

MICROBICIDES
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The Developing World, Women and Microbicide Trials: *A Few Dilemma's*

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Vulnerable Communities

For most people in the world, every step of life, from infancy to old age, is taken under the twin shadows of poverty and inequity, and under the double burden of suffering and disease'

WHO Report, Bridging the Gaps?

Vulnerable Communities?

UNAIDS define vulnerable communities as having all or some of the following characteristics:

- Limited economic development
- Inadequate protection of human rights
- Discrimination on the basis of health status

Vulnerable Communities?

- Inadequate community/cultural experience with the understanding of scientific research
- Limited availability of health care and treatment options
- Limited ability of individuals in the community to provide informed consent

Vulnerable Communities?

South Africa's Projected Life Expectancy for Women:

- 1999 – 58 years
- 2004 – 48 years
- 2009 – 37 years

Small and Medium Enterprise Analytical Group Figures

**‘Fate has allowed humanity such a
pitifully meager coverlet
that in pulling it over one part of
the world,
another has to be left bare’**

***Rabindranath Tagore
Nobel Prize for Literature 1913***

Vulnerable Communities?

- Women in developing countries are vulnerable
- Women in minority groups of developed countries are vulnerable e.g. South Florida minority groups
- Researchers need to constantly strive to protect their interests and their rights

Informed Consent

- Informed consent may be difficult to achieve, especially when engaging people from disadvantaged and vulnerable communities where literacy and education opportunities are inadequate and where there are language barriers,
- however every effort must be carried out to achieve informed consent

*Clinical Trials Guidelines 2000
Department: Health
Republic of South Africa*

Informed Consent

- In the AIDS VAX® B/E trial in Thailand the consent form grew to 14 pages long to cover all issues required for informed consent
- The Carragaud™ Trial a study exam was conducted to be eligible, women needed to answer 80% of 20 questions
- Col 1492 in Durban used a community liaison person to help explain and evaluate understanding, role plays and analogies

*Kilmarx et al
Human Subjects in HIV Prevention Trials
AIDS 2001, vol15 (suppl 4)*

Informed Consent

In many ethnic languages in Africa we do not have words for:

- Microbicide
- Research
- Placebo
- Randomisation
- Informed consent
- Double blind
- “Different arms”



Obtaining fully informed Consent is not an easy process

Suspicion and Stigma

- Suspicion in communities about participation in trials
- Botswana uptake for VCT in MTCT and mines programmes is extremely low
- Suspicion among politicians that “... *people are being used as guinea pigs*”
- Stigma attached to trials

Suspicion and Stigma

- Everyone is committed to GCP
NIH rep quote unfortunate:
-The HIVNET 012 study was never developed for FDA registration purposes but as a public health intervention.....

To treat or not to treat?

Zoysa, Elias and Bentley 'Ethical Challenges in Efficacy Trials of Vaginal Microbicides for Prevention' *Am J Public Health*. 1998;88:571-575

- *'...This paper discusses an issue that looms large in the design of such [microbicide] trials: the provision of HIV prevention services to participants'*

To treat or not to treat?

- What is standard of care?
- How do we define the best possible standard in a country and what do we do to ensure it?

To treat or not to treat?

- Access to treatment what does it mean?
- Should we provide treatment to women who are found to be positive or is this coercion and unfair inducement?

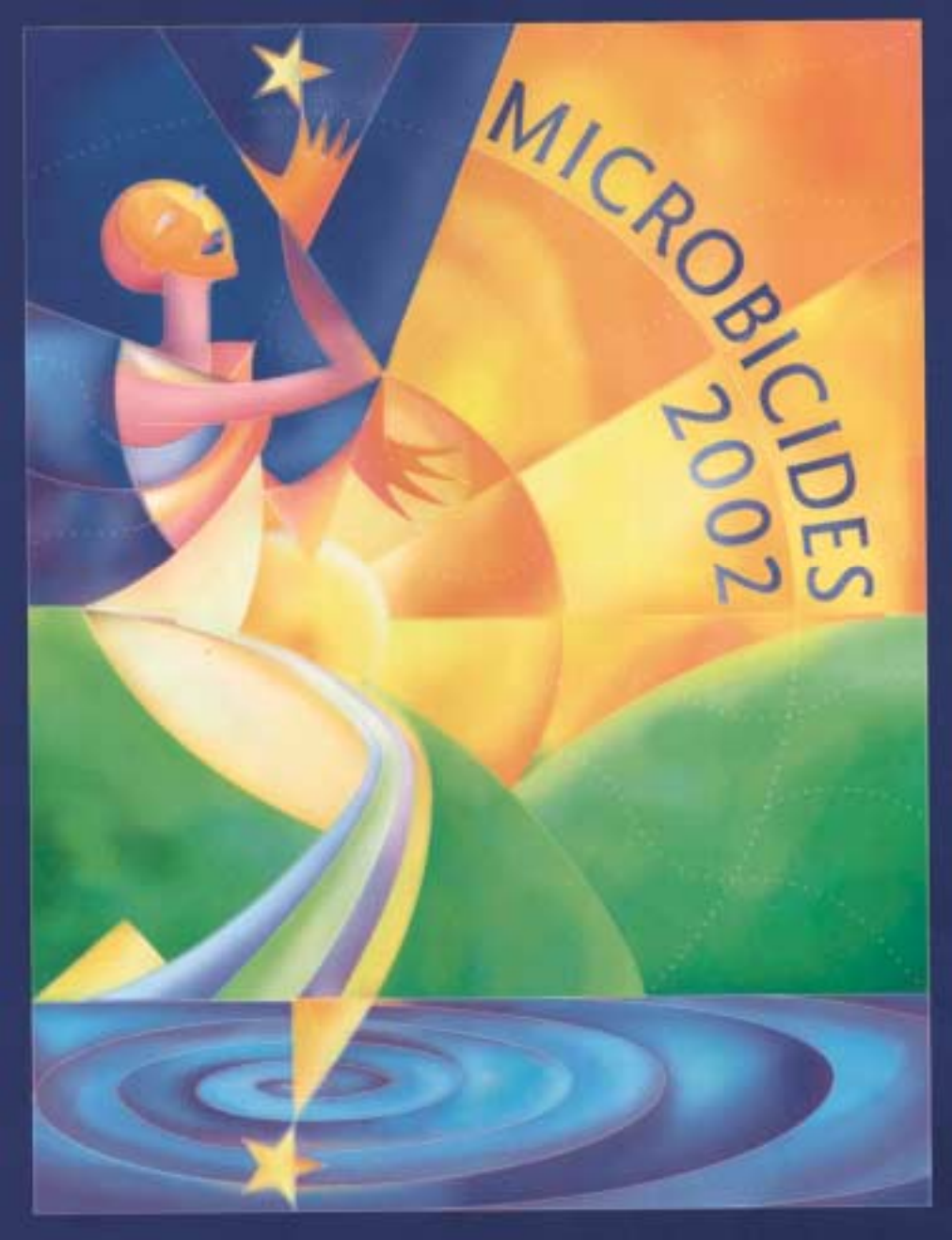
To treat or not to treat?

- How about people who seroconvert during the trial?
- How do we look after them as they will require treatment probably 5 years later
- What infrastructure do we put in place?
- Do we have the capacity to do this?

We cannot afford to keep quiet

**“If you do not cry out,
you will die unheard....”**

Swaziland Proverb



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