80	2.70	3.90	3.40	2.60	3.60	3.60	3.30	2.60	1.20	1.30	32.00
SD	0.27	1.30	0.22	0.89	0.89	0.65	0.22	0.57	1.02	0.27	0.67	2.62

(p=0.001, Friedman non-parametric ANOVA equivalent)

Adapted from Kung et al, 2010

In brief: SR's for Obtaining the **Best Available Evidence**





From Systematic Reviews (SR's) to Clinically Relevant Complex Systematic Reviews (CRCSR's)

SR's & CRCSR's in Effectiveness vs. Efficacy Decisions

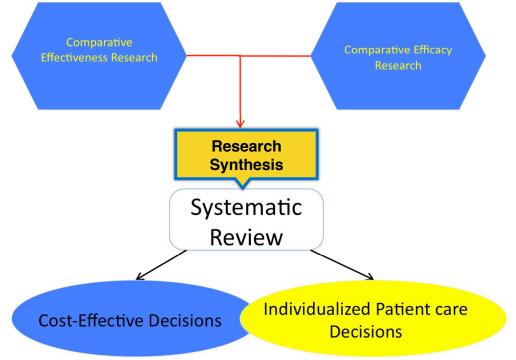
CER Agenda for the Next Decade

Comparative effectiveness <u>differs</u> from efficacy research

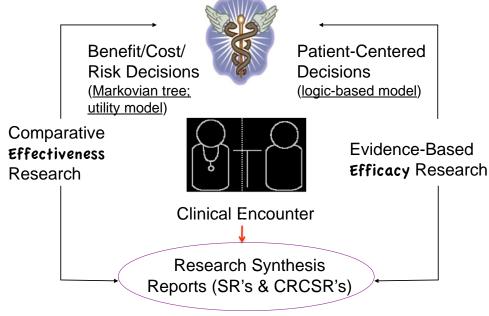
because it (comparative effectiveness research) ... [applies]... to real-world needs and decisions faced by patients, clinicians, and other decision makers [generally including assessment of risks, costs vs. benefits].

[by contrast, i]n **efficacy research**, ...the question is typically whether the treatment is efficacious [i.e., **works clinically**] under ideal, rather than real-world, settings ...[and]....[t]he results ... are ... not necessarily generalizable to any given patient.

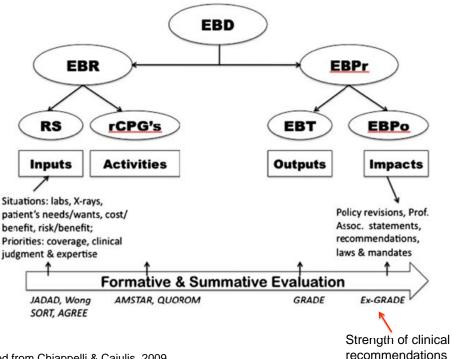
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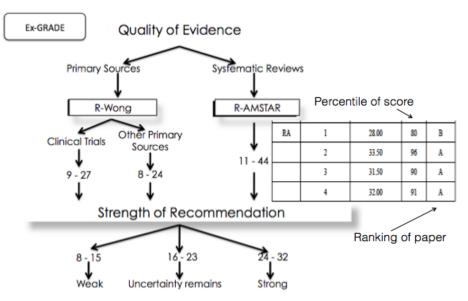


Adapted from Chiappelli et al, 2009



Clinical Decision Models in Effectiveness vs. Efficacy Research





Extension of the Grading of Recommendations Assessment, Development, and Evaluation

Adapted from Phi et al, 2011 (in press) & Kung et al, 2010

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CER Agenda for the Next Decade



Unprecedented Investment in Research Synthesis

Until today...

 2005-2009 - AHRQ received \$129 million from Congress for comparative effectiveness research

For the next decade...

 2009 - The American Recovery and Reinvestment Act contained \$1.1 billion for comparative effectiveness research...



data infrastructure, including HIT

III.

comparing priority patient groups & priority types of interventions

II.

dissemination and translation of CER findings

IV.

methods and training
viewed as essential to
the CER enterprise

[&]quot;...doing so empowers doctors and patients, and helps make our practice of medicine more evidence-based..."

Federal Coordinating Council - Priority ONE:

Further Development of <u>CER methodologies</u> to generate evidence about the comparative effectiveness, comparative safety, and cost effectiveness of clinical interventions

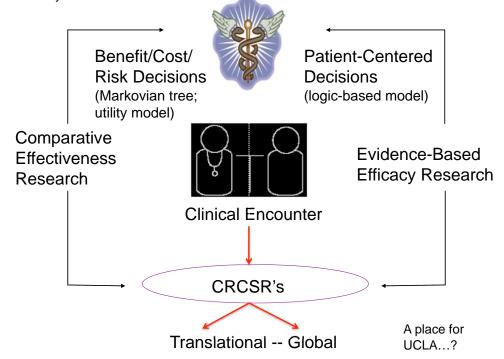
How should CER best be undertaken?

Need for a <u>broad Federal CER enterprise</u> that cuts across treatment, prevention, promotion, and health-determinant interventions designed for both people and populations.

Need for information principles and tools to prioritize CER investments on those studies where there is a greater likelihood that the research will lead to changes in practice.

Need for funding instrument to support <u>research</u>, including multicenter research, into "the science of CER" to build a foundation for this work, and to ensure generalizability of the findings.

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Thank you for your attention

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"Knowledge is of two kinds: we know a subject ourselves, or we know where we can find information upon it."
— Samuel Johnson (1709 - 1784) English author and critic