Tufts Clinical and Translational Science Institute

Stakeholder and Community Engagement in Patient-Centered Comparative Effectiveness Research

Thomas Concannon, PhD

September 28, 2016

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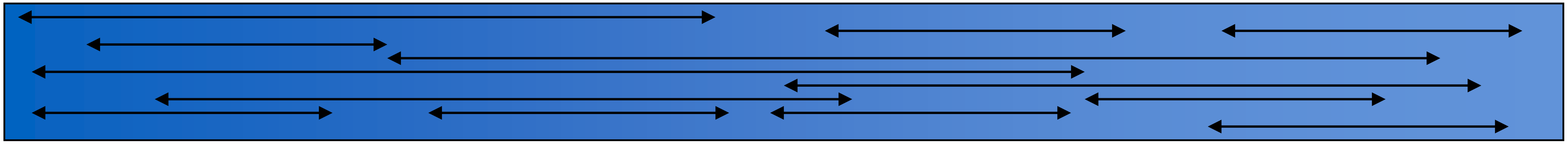
Clinical and Translational Science Awards (CTSA) Program

- National Institutes of Health (NIH) program
- Launched in 2006
- A national consortium of 64 institutions
- **Mission:** to develop innovative solutions that will improve the efficiency, quality and impact of the process for turning observation in the laboratory, clinic and community into interventions that improve the health of individuals and the public

NIH National Center for Advancing Translational Sciences

Spectrum of Clinical and Translational Research



Bench to Bedside… ↔ **...to Widespread Clinical Practice…** ↔ **…to Public Health…** ↔ **…to Health Policy**

Translation (T1)

Translation (T2)

Translation (T3)

Translation (T4)

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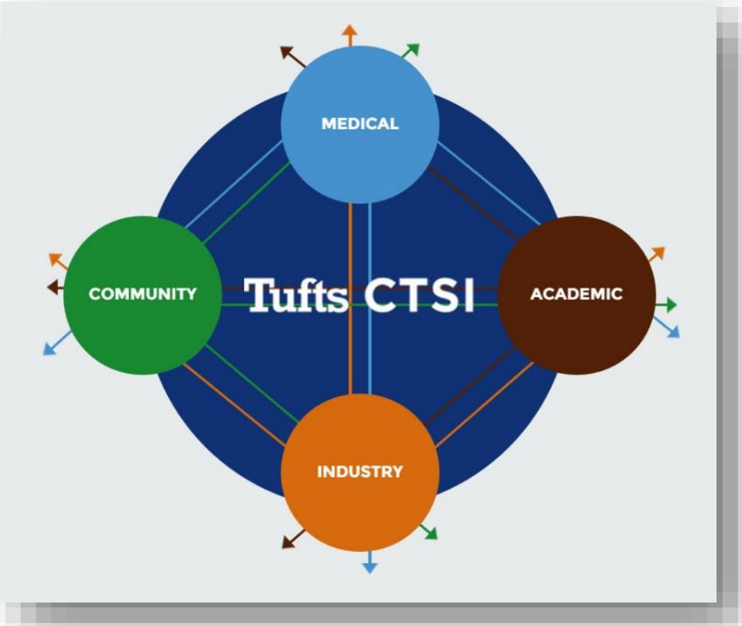
Tufts CTSI's Mission & Purpose

Established in 2008 to translate research into better health



- Stimulate and expedite innovative clinical and translational research, with the goal of improving the public's health
- *Entire spectrum* of clinical and translational research is critical to meeting the promise and the public's needs of biomedical science

39 Tufts CTSI Partners

13 Tufts Schools & Centers

Cummings School of Veterinary Medicine
Fletcher School of Law & Diplomacy
Friedman School of Nutrition Science & Policy
Graduate School of Arts & Sciences
Institute for Clinical Research & Health Policy Studies at Tufts Medical Center
Jean Mayer USDA Human Nutrition Research Center on Aging
Sackler School of Graduate Biomedical Sciences
School of Dental Medicine
School of Engineering
School of Medicine
Tisch College of Citizenship & Public Service
Tufts Center for the Study of Drug Development
Tufts Innovation Institute

3 Academic Partners

Brandeis University
Northeastern University
RAND Corporation

7 Tufts-Affiliated Hospitals

Baystate Medical Center
Lahey Clinic
Maine Medical Center
New England Baptist Hospital
Newton-Wellesley Hospital
St. Elizabeth's Medical Center
Tufts Medical Center

6 Industry/Non-Profit Partners

Blue Cross Blue Shield of Massachusetts
Eli Lilly and Company
Institute for Systems Biology and P4 Medicine Institute
Minuteman Health Network
Pfizer, Inc.
Tufts Health Plan

10 Community-Based Partners

Action for Boston Community Development (ABCD)
Asian Community Development Corporation
Asian Task Force Against Domestic Violence
Asian Women for Health
Boston Chinatown Neighborhood Center
Center for Information and Study on Clinical Research Participation
Greater Boston Chinese Golden Age Center
Health Resources in Action
Museum of Science, Boston
New England Quality Care Alliance

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How Can CTSI Help?

- Connections with other researchers, industry, the community, and policy-makers across the Tufts CTSI network and national CTSA consortium via our **Navigators & Research Collaboration team**.
- Consultations on **comparative effectiveness**, **one health**, **research process improvement** and **stakeholder and community engagement** projects and grants, as well as **regulatory issues** and other areas of translation.
- Study design and data analysis (pre- and post-award) through the **Biostatistics, Epidemiology, and Research Design (BERD) Center**, including drop-in sessions.

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How Can CTSI Help?

- 24/7 clinical trial support through our **Clinical and Translational Research Center (CTRC)**.
- Informatics tools for electronic data capture (**REDCap**), resource sharing, and collaboration.
- Training & professional development including MS and PhD degrees, certificate programs, seminars & workshops, and **paid career development awards and fellowships**.
- Funding through one-year interdisciplinary **pilot studies grants** that support the initial stages of research.

