Duplicate

Women, Science, Ethics and HIV Vaccine Trials in Africa

Nicola W Barsdorf, MHS
Douglas R Wassenaar, PhD
Linda M Richter, PhD
African AIDS Vaccine Programme (AAVP)
Ethics, Law and Human Rights Working Group (ELH)
School of Psychology
University of KwaZulu-Natal, Pietermaritzburg
South Africa
Email:
barsdorfn@ukzn.ac.za
wassenaar@ukzn.ac.za

African AIDS Vaccine Programme

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Objectives

1. To motivate for the importance of a gender focus in HIV vaccine research.
2. To highlight the position of women in the HIV/AIDS pandemic in Africa.
3. To discuss the implications of women's higher risk and lower societal status for HIV vaccine research.

Objectives cont'd

4. To selectively review trial enrollment of women to date, more specifically HIV vaccine trials.
5. To suggest strategies to address challenges for participation of women in HIV vaccine preventive research.

1. The need for a focus on gender

Context:

- "Vaccine science has rarely paused to consider gender differences, and has rarely had to."
- "…vaccine trials will need to address gender both from a scientific and social perspective."

(IAVI Report, 5, 2001)

1. The need for a focus on gender cont'd

How gender might impact transmissibility and acquisition of HIV:

- Zambia
  - Study of serodiscordant couples
  - Suggests gender differences in how viral load relates to transmissibility
- Kenya
  - HEPS
  - Sex worker cohort
  - Small minority of women do not seroconvert despite repeated exposure to HIV from multiple partners

1. The need for a focus on gender cont'd

- Could a vaccine really show significant differences in men versus women?

- Experimental vaccine against HSV-2 (virus that causes genital herpes)
  - Two Phase III trials suggest vaccine provides
    - SOME protection for women
    - NONE for men

- Vaccines may not always be gender-blind

1. The need for a focus on gender cont'd

- To get the gender-specific data that are needed, vaccine trials will need to address gender both from a scientific and social perspective.

2. Women and HIV/AIDS in Africa

- There is general recognition by bioethicists that rural women in developing countries may need to be regarded as vulnerable populations.

