

# Stakeholder Engagement in Research

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Introduction to Clinical and  
Translational Research at UMB



**Ellen Tambor | August 10, 2021**

**CENTER FOR MEDICAL TECHNOLOGY POLICY**

# Who We Are

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## Center for Medical Technology Policy

- Independent non-profit located in Baltimore, MD
- Our Mission:  
To improve the quality, relevance, and efficiency of clinical research so that patients, clinicians, and other healthcare stakeholders have the evidence they need to make informed decisions

*Better Evidence. Better Decisions. Better Health*



# Topics

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- Rationale for engagement
- Deciding who to engage
- Stakeholder contributions to research
- Engagement principles and methods

# Definitions

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

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

*Concannon et al, 2012*

# Taxonomy of Stakeholder Roles

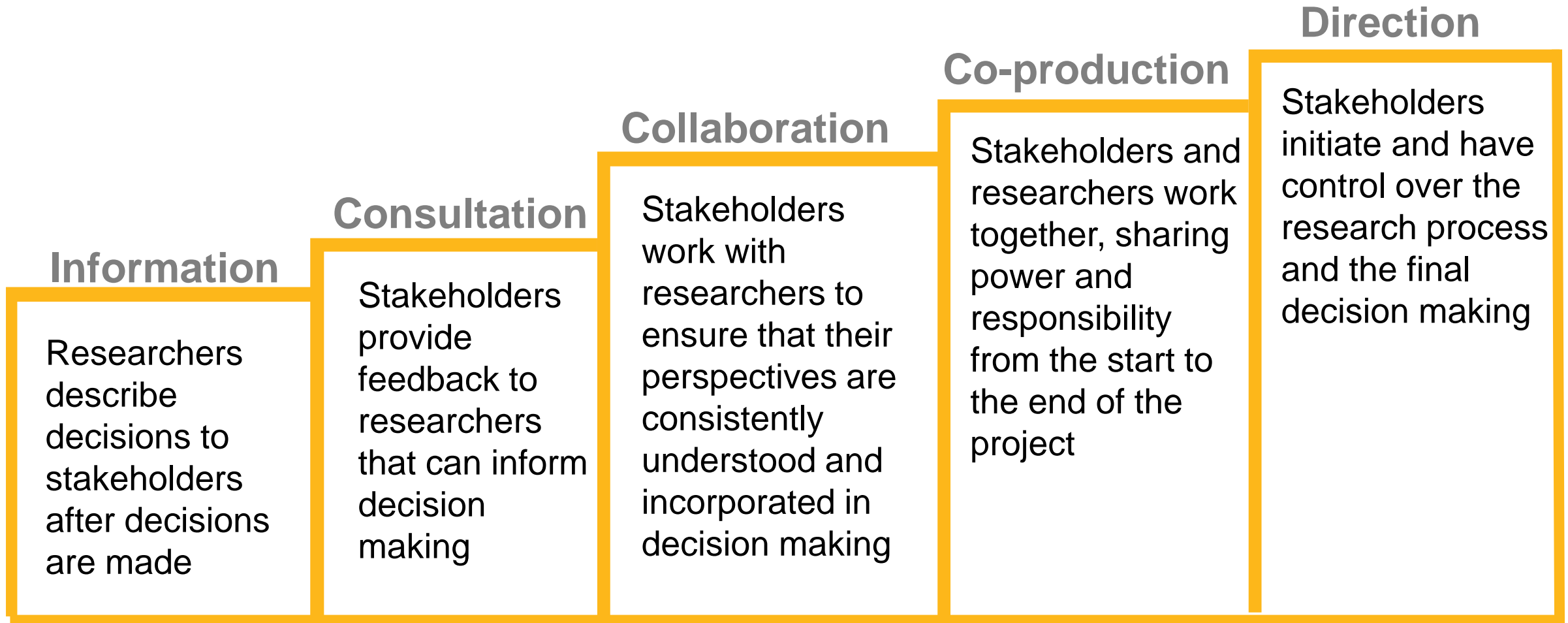
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- **Study personnel:** Interact with research subjects in a study-related capacity and/or have access to identifiable data
- **Advisor:** Do not have access to research subjects and/or identifiable data but do formally advise on protocol development, study end points, or recruitment strategies or participate in activities that may inform the design or conduct of the study
- **Research subject:** Patients and other stakeholders should be considered research subjects when they satisfy the definition provided in the federal regulations.