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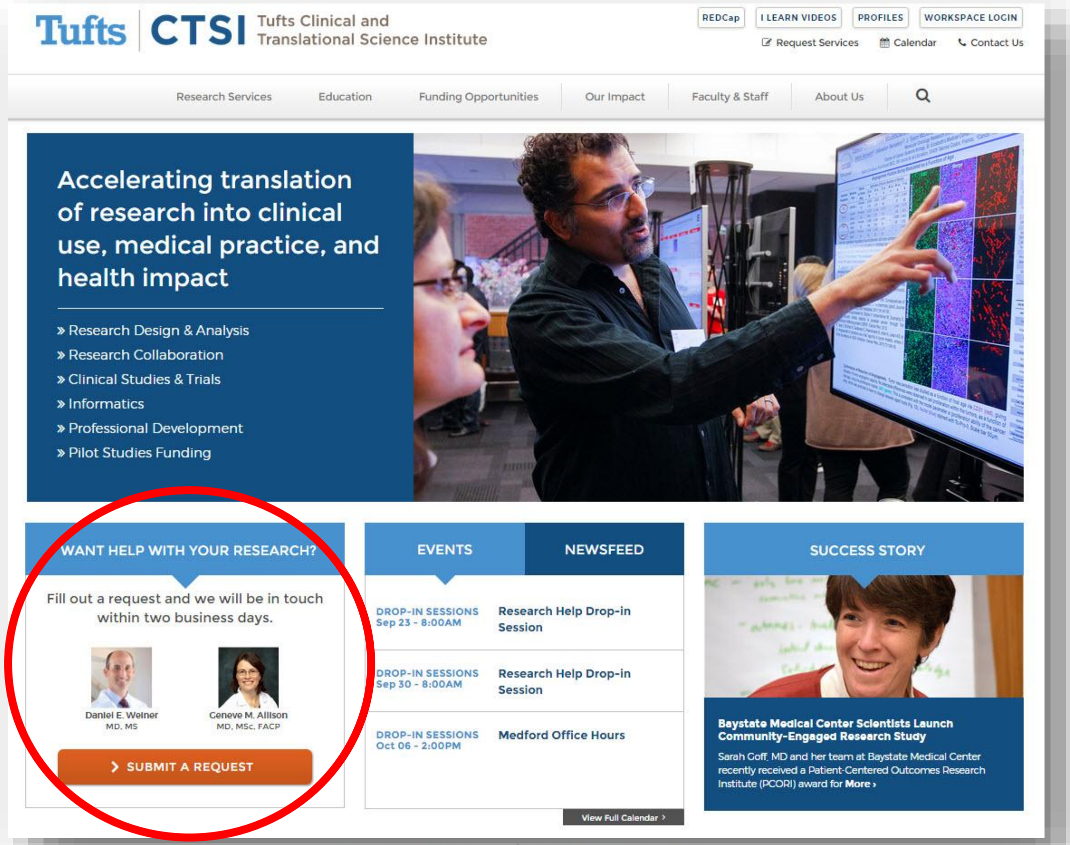
How to Request
Tufts CTSI Services

- Visit www.tuftsctsi.org and submit a request



Accelerating translation of research into clinical use, medical practice, and health impact

» Research Design & Analysis
» Research Collaboration
» Clinical Studies & Trials
» Informatics
» Professional Development
» Pilot Studies Funding

WANT HELP WITH YOUR RESEARCH?

Fill out a request and we will be in touch within two business days.

Daniel E. Weiner
MD, MS

Geneve M. Allison
MD, MSc, FACP

EVENTS	NEWSFEED
DROP-IN SESSIONS Sep 23 - 8:00AM	Research Help Drop-in Session
DROP-IN SESSIONS Sep 30 - 8:00AM	Research Help Drop-in Session
DROP-IN SESSIONS Oct 06 - 2:00PM	Medford Office Hours

SUCCESS STORY

Baystate Medical Center Scientists Launch Community-Engaged Research Study

Sarah Goff, MD and her team at Baystate Medical Center recently received a Patient-Centered Outcomes Research Institute (PCORI) award for **More ›**

http://ilearn.tuftsctsi.org/

Live seminars are recorded for our I LEARN site.
Seminar videos can be viewed at any time, and are free!

Welcome to I LEARN, the Tufts CTSI interactive education website. Tufts CTSI I LEARN is a new resource that offers a comprehensive library of educational courses in clinical and translational research for both professional development and CME credit. Building on our unique curriculum, we are offering some of our courses and workshops in an online learning format, combining professionally videotaped recordings of live lectures with other learning materials to transcend the traditional in-classroom experience.

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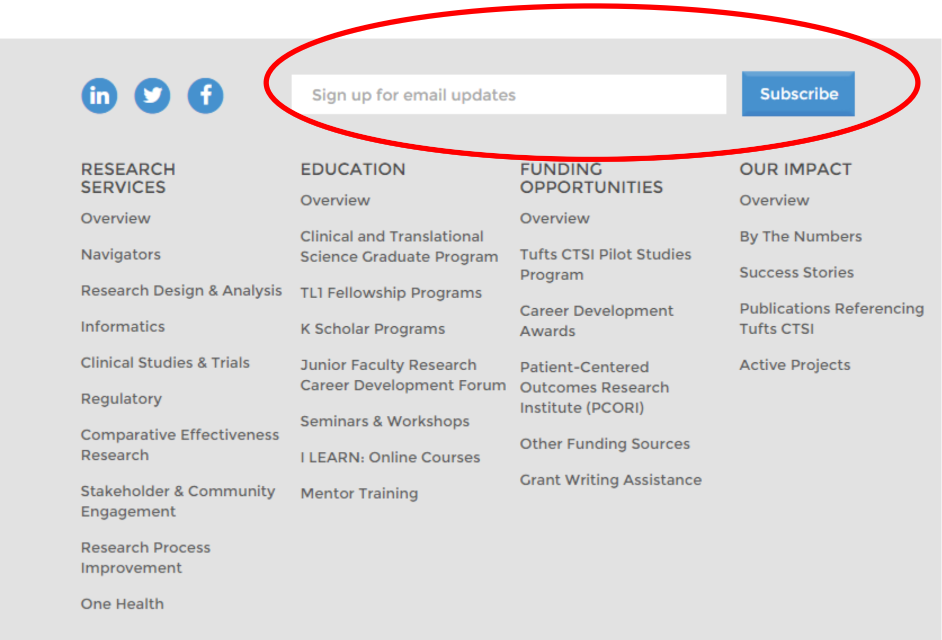
HAPPENINGS