2. Women and HIV/AIDS in Africa cont'd

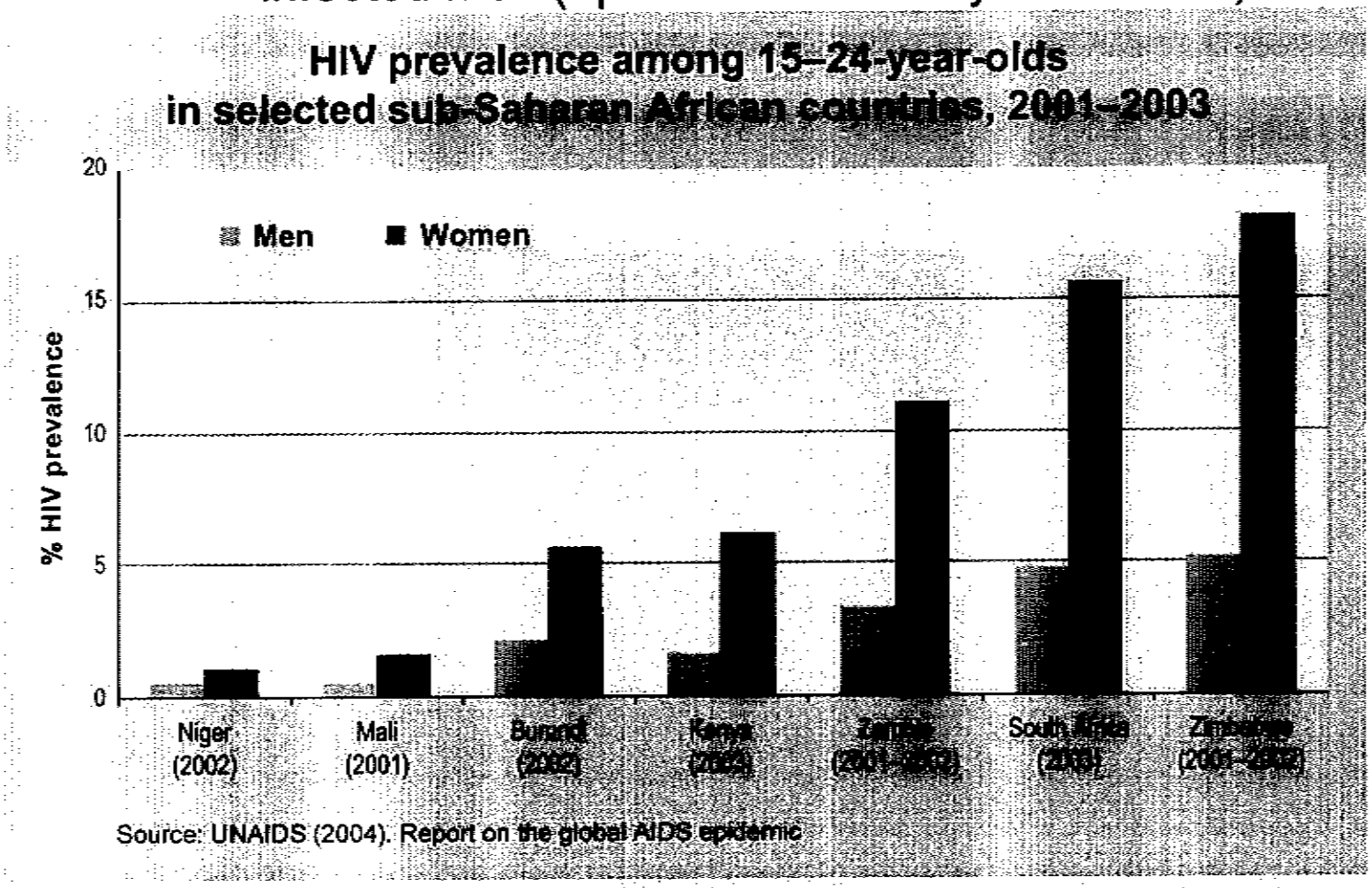
- Some acquired vulnerabilities are generic to developing countries, such as:
  - Poverty, landlessness
  - Migrancy, decline of traditional structures
  - Mixed economies (formal vs. informal sector)
  - Acculturation
    - Postcolonial degradation of traditional protective factors and social cohesion
    - Male migrancy in search of employment

2. Women and HIV/AIDS in Africa cont'd

- Women are the Axle around which HIV infection turns in the developing world.
- The statistics show that:
  - 57% of adults infected are women
  - 75% of young people infected are women and girls
  - Women in Sub Saharan Africa:
    - carry 82% of the global burden of infection in adult women
    - 30% more likely to be HIV positive than men
  - Some infection rates among pregnant women (2003):
    - 23% in Namibia
    - 26% in South Africa
    - 39% in Swaziland and Zimbabwe

2. Women and HIV/AIDS in Africa

Today there are on average 13 infected women for every 10 infected men (up from 12 to every 10 in 2002)



2. Women and HIV/AIDS in Africa cont'd

Women's risk can be identified in the following domains:

- Biological
- Economic
- Legal
- Social

2. Women and HIV/AIDS in Africa cont'd

Biological reasons

- Susceptibility of vaginal tract – especially in younger women
- Men are more likely to transmit HIV to women than women to men
  - Women 7 times more likely than men to become infected during a sexual encounter
- Women are more likely to have asymptomatic STDs which increase risk of HIV infection

2. Women and HIV/AIDS in Africa cont'd

Economic reasons

- Generally women make less money than men/less opportunity to work
- Financially dependent on men – especially if mothers supporting children
- Economically dependent women find themselves in relationships where don't have much power
  - give sex in return for food, shelter, money (transactional sex)
  - Frequently have no power to refuse sex or insist on condom use
- Lack of economic agency – implications for access to and control of resources to protect health

2. Women and HIV/AIDS in Africa cont'd

Legislation as risk

- Gender insensitive or even biased laws keep women subservient to men and perpetuate male-female power dynamics
  - **Botswana:** tribal courts = adultery as a female crime only
  - **Lesotho & Swaziland:** marriage in community of property = woman is considered a legal minor
  - **Mozambique:** husband has authority to control wife entering into commercial transaction.

