

Community engagement in research

Liza Dawson, PHD MA

July 18th, 2018

disclaimer

- The views expressed are those of the presenter alone and do not represent any position or policy of the US National Institutes of Health, the US Department of Health and Human Services, or any of its components.

outline

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

What is community engagement in the context of health research?

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

What exactly is meant by “community?”

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

What are the origins of these CE strategies?

*King et al 2014

“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

Types of communities—examples (Weijer and Emanuel)

- aboriginal
- 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

Community engagement strategies have been used in diverse domains

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

CE 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 COMMUNITY 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

Activity (not an exhaustive list)	Purpose of the activity	Similar methods can be used in these diverse activities:
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	

- 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; (ethnobotany case)
- **Impasse:** community groups may have demands that researchers are not willing or able to meet (IDU Bangkok case)
- **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?

Who represents the community? ICBG—chiapas bioprospecting study

- Ethnobotany is the study of plants used in traditional medicine to document traditional practices and search for novel compounds of value for future product development
- International cooperative biodiversity group (ICBG) proposed study plants used by indigenous Maya community in Chiapas, Mexico.
- The two lead investigators of the study had worked in the Chiapas region for nearly 40 years. They worked at US university and had affiliations with a local Mexican university as well as a small biotech company in Wales with 14 employees.
- The investigators conducted extensive education and engagement activities in local Maya communities; 50 of the local communities in 15 municipalities agreed to the ICBG project.

While the majority of local communities approved of the project, the Council of Indigenous Midwives and Healers (COMPITCH) resisted the Maya ICBG project. COMPITCH received support from an international NGO (not local to Chiapas) which also objected to the study.

Ultimately, due to the controversy over the study, the research was cancelled.

The case raises questions:

- Who is the legitimate authority to represent a community or group of communities?
- Who gives permission for community based research?
- How can shared traditional resources be managed ethically and appropriately?

Impasse: example IDU study in Bangkok

A study of tenofovir for pre-exposure prophylaxis of HIV for people who inject drugs was initiated in 2004

Study was sponsored and conducted by US CDC, to be carried out in Bangkok.

Thai Drug Users Network and other groups represented drug users in Bangkok were contacted by research team in Sept 2004 to discuss protocol.

However, research team indicated no changes would be made to the study

Community groups protested lack of clean injecting equipment being provided in the trial (despite WHO recommendations on this evidence based prevention method)

Research team stated that US regulations barring of funds for distribution of clean syringes prohibited them from including this; also Thai government not in favor of this intervention;

An NGO offered to provide clean syringes for the purpose of the study but this offer was not taken up;

Ongoing negotiations from Sept to Dec 2014 failed to produce any resolution

Community advocates increasingly protested the trial, writing open letters to the research team and publishing opinion pieces critical of the study

Study was ultimately conducted over the objections of community advocates

Relevance—example: HIV phylogenetics and CE

NIH funded researchers are using **phylogenetic analysis of HIV** to determine HIV transmission patterns in various US locations

Closely related viral sequences from different individuals may indicate “clusters” of transmission, possible high risk groups or recent transmission events

NIH is developing ethical guidance for this work due to concerns about **stigma and criminalization of HIV transmission.**

Debate about community engagement:

- Do all phylogenetic projects require community engagement? If not, which ones need it, and can we develop useful criteria?

summary

- CE 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
- CE requires resources and commitments—this can be difficult to mobilize
- CE does not always result in agreement among stakeholders about best path forward
- Not all studies require CE—further refinement is required on these issues