Partnership for Male Circumcision: Achieving Scale

Population Council/PSI Research Plans for Zambia and Swaziland

Male Circumcision and HIV Prevention: Operations Research Priorities
WHO/UNAIDS Meeting
Nairobi, Kenya June 1 & 2 2009
Overview of Research Plans

Formative Research

- Validation study of reporting of MC status (2009, 2010)
- Evaluation of the informed consent process (2009, 2010)
- Determinants of MC uptake or intent for MC (PSI 2009)

Impact Evaluation

- Longitudinal cohort study of risk compensation (2009-2012)

Operations Research (2010-2012)

- Assessment of cost and quality of fixed/mobile clinics, physicians/non-physicians provision of MC
- Optimal post-operative visit schedule
- Methods Improving informed consent
OR Conceptual Framework

Individual and community
- Determinants of MC
- Risk Profiles MC
- IC: Parental Decisions
- Informed Consent

Individual
- Mobile vs. Static
- Physicians vs. Non-Physicians
- Early resumption of sexual activity
- Post-operative visit schedule

Individual and community
- Risk Compensation

Diagram:
- DEMAND
- PRE-SURGERY
- SURGERY
- EARLY POST-SURGERY (ONE MONTH)
- LATE POST-SURGERY
Formative Research: Validation Study

Study Objectives

- Provide recommendations for improving the validity of self-reported MC status
- Inform the PSI TRaC surveys and PC longitudinal behavioral surveys

Specific Objectives

- Assess the improvement in MC reports when an illustration is provided versus a verbal description of MC
- Assess the improvement in MC reports with audio-computer assisted self-interview (ACASI) versus face-to-face interviews
- Determine if MC self-reports vary by type (traditional vs. medical) and completeness of MC
### Formative Research: Validation Study

#### Study Design

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<th>Control</th>
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<tr>
<td>Face-to-Face</td>
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<td>ACASI</td>
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<td>Verbal Description</td>
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- Men aged 18-34 and their female partners; male adolescents aged 13-17 years
- Zambia (Lusaka N=1125, Northern Regional N=600); Swaziland (Mbabne, Manzini N=855)
- Validated of reports by clinician assessment
Formative Research: Informed Consent

Study Objective

• Provide recommendations for standardizing and streamlining the IC process, while adhering to WHO, UNAIDs and other accepted IC guidelines

Specific Objectives

• Investigate the IC process for males (adult and minors) who have recently undergone MC

• Assess male clients’ comprehension of key concepts in the IC process: partial efficacy, condom use, risks/benefits

• Examine the attitudes and opinions of parents/guardians whose minors are circumcised and their experience of the IC process

• Explore attitudes and opinions of parents/guardians who have elected not to have their minors circumcised
Formative Research: Informed Consent

**Study Design**

- Semi-structured interviews with MC clients (N=30 adults, N=30 adolescents) at 1st post-op visit
- Focus group discussions (FGDs) with parents of minors (MC uptake and refused MC)
- Client and provider observation
- Comprehension assessment of MC clients (N=300 adult men)
- Informal discussions with key MC stakeholders
Determinants of Demand (PSI)

**Objective**

- Inform demand creation: recruitment methods, messaging

**Determinants Framework**

- Opportunity: availability, perceived quality of care, norms
- Ability: knowledge, expected outcomes (HIV risk, sexual pleasure, hygiene, appearance), social support
- Motivation: beliefs, willingness to pay

**Design**

- Nationally representative TRaC surveys
- Cross-sectional
- Zambia and Swaziland
Longitudinal Behavioral Study

**Study objectives**

- Assess whether MC men are resuming sexual relations prior to wound healing (6 weeks)
- Compare risk behavior among circumcised men and their partners pre and post operatively
- Compare whether age of sexual initiation differs for circumcised and uncircumcised adolescents
- Assess differential risk profiles of those who decide to be circumcised and those who do not
- Determine if women’s negotiating power concerning sexual behavior changes after MC
Longitudinal Behavioral Study

Key indicators

- Timing of resumption of sexual activity (post-operative)
- Consistency of condom use
- Number and concurrency of partnerships
- Frequency of sex acts
- Age at sexual initiation (adolescents)
- Women’s agency and decision making ability regarding sex
Longitudinal Behavioral Study

Study Design (Zambia and Swaziland)

- ~ 800 men (circumcised, uncircumcised)
- ~ 800 partners of study men
- ~