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- Regulatory
- Comparative Effectiveness Research
- Stakeholder & Community Engagement
- Research Process Improvement
- One Health

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- K Scholar Programs
- Junior Faculty Research Career Development Forum
- Seminars & Workshops
- I LEARN: Online Courses
- Mentor Training

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- Career Development Awards
- Patient-Centered Outcomes Research Institute (PCORI)
- Other Funding Sources
- Grant Writing Assistance

OUR IMPACT

- Overview
- By The Numbers
- Success Stories
- Publications Referencing Tufts CTSI
- Active Projects

- Weekly e-newsletter with news, professional development and funding opportunities, resources, and success stories.
- Issued every Monday at 8AM
- Sign up on our website or at http://eepurl.com/C4d9X

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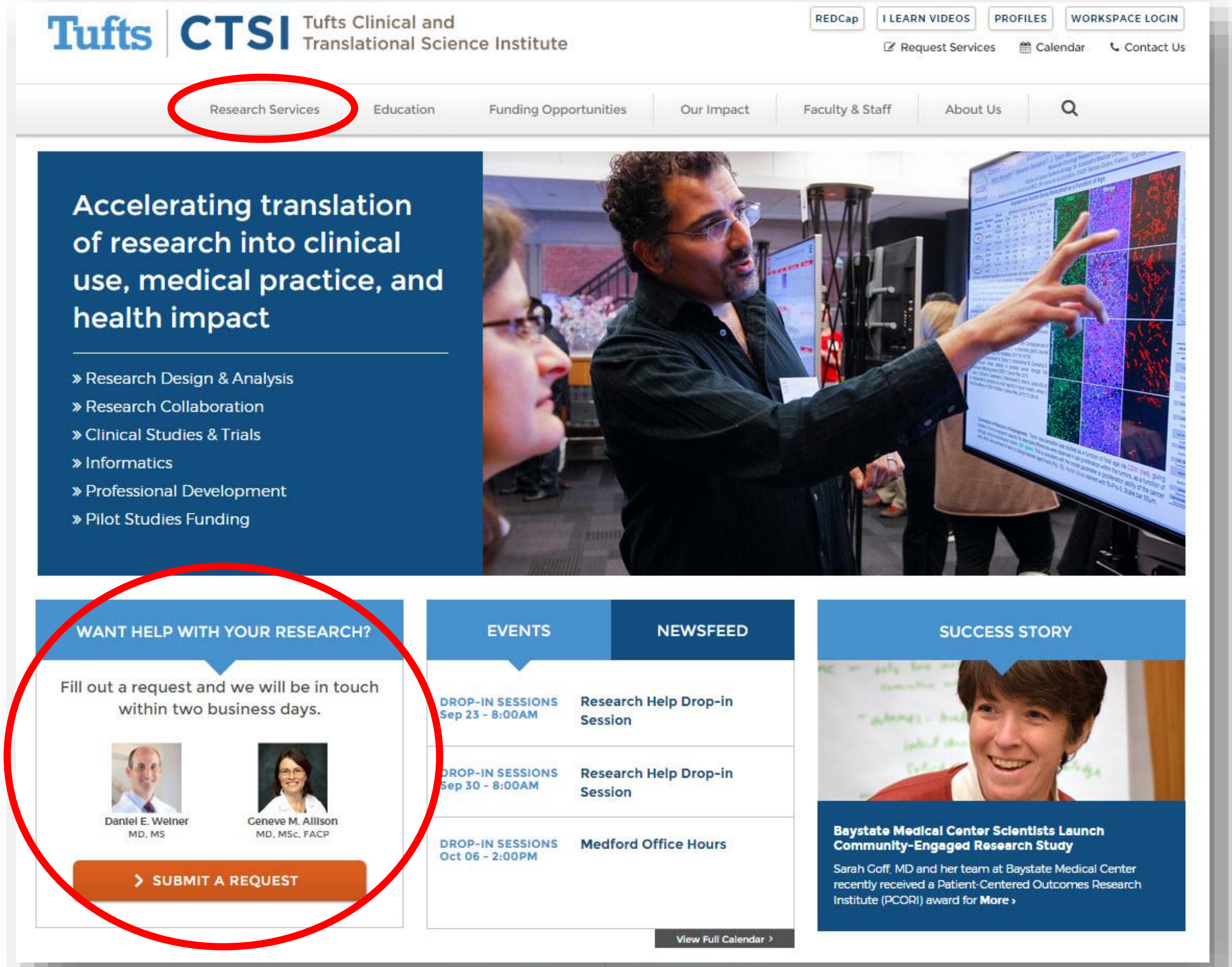
For more information: www.tuftsctsi.org



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Questions?

