

# Stakeholder engagement in research

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# outline

- What is stakeholder engagement (SE)?
- Definitions and clarification
- Ethical significance of SE
- Instrumental value of SE
- Strategies for engagement
- Example: site selection for a trial of genetically modified mosquitoes
- Example: H3Africa and community engagement
- SE in clinical trials: brief history of AIDS activism and engagement in clinical research
- Strategies for evaluation of SE
- Pitfalls and challenges in SE
- Summary

# What is Stakeholder engagement in the context of health research?

“Stakeholder engagement refers to a set of practices that help researchers establish and maintain relationships with the stakeholders to a research program.”\*

\*King et al 2014

What exactly is meant by “Stakeholder?”

What exactly is meant by “community?”

What kind of engagement is used in the context of research?

What are the origins of these SE strategies?

# “Community” is a concept referring to diverse types of groups

A definition derived from qualitative research (MacQueen et al 2001) with several groups in different US contexts:

**“A community is a group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings.”**

# More on communities

Aboriginal    Geographic/Political    Religious    Disease    Ethnic/Racial    Occupational    Virtual

## Types of communities--examples (Weijer and Emanuel)

- indigenous
- geographic/political
- religious
- disease
- ethnic/racial
- occupational
- virtual

## Communities versus stakeholders

**Stakeholders** is often used to refer to a diverse collection of groups, for example researchers, institutions, regulatory authorities, ministries of health, as well as lay communities, geographical communities, or population subgroups

Stakeholder engagement strategies have been used in diverse domains

ACTIVITY	EXAMPLES
<b>Public health</b>	<b>Vaccination campaigns; health education initiatives</b>
<b>Environmental protection</b>	<b>Natural resources governance</b>
<b>Economic development</b>	<b>Microcredit schemes; participation in civic society organizations</b>
<b>Political activism</b>	<b>Grassroots political movements; social media campaigns</b>

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# **SE IS USED IN DIFFERENT TYPES OF health RESEARCH**

- **Public health research**
- **Observational/cohort studies**
- **Community-based participatory research (also called CBPR)**
- **Genetic research**
- **Emergency research**
- **Clinical trials**

# WHAT IS THE ETHICAL RATIONALE FOR STAKEHOLDER ENGAGEMENT in health research?

**Communities have interests, needs, and desires** related to health care and health research

**Community interests may not be well represented** in the groups that fund, design, and conduct research

**Community members bring experiential knowledge, cultural context and representation of local values and priorities** to plans for research

Community deliberation can help adjudicate difficult questions regarding **risks, benefits and community—level permissions** in research

# Summary of published literature on ethical goals of CE

(Macqueen et al 2015)

Major themes in the 10 articles describing ethical goals of CE:

- **Fairness** (non-exploitation, fair partnership, avoiding exacerbation of inequalities)
- **Respect** (legitimacy, respect for local culture)
- **Addressing risks and benefits**, including stigma
- **Practical issues** (feasibility, avoiding disruption, minimizing burden, increasing acceptance)
- **Scientific quality and impact** of the research

# *Instrumental reasons for* **community engagement—examples**

- Enhance community understanding of research and improve recruitment
- Avoid misunderstandings and controversies due to rumors and misconceptions about the research
- Help understand and manage tensions and ethical challenges faced by research staff
- Design research procedures that are more acceptable and feasible for local population and setting
- Help with media coverage of research
- Help lead to better implementation of research findings at the end of a study

# Strategies and processes for engagement

(Tindana et al)

## Direct engagement strategies

- Town hall meetings, community meetings, public meetings

### Advantages:

- Wider reach of diverse community members
- Opportunities for direct dialogue with researchers

## Indirect strategies

(engaging with representatives)

- Community Advisory Boards (CABs)
- Interviews
- Consultations with community leaders

# Distinguishing CE from other related activities: *purpose of activity versus methods used*

Activity (not an exhaustive list)	Purpose of the activity
Public health programming	Deliver public health interventions
Social and/or behavioral research	New knowledge about social or behavioral processes
Community-based research	Health interventions delivered at community level
Community engagement in biomedical research	Support and enhance biomedical research

## Similar methods can be used in these diverse activities:

- Interviews
- Focus groups
- Ethnographic studies
- Public meetings
- Deliberative democracy
- Social media dissemination and gathering of information

# Community engagement for field trials of genetically modified mosquitoes (Lavery et al)

CE may be particularly appropriate for community level interventions

Individual consent and agreement to participate is impossible in large community wide mosquito release programs

In this case, two main criteria for site selection:

(1) regulatory authorities and administrative authority

(2) community engagement and authorization

**Regulatory/administrative authorities essential** for oversight of research activities and translation to meaningful public health programs; for risk assessment; for research ethics oversight

**Community engagement undertaken after site selection;** sites chosen on the basis of capacity for deliberation and engagement; experience with vector control programs.

