FACILITATING AND MEASURING SUCCESSFUL PATIENT ENGAGEMENT IN CER

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CENTER FOR MEDICAL TECHNOLOGY POLICY

- Independent, non-profit 501(c) (3) organization
- Mission is to advance health care innovation and effectiveness by improving the quality, relevance, and efficiency of health care research
- Focus is on methods, infrastructure and policy projects to support the conduct of **comparative effectiveness research**
- Patient and Consumer Advisory Council (PCAC) integral to company mission, goal and individual projects
  - 9 member standing committee of the Board of Directors
  - Started in 2008 since beginning of CMTP
  - Strategic and tactical role

BARRIERS TO INVOLVING STAKEHOLDERS IN CER

- Confusing terminology
- Lack of shared understanding of what it means to "successfully" involve stakeholders in research
- Limited data regarding impact; systematic evaluation rare
- Timing, restrictions on number/availability of stakeholders
- Concerns that process will add time and costs to project plans

O'Haire, McPheeters, Nakamoto, et al. Methods for Engaging Stakeholders To Identify and Prioritize Future Research Needs. Methods Future Research Needs Report No. 4. AHRQ Publication No. 11-EHC044-EF. Rockville, MD: Agency for Healthcare Research and Quality. June 2011. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

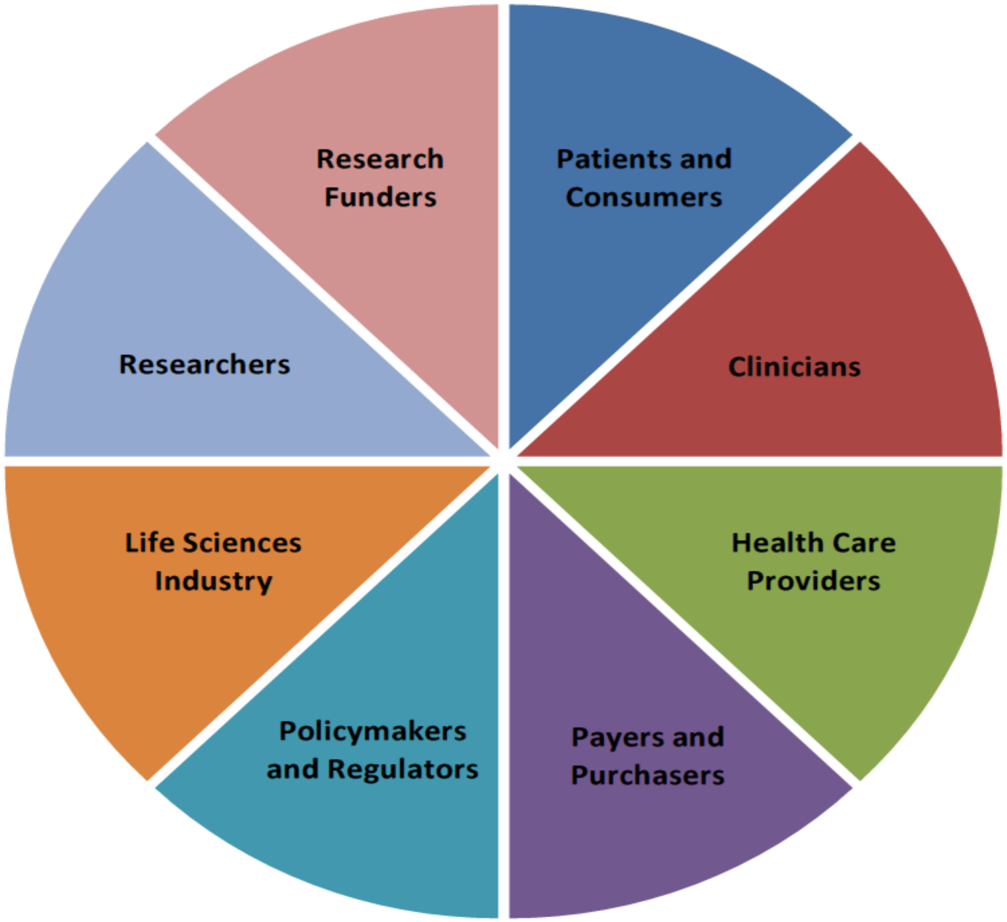
STAKEHOLDERS

Individuals, organizations, or communities that have a direct interest in the process and outcomes of a project, organization, or policy.