*Gelinas et al, 2018*

# Levels of Engagement

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# Rationale for Engagement

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**Moral/Ethical  
Arguments**

**Pragmatic  
Arguments**

# Rationale for Engagement

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**Moral/Ethical Arguments**

Right of citizens to have a voice in the use of public funds

**Pragmatic Arguments**



# Rationale for Engagement

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Right of individuals to be involved in shaping research that pertains to them

## Pragmatic Arguments

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*“Nothing about us, without us”*

**Pragmatic Arguments**

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## Pragmatic Arguments

Improving the quality, relevance, and usefulness of clinical research

Increasing transparency, credibility, trust in the clinical research enterprise

# Engagement to Increase Health Equity

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**Growing national focus on health disparities and the critical need to increase diversity among clinical trial participants**

*“**Authentic partnerships** between and among patients and participants, their caregivers, patient advocacy groups, community-based organizations, cultural and faith-based organizations, places of worship, and non-profit organizations, on the one hand, and with investigators, research teams, sponsors, clinicians, and clinical research sites on the other, **are necessary for research programs to be responsive to the needs of affected populations and successfully to recruit and retain underrepresented and underserved populations.**”\**

*Bierer et al, 2021*

# Who to Engage

# Who to Engage

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- Who will use the evidence to make decisions or be affected by those decisions?
- Whose involvement is necessary to successfully complete the study?

# Who to Engage

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**“Patients”**

**Clinicians**



# Who to Engage

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## “Patients”

Patients

Advocates

Family Members

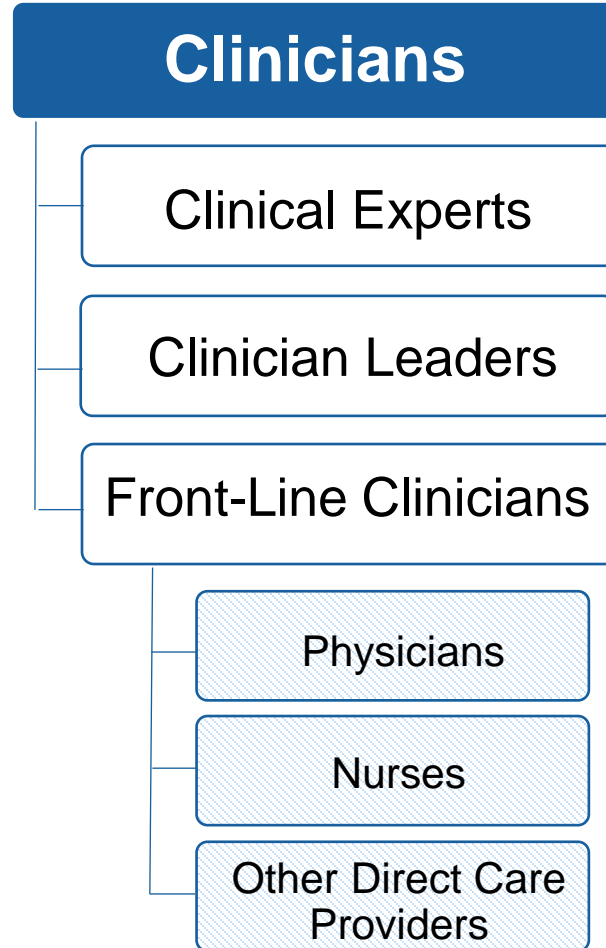
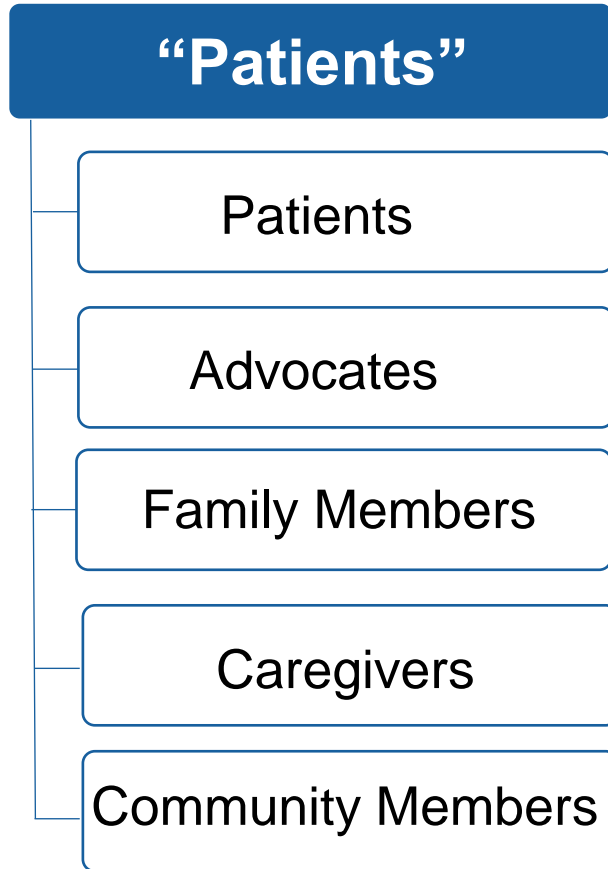
Caregivers

