

Ethical Assessment of standard of prevention

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Ethical & Scientific challenges to researchers

- Management of conflict of interest by researcher.
- Balancing the human protection and promotion research interest
- Balancing safety and efficacy
- Management of ethical dilemma

What are these ethical & scientific challenge?

(Isabelle de Zoysa et tal.,)

(High levels of condom use could undermine the ability of the study to assess the protective effect of the microbicides).

Bhave G, Lindan CP, Hudes ES, et al. (intensified HIV prevention education had less impact on commercial sex workers).

See Bhave G et al., Impact of an intervention on HIV, sexually transmitted diseases, and condom use among commercial sex workers in Bombay, India. *AIDS* 1995;9(suppl 1):S21-S30).

What are IRB ethical expectations?

- Provision of standard of care-condom use promotion and provision, AIDS education (See Global Campaign for microbicides report -March 2005)
- Circumcision
- Provision of “independent” AIDS prevention education services.
- Potential risk of believing in efficacy of drug trial (inhibition).
- Provision of care of sero-converted research participants.
- Drug safety issues e.g., drug resistance issue and risk management plan
- Care and support plan
- How independent are HIV and prevention services from research interest?
- Ancillary care
- Capacity building

Politics & socio-economics of microbicides

- Political opportunism and demagogue
- Bad press coverage and rumor mongering
- Issues of exploitation (Avoidance of giving false impression of being taken advantage of)
- Lack of planning for care and support for sero-converted research participants
- Lack of human protection equivalence in research -NBAC
- Absence of prior debate/discussion of post trial access
- Avoiding giving false impression that the long and complicated informed consent is not meant to inform but to protect the researcher

Core Bioethical Principles

1. Respect for persons
 - Voluntary informed consent.
 - Protection of vulnerable persons.
 - Respect of persons rights and claims
 - Respect of the communities
2. Beneficence
 - Favorable benefit-risk ratio
 - Benefit-risk assessment
 - Maximizing benefits
 - Minimizing harms.
 - Act in “the best interest” of research participants
3. Justice often ignored misinterpreted
 - Fairness: Sustainability and capacity building
 - Access to information, standard of care and prevention
 - Fair Benefit sharing-Non-exploitation-post trial access

How to deal with Bad media coverage & rumor mongering

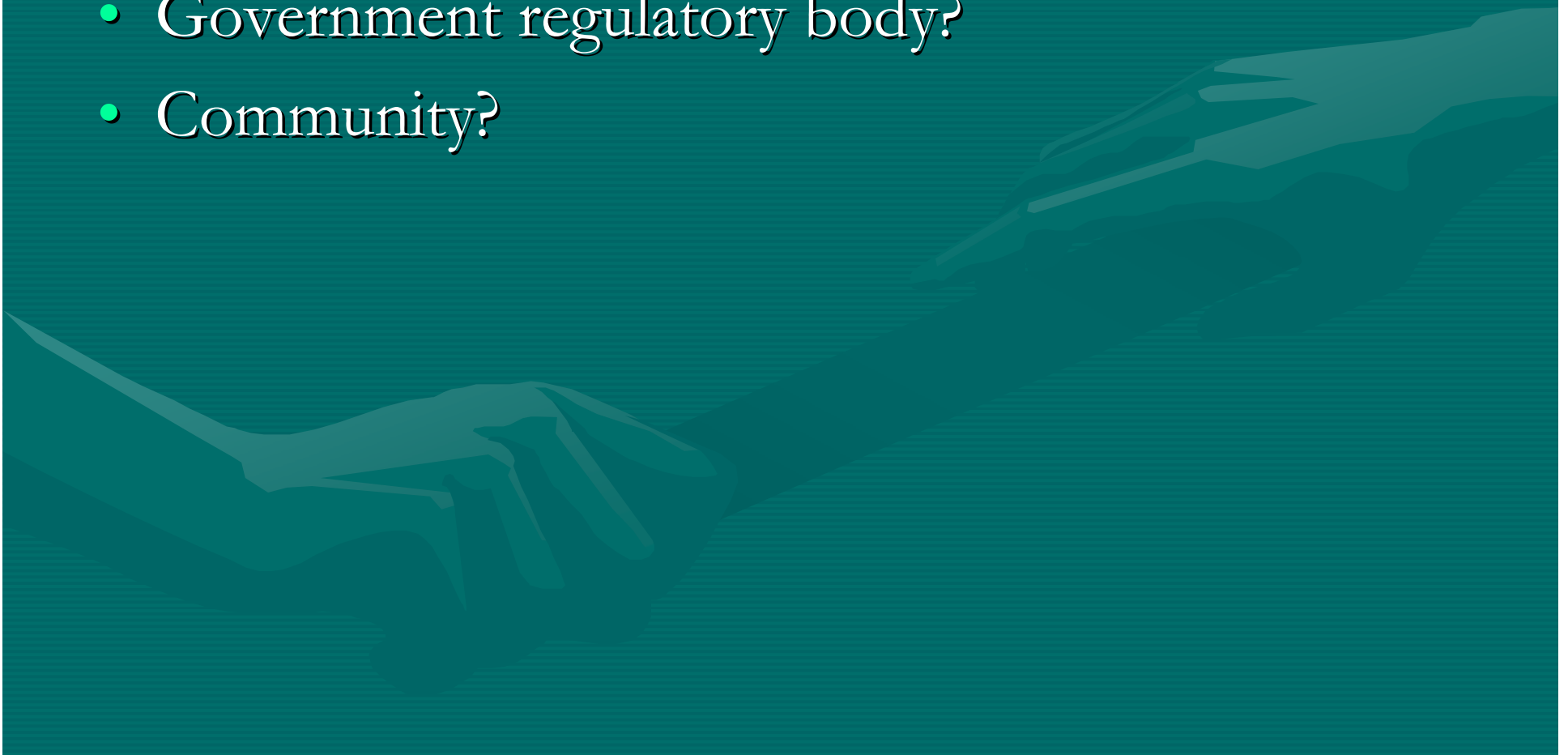
- Targeted Proactive Media education
- Targeted community education
- Research participants education
- Prepare and develop early drafts of IEC materials

What makes public engagement effective in IRB review process?

- Prepare memorandum of engagement
- Inclusion/exclusion criteria (Not every one who is interested & excited is a stakeholder)
- Memorandum of engagement should include: names of “real stakeholders”, objectives of engagement, description of research study-risk and benefits, GPP plan.
- Identifying the key decision and opinion maker.
- Formative research vs public engagement
- Public Engagement is credible but does it always work?
- Public engagement for it to work should be targeting, proactive, timely, honest and strategic.

Who is the main stakeholder?

- Ethics committee?
- Government regulatory body?
- Community?



GCP GUIDE

- Scientific and ethical integrity
- Respect
- Clarity
- Shared responsibility
- Participatory management
- Autonomy
- Transparency
- Standard of prevention
- Access
- Building research literacy

What makes clinical trial ethical in resource poor setting? (Zik Emmanuel JAMA 2002)

- Public engagement & Community partnership
- Social value
- Scientific value
- Fair subject selection
- Favorable risk-benefit ratios
- Independent scientific and ethics review
- Meaningful Informed consent
- Respect of enrolled volunteers
- justice
- *Moral reasoning*
- *Equivalent protection*
- *Post trial access*
- *Capacity building*
- *Local dissemination*

What can we learn from global credit crunch?

1. Ethics of conformity
2. Ethics of transformation
3. Ethics of appeasement



Conclusion

- ZIKOMO
THANK YOU

