Bioethics and public health research, including ethical guidelines related to post-trial access to drugs.

REPORT 2

AFRICANS DISCUSS ETHICS OF BIOMEDICAL RESEARCH

By Bebe Loff

Cape Town, South Africa, provided the scenic backdrop for the Third Global Forum on Bioethics in Research held on Feb 21–23, which was followed by the Pan-African Bioethics Initiative (PABIN).

The forum provides a venue in which developing countries have significant input into the ethical debate on international collaborative research sponsored by industrialised countries and done in developing countries. Two thirds of the 110 delegates came from developing countries. Of the 40 countries represented, half were African. The forum is sponsored by the US National Institutes of Health and the Medical Research Councils of South Africa and the UK, WHO, and other international agencies. This year's forum was organised by the UK's Medical Research Council.

The meetings focused on some of the key issues in international collaborative research. These include whether current ethical guidelines constrain or promote post-trial access to drugs, devices, or vaccines; the difficulties in creating ethical guidelines and review processes in developing countries; the standard of care to be provided during trials; traditional medicines; genomics and global health; and culture and informed consent. Participants suggested that we need to move from the discussion on the content of ethical guidelines to their implementation.

Churchill Lukwiya Onen, from the Princess Marina hospital in Botswana, discussed concepts of justice in relation to post-trial access to drugs and devices. He noted that "differences in our interpretation and difficulties in translating research principles into realities must be urgently and amicably resolved".

A comprehensive picture of the difficulties of doing HIV vaccine trials involving women in South Africa was provided by Douglas Wassenaar of the University of Natal. Women in sub-Saharan Africa carry 82% of the global burden of HIV infection. Their vulnerability to infection is, not surprisingly, affected by their status. This in turn is affected by sexual practices including the decreasing age of sexual debut, dry-sex practices—where foreign material is placed in the vagina to lessen lubrication and create more friction, male refusal to use condoms, a higher incidence of untreated STDs, female inability to behave assertively, transactional sex, and acceptance of multiple partners for males. There has also been an increase in child rape because of the belief that intercourse with a virgin will provide cure STDs.

He noted that fostering voluntary consent is a new ethical agenda in some communities and "would be perceived as a subversive and politically destabilising action". Women's experiences of consent are likely to be severely compromised and it is these women who may be candidates for HIV trials. Like Onen, Wassenaar called for a transition from aspirational ethical codes to their practice relying on "emancipatory informed and sensitive social-scientific research and action...built on the voices of women".

Godfrey Tangwa of the University of Yaounde, Cameroon, talked about the second scramble for Africa and how the continent presents the biggest and most attractive laboratory for western researchers. Where ethical review committees exist they are inundated with applications. He highlighted the lack of regulation of research in some African countries, and called for the establishment of strong regional and national regulatory frameworks. This would also enable developing countries to make informed contributions to discussions about international guidelines.

With the greater involvement of genomics in drug development Peter Singer of the University of Toronto, Canada, posited that this science has the potential to increase the global pharmaceutical divide and increase health inequities. This effect, he said, was not unavoidable but much activity was required now. An opinion leader network should be created across different sectors: government, industry, NGO/patient organisations, scientists, and health-care leaders. Participants should familiarise themselves with the current state of genomics technology and frameworks for analysing ethical and legal issues. He called for a Commission on Global Genomics Governance to make recommendations for genome-related issues and activities. He asserted that there was an opportunity for pharmaceutical companies to become positive players.

The forum was treated to a visit to the South African Medical Research Council where the meeting heard from Motlalepula Gilbert Matsabisa. He discussed traditional medicines and a scheme being developed by the Council to try to ensure that any benefit derived from knowledge acquired from local communities about traditional medicines would be shared by those communities.

PABIN is part of the Strategic Initiative for Developing Capacity in Ethical Review, a worldwide collaborative of institutions and people interested in promoting ethical review. It was established within the tropical disease research division in WHO. The intention behind PABIN is to “share understandings of good ethical practices between African experts and international organisations involved in research in Africa” and the meeting continued discussion of the issues raised during the forum.

Participants from African countries discussed the difficulties they face in creating rigorous ethical review processes. The lack of regulation of ethical review and unavoidable conflicts of interest arising amongst the small number of people with the skills to be members of ethics committees were consistent themes. Formal academic training in ethics is limited and, in many countries, non-existent.

Donna Knapp van Bogaert of South Africa talked about the challenges of corruption, which she said thrived in environments of poor governance, and were exacerbated by poverty. She described the politicisation of research, noting that in some states research could only proceed if it was authorised by a particular individual. People may be appointed to boards for factors unrelated to their knowledge or experience. It may be exceedingly difficult to act as a whistleblower, she said.

While the challenges of creating ethical guidelines and processes for research are significant in industrialised countries, fundamental issues arise for developing countries who may not have sufficient resources to create the infrastructure for ethical research. All participants agreed that it is crucial that support continues for initiatives such as PABIN.