Community Members

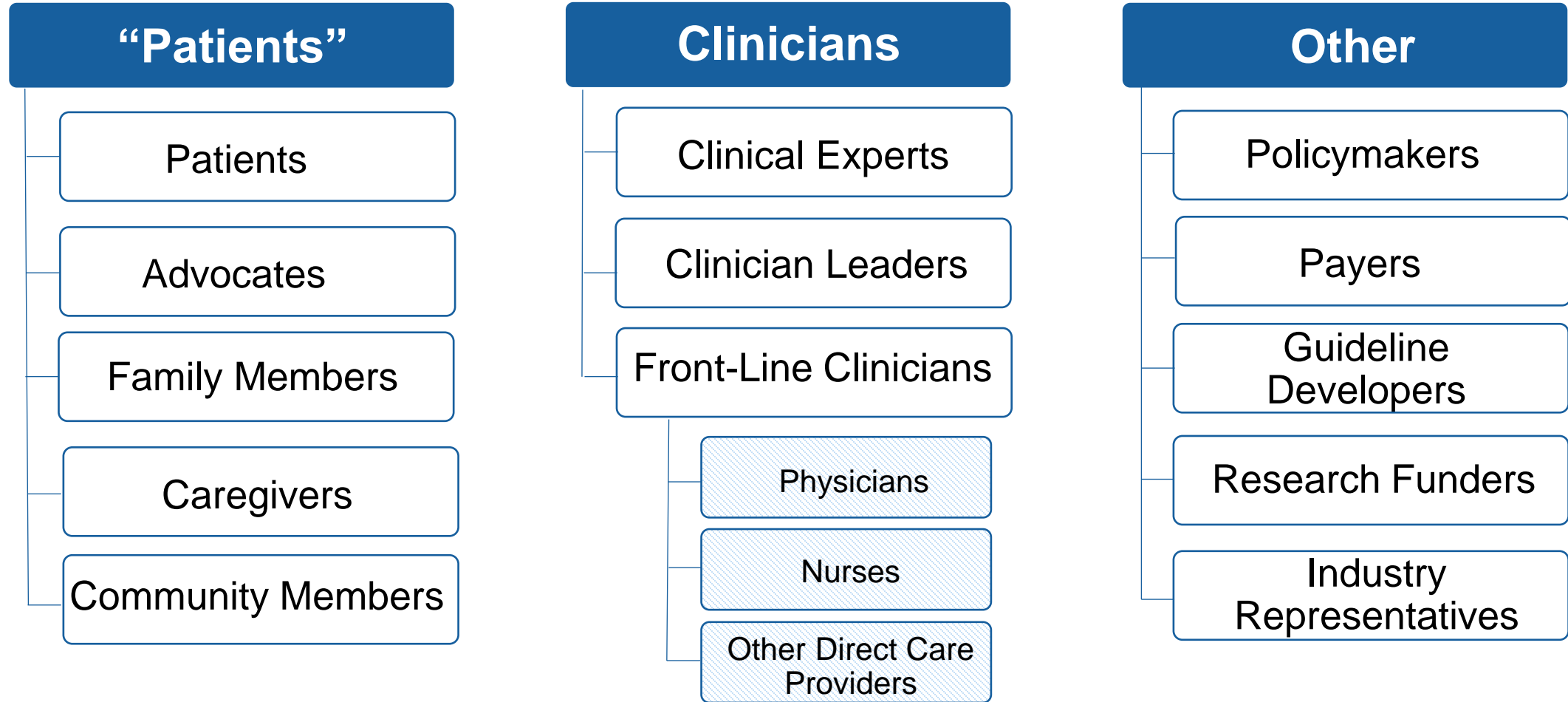
## Clinicians

# Who to Engage

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# Who to Engage



# Recruiting Patient/Community Stakeholders

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*Vat et al, 2017*



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Recruitment by health care providers or research staff who approach potential patients within the health care system

