



*Community Participation
In HIV Research*

Reflections from Thailand

research ethics in exercise, health and sport sciences

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Research 101





**Messenger
of changing
expectations
in clinical
research**

05

DON'T SHOOT THE MESSENGER: AN UPDATE ON TENOFOVIR RESEARCH



Reflection - PrEP trials

- ✧ Cambodia: high-risk women, stopped
- ✧ Malawi: high-risk men, stopped
- ✧ Nigeria: high-risk women, stopped
- ✧ Cameroon: high-risk women, stopped
- ✧ Thailand: on-going problems



Other disappointments

- ✧ Intensive counseling in MSM
- ✧ Microbicide trials
- ✧ Diaphragms
- ✧ Mass STI treatment
- ✧ Herpes suppression
- ✧ An adenovirus-vectored vaccine

(from "Perception of Male Circumcision for MSM in Brazil" by José Henrique Pilotto)

What the news said.....

- ✧ Trial for Vaccine Against H.I.V. Is Canceled (July 2008)
- ✧ HIV Vaccine Trial Canceled Over Possible Volunteer Risk (July 2008)
- ✧ Vaccine Failure Is Setback in AIDS Fight Test Subjects May Have Been Put at Extra Risk Of Contracting HIV (March 2008)
- ✧ Failure of AIDS Shot Linked to Cold Virus (November 2007)
- ✧ Failure of Vaccine Test Is Setback in AIDS Fight (Sept 07)
- ✧ Company Tried to Block Report That Its H.I.V. Vaccine Failed (November 2000)



Reading the news

✧ AIDS Vaccine Fails in Studies

The New York Times

February 25, 2003

✧ Vaccine for AIDS appears to work

USA Today

February 25, 2003



STEP Trial to PAVE 100: Lessons from the real world

- ✧ PAVE 100 was delayed
- ✧ Scaled back
- ✧ No go (July 2008)
- ✧ OK go - smaller, learner, meaner (September 2008)

How will the communities react to these news?

Food For Thought

- ✧ “We know communities can understand complicated topics, but we need to invest in research literacy and that hasn’t happened yet.”
Activist
- ✧ “Researchers seem to believe that Science is a cult of the learned, and they have the answers which the community must receive.” Community representative and activist
- ✧ “You have come here with the ball and all the rules of the game, and asked us to kick the ball.”
Researcher and advocate

(Courtesy Mitchell Warren - AVAC)

Ethical considerations in biomedical HIV prevention trials

UNAIDS/WHO guidance document



Good participatory practice guidelines for biomedical HIV prevention trials



Good participatory practice: Core principles

- ✧ Scientific and ethical integrity
- ✧ Respect
- ✧ Clarity in roles and responsibilities
- ✧ Towards shared responsibility
- ✧ Participatory management
- ✧ Autonomy
- ✧ More transparency
- ✧ Standard of prevention
- ✧ Access to care
- ✧ Building research literacy



Good participatory: Essential issues and activities

- ✧ Formative research with the community
- ✧ Development of community advisory, outreach and education plan, and....
- ✧ Development of informed consent documents
- ✧ Development of standard of prevention, treatment, and care....
- ✧ Development of policy for research-related harm
- ✧ (total 7 activities)

Essential issues (cont.)

Formative
research - 5
elements

Development of
community
advisory and... - 5
steps

Development of
informed consent
documents - 5 steps
and many more
issues

Development of
standard of
prevention,
treatment, and care..
- 5 issues and 8
elements

Development of
policy for research-
related harm



No simple answer, because....

- ✧ Community voices are heard through a myriad of structures.
- ✧ Involvement is varied, depending on geography, language, culture, complexity, focus and scope of HIV research.

From “Community Partners: Community Involvement and Emerging Challenge” by Hamilton Richardson and Dorothy Shaw

