



African AIDS Vaccine Programme



Revisiting ethical issues in preventive HIV vaccine trials in the light of the early closure of the STEP and Phambili trials

2 December 2008, 14.00-17.00pm, Quay West, Auckland, New Zealand,
UNAIDS African AIDS Vaccine Programme Satellite Session
at the 9th Global Forum on Bioethics in Research

Sponsor

WHO UNAIDS African AIDS Vaccine Programme

Organisers

Prof Doug Wassenaar (AAVP ELH)

Ms Nicole Mamotte (AAVP ELH)

Background

Many stakeholders are processing the implications of the HVTN 502 ("STEP") trial results, which indicated that firstly, the Merck vaccine candidate was not efficacious and secondly, it may have enhanced the susceptibility of certain participants to HIV infection (Merck/ HVTN, 2007). The results of a sister trial which was closed early in South Africa, HVTN 502, ("Phambili") are also being analyzed. The STEP trial provided the field with important answers (ie., the candidate vaccine does not prevent infection) and alerted the field to some significant concerns (ie., the candidate may have not be safe for certain sub-groups of participants). As such, the trial has yielded information that is, on the one hand, critical but, on the other, disappointing and alarming for many stakeholders.

Negative trial results are an opportunity for careful reflection on both scientific and ethical concerns. In this instance, ethical issues could include: community participation; collaborative partnerships; informed consent; assessment of risk behaviour; ethical or regulatory review; monitoring by DSMBs, access to treatment and care; or dissemination of results. To be more specific: maintaining the confidence of the public and other stakeholders in HIV vaccine trials in the face of disappointing results is a current ethical challenge. Communicating the likelihood and magnitude of the risk of enhancement in other HIV vaccine trials is a critical informed consent issue.

On 13 October 2008, the Ethics, Law and Human Rights Collaborating Centre of the African AIDS Vaccine Programme hosted a satellite session on the 'Post STEP/Phambili Ethics Landscape' at the AIDS Vaccines 2008 Conference, Cape Town, South Africa, to provide stakeholders with an opportunity to identify the ethical issues that emerged from the closure of these trials and identify how future trials might most appropriately respond to similar issues.

Description of session

A follow up session is planned for 2 December 2008, 14.00-17.00pm, at the 9th Global Forum on Bioethics in Research, Quay West, Auckland, New Zealand. The purpose of this follow up session is 1) to report on the ethical concerns identified at the October meeting, 2) to get feedback on the brief resource document developed as a result of the October meeting, and 3) to identify how to take ethical concerns further. Global Forum participants will be invited to further debate and identify additional concerns with regard to the potential impact of the STEP/Phambili results on current ethical norms and standards. There will be brief inputs from invited speakers followed by facilitated discussion with the aim of drafting a short collaborative paper on the outcomes of the session.



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Chair

Prof Doug Wassenaar (AAVP ELH)

Presenters

Ms Nicole Mamotte – AAVP ELH: Report back on Cape Town satellite session, 13 October 2008, “The Post-STEP/ Phambili Ethics Landscape” (20 minutes)

Dr Reidar Lie - NIH: Commentary 1 (20 minutes)

- Dr Reidar Lie is a senior staff scientist in the US NIH Department of Bioethics, where he is responsible for the Unit on Multinational Research. Dr. Lie has co-edited five books or special issues of journals, and published in the areas of basic cardiology, history and philosophy of medicine, decision theory, research ethics and ethics and health policy. His current research interests include ethical issues of international collaborative research and ethical issues in health sector reform in developing countries. He has directed major collaborative projects on ethics and health policy in Thailand and Sri Lanka, and coordinated and participated in several bioethics projects funded by the European Commission. He has been a consultant to WHO and UNAIDS on international research ethics, and has organized training workshops on ethical issues in research and health care in Latin America, Asia, Europe and Africa on behalf of WHO.

Dr Zarifah Reed* – Formerly of UNAIDS/WHO, now with the Regional Emerging Diseases Intervention Centre, Singapore. Commentary 2 (20 minutes) (*Speaker to be confirmed)

Target audience

Stakeholders include investigators, sponsors, research ethics committee (REC) members, regulators, community representatives and advocates. It is anticipated that 20-25 people, already in Auckland to attend the 9th Global Forum on Bioethics in Research, Dec 3-5, will attend the session. Admission to the session will be free of charge for GFBR delegates on a first-come first-admitted basis until the session is full. Interested parties are requested to RSVP to Ms Nicole Mamotte by Email aavp1@ukzn.ac.za as soon as possible. Refreshments will be served.

Rapporteurs

Ms Jenny Koen (HIV AIDS Vaccines Ethics Group (HAVEG))

Ms Zaynab Essack (HAVEG)

Draft Agenda

Revisiting ethical issues in preventive HIV vaccine trials in the light of the early closure of the STEP and Phambili trials		
Welcome Tea		14.00 – 14.15
Welcome and introduction	Prof D Wassenaar	14.15 – 14.20
Report-back on Cape Town satellite session, 13 October 2008, “The Post-STEP/ Phambili Ethics Landscape”	Ms N Mamotte	14.20 – 14.40
Commentary 1	Dr R Lie	14.40 – 15.00
Commentary 2	Dr Z Reed	15.00 – 15.20
Afternoon Tea		15.20 – 15.40
Facilitated Discussion	Prof D Wassenaar	15.40 – 16.55
Close	Prof D Wassenaar	16.55 – 17.00