2018 Online KT Conference: Engaging Ways to Engage Stakeholders

Hosted by AIR’s Center on KTDRR

November 5, 7, and 9, 2018
How Do You Know Stakeholders Have an Impact on Research?

Thomas Concannon, PhD
November 9, 2018
Road Map

1. Motivation (1987)
2. Motivation (2009 remix)
3. How to plan engagement
4. How to know if engagement works
Road Map

1. Motivation (1987)
2. Motivation (2009 remix)
3. How to design engagement activities
4. How to know if engagement works
Road Map

1. Motivation (1987)
2. Motivation (2009 remix)
3. How to plan engagement
4. How to know if engagement works
Motivation (a Success Story)

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

“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.

Peter Staley, 1989
“How to Survive a Plague”
https://surviveaplague.com
ACT UP emerged in 1987

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

- Devastating illness
- Inaction of most policy makers
- Grindingly slow pace of research

Source: Morbidity and Mortality Weekly Report: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6021a1.htm

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.
What’s the upshot?

Activism by people living with HIV and AIDS encouraged waves of patient-initiated engagement in health care and research.
But academic and industry research were (mostly) shielded from patient activism, until recently

- 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 job would be great if there were no patients.”

— Patient advocate, sometime between 1996 and 2001
If researchers engage patients and other stakeholders, will there be more success stories?
Road Map

1. Motivation (1987)
2. Motivation (2009 remix)
3. How to plan engagement
4. How to know if engagement works
Motivation (a Spectacular Failure)

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

Diana Petitti, 2009
(Video still from CNN.)
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...

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...

**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
The release unleashed vehement opposition from radiologists, oncologists, patients, and 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.”
• Bipartisan legislation guaranteed coverage of annual screening
• Many physicians and institutions resisted the guidelines
• Guidelines did not substantially alter screening practices
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
How you engage is important

• Prepare everyone
• Same place, same time
• Sustained relationships
• Expert-led
• Choose modes and methods carefully
• Get advice
Engagement is like any other activity in research

• Doing it right is no guarantee of success
• It may require trade-offs with other goals of research
Road Map

1. Motivation (1987)
2. Motivation (2009 remix)
3. How to plan engagement
4. How to know if engagement works
Four considerations before you begin

1. Why are you working with stakeholders?
   • What are the intrinsic reasons?
   • How will engagement improve your research?
   • How engagement improve health care or outcomes?
Four considerations before you begin

2. With whom will you partner?
   – What model will you use to identify stakeholders?
   – What is the research for?
     • Which communities make decisions the research is meant to inform?
     • Which communities are affected by decisions the research is meant to inform?
   – How do the communities wish to be engaged?
Choose a framework for identifying stakeholders

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
<th>Type</th>
<th>Description</th>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patients and the Public</strong></td>
<td>Current and potential consumers of patient-centered health care and population-focused public health, their caregivers, families and patient and consumer advocacy organizations.</td>
<td>Patients</td>
<td>Persons with current or past experience of illness or injury, family members or other unpaid caregivers of patients, or members of advocacy organizations that represent patients or caregivers.</td>
<td>Patients and Consumers</td>
<td>Persons or organizations that represent the patient or consumer perspective generally, or within specific disease states, such as individuals with particular conditions, caregivers, patient advocates and advocacy organizations.</td>
</tr>
<tr>
<td><strong>Providers</strong></td>
<td>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.</td>
<td>Clinicians</td>
<td>Providers of health care in a clinical setting, including physicians, nurses, physician assistants, rehabilitative professionals, pharmacists, mental healthcare providers, complementary and alternative healthcare providers, and professional societies serving clinicians.</td>
<td>Clinicians</td>
<td>Individuals who provide healthcare services, such as physicians, nurses, pharmacists, nurse practitioners, physician assistants and mental health providers.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hospitals and Health Systems</td>
<td>Organizations where care is delivered, including public and private hospitals and health systems, urgent care centers, retail health clinics, and community health centers, and organizations representing these facilities.</td>
<td>Healthcare providers</td>
<td>Institutions that deliver healthcare services, such as hospitals, nursing homes, outpatient clinics, clinical laboratories and accountable healthcare organizations.</td>
</tr>
<tr>
<td><strong>Payers</strong></td>
<td>Insurers, Medicare and Medicaid, state insurance exchanges, individuals with deductibles, and others responsible for reimbursement for interventions and episodes of care.</td>
<td>Payers</td>
<td>Those who function as financial intermediaries in the health system, including private insurers and public insurers, and organizations representing insurers, such as America’s Health Insurance Plans.</td>
<td>Payers and purchasers</td>
<td>Organizations that pay for healthcare goods and services, such as public and private insurers, health plans and employers.</td>
</tr>
<tr>
<td><strong>Purchasers</strong></td>
<td>Employers, the self-insured, government and other entities responsible for underwriting the costs of health care.</td>
<td>Purchasers</td>
<td>Those who purchase health benefits for employees and their dependents, including individual businesses as well as local, state, regional, and national business groups, coalitions that represent businesses, and health coalitions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Product Makers</strong></td>
<td>Drug and device manufacturers.</td>
<td>Industry</td>
<td>Companies that design, invest in, or manufacture diagnostics, devices, pharmaceuticals, electronic records systems, and mobile apps, and organizations representing the life sciences industry, such as the Advanced Medical Technologies Association.</td>
<td>Life sciences industry</td>
<td>Entities that develop and market medical technologies, such as pharmaceutical, medical device, diagnostic, biotechnology companies and organizations that represent life science company interests.</td>
</tr>
<tr>
<td><strong>Policy Makers</strong></td>
<td>The White House, Department of Health and Human Services, Congress, states, professional associations, intermediaries, and other policy-making entities.</td>
<td>Policy Makers</td>
<td>Those who help craft public policy at any level of government, including federal, state, and local government officials; federal, state, and local units of government; and organizations that represent policy makers.</td>
<td>Policy-makers and regulators</td>
<td>Individuals and organizations that create, monitor and oversee policies or regulations of healthcare-related issues, such as federal, state and local government agencies, medical and professional organizations and clinical guideline developers.</td>
</tr>
<tr>
<td><strong>Groups described in PCORI’s definition of Training Institutions are distributed in 3Ps: Principal Investigators, Providers and Policy Makers</strong></td>
<td>Training Institutions</td>
<td>Those that deliver health professional education include public and private universities and colleges, individuals affiliated with the delivery or administration of health professional education, and trade or professional associations representing these Institutions, organizations, and individuals</td>
<td>Groups described in PCORI’s definition of Training Institutions are distributed in 3 CMTP types: researchers, policy makers and regulators, and healthcare providers</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Principal Investigators</strong></td>
<td>Other researchers and their funders.</td>
<td>Researchers</td>
<td>Those who conduct clinical research, including investigators or funders of research and organizations or associations representing the research community.</td>
<td>Researchers</td>
<td>Individuals and their related organizations that develop scientific and clinical evidence, such as clinical researchers, health services researchers, social scientists and basic scientists.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Research Funders</td>
<td>Entities that provide monetary support for research efforts, such as government, foundations and for-profit organizations.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The Seven Ps Framework