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September 28, 2016

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Learning Objectives

At the end of this talk, you will be able to describe

- a rationale for engaging stakeholders
- successful frameworks for identifying and recruiting stakeholders, and
- basic principles for planning engagement activities
- how well-intentioned but poorly planned engagements can go wrong

Motivation (a Success Story)

‘This is only Round One. Lower the price or we’ll escalate.’

Peter Staley, 1989

“After [the demonstration], they buckled and lowered the price by 20%. From then on, the industry said it’s probably smarter to try to talk to [activists] and placate them as much as we can.”

Six months later, the FDA reduces the standard dose by half.

-Peter Staley on ACT-UP demonstrations in response to the $10,000/year price of AZT.

ACT UP emerged in 1987

In the first decade of the pandemic, people living with HIV faced

- Devastating illness
- High mortality rates: 31 in 1981 and 18,447 in 1990
- Inaction of most policy makers
- Grindingly slow pace of research

ACT UP was founded to take "direct action to end the AIDS crisis."

Its members went everywhere…

No corner of health care was off limits

Members engaged with health care decision makers in:

- Government
- Industry
- Insurance
- Employment

And they became self-taught experts in:

- Drug development and markets
- Virology, immunology, biostatistics
- Regulatory affairs

…and achieved dramatic change

- Drug marketing and pricing (Burroughs Wellcome)
- Accelerated drug development (NIH & FDA)
- Alternatives to strict placebo control (NIH & FDA)
- Community research initiatives (NIH & AHCPR-now AHRQ)
- Health care delivery (HHS—Ryan White Care Act)
- Updated definition of AIDS (CDC, NIH)

HIV treatment is a home-run for drug therapy

ACT UP became part of the success story that culminated in discovery, development, and rapid uptake of effective treatment for millions of people in the US and across the globe.

What’s the upshot?

ACT UP became *part of the success story* that culminated in discovery, development, and rapid uptake of effective treatment for millions of people in the US and across the globe.

Twenty years later: stakeholder engagement reaches academic and industry research

- New funding for CER (ARRA and ACA 2008-present)
- Requirements for patient and other stakeholder engagement
- PCORI has developed detailed guidance on engagement
- PCORI guidance has influenced funding from AHRQ, NIH and other HHS agencies

“This is hard and I don’t know if it’s worth it.”

If researchers engage patients and other stakeholders, will there be more success stories?

Roadmap

1. Motivation (ACT UP)
2. A framework for engagement
3. How well are researchers doing?
4. Motivation (2009 remix)
5. What have we learned?

Roadmap

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2. **A framework for engagement**
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A New Taxonomy for Stakeholder Engagement in Patient-Centered Outcomes Research

A New Taxonomy for Stakeholder Engagement in Patient-Centered Outcomes Research

Thomas W. Concannon, PhD[1], Paul Meissner, MSPH[2], Jo Anne Grunbaum, EdD[3], Newell McElwee, Pharm.D, MSPH[4], Jeanne-Marie Guise, MD, MPH[5], John Santa, MD, MPH[6], Patrick H. Conway, MD, MSc.[7,8], Denise Daudelin, RN, MPH[1], Elaine H. Morrato, DrPH, MPH[9], and Laurel K. Leslie, MD, MPH[1]

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Despite widespread agreement that stakeholder engagement is needed in patient-centered outcomes research (PCOR), no taxonomy exists to guide researchers and policy makers on how to address this need. We followed an iterative process, including several stages of stakeholder review, to address three questions: (1) Who are the stakeholders in PCOR? (2) What roles and responsibilities can stakeholders have in PCOR? (3) How can researchers start engaging stakeholders? We introduce a flexible taxonomy called the 7Ps of Stakeholder Engagement and Six Stages of Research for identifying stakeholders and developing engagement strategies across the full spectrum of research activities. The path toward engagement will not be uniform across every research program, but this taxonomy offers a common starting point and a flexible approach.

KEY WORDS: stakeholders; research; guidance.
J Gen Intern Med
DOI: 10.1007/s11606-012-2037-1

BACKGROUND

To work well, research needs to address questions that are relevant to patients, physicians, and other health decision makers. While the US research enterprise produces new evidence in great volume,[1] much of this evidence has been difficult to implement in practice.[2] Clinical and health services research has been found wanting because of differences between settings where research is conducted and settings where medicine is practiced;[3] for failure to report how treatment effects vary in individual patients and subgroups;[4–6] and for the under-representation of women, children, racial and ethnic minorities, and patients with co-morbidities.[7–9] Although researchers may prefer to see their work being used in practice, the presumed link between publication and application of research has not been especially strong and is in need of reinforcements.

There is widespread agreement that better stakeholder engagement can help to address this need. Advocates for comparative effectiveness research (CER) and patient-centered outcomes research (PCOR) have been especially strong proponents of this recommendation, on the basis that stakeholder engagement could improve the relevance of research, increase its transparency, and accelerate its adoption into practice.[10–14] These entreaties could result in a new era of stakeholder-engaged research, and an important benchmark for patient-centered research in future years may be that it "is useful to clinicians and patients—and is used."[15]

A NEW TAXONOMY

To date, however, no common taxonomy exists to guide researchers and stakeholders into a new era of stakeholder engaged research. We set out to develop such a taxonomy by offering a definition of "stakeholder" and "engagement," and by addressing three key questions: (1) Who are the stakeholders in PCOR and CER? (2) What roles and responsibilities can stakeholders have in PCOR and CER? (3) How can researchers start engaging stakeholders?

We developed this taxonomy by following an iterative process of drafting and vetting definitions, key questions, and content. The first three drafts and reviews were conducted internally by co-authors to address the key questions, until a complete fourth draft was prepared for

Received December 1, 2011
Revised February 8, 2012
Accepted March 2, 2012

Journal of General Internal Medicine

Thomas Concannon, Paul Meissner, Jo Anne Grunbaum, Newell McElwee, Jeanne-Marie Guise, John Santa, Patrick Conway, Denise Daudelin, Elaine Morrato, Laurel Leslie

Guiding Questions

1. **Who is a CER stakeholder?**
2. **What kind of research qualifies as CER?**
3. How can researchers start engaging stakeholders?