Continuum of meaningful participation

Paternalistic to Empowerment

Tokens

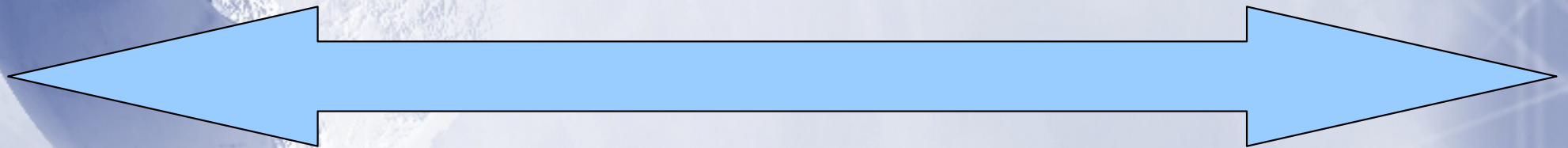
Rubber stamps

Advisors

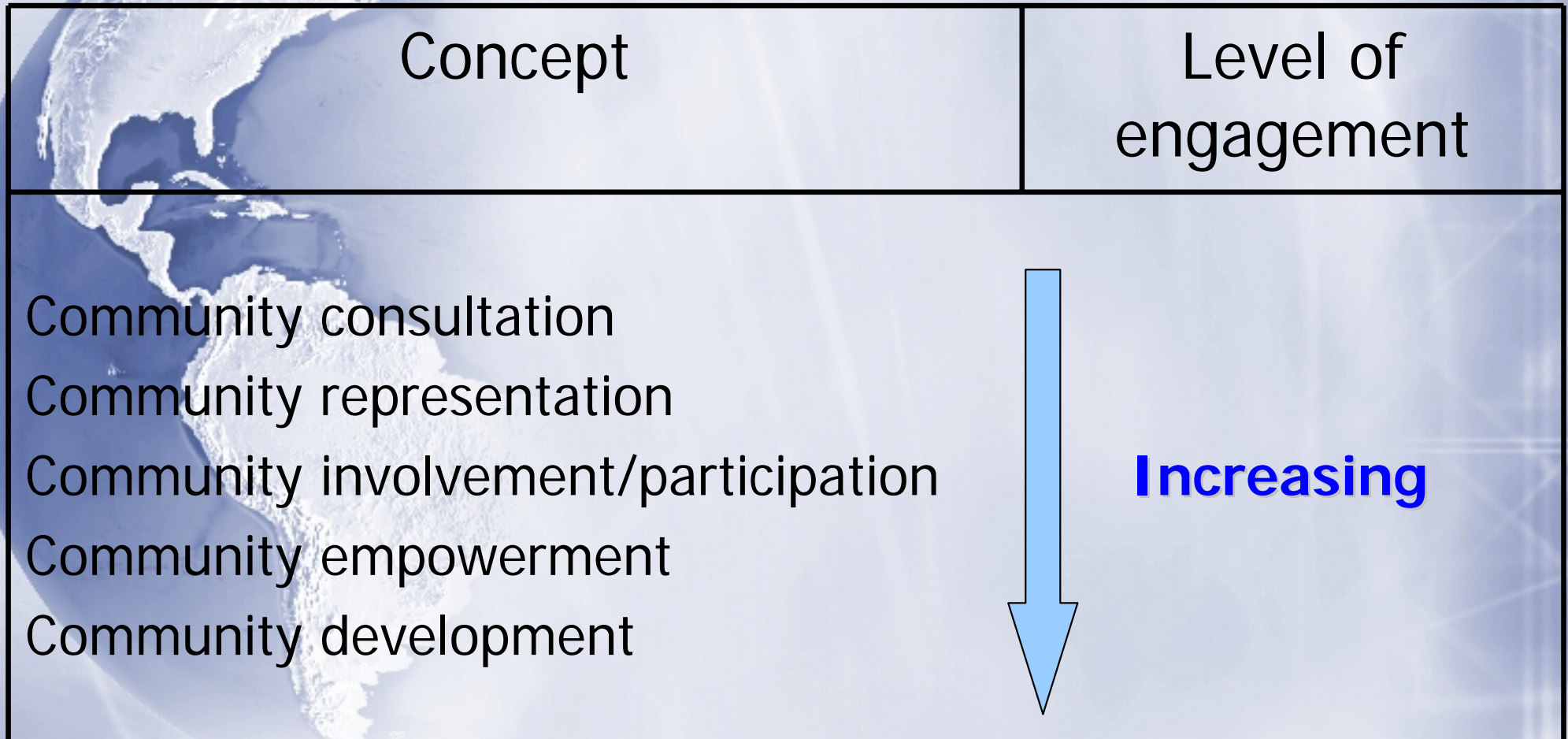
Consultants

Partners

Collaborators



The big aim



Source: Tamarack - An Institute for Community Engagement

Ethical goals

- ✧ Enhancing protection
- ✧ Enhancing benefits
- ✧ Creating legitimacy
- ✧ Sharing responsibility

(From Dickert N, Sugarman J (2005) Ethical goals of community consultation in research. Am J Public Health 95, cited by Paulina O. Tindana, Jerome A. Singh et al. in Grand Challenges in Global Health: Community Engagement in Research in Developing Countries)

Examples of community input and its impact

- ✧ Community reps educated study team on IDUs; persuaded team that risk of IDUs participation on study should be determined by personal physician (ACTG)
- ✧ CAB-initiated NGO program, which has identified 115 community peer advocates (India-HPTN)
- ✧ Participant Bill of Rights and Responsibilities (HVTN)
- ✧ Amendment to the patients' informed consent sheet re: data/samples being used by other cohorts (Germany-INSIGHT)
- ✧ Engagement of community at different levels - with local PIs, through CAB and community educators, and through Network CAB members - has given community a sense of owner to proposed research (Nigeria-MTN)
- ✧ Community Partners provides cross-network communication and inputs. (DAIDS, NIH)

From “Community Partners: Community Involvement and Emerging Challenge”
by Hamilton Richardson and Dorothy Shaw

Why so many controversies?