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## Partnering

Collaboration with an organization or group who have members or represent a particular patient perspective such as advocacy groups or charitable organizations

*Vat et al, 2017*



# Stakeholder Contributions

# Engagement Throughout the Research Process

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Planning the  
Study

Conducting the  
Study

Disseminating  
the Results

# Engagement Throughout the Research Process

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## Planning the Study

- Identifying research questions that align with stakeholder priorities
- Selecting outcomes that matter
- Designing the study protocol to minimize burden to patients and clinicians

## Conducting the Study

## Disseminating the Results

# Engaging Front-Line Clinicians in Study Planning

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Customizing the protocol	Every clinic works differently; researchers need to learn about the constraints and not underestimate the degree of disruption that might be caused
Clinician buy-in	You can't stop at getting buy-in from administrators; clinicians need to believe in the importance of the study so they can translate that to patients and staff

# Multi-Stakeholder Engagement in Outcome Selection for Sickle Cell Disease

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## Objective

- Agree on a minimum set of outcomes to be used in clinical trials of SCD therapies using a multi-stakeholder consensus process

## Rationale

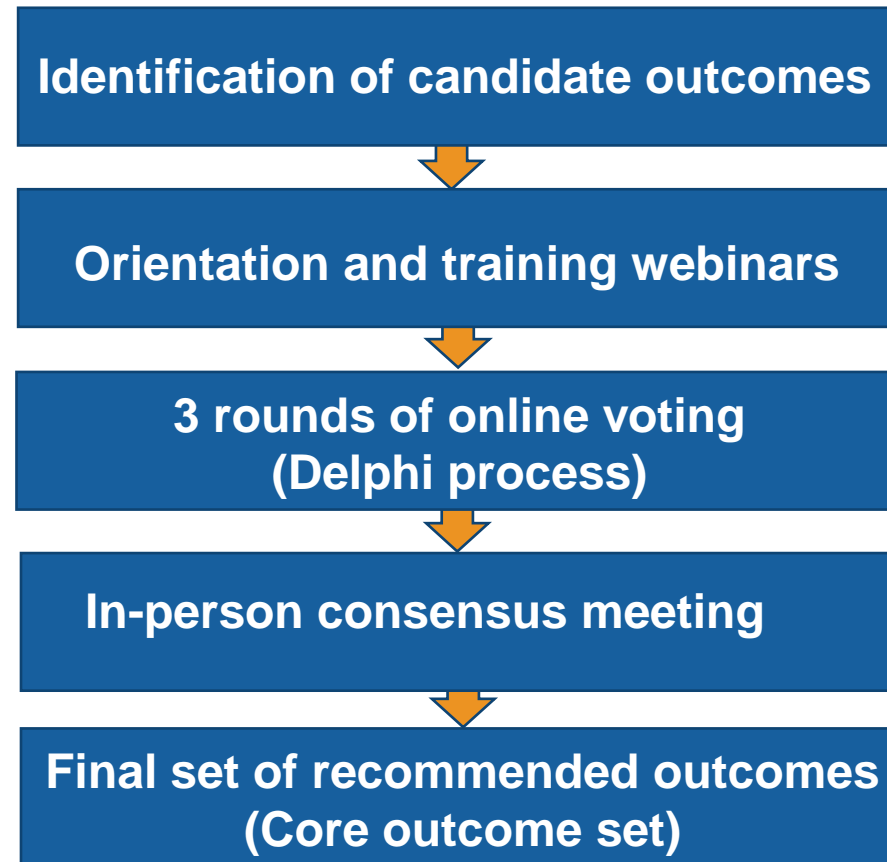
- Active area of therapeutic development
- When trial outcomes selected by individual groups of researchers
  - May not include those most important to patients and other decision makers
  - Variation makes it difficult to compare or combine the results of different studies