2. Women and HIV/AIDS in Africa cont'd

Social reasons: Gendered norms and practices as risks

- Lower female social status
- Women as property of males
- Access to VCT (or follow-up) viewed with deep suspicion by male partners (and others)
- Women are the caretakers of the ill and dying

2. Women and HIV/AIDS in Africa cont'd

Social Reasons: Education

- Males favoured in access to education
- Lower female literacy: 41% illiteracy in South Africa
- Result is that many African women have reduced access to information on HIV
  - Somalia: >70% & Guinea Bissau & Sierra Leone: 40% adolescent girls (15-19) have never heard about HIV
  - Tanzania: 50% know can get tested but only 6% have been
  - Zimbabwe: 11% been tested
- Young women often resort to anal intercourse to avoid pregnancy but this is higher risk

- How do you reach a poor, isolated, illiterate rural or urban woman who is not at school, at work, at church or a clinic attendee?

2. Women and HIV/AIDS in Africa cont'd

Social Reasons: Sex practices

- Dry sex
- Male refusal of condoms - suspicion of infidelity
- Cultural norm availability of women for sex on demand
- Women's refusal of sex highly likely to lead to divorce or lack of access to resources provided by relationship
- Transactional sex
- Older men seek younger women because they are perceived as lower risk
- Acceptance of multiple partners for males

2. Women and HIV/AIDS in Africa cont'd

Social Reasons:

- Rape
  - Dramatic incidence in this region estimates of 55/100K – or one rape every 23 seconds in SA.
  - South Africa: highest reported number of rapes in the world.
- Violence
  - Women as victims of coercive, non-consensual sex.
  - 19% to 28% women in South Africa subjected to violence by current or ex-partner.
  - Soweto: Significantly higher rates of HIV found in women who were physically abused, sexually assaulted or dominated by their male partners.
- Violent sex leads to tearing of soft tissues and higher risk of infection

2. Women and HIV/AIDS in Africa cont'd

- Women's role as caregivers – additional psychosocial burden and vulnerability
  - Up to 37% of pregnant women HIV+
  - Young girls may drop out of school to care for ailing parents or siblings
  - Mothers more likely than fathers to care for children or take in orphans
  - Social stigma and discrimination often lead to social isolation of women caregivers denying them psychosocial and economic support

3. Implications of women's status for HIV preventive research

- Women's vulnerability to HIV and their social inequalities are **not** independent

"Despite women's higher biological vulnerability it is the legal, social and economic disadvantages faced by women and girls in most societies that greatly increases their HIV vulnerability."

(UNAIDS, 2004)

3. Implications of women's status for HIV preventive research

- Gender-sensitive approaches are therefore key when designing HIV prevention programs.

- This is especially true with methods such as the HIV vaccine, female condoms and microbicides that can be woman-controlled and that would not require negotiation with the partner.

3. Implications of women's status for HIV preventive research

- Successful implementation of HIV vaccine trials will need to look at gender issues when considering:
  - The ability of participants to undergo VCT for HIV
  - Willingness or ability to meet the requirements of trial participation (clinic visits, blood draws, use of contraceptive methods)
- These issues will have different impacts on:
  - Women in stable partnerships
  - Women with multiple partners
  - Women engaged in commercial sex work

3. Implications of women's status for HIV preventive research

Problematising informed consent:

- Women's active informed participation in science is vital to
  - Prevention efforts in general
  - Prevention efforts that could benefit women

- However, the account of women's circumstances in many parts of Africa suggests that:
  - The experience of consent in such populations may be seriously compromised or absent.
  - Enrollment and retention of women in interventions may be compromised

3. Implications of women's status for HIV preventive research

Problematising informed consent cont'd:

- IC rests on assumptions about Autonomy
- Informed consent requires:
  - Information and comprehension
  - Voluntariness and consent
- "Impairment of voluntariness" (vulnerability) calls the ethics of standard IC procedures in such settings into question.
- We have very little empirical social and anthropological data on women's actual, grounded, daily experience of voluntariness and consent.