The approach

- ✧ Exposure to HIV
- ✧ Placebo
- ✧ High-risk populations - marginalized or discriminated groups, often from developing countries
- ✧ Different routes of infection
- ✧ Diverse strains in different regions of the world

Why community participation

- ✧ HIV is highly stigmatized disease
- ✧ HIV-related stigma is pervasive and entrenched in society
- ✧ HIV-related stigma is multi-dimensional, conceals misogynistic, homophobic, xenophobic, and racist attitudes
- ✧ Involve vulnerable populations - stacked stigma
- ✧ Candidate products are developed in wealthy countries but tested in poor countries (disparity of wealth, of power)

Community Engagement

"....It is now generally accepted that community engagement is an essential part of HIV programme implementation and service delivery. Unfortunately, such involvement in Asia and in many places is tokenistic...Community involvement can open space for discussion about controversial to issues and help promote greater understanding of HIV among political and social leaders. NGOs and Community-based organizations are often willing to broach these sensitive issues publicly. Also partnerships and community engagement can foster a sense of 'ownership' of response that tends to be absent when projects are externally run."

from The Commission on AIDS In Asia 2008: Redefining AIDS in Asia.
Crafting an Effective Response

Definitions of Community

- ✧ As a sense of place: based on physical location, sharing of sets of values, cultures, beliefs, languages and dialects
- ✧ As a form of identity and belonging: sharing of common circumstances, experiences, concerns, interests, or behaviors



Historical context

✧ Myths and perceptions

- ✧ “Guinea Pigs” - 1973 controversy on female injecting contraceptive

- ✧ 1993 - The national ethical guidelines on research

✧ Why Thailand?

- ✧ Testing vaccines originated in other countries

- ✧ Difference in sub-types

- ✧ History of testing on “vulnerable populations” (sex workers, STI patients, military conscripts, injecting drug users from rehabilitation centers)

- ✧ Raising research fund from private sector - commercial gain?

Cause for concern

- ✧ Who is representing whom? Is CAB enough?
- ✧ What is the role and responsibility of CAB - advisory, advocacy, cheer leader, decorative??
- ✧ CAB - how to recruit and retain, supports provided, degree of autonomy?
- ✧ Community HIV education and HIV research
- ✧ Participatory approach (the nitty-gritty issues)
- ✧ Little big world - shrinking distances, expanding involvement, increasing diversity

Challenges

- ✧ Original language, translation, technical terms, English, medicalese
- ✧ Power relationship in Thai context:
 - ✧ Paternalistic attitudes toward trial participants, the public
 - ✧ Bias towards activists and advocates
 - ✧ Service provider and client/patient relationship
- ✧ Immature regulatory (small research community and culture issues)
- ✧ Lack of focal point/s for coordination and monitoring among CABs and trials
- ✧ Small pool of HIV researchers

Challenges

- ✧ Low hanging fruit mentality - pressure to recruit and retain volunteers (high retention = high statistic power), using out-of-date templates, existing materials for
- ✧ Challenges of pluripotent sites
- ✧ Capacity building for research staffs and CAB:
 - ✧ Basic scientific research
 - ✧ Human rights, research ethics, related laws and regulations
 - ✧ Community outreach skills
 - ✧ Communication skill and translation skills (English to Thai, medicalese - layperson)

Challenges

- ✧ Mass media culture and lack of scientific reporters, or health reporters/journalists
- ✧ Broad-based and comprehensive community education
- ✧ No meaningful communication strategies and plans
 - ✧ Secondhand news about the trials
 - ✧ Inaccurate reporting, sensational news by media
- ✧ Tendency to generalizing people from particular subgroups

Caveats

- ✧ CAB for participation optimism
- ✧ Time and resources required to ensure meaningful community involvement
- ✧ Using research trials to advance agenda of HIV (and health) education, counseling, and care geared to specific population
- ✧ Delivery of benefit - good planning, ways and mechanism to carry out the plan
- ✧ Competing agendas - ARV scale-up, CL, round after round of GF

Conclusions

- ✧ Shared responsibility among duty bearers (investigators, community leaders, community members, civil society, media, etc.)
- ✧ Access to information, increase dialogue and remain close contact, provide channels that community can make its concerns heard throughout the process
- ✧ Proactive and pre-trial engagement
- ✧ Institutional commitment to community engagement