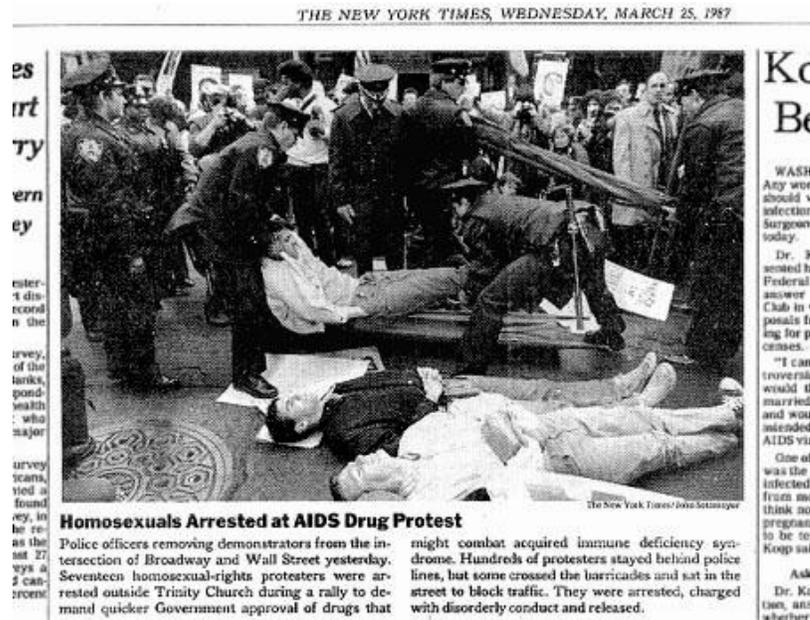
# Community engagement in a genetic research program: H3 Africa

- H3Africa is a large NIH-funded program to gather genetic data from multiple African populations
- Project creates large repository of genetic data
- Project aims also include capacity building and partnership with African investigators
- Goal is support for African-led genetic research programs
- Ethics working group of H3Africa is conducting engagement activities with relevant communities
- Concerns about genetic technology, fair distribution of benefits and burdens of research

# CE in the context of biomedical clinical trials

- The need for CE naturally arises in research projects that are community based, e.g. public health initiatives, community based field trials, etc.
- Biomedical clinical trials are conducted under more controlled conditions: large research centers, hospitals, etc.
- Early years of HIV research stimulated CE in the context of biomedical trials

# A little history: how AIDS activists changed research, and vice versa



- Early AIDS trials activists challenged the conventional way that clinical trials were designed and conducted
- --demanded faster regulatory processes
- --weighed in on the design of clinical trials
- --sought broader inclusion criteria so that more AIDS patients could join studies



AIDS Coalition to Unleash Power (ACT-UP) was formed in March 1987 in response to US government inaction on the AIDS crisis

# Activists challenged study designs in early aids trials

In early AIDS trials (late 1980s, early 1990s), before effective drugs were available, experimental treatments were tested in trials to measure improved survival. Primary study endpoint was survival

Activists challenged this design, wanted surrogate markers like CD4 counts to be used as endpoints