Definitions

Stakeholder – An individual or group who is responsible for or affected by health- and healthcare-related decisions that can be informed by research evidence.

Stakeholder Engagement – A bi-directional and sustained relationship between stakeholder and researcher that results in informed decision-making about the selection, conduct and use of research.

Definitions

Stakeholder – An individual or group who is **responsible for or affected by health- and healthcare-related decisions** that can be informed by research evidence.

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Introduces Three Items

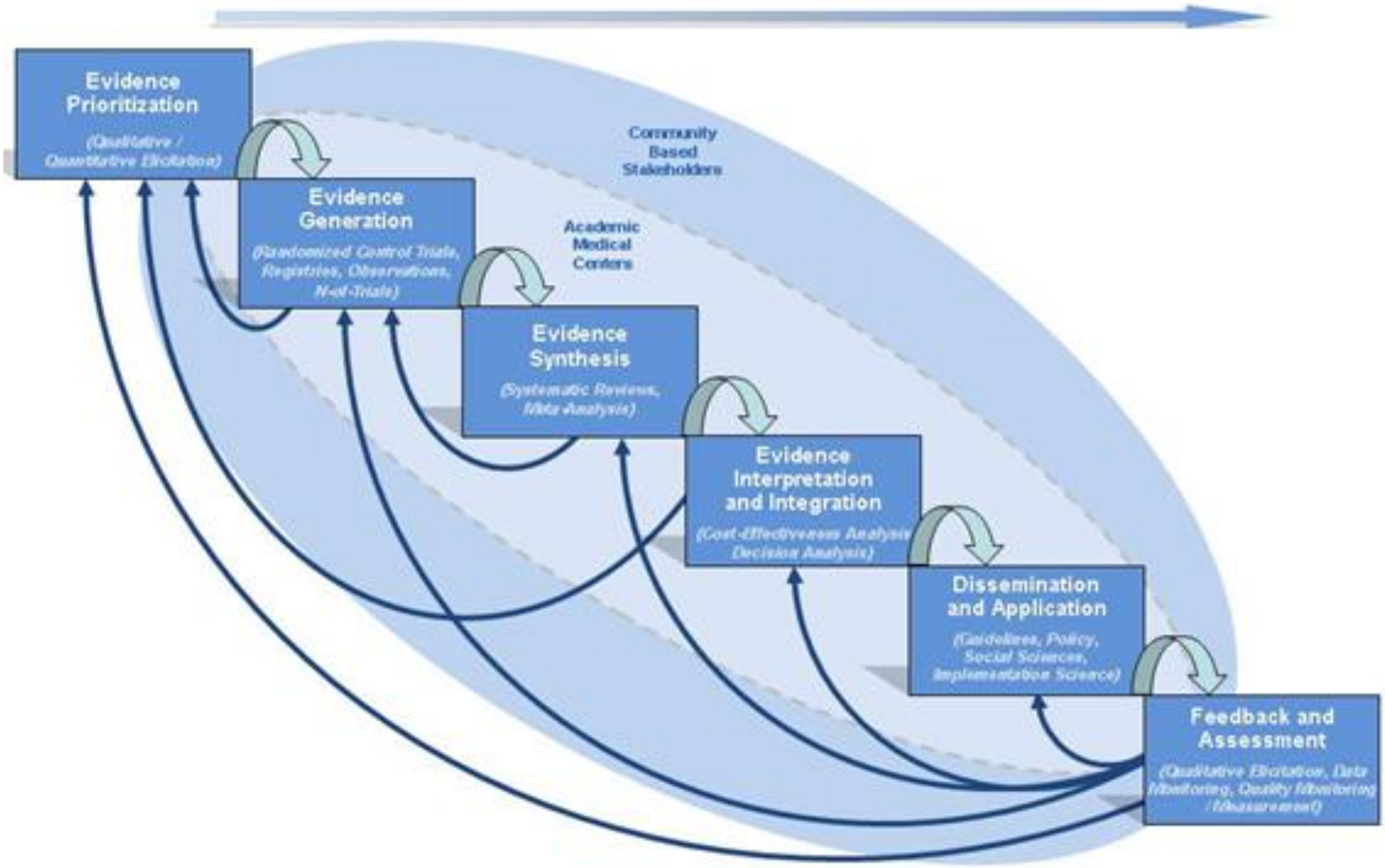
1. **7Ps Framework – types of stakeholders**
2. **6 Stage Model of CER – stages of research**
3. A Plan-Do-Study-Act approach to stakeholder and community engagement

The 7Ps Framework

Category	Description
Patients and Public	Current and potential consumers of patient-centered health care and population focused public health, their caregivers, families and patient and consumer advocacy organizations.
Providers	Individuals (e.g. nurses, physicians, mental health counselors, pharmacists, and other providers of care and support services) and organizations (e.g. hospitals, clinics, community health centers, community based organizations, pharmacies, EMS agencies, skilled nursing facilities, schools) that provide care to patients and populations.
Purchasers	Employers, the self-insured, government and other entities responsible for underwriting the costs of health care.
Payers	Insurers, Medicare and Medicaid, state insurance exchanges, individuals with deductibles, and others responsible for reimbursement for interventions and episodes of care.
Policy Makers	The White House, Department of Health and Human Services, Congress, states, professional associations, intermediaries, and other policy-making entities.
Product Makers	Drug and device manufacturers
Principal Investigators	Other researchers and their funders

The Six Stage Model of CER

Translational Spectrum of Comparative Effectiveness Research at Tufts CTSI



Evidence Prioritization
(Qualitative / Quantitative Elicitation)

Evidence Generation
(Randomized Control Trials, Registries, Observations, N-of-Trials)

Evidence Synthesis
(Systematic Reviews, Meta Analysis)

Evidence Interpretation and Integration
(Cost-Effectiveness Analysis Decision Analysis)

Dissemination and Application
(Guidelines, Policy, Social Sciences, Implementation Science)

Feedback and Assessment
(Qualitative Elicitation, Data Monitoring, Quality Monitoring /Measurement)

Community Based Stakeholders

Academic Medical Centers

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Roadmap

1. Motivation (ACT UP)
2. A framework for engagement
3. **How well are researchers doing?**
4. Motivation (2009 remix)
5. What have we learned?

