

# **Community Advisory Groups: can they facilitate ethical research in clinical trials?**

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# Community engagement in research

- Increased focus in recent years
- Seen as a way of working with communities 'in partnership'
- Way of involving communities at various stages of studies

# CE- definition

- a process of working collaboratively with and through groups of people affiliated by geographical proximity, special interest, or similar situations to address issues affecting the well-being of those people

US CDC 1997

**Table 1. Six steps for acquiring community permission in developing countries.**

Steps	Procedures
Study of the community	Elucidate community's sociocultural structure and health system Identify political and traditional leadership
Introductory meeting with leaders	Introduce research team Begin explaining research project Solicit best process for community permission
Formal meetings with leaders	Explain the research project, risks, benefits, etc., in detail Take and respond to questions
Personal visits with leaders	Visit leaders personally in their homes for further explanation and opportunity to answer their questions.
Meeting with traditional health providers	Develop formal agreement with traditional health care providers for collaboration on the research project
Obtaining permission as a dynamic process	Conduct a modified consultation process with leaders at each modification in the protocol or new research project

# Community Permission for Medical Research in Developing Countries

# Operationalization of CE

- community outreach, including gatekeepers
- working through community educators
- community member of the IRB
- civil society organizations
- setting up of Community Advisory Groups

# Working with communities

- Is a way of applying the principles of respect, beneficence and justice beyond individuals to communities
- Came into focus (in the west) after the Belmont Report was criticized for being too individual focused.
- CAGs initially used extensively in HIV-AIDS especially larger trials after activists protested about non-participation in decision making .
- Now extending to other forms of research

# Terminology: variations

- Community Advisory Groups (CAGs)
- Community Advisory Boards (CABs)
- Community Research Support Groups (CRSG)-  
might be separate from CAG/CAB
- Different from the community member on the  
IRB



# Community Advisory Groups (CAGs)

- **an attempt at involving the community for regular coordination with the researchers: framing the research, guidance through planning/site selection and rolling-out of research trials (participant recruitment & retention) and dissemination of research findings.**
- **attempted in varied settings across the world.**
- **have been successful to a certain extent in bridging the divide between researchers and the community (from where the participants are drawn from).**



# Types of CAGs

- Study specific Vs Institution specific
- Wide representation of population: community leaders, NGOs/CBOs, government officials, faith leaders, ordinary community members etc. Vs Specific population groups: PLHIV, SWs, Parents
- World CAB: HIV activists from across the world which interacted with generic drug industry representatives in Mumbai in 2005

# CAGs

- Process of development of CAG is important and needs to be given attention: formation, training, support, mandate, term, goals, ToRs, vision/mission etc.
- Confidentiality of members: some might prefer to be study/institution advocates
- Regular meetings with defined objectives and follow up: of the CAB and of CAB with research team
- Rotation of membership
- Payment: fair reimbursement, can lead to resentment among other community members
- Should not play a 'direct' role in trial recruitment



| HEALTH POLICY AND ETHICS FORUM |

## Ethics in Public Health Research

### Protecting Human Subjects: the Role of Community Advisory Boards

| Sandra Crouse Quinn, PhD

American Journal of Public Health | June 2004, Vol 94, No. 6

CAGs provide a mechanism for community consultation that contributes to protecting communities and fostering meaningful Research.

# Roles of CAGs

- act as a liaison between researchers and community,
- represent community concerns and culture to researchers,
- assist in the development and review of study plans, proposals and study materials
- advocate for the rights of research participants and facilitate their participation
- consult with potential study participants to provide recommendations about research study enrollment.

# Roles of CAGs

- help in dissemination of findings
- assist in developing acceptable amounts of reimbursement
- Help in handling controversies or sudden trial amendments- e.g. halting of trial due to futility (on DSMB's recommendation)

# CAGs- optimization

- Recognizing needs of CAGs
  - Training: their role, expectations, science, review documents such as IC forms and proposals
  - Flexibility with time
  - Reimbursement for expenses
  - Participation in defining research areas
  - Opportunities to represent/attend at meetings with sponsors and conferences
  - Interaction/networking with community educators and other CAGs
  - Developing mission statements for the CAGs
  - Working with IRB in a symbiotic manner



# Working with CAGs

- Does not mean that there is no need to do anything else with the community-other avenues for engagement
  - (a) Participant Advisory Group
  - (b) Extensive Community Involvement Plan (CIP)
- Requires that the researchers and sponsors respect the relationship and provide avenues for joint decision making

# Challenges in working with CAGs-1

## ■ Challenges in ensuring effective functioning:

a) 'choosing' the right and representative membership

b) ensuring continuity and retention

c) voluntary nature of work: Time commitment

d) retention of members

e) amount of work can seem overwhelming

# Challenges of working with CAGs-2

- f) sphere of influence, and what degree of confluence with work of IRB**
- g) leadership: role of chair/co-chairs**
- h) how to ensure adequate and wide representation from the community**
- i) prevent politicization**
- j) prevent feeling among the CAG that they are decorative**
- k) need to do more research on effectiveness and best ways of working with CAGs**

# Summary

THANK YOU

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