Deverka PA, Lavallee DM, Desai PJ, Esmail LC, Ramsey SD, Veenstra DL, Tunis SR. Stakeholder participation in comparative effectiveness research: defining a framework for effective engagement. J. Compar. Effect. Res. 2012; 2:181-194.

TARGET STAKEHOLDER GROUPS FOR CER

Stakeholder Categories



- Research Funders
- Patients and Consumers
- Researchers
- Clinicians
- Life Sciences Industry
- Health Care Providers
- Policymakers and Regulators
- Payers and Purchasers

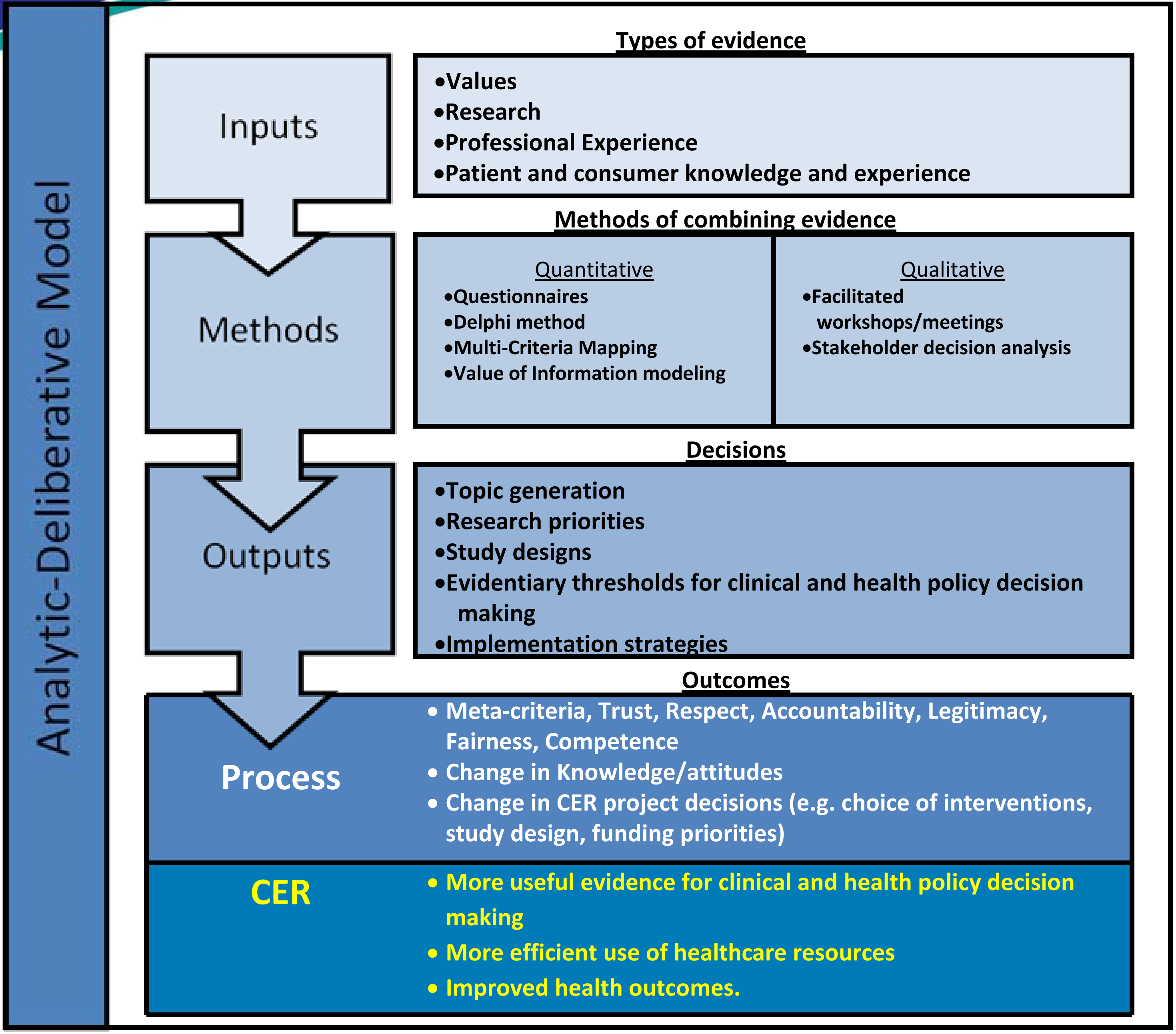
STAKEHOLDER ENGAGEMENT

A process of actively soliciting the knowledge, experience, judgment and values of individuals selected to represent a broad range of direct interests in a particular issue, for the dual purposes of:

1) Creating a shared understanding;

2) Making relevant, transparent, and effective decisions.