3. Implications of women's status for HIV preventive research

Problematising informed consent cont'd:

- In contrast, we have overwhelming information that for many women in Sub-Saharan Africa, voluntariness and the experience of consent are either absent or compromised; particularly for those women most likely to be candidates for HIV vaccine trials.
- Interestingly, some vaccine trials have failed to recruit and retain significant numbers of women (e.g. Kenya & New York "pretty horrendous" >5%, IAVI Report 2001 5, p. 16).

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4. Enrollment and retention of women in HIV vaccine trials.

- Health researchers need to take women's position into account when planning recruitment into trials:
  - Kenya: Only 2 of 18 Phase I trial volunteers were women: "many women don't have the capacity to make the decision themselves" (IAVI Report 5, 2001 p. 7).
  - South Africa: Chris Hani Baragwanath data is very promising.
  - Other trials: We need data on enrollment by gender.

5. Addressing challenges for participation of women in HIV preventive research

- The position of women, as outlined above, and the standard western assumptions about true voluntariness to participate in research appear to be separate worlds.

- There is a need for a bridge between these worlds to ensure ethical, emancipatory health research practice.

5. Addressing challenges for participation of women in HIV preventive research

- This bridge requires informed and sensitive social-scientific research and action.

- This bridge must be built on the voices of women.

5. Addressing challenges for participation of women in HIV preventive research

How do we operationalise this?

1. Commission a desk-study to identify the enrollment practices and outcomes by gender for HIV vaccine trials in Africa and other developing countries.

2. A systematic study of the sites with the best enrollment strategies to identify key factors associated with best enrollment outcomes by gender.

5. Addressing challenges for participation of women in HIV preventive research

How do we operationalise this? Cont'd

3. Develop a "resource pack" of materials outlining key elements of best recruitment and enrollment practices to build capacity at other African sites

4. Build a network and database of key persons especially committed to improving the enrollment of women in African settings

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Thank You

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Questions & comments to:

Nicola Barsdorf

barsdorfn@ukzn.ac.za

Douglas Wassenaar

wassenaar@ukzn.ac.za

References and resources:

- Abdool Karim, Q. (2000). *Women and AIDS: Epidemiology and gender barriers to prevention in KwaZulu-Natal, South Africa*. University of Natal: Unpublished doctoral dissertation.
- Bot, M., Wilson, D., & Dove, S. (2000). *The education atlas of South Africa*. Johannesburg: Education Foundation.
- Beksinka, M., Rees, H., Keinschmidt, I., & McIntyre, J. (1999). The practice and prevalence of dry sex among men and women in South Africa: A risk factor for sexually transmitted infections? *Sexually Transmitted Infections, 75*, 178-180.
- Crawford, N. (October, 2003). *Helping women beat the odds*. Monitor on Psychology.

References and resources:

- Decosas, J., Kane, F., Anarfi, J., Sodji, K., & Wagner, H. (1995). Migration and AIDS. *Lancet, 346*, 1304.
- DeZoysa, I., Sweat, M., & Denison, J. (1996). Faithful but fearful: Reducing HIV transmission in stable relationships. *AIDS, 10*, S197-S203.
- Dunkle (2004).
- Fischbach, R., & Herbet, B. (1997). Domestic violence and mental health: Correlates and conundrums within and across cultures. *Journal of Holistic Nursing, 15*, 282-302.
- Fowler, M., Melnick, S., & Mathieson, B. (1997). Women and HIV: Epidemiology and global overview. *Obstetrics and Gynecology Clinics of North America, 24*, 705-729.

References and resources:

- Harrison, A., Smit, J. A., & Meyer, L. (2000). Prevention of HIV/AIDS in South Africa: A review of behaviour change interventions, evidence and options for the future. *South African Journal of Science, 96*, 285-291.
- Heise, L., & Elias, C. (1995). Transforming AIDS prevention to meet women's needs: A focus on developing countries. *Social Science and Medicine, 40*, 931-943.
- Kapoor, S. (2003). *Gender issues in HIV vaccine trials in India: Analyses and recommendations.* Report based on consultations held in New Delhi, 2002-2003.
- Kruger, A. M. et al. (2003). HIV/AIDS: Impact on maternal mortality at the Johannesburg Hospital, South Africa, 1995-2001. *Journal of Obstetric Anesthesia, 12,* 164-168.

References and resources:

- Larson, A. (1989). Social context of immunodeficiency virus transmission in Africa: Historical and cultural bases of East and Central African sexual relations. *Review of Infectious Diseases, 2*, 716-731.
- Leclerc-Madlala, S. (2000). *Demonizing women in the era of AIDS: An analysis of the gendered construction of HIV/AIDS in KwaZulu-Natal*. Unpublished doctoral dissertation, University of Natal, Durban.
- McIntyre, J., & Gray, G. (2000). Antiretroviral treatment to prevent mother-to-child transmission of HIV-1. *South African Journal of Science, 96*, 277-280.
- O'Leary, A. & Neighbors, C. J. (unknown). Title unknown. *Health Psychology, 18*(4).

References and resources:

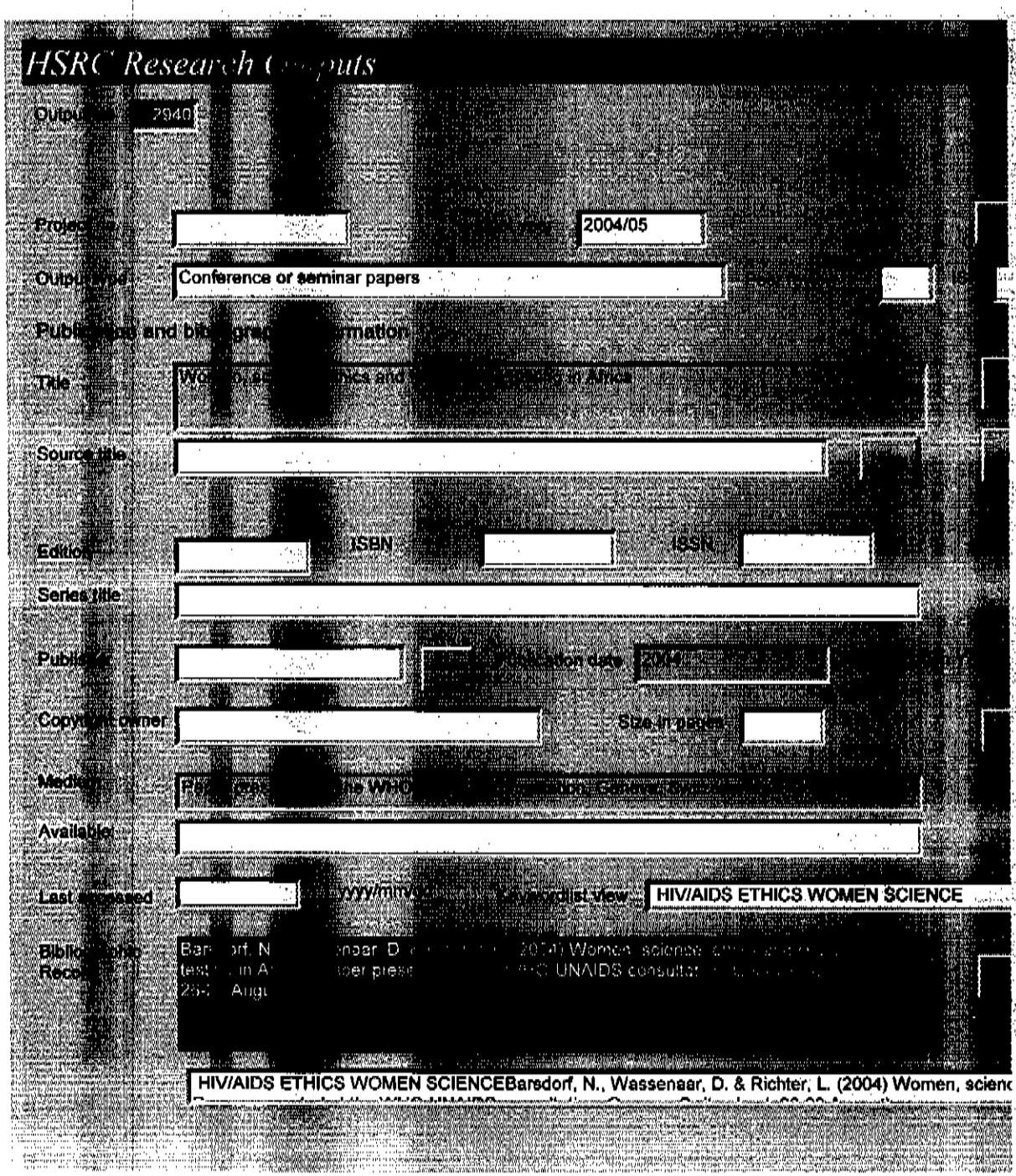
- O'Leary, A. & Neighbors, C. J. (unknown). Title unknown. *AIDS Education and Prevention, 15*(1).
- Orubuloye, I., Caldwell, J., & Caldwell, P. (1993). African women's control over their sexuality in the era of AIDS: A study of the Yoruba of Nigeria. *Social Science and Medicine, 37*, 859-872.
- Ramjee, G. (2000). Reducing women's risk of HIV infection: South Africa's contribution to microbicide research and development. *South African Journal of Science, 96*, 280-285.
- Reid, E., & Bailey, M. (1993). Young women: Silence, susceptibility and the HIV epidemic. HIV and Development, Issues Paper No. 12. New York: United Nations Development Programme.
- Roux, P. (2001). *Informed consent for voluntary counselling and testing for HIV infection in South African mothers and children: An assessment of burdens and consequences and an argument for a modification in the process of informed consent*. Unpublished M.Phil. (Bioethics) Dissertation, University of Cape Town.

References and resources:

- Sinka, K., Mortimer, J., Evans, B., & Morgan, D. (2003). Impact of the HIV epidemic in Sub-Saharan Africa on the pattern of HIV in the UK. *AIDS, 17*, 1683-1690.
- UNAIDS (2004). *Report on the global HIV/AIDS epidemic*. Geneva: UNAIDS.
- UNAIDS (2003). *Report on the global HIV/AIDS epidemic*. Geneva: UNAIDS.
- UNAIDS (2000). *Report on the global HIV/AIDS epidemic*. Geneva: UNAIDS.
- UNICEF (2001). AIDS Epidemic update December 2001: 17.
- Van der Straten, A., King, R., Grinstead, O., Serofilira, A., & Allen, S. (1995). Couple communication, sexual coercion and HIV risk reduction in Kigali, Rwanda. *AIDS, 9*, 935-944.
- Van der Vliet, V. (1999). The ecology of South Africa's AIDS epidemic. *Pulse Track*, July 15, pp. 1-5.

References and resources:

- Van der Vliet, V. (1996). *The politics of AIDS*. London: Bowerdean Publishing Company.
- van Niekerk, A. A. (no date). *Sexuality, power and women's health in Africa's HIV/AIDS pandemic*. Unpublished manuscript, University of Stellenbosch, Centre for Applies Ethics, Stellenbosch.
- Wasserheit, J. (1992). Epidemiologic synergy: Interrelationships between HIV and other STDs. *Sexually Transmitted Diseases, 19*, 61-77.
- Wilkinson, D., Abdool Karim, S., Harrison, A., Lurie, M., Colvin, M., Conolly, C., & Sturm, W. (1999). Unrecognized sexually transmitted infections in rural South Africa women: A hidden epidemic. *Bulletin of the World Health Organisation, 77*, 22-28.
- Williams, B. G., Gouws, E., & Abdool Karim, S. S. (2000). Where are we now? Where are we going? The demographic impact of HIV/AIDS in South Africa. *South African Journal of Science, 96*, 297-305.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