# Multi-Stakeholder Engagement in Outcome Selection for Sickle Cell Disease

## Stakeholder Panel (N=44)



## Process



# Engagement Throughout the Research Process

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## Planning the Study

- Identifying research questions that align with stakeholder priorities
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## Conducting the Study

- Drafting or revising study materials
- Advising on recruitment and retention strategies
- Serving as study champions

## Disseminating the Results

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## Disseminating the Results

- Determining key messages for different stakeholder groups
- Identifying avenues for dissemination
- Supporting implementation of effective interventions

# Dissemination Example: COMPARE-UF

- National registry to generate evidence on comparative effectiveness and safety of treatment options for uterine fibroids
- Multi-stakeholder advisory group has provided guidance at every project phase from registry design to dissemination



## Research Summary #1

Comparing Surgical Treatments for Uterine Fibroids: Hysterectomy vs. Myomectomy



### Surgical Treatments

**Hysterectomy**

Removal of the uterus

**Myomectomy**

Removal of fibroids without removing the uterus

### Type of Surgery

**Abdominal surgery**

Major surgical procedure that involves incision through lower abdomen

**Minimally invasive surgery**

Involves multiple tiny incisions and special instruments or removal of fibroids through the vagina with no incision needed

### What was the purpose of the research?

- The goal was to compare how women felt and functioned after having the two most common surgical treatments for women with uterine fibroid symptoms
- Researchers also looked at both treatments by type of surgery
- Assessments were made soon after their treatment (6-12 weeks) and after a longer period of time (1 year).

### Who was in the study?

Over 1,000 women who:

- Had either a hysterectomy or myomectomy for uterine fibroids at one of 8 clinical sites in the United States
- Were over age 30 and not trying to become pregnant

### What were the results?

- Both treatments resulted in large improvements in fibroid symptoms and quality of life.
- These improvements were seen at 6-12 weeks and 1 year after surgery.
- Women who had a minimally invasive hysterectomy seemed to have a greater increase in quality of life at 1-year post-surgery compared to women who had a minimally invasive myomectomy
- There was no difference in quality of life between women who had an abdominal hysterectomy vs. abdominal myomectomy.

### How can women use the results of this study?

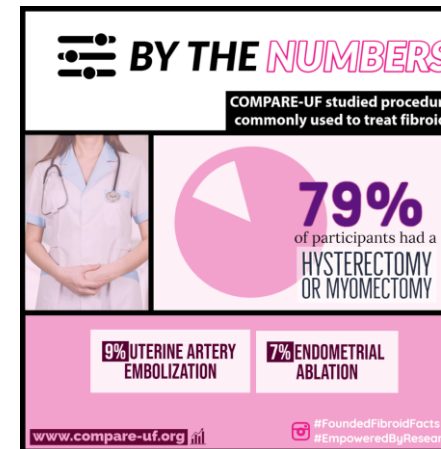
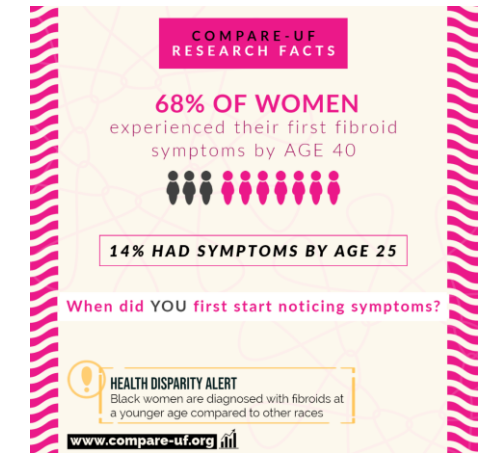
This study suggests that both myomectomy and hysterectomy are effective for treating symptoms and improving quality of life for women with uterine fibroids. The finding that women who had minimally invasive hysterectomy did somewhat better at one year than women who had minimally invasive myomectomy can be part of the discussion that women have with their physicians when deciding on the best treatment option for them.

