



UNAIDS
JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS

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Consultation on Standards of Prevention in HIV Prevention Trials

**Speke Resort Munyonyo
Kampala, Uganda
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Summary

- Urgency
 - Pro 2000 results
 - PrEP trials – Thailand IDU and iPrEX
 - Interim looks in next 6-9 months
 - Research development realities (eg IRB)
- UNAIDS guidance; evolution
 - Beyond vaccines
 - Treatment availability (feasibility not static)
 - Negotiation vs. consultation
 - Stakeholders – “key”, “all”
 - Community, government
 - Ethical review committee
 - Procedural vs. substantive

Summary

- Issues “resolved” in guidance vs. community and country
 - “Researcher’s dilemma”; conflict of interest (obligation)
 - » Empirical evidence
 - Benefits and burdens
 - » Individual
 - » Community
 - » Country
 - “Undue” inducement
- Ethics beyond research
 - Resource constraints and allocations
 - Stewardship of resources

Ethical Frameworks

- Different frameworks
- Ethical frameworks somewhat limited for public health research
- “Public Health Ethics”
 - More intellectual development
 - Need to act
 - Public health “equipoise”

Decision making

- Areas
 - Research
 - Normative guidance
 - Implementation
- ?? Criteria about evidence
 - How much
 - How strong
 - Populations
 - Routes of transmission
 - others

Act despite uncertainty

- Implementation/policy
 - PrEP roll out
 - Trials phased but pressure for guidance
 - Urgency – already in community
 - HPV Vaccine
 - Impact on Uptake?
- Trials
 - “back of room” exercise
 - Facts and predictions
 - “Ethical disagreements” sometimes due to lack of clarity on facts
 - Distinguish

Male Circumcision

- Ethical
 - Informed consent – info on risks
 - Inclusion criteria – “coercion?”
- Scientific
 - Eastern Cape
- Feasibility
 - Variable by setting
 - Counsel, refer, provide, pay for, etc.

Pro 2000

- Ethical
 - Level of efficacy, use effectiveness
- Scientific
 - Safety at high frequency of use ??
 - Will MDP be enough?
- Feasibility
 - Timing
 - Registration, manufacturing, sustainability
 - Use in trials of other gels

PrEP

- Ethical
 - Resistance ?
- Scientific
 - Effectiveness
 - Resistance
- Feasibility
 - Exists, in community
 - Cost
 - Public understanding about use and effectiveness

Important Factors : Pro 2000

- Ethical
- Scientific
 - Strength of evidence (one or multiple trials)?
 - Confidence intervals, confidence
 - Registration, normative agency recommendation
 - Policy
 - Proxy for rigorous review
 - Safety of product (e.g. residual safety concerns)
- Feasibility
 - Manufacturing
 - Likely post-trial sustainability
 - Availability in general community
 - Community preparation for introducing partially-effective NPT

Important Factors – Circumcision

- Ethical
 - Benefits accrue to partner not participant (microbicide)
 - “Undue inducement” (depending on availability, cost)
 - Conflict of interest if counseling only?
 - Acceptability?
 - Risk research overall?
- Scientific
- Feasibility
 - Counseling v. referring vs. providing vs. paying for
 - Depends on:
 - Availability on site
 - Availability in community
 - » Local vs. international standard of care
 - Cost? Who pays?

Today

- Emphasize scientific and feasibility
 - What are we doing now?
 - Implications for trial size and feasibility
 - Evidence
 - What we are doing now
 - Diverse views on thresholds of evidence
 - Exercise: Criteria, questions
 - “real life” prevention trials
- Identify and refine criteria
- Areas of agreement, ongoing work