

# Current Practice: Prevention Services Across HIV Prevention Research Trials



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# Goals of the Mapping Exercises

- Assess the care and prevention services provided to HIV prevention trial participants.
- Explore the factors that inform care- and prevention-related decisions at trial sites.
- Provide recommendations that strengthen the field's ability to provide appropriate care and respond to challenges.



# Information Sources

- Mapping the standards of prevention and access to care across microbicide trials, and one trial of the diaphragm to prevent HIV (*SOC mapping*).
- Separate abbreviated mapping looking specifically at prevention services across a wider range of HIV prevention research trials.

# Microbicide Mapping Exercise

- Standards of Prevention and Access to Care (SOC) mapping:
  - Reviewed 6 late-stage microbicide studies and 1 of the diaphragm
  - Desk review of study protocols & international and site-level documents (SOPs, manuals)
  - In depth interviews with international investigators and sponsors
  - Visits to 6 sites and community clinical facilities in 4 countries
  - In-depth interviews with trial site staff
  - Consultation in Johannesburg, SA (*June, 2007*)

# Variation of Prevention Services

- The type and level of prevention services provided to participants at HIV prevention research sites vary greatly.
- We will look at:
  - Risk reduction counseling( SOP)
  - Condom promotion and provision
  - STI screening and treatment
  - Prevention services for partners



# Risk Reduction Counseling

- All studies but one offered risk reduction counseling on-site.
- Counseling typically was of higher quality than what was available at public facilities.
- In one study, all participants were referred to the nearby VCT clinic for risk reduction counseling.
- Site-level variation was seen for:
  - The frequency and intensity of the counseling;
  - What the counseling included; and
  - Who did the counseling.



# Risk Reduction Counseling: Frequency and Staff

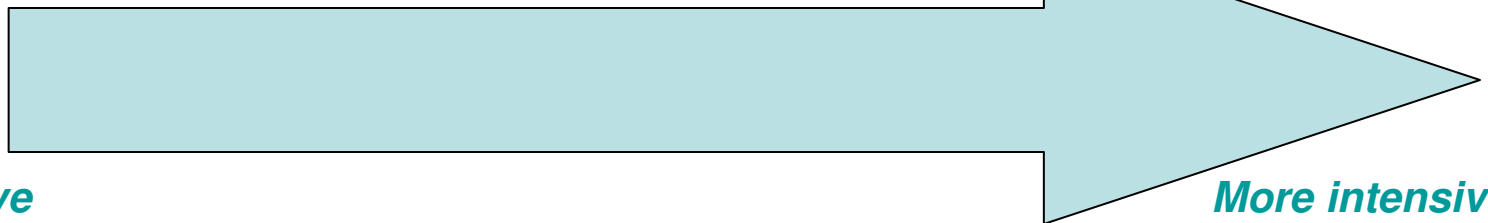
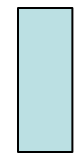
- Some studies offered risk reduction counseling monthly, others quarterly or biannually.
- At most sites, participants could return to the study in between regular visits for additional counseling.
- Who performed risk reduction counseling varied between studies and sites, and included:
  - Counselors, Clinicians, Social Workers, Field and Outreach Workers, Peer Educators, Psychologists, and Social Scientists.

# Risk Reduction Counseling: Content

Referred all  
participants to  
nearby VCT

Study-wide  
standard script

Tailored  
messages & RR  
plans to specific  
client needs



*Least intensive*

*More intensive*

# Promotion and Provision of Condoms



## Male Condoms

- All studies provided male condoms and technical demonstrations
- 8 out of 16 studies taught condom negotiation skills



## Female Condoms

- Large variation seen in the provision of female condoms across studies and individual research sites.
- Only 5 out of 16 studies demonstrated the use of female condoms. Of these, 3 of 5 demonstrated use using a penile model.

# Microbicides Mapping: STI Care Example

- **CONRAD Cellulose Sulfate Study (*Benin*):**
  - Screening, enrollment, and quarterly
  - Syndromic management used between screening visits
  - Single-dose oral medications where possible, including Acyclovir
    - Went beyond local guidelines to treat chlamydia with single-dose azithromycin
  - Free partner treatment for STIs available on-site
- **FHI SAVVY Study (*Ghana/Nigeria*):**
  - Screening, enrollment, and at 6 months
  - Follow-up visits at outreach posts, participants would be referred to study clinic if they reported symptoms
  - Treatment based on local guidelines
  - Women told partners should be tested and treated for STIs if possible (no services available at site)

# Example of the Range of Services

TABLE 4. Sexually Transmitted Infection Prevention, Diagnosis, and Treatment

Site	At initial screening	At enrollment	Follow-up	Treatment	Partner treatment
CONRAD Cotonou, Benin	Screening for NG/CT, with NAAA; RPR; pH; gram stain; pelvic; STI treatment; risk reduction counseling; condoms	Screening for NG/CT, with NAAA; RPR; pH; gram stain; pelvic; STI treatment; risk reduction counseling; condoms	All tests quarterly, as needed and requested	Single-dose oral medications where possible	Free treatment or referral
FHI Cellulose Sulfate Nigeria <i>Site not visited</i>	Screening for NG/CT, with NAAA; STI treatment; risk reduction counseling; condoms	Pelvic; wet mount; RPR	Self-vaginal swabs monthly at outreach sites	Based on national guidelines; no acyclovir	Women given partner treatment if requested

*Extracted from the SOC Mapping Report*

# STI Screening & Care from the Prevention Mapping

- 6 of the 9 studies reviewed provided STI treatment to participants.
- 2 of the 9 offered referrals for treatment  
(*CDC Bangkok PrEP Study & HVTN 204 Vaccine Study*).
- 1 of the 9 offered treatment “only if indicated”.  
(*HVTN 502 STEP Vaccine Study*)

# Microbicides: Cervical Screening

- Provision of cervical screening varied across studies and study sites.
  - South Africa: Free national screening program
    - Study offered screening, ensured diagnosis and treatment
  - Zimbabwe: Limited public services
    - HPTN 035 offered screening, diagnosis, and treatment
    - Study investigator helped to establish a visual cervical screening program
  - Tanzania & Benin: No public services
    - Study did not offer screening
- Cervical screening is not of much use if a system is not in place to address continuing need for diagnosis, treatment & follow up

# Prevention and care services for partners

- Issues associated the provision of partner care and services:
  - Participant confidentiality
  - Participant retention
  - Adherence
  - Disclosure of STI/HIV status
  - Reduce risk of STI re-infection

**No services for partners**

**Referrals and/or tx given to participant to take to partner**

**Individual and couples counseling, STI tx, HIV counseling & testing**



*Least intensive*

*More intensive*

# Provision of other prevention methods

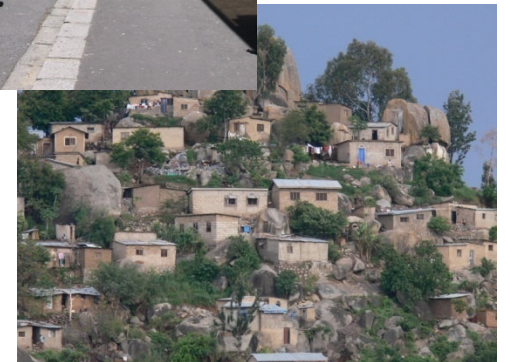
The prevention mapping study asked about other HIV prevention tools offered to trial participants:

- 3 of 9 studies provided education and referrals for **male circumcision**. 1 study offered free circumcision on-site.
- 3 of 9 provided **clean needles** for IDUs (usually only at US sites or upon request). 2 others studies provided education around clean needles.
- One study provided **methadone maintenance**.
- One study provided referrals for **drug treatment**.
- Of the non-herpes suppression studies, only one provided **acyclovir**.

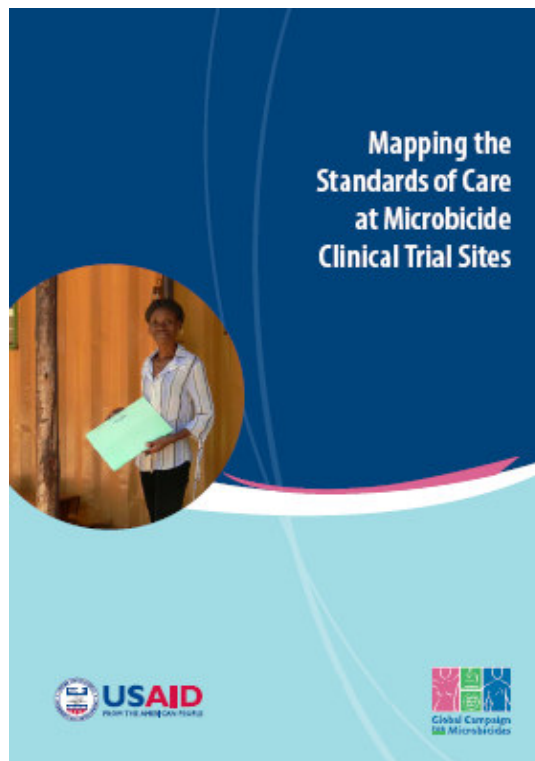


# Variation of Prevention Services

- Overall, the types and level of prevention services provided to participants at HIV prevention research sites vary greatly.
- This variation is due to a range of factors, including:
  - Local guidelines and standards
  - Trial design
  - Locally available services
  - Local resources and context
  - Provider knowledge, comfort, training, and beliefs
  - When the study started



# Conclusions



- Risk reduction services, vary greatly in intensity
- Prevention services offered also depend on the endpoints being studied (e.g. STI)
- The final report offers a **series of recommendations** for the conduct of future HIV prevention research trials

# Conclusion

- Mainly interpreted in the public health context
- Probably a procedural implementation route would be national prevention plans.

# Acknowledgements

- Katie West, Sean Philpott and Lori Heise

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Thankyou