<table>
<thead>
<tr>
<th>Stakeholder Community</th>
<th>Rationale for Involvement</th>
<th>Target #</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Decisions they make</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>How they are affected</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Providers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchasers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Policy Makers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Makers</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Principal Investigators</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Four considerations before you begin

3. How extensively will the stakeholders be engaged...
   • in preparing for research?
   • in conducting the research?
   • in using the research?
   • How intensively can stakeholders be involved in each activity?
   • What resources and time will be devoted to engagement activities?
Four considerations before you begin

4. What are the appropriate roles and modes by which stakeholders may be engaged?
   • Roles
     • Will stakeholders have control over the project?
     • Will stakeholders help the research team carry out the research?
     • Will stakeholders provide input but neither conduct nor help with the research directly?
   • Modes
     • Will activities be conducted in person or remotely?
     • Will activities be conducted with individuals?
     • Will activities be conducted with groups?
     • Will stakeholder communities be mixed in multi-stakeholder activities?
     • What conflict of interest procedures and conflict management resources are needed?
## Select roles and describe modes

<table>
<thead>
<tr>
<th>Research Stage</th>
<th>Research Activity</th>
<th>Stakeholder Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparing for research</td>
<td>Building research capacity of patients and other stakeholders</td>
<td>Patients &amp; the public, Providers, Payers, Purchasers, Product Makers, Policy Makers, Principal Investigators</td>
</tr>
<tr>
<td></td>
<td>Training researchers to work with stakeholders</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prioritizing evidence gaps</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Choosing research topics</td>
<td></td>
</tr>
<tr>
<td>Conducting research</td>
<td>Defining the research question</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Choosing relevant outcomes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Designing a research protocol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Defining participant inclusion &amp; exclusion criteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drafting or revising study materials &amp; protocols</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recruiting participants</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitoring patient data and safety</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Collecting data</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Analyzing data</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Identifying findings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Interpreting findings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disseminating results</td>
<td></td>
</tr>
<tr>
<td>Using research</td>
<td>Implementing evidence in practice</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evaluating research</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evaluating engagement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Identifying topics for future research</td>
<td></td>
</tr>
</tbody>
</table>

Copyright © Dr. Thomas Concannon.
Road Map

1. Motivation (1987)
2. Motivation (2009 remix)
3. How to plan engagement
4. How to know if engagement works
Three Dimensions of Impact

1. Inventories of engaged research
2. Adherence to principles of
   - Patient centeredness
   - Engagement
   - Translation
3. Impact on health care and outcomes
## Inventory: Study Registration

<table>
<thead>
<tr>
<th>Research Stage</th>
<th>Research Activity</th>
<th>Stakeholder Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparing for research</td>
<td>Building research capacity of patients and other stakeholders</td>
<td>Patients &amp; the public, Providers, Payers, Purchasers, Product Makers, Policy Makers, Principal Investigators</td>
</tr>
<tr>
<td></td>
<td>Training researchers to work with stakeholders</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prioritizing evidence gaps</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Choosing research topics</td>
<td></td>
</tr>
<tr>
<td>Conducting research</td>
<td>Defining the research question</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Choosing relevant outcomes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Designing a research protocol</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Defining participant inclusion &amp; exclusion criteria</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drafting or revising study materials &amp; protocols</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recruiting participants</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monitoring patient data and safety</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Collecting data</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Analyzing data</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Identifying findings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Interpreting findings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disseminating results</td>
<td></td>
</tr>
<tr>
<td>Using research</td>
<td>Implementing evidence in practice</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evaluating research</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evaluating engagement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Identifying topics for future research</td>
<td></td>
</tr>
</tbody>
</table>

Copyright © Dr. Thomas Concannon.
Ask stakeholders

1. Is the research question relevant to decisions you make?
2. Can you describe what the research was about?
3. How will the evidence be used?
Thank you!

tconcann@rand.org
Disclaimer

The contents of this presentation were developed under grant number 90DPKT0001 from the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). NIDILRR is a Center within the Administration for Community Living (ACL), Department of Health and Human Services (HHS). The contents of this presentation do not necessarily represent the policy of NIDILRR, ACL, HHS, and you should not assume endorsement by the Federal Government.

Don’t forget to fill out the evaluation form!