Conceptual Model for Stakeholder Engagement in CER



Types of evidence

- **Values**
- **Research**
- **Professional Experience**
- **Patient and consumer knowledge and experience**

Methods of combining evidence

Quantitative

- **Questionnaires**
- **Delphi method**
- **Multi-Criteria Mapping**
- **Value of Information modeling**

Qualitative

- **Facilitated workshops/meetings**
- **Stakeholder decision analysis**

Decisions

- **Topic generation**
- **Research priorities**
- **Study designs**
- **Evidentiary thresholds for clinical and health policy decision making**
- **Implementation strategies**

Outcomes

Process

- **Meta-criteria, Trust, Respect, Accountability, Legitimacy, Fairness, Competence**
- **Change in Knowledge/attitudes**
- **Change in CER project decisions (e.g. choice of interventions, study design, funding priorities)**

CER

- **More useful evidence for clinical and health policy decision making**
- **More efficient use of healthcare resources**
- **Improved health outcomes.**

BACKGROUND

- Few well-established models for effectively engaging patients in research
- In US, investigators, funders or advocates make decisions unilaterally if and how to incorporate the patient perspective into research
- Review of literature confirmed the absence of a clear, shared conceptualization of what it means to effectively engage patients in research
  - Limits our ability to measure the impact of patient contributions to the research process
  - No criteria for assessing the relative effectiveness of various engagement strategies, identifying gaps or making recommendations for improvements.
  - Limits the advancement of meaningful patient engagement in research
  - Presents a critical barrier to the progress of CER/PCOR

OBJECTIVES

- To develop principles and indicators of successful patient engagement in PCOR, so that all participants in the research process can assess individual PCOR studies or proposals for evidence that follow consensus-based principles.
- Build on work done in the UK[1], starting with principles developed by researchers and patient advocates through a 2-round Delphi procedure
- Pilot work to serve as basis for larger proposal to conduct stakeholder-driven consensus research to develop principles for successful involvement of patient in PCOR and indicators to facilitate effective engagement of patients in research activities
  - Principle defined as: "Something we agree should be a standard of successful patient & consumer engagement in research."
  - Indicator defined as: "How we measure the principle; a way tell if the standard has been met; a ruler."

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[1] Boote J, Barber R, Cooper C. Principles and indicators of successful consumer involvement in NHS research: Results of a Delphi study and subgroup analysis. *Health Policy*. 75:280- 297, 2006.

TECHNICAL WORKING GROUP

Center for Advancing Health

Childbirth Connections

Día de la Mujer Latina

3 Patient Representatives: Cancer, CF, Diabetes and Transplantation
(FDA Patient Consultants)

Juvenile Diabetes Research Foundation

Friends of the World Heart Federation Foundation

Consumers United for Evidence-Based Healthcare

Informed Medical Decisions Foundation

Arthritis Foundation

National Coalition for Cancer Survivorship

n = 12

STUDY PROCESS

Draft Principles for Engagement

Online Survey

- Rate Importance and Clarity

In-Person Meeting

- Discuss Content and Wording

Revised Principles for Engagement

Key informant interviews

- Researchers and Research Funders (n=7)

RESULTS

Online Survey and TWG Meeting

- 10/12 TWG members completed the online survey
- None of the principles received a rating lower than 3 (*moderately important*)
- All principles were rated as *very* or *extremely important* (4 or 5) by at least 8 out of the 10 respondents
- 9/13 items were rated as lacking clarity
- Discussion at the TWG meeting focused primarily on improving clarity
- Principles revised based on facilitated discussion of day-long TWG meeting

RESULTS – SELECTED PRINCIPLES

- Researchers and patients make their mutual expectations for patient involvement know to each other
- Researchers provide patients with access to training, personal support and resources so they can be fully involved in research
- The research team obtains feedback from patients to evaluate the engagement process

CONCLUSIONS

- Pilot work confirmed need for principles and indicators to facilitate and measure successful patient engagement in CER
- Consensus development among patients, researchers and research funders is innovative while building on prior work and lessons learned both in US and internationally

NEXT STEPS

- Develop indicators
- Develop appraisal criteria to enable reliable and transparent assessments of proposals or as part of project evaluations
- Applications
  - Provide research funders with specifications for RFPs
  - Provide patients with criteria for evaluating their participation in the research process

THANK YOU!

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