<https://compare-uf.org/sharing-results/>

# Dissemination Example: COMPARE-UF

## July 2020 Social Media Campaign

- Objectives:
  - Raise awareness among the UF patient community about study results emerging from the COMPARE-UF registry
  - Communicate the value of these results for treatment decision-making
  - Drive traffic to the COMPARE-UF website where results are posted



# **Engagement Principles and Approaches**



# Principles of Engagement

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*Adapted from Liabo et al, 2020*



# Principles of Engagement

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## Inclusivity

Involvement of a diverse range of people

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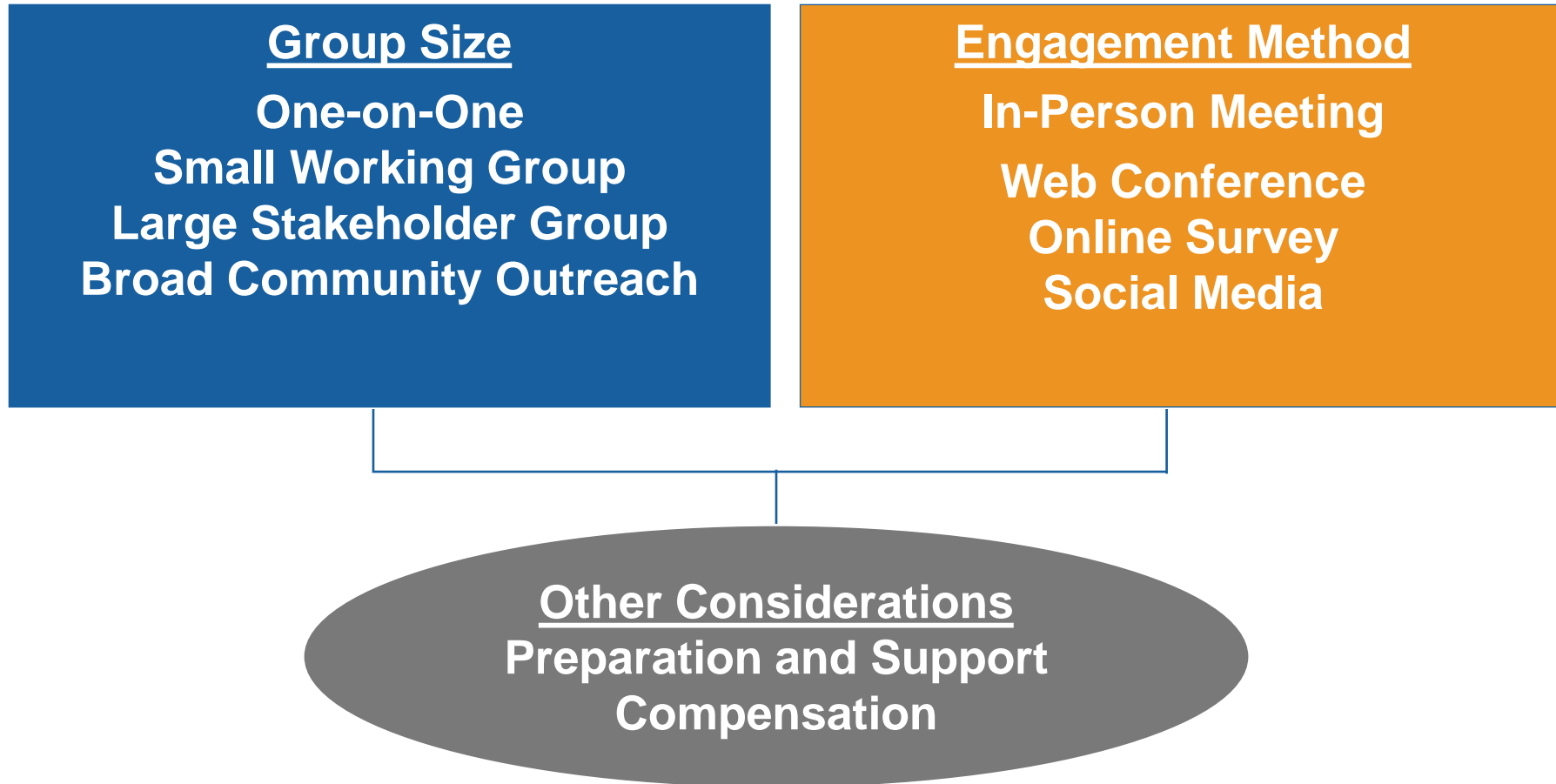
Open and honest communication between researchers and stakeholders

## Valuing different kinds of knowledge

Recognition that stakeholders have expertise that complements researchers' technical knowledge

# Methods of Engagement

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# Questions

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