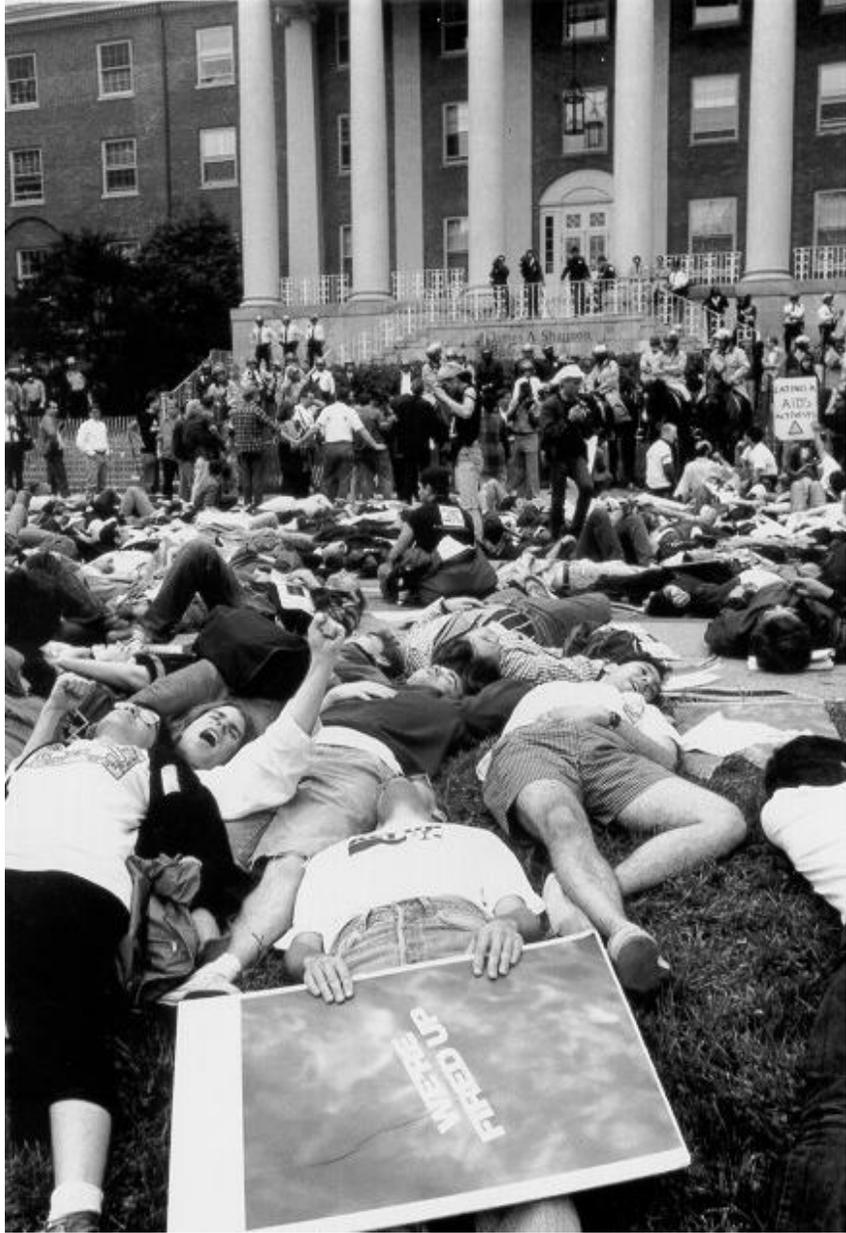
- Researchers could abandon ineffective treatments more quickly
- Give patients a chance to try other regimens

- Activists demanded wider inclusion criteria—so that patients with co-morbidities would not be excluded from research
- Activists spurred the FDA to issue regulatory approvals more quickly and allow access to experimental drugs to patients outside of clinical trials
- These processes are still in place today and are not restricted to HIV research

# Shifting the paradigm of clinical research

**Communities of people affected by disease demanded to be included in decision-making about biomedical research**

The concept that people simply needed to be **protected from the risks of biomedical research** was now counterbalanced with the concept that **people need (and deserve) access to the benefits of research—** both short term and long term.



# LEGACY OF AIDS ACTIVISM: COMMUNITY ENGAGEMENT IN HEALTH RESEARCH

In HIV clinical research, **Community Advisory Boards (CABs)** are standard practice

These Boards consist of non-scientist representatives of the community affected by HIV;

CABs weigh in on protocol design, informed consent, recruitment of subjects, communication with surrounding communities, and other issues

As noted previously, CABs are only one form of community engagement.

# How can we tell if community engagement is effective?

- What are the outputs or benchmarks of successful CE?
- Do goals vary in different settings/studies?
- **No standard metrics have been developed;**
- MacQueen et al (2015) have proposed evaluating the success of CE for each of the ethical goals previously outlined

## **Some methods to evaluate could include:**

- Evaluation of processes of engagement;
- Surveys of acceptability of research
- Measurement of level of engagement by community members (e.g. attendance at town hall meetings)
- Assessment of overall success of the research
- Interviews, focus groups, surveys

# Some evaluative techniques

Case studies within participatory action research,  
Qualitative research methods to elicit the views of community members on the engagement strategy used:

- ethnographic fieldwork,
- in-depth interviews
- focus group discussions

# Special challenges in community engagement

- **Diverse community views:** specific groups within a community may not agree with each other;
- **Impasse:** community groups may have demands that researchers are not willing or able to meet
- **Superficiality:** some community advisory groups are “rubber stamps” for research without meaningful input
- **Relevance:** not all studies require CE--how can we tell which kinds of studies benefit from or need CE?

# summary

- SE is ethically and pragmatically important in many settings
- Diverse approaches are required
- Evaluation and development of metrics for CE is an ongoing area of scholarship and research
- SE requires resources and commitments—this can be difficult to mobilize
- SE does not always result in agreement among stakeholders about best path forward
- Not all studies require SE—further refinement is required on these issues