Research Question

What are researchers *reporting about engagement*?

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stakeholder and community - engaged

^

A systematic review of what we (researchers) have been publishing

Four steps:

1. Describe what we want to know
2. Search and screen literature
3. Extract data
4. Evaluate what we find

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Stakeholders

Category Subcategory	Name	Organization
Patients and the public		
Consumer	Grant P. Thompson	Consumer Reports Panel
Consumer	Gerald Rasmussen	Consumer Reports Panel
Providers		
Provider group	Judy Bradford	Fenway Institute/Fenway Health
Payers and Purchasers		
Self-insured employer	Lawrence Becker	Xerox
Policy Makers		
Federal research	JoAnne Grunbaum	Centers for Disease Control & Prevention
Product Makers		
Pharmaceutical	Eleanor Perfetto	Pfizer
Principal investigators		
Health services	Julie Lynch	University of Massachusetts Boston
Clinical	Radley (Chris) Sheldrick	Tufts Medical Center

What do we want to know?

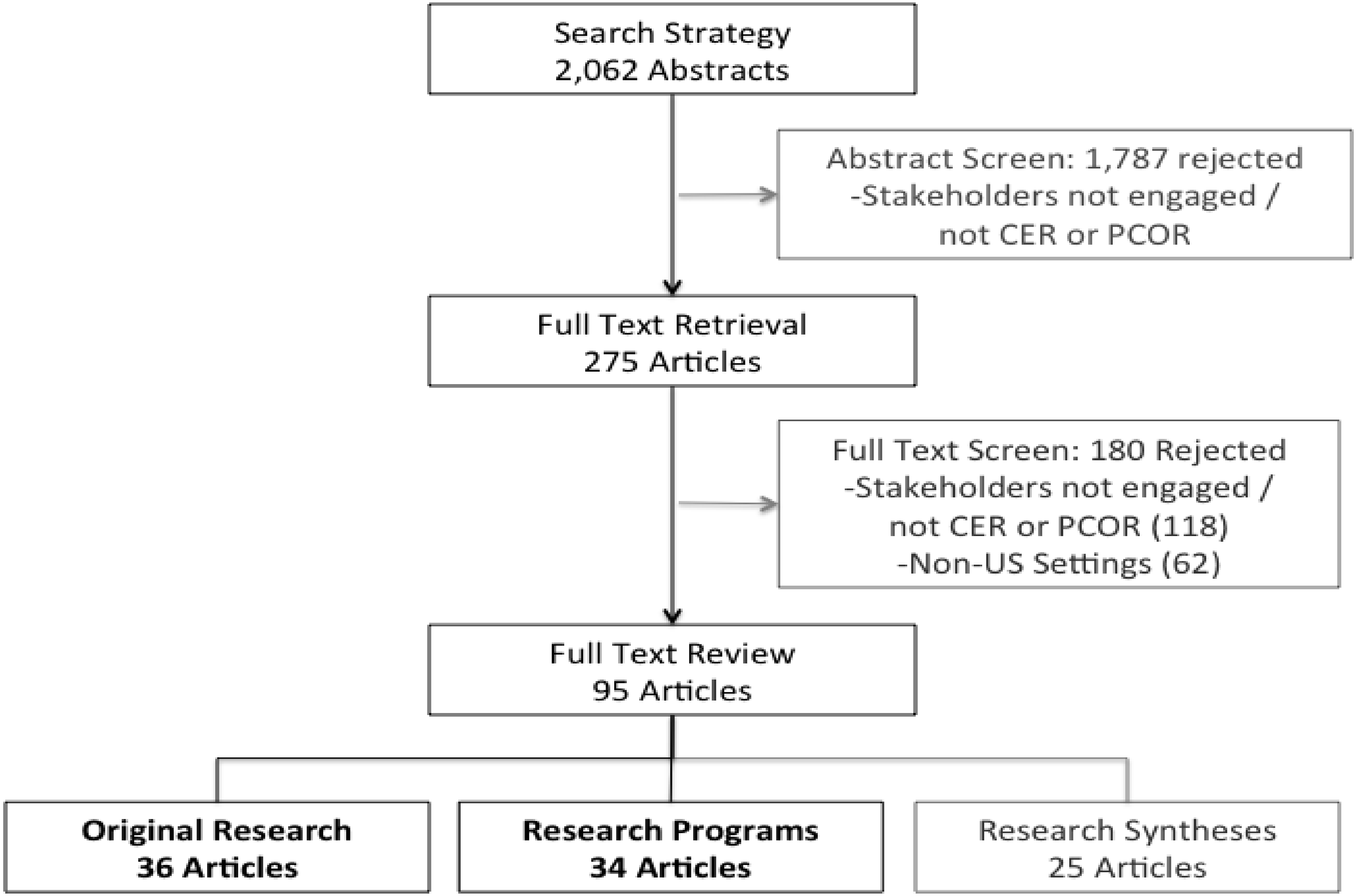
1. **Types of stakeholders?**
2. **Stages of CER?**
3. Types of engagement?
4. Special provisions for patients?

We searched published literature with key words

1. Stakeholders – patients through principal investigators
2. Stages of research – prioritization through feedback and assessment
3. PCOR and CER

76 terms

A summary of what we found



Search Strategy
2,062 Abstracts

Abstract Screen: 1,787 rejected
-Stakeholders not engaged /
not CER or PCOR

Full Text Retrieval
275 Articles

Full Text Screen: 180 Rejected
-Stakeholders not engaged /
not CER or PCOR (118)
-Non-US Settings (62)

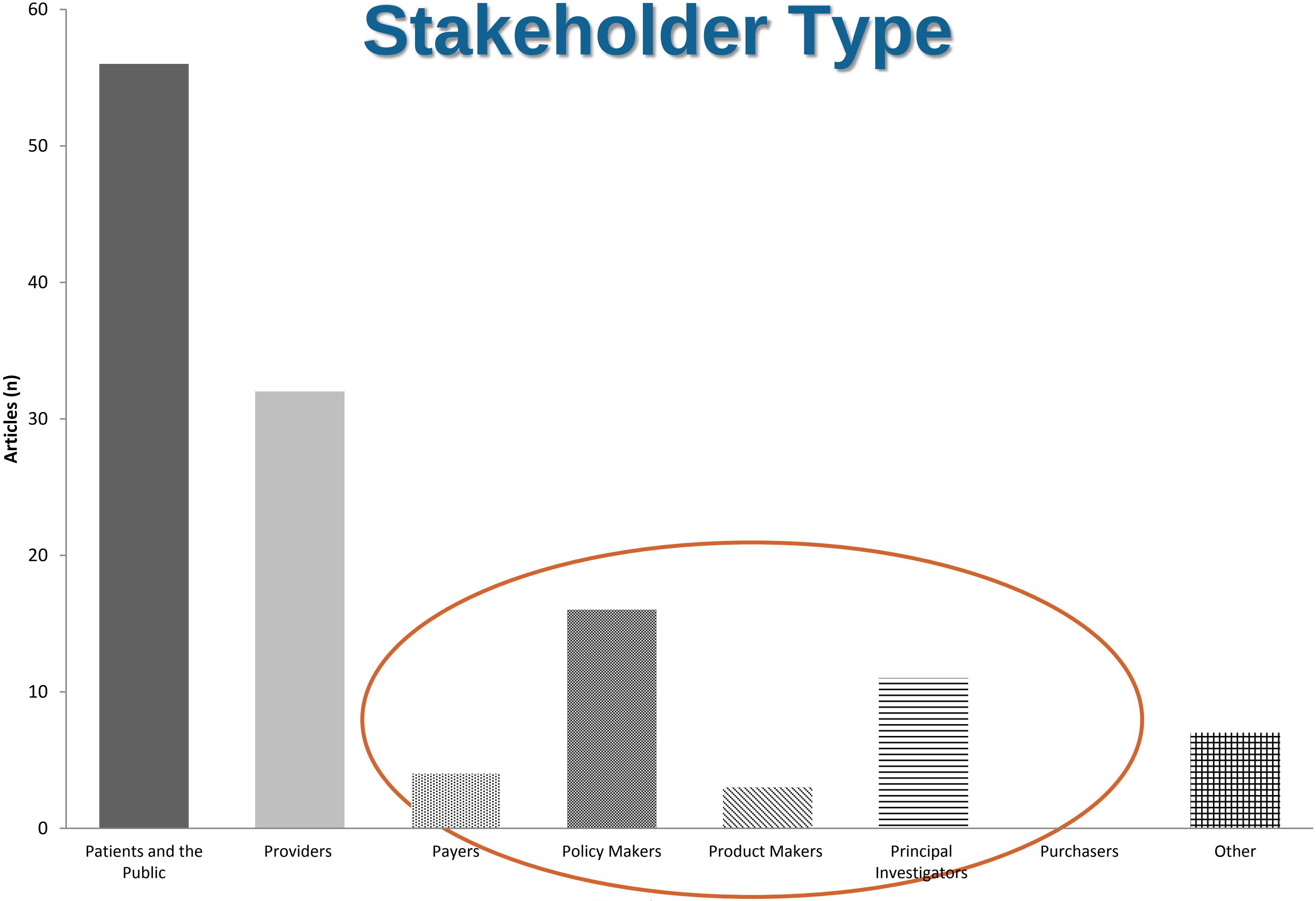
Full Text Review
95 Articles

Original Research
36 Articles

Research Programs
34 Articles

Research Syntheses
25 Articles

Stakeholder Type



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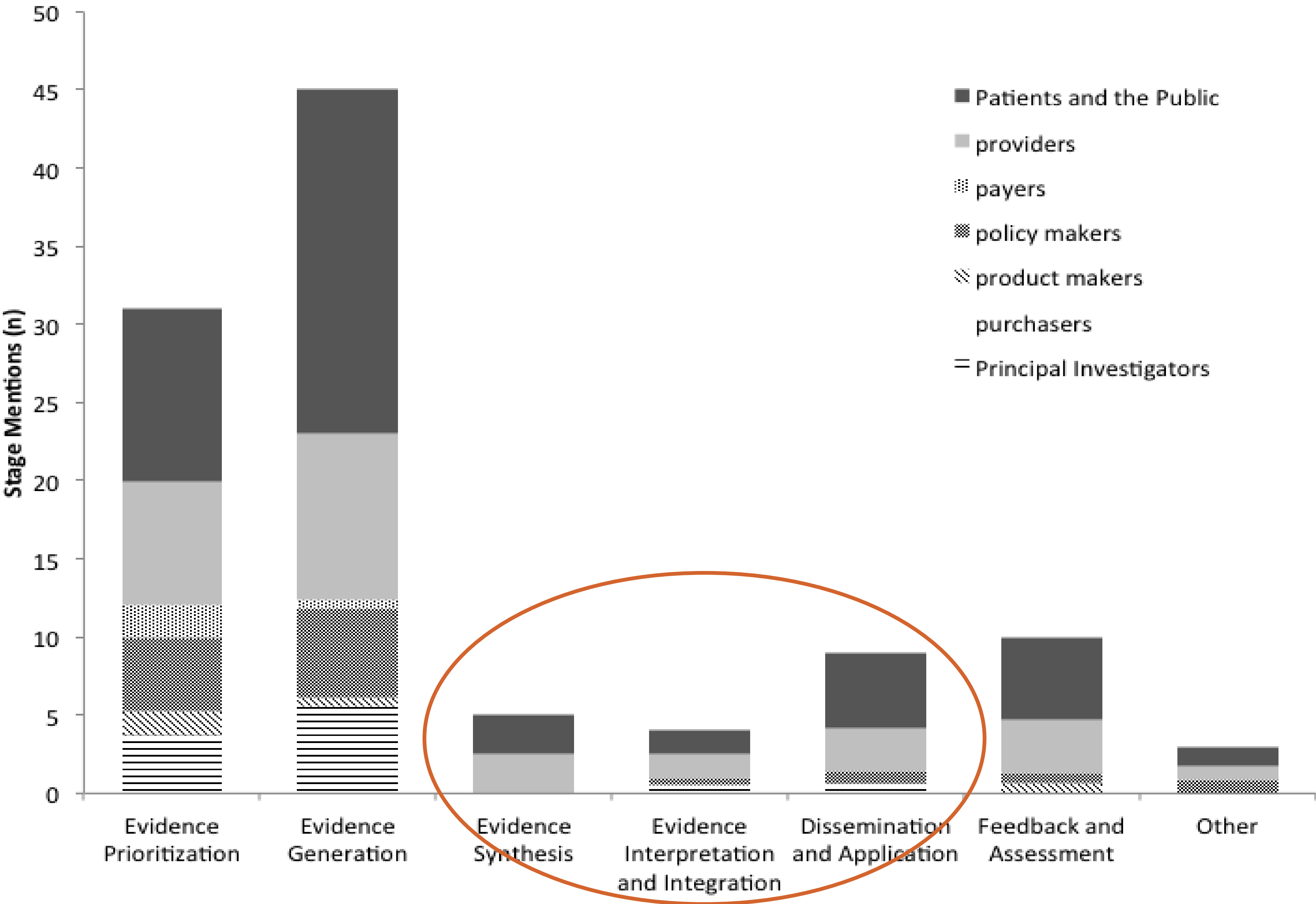
Stage of Research x Stakeholder Type



Seven-Item Reporting Questionnaire

1. What types of stakeholders?
2. A priori target number(s) used and met?
3. How was balance considered and achieved?
4. Methods to identify, recruit and enroll stakeholders?
5. Engagement before, during and after research?
6. Methods and modes of engagement?

Seven-Item Reporting Questionnaire

7. Impact of engagement on:
   - the **relevance** of research questions;
   - the **transparency** of the research process;
   - the **adoption** of evidence into practice settings?

Roadmap

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Motivation (a Spectacular Failure)

”[F]eedback about the recommendations …makes it clear that we need to have better messages.”

Vice Chair of USPSTF on the widespread opposition to the Mammography Screening Guideline.

Diana Petitti, 2009

USPSTF includes some experts and engages with some stakeholders…

Has 16 volunteer members who are experts in prevention, evidence-based medicine, and primary care

Engages partner organizations such as medical societies, insurers and consumer organizations

- *Before* guideline development: topic identification
- *After* guidelines are completed: dissemination

…but does not engage with all stakeholders

Some stakeholders are excluded *during* guideline development

- If they do not have methodological expertise (patients)
- If they have a perceived conflict of interest (industry, payers, employers, subspecialties)

Breast cancer screening review and guidelines were re-issued in 2009…

Review

Mammography screening reduces breast cancer mortality *on average* by

- 15% in women ages 39-49
- 14% in women ages 50-59
- 32% in women ages 60-69

Younger women are more likely to have false positive diagnoses from mammography screening

Breast cancer screening review and guidelines were re-issued in 2009…

Recommendations

Routine, biennial mammography for women ages 50-74

Mammography for women younger than 50 only after considering individual factors and patient preferences

- Should be available but not routine

Women of all ages should talk with their doctors about their risks for breast cancer and their preferences for screening

Breast cancer screening review and guidelines were re-issued in 2009…

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Mammography for women younger than 50 only after considering individual factors and patient preferences

- Should be available but **NOT ROUTINE**

Women of all ages should talk with their doctors about their risks for breast cancer and their preferences for screening

The release unleashed vehement opposition from radiologists, oncologists, patients advocacy groups

The release unleashed vehement opposition from *groups that were excluded from guideline development*

- New guidelines would “turn back the clock in the war on breast cancer.”
- Bi-partisan legislation guaranteed coverage of annual screening
- Many physicians and institutions resisted the guidelines
- Guidelines did not substantially alter screening practices

Roadmap

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3. How well are researchers doing?
4. Motivation (2009 remix)
5. **What have we learned?**

Lessons

1. Engage with all stakeholders
    - Exclusions can backfire
    - Use a structured process to identify and recruit stakeholders
    - All stakeholders are experts on their own views, including patients
    - Conflict of interest can be managed and is not an excuse to exclude industry and subspecialists

Lessons

2. How you engage may be as important as that you engage
    - Prepare everyone
    - Same place, same time
    - Sustained relationships
    - Expert-led
    - Choose modes and methods carefully
    - Get advice

Lessons

3. Engagement is like any other activity in research
    - Doing it right is no guarantee of success
    - It may require tradeoffs with other goals of research

Thank you

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