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Poster presentation

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P15-29 LB. From ethical principle to practice: Training the trainers CA Hankins*1, S Osmanov² and RS Gutnick²

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Background

UNAIDS and the World Health Organization (WHO) initiated a series of consultations aimed at developing clearer definitions of ethical principles and procedures for the conduct of scientifically rigorous, ethically sound trials. The result was a revision of the 2000 UNAIDS guidance document on ethical considerations for HIV vaccine trials that better reflects current key scientific and ethical concerns. To assist mainly low- and middle-income countries to utilize these documents in the ongoing development of their own regional, national, and local research, regulatory, and legal frameworks, WHO, UNAIDS, and the African AIDS Vaccine Programme (AAVP) embarked on a process to develop training curricula and materials.

Methods

Two regional African workshops (English and French) convened to pilot test training curricula brought together key stakeholders, including ethics committee members, researchers, advocates, policy makers, research sponsors, government representatives, and regulators. They exchanged perspectives on the UNAIDS/WHO guidance document Ethical considerations for biomedical HIV prevention trials and other relevant documents. Application of the guidance was explored using an interactive case-based 'train the trainers' methodology.

Results

Workshop participants made a strong case for engaging all relevant stakeholders in structured, participatory, and transparent decision-making processes for ethical trial conduct. In addressing several contentious issues including access to care and treatment and evolving standards of

prevention, a procedural approach focused on structured negotiating processes was seen as the optimal strategy. Specific guidance points - e.g. issues related to women and adolescent girls in trials - were identified as complex in their application and further discussion both in the workshop and at trial sites was recommended, along with more training materials exploring these issues.

Conclusion

Based on recommendations from the workshops' positive evaluations, revised training curricula and materials and a facilitator's guide are being published as a complementary kit to the guidance. Additional regional workshops are being planned.