Anticipating ethical concerns during disaster research: perspectives from South Africa

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South Africa

Population 50 million

GDP $287 billion

(US) 19.3%------9.1% on health------1.3% (Pakistan)

Clinical trials - +/- 1082
GINI COEFFICIENT
0.72
Major tectonic plates of the world.
Disasters in SA

- Natural – floods

- Man made – political unrest
  1976 Soweto Riots
1976 Soweto Riots

600 deaths
Disaster Research Ethics in Africa

- Kano, Nigeria – 1996
- 11/200 children
Disasters

- Sudden + catastrophic vs Insidious

- Loss of life - 3000/20 000 vs 310 000/yr

- Psychosocial impact – chronic

- AFTERMATH - RESEARCH
A Public Health Disaster - HIV

- 1999 – 2000
  - More people died of AIDs in Africa than in all the wars on the continent.

Kofi Annan
A Public Health Disaster - HIV

- 310,000 deaths in 2009!
- Access to treatment ??? 50%
- Adherence to treatment...
- ARV Resistance...
A Public Health Disaster - HIV

Psycho-social sequelae

- Orphans
- Child headed households
- School & Work
- Stigma
A Public Health Disaster

Drug Resistant TB

440,000 new cases/year
Less than 7% on treatment
150,000 deaths/year
HIV & Ethics

- **Before Antiretrovirals**
  - (1980s.....)

- **Antiretrovirals**
  - (1994.....)

- **After Antiretrovirals**
  - (2005.....)
Research Ethics Regulation in SA

- National Health Research Ethics Council (NHREC)

- Research Ethics Committees (RECs) - 27
Guidelines

- Declaration of Helsinki 2008
- ICH GCP – 1997
- SA GCP – 2000 & 2006
Guidelines

- South African based PIs

- Respect for local communities – their cultures & value systems

- Vulnerability

- HIV/AIDS specific guidelines
HIV Specific Issues

- Standard of care
- Alternatives & Therapeutic Misconception
- Treatment of HIV seroconverters
- HIV Vaccine Trials - IC
- Microbicides
- Circumcision
- HIV & TB Co-infection
Vulnerable Communities – UNAIDS
Definition

- Limited economic development
- Inadequate HR protection & discrimination based on health status
- Inadequate understanding of scientific research
- Limited health care & treatment options
- Limited ability to provide individual informed consent
1997 std of care ???
Epidemic 3 million HIV +

- PMTC transmission trials – 1997
- ACTG 076 and PETRA trials in SA
- Standard of Care & Placebos
Treatment of HIV positives

- Screened out
- Trial and post-trial seroconversion
Adolescent Enrollment in Microbicide Trials in SA

Girls bunk school to cash in on HIV trials

Schoolkids offered money to test gel product each time they have sex

PREDA COVENDER

TEENAGE schoolgirls are bunking school to visit a research centre that offers them R2 700 to test an anti-HIV gel whenever they have sex.

The North West Education Department has launched an investigation into claims that the Setswasha Research Centre in Soshanguve, Pretoria, is recruiting pupils during school hours to become guinea pigs.

The centre, an arm of the Microbial Pathology unit at the University of Limpopo, is one of three in the country conducting research trials into the efficacy and safety of a microbicide, Carvacrol, in the prevention of HIV infection in women through sex.

Researchers hope at least 6 270 women aged 16 years and older will volunteer for the two-year study.

The centre's HIV support officer, Malebo Rathaga, this week confirmed that it had approached five schools to participate in the trial — three in Limpopo and four in Soshanguve, to encourage young girls to participate in the trial.

But the centre’s request for permission to use schoolgirls from the Bojanala East Region in Ga-Rankuwa was turned down by a senior education department official, Moloko Nke.

Nke said in a letter to her seniors that she refused permission because the trials would encourage the girls to become sexually active.

Hlahlalela Kalongo, the principal of the Vamalapukwe High School in Ga-Rankuwa, outside Pretoria, complained to the department about the “serious problem of learners dodging after lunch.”

“We are very concerned. We discovered that a car, which we later very high compared with women in their mid-30s.

A leaflet containing information on the gel warns couples to use condoms whenever they have sex because “Carv-

agula has not yet been shown to prevent HIV.”

Half of the participants will be given a placebo, and when a participant has not used a condom, this is noted for the trial.

Rathaga said girls could qualify only if they had had sex in the previous three months.

“Age 16, sexually they don’t need [parental] consent,” she said.

She denied that the trials would encourage girls to become more sexually active.

‘You might get a few kids who are going to use the opportunity to bunk school, but that is not within our control’

“We are not saying do it (have sex) every day. We are not saying, go out and do double,”

Dr. Khattis Ahmed, the principal investigator at the Setswasha Research Centre. Sunday Times 2005
“Phase III Trials Of Cellulose Sulfate Microbicide For HIV Prevention Closed”

“Microbicide Trials Halted In Africa, India Because Of Possible Increased Risk Of HIV Transmission” February 2007

“The closure of these trials is a stark reminder that drug development in general is a difficult and unpredictable process”

Zeda Rosenberg IPM
Co-enrollment – 2008 Microbicide Trials

- CAPRISA 004 – Tenofovir gel
- MRC sites - Buffergel
- 201 patients co-enrolled
2010: “A Study That Should Not Have Been Done”
Philpott & Schuklenk - Hastings Centre Report 2010

- Timing & initiation of ARVs during TB Therapy – NEJM Feb 2010 - SAPIT study

- 640 TB + HIV
- Gp 1 TB Rx – 4 weeks later – ARVs
- Gp 2 TB Rx – 4 weeks after intensive phase TB Rx
- Gp 3 TB Rx – 4 weeks after TB RX
2010: “A Study That Should Not Have Been Done”
Philpott & Schuklenk - Hastings Centre Report 2010

- Gp 1 + 2 – integrated Rx – 25 deaths/429 pts – death rate = 5.4 per 100 person yrs

- Gp 3 - sequential Rx – 27 deaths/213 pts – death rate = 12.1 per 100 person yrs
2010: “A Study That Should Not Have Been Done”
Philpott & Schuklenk - Hastings Centre Report 2010

CRITIQUE:

- unnecessary study
- standard of care
- unnecessary deaths
- REC's in SA
- ? No IRB from US
- authorship
Guidelines & Disaster Research - 2011

- Emergency Care Research
- Dependent Relationships
- Traumatised Participants
Emergency care research

- Religious & cultural sensitivities
- Condition of patient precludes IC
- Inclusion in trial – best interests of pt
- Therapeutic research
- Next of kin/patient informed
- Retrospective IC
- Valid scientific hypotheses – scientific benefit over std of care
SA Guidelines

Research during “acute disasters”:

1. CARE vs RESEARCH

2. If Research possible….Expedited Reviews
   - Risks vs Benefits
   - Capacity to consent – waivers?
   - Therapeutic Misconception
   - Community Advisory Groups
   - Post-research benefit
33. At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study & to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to any other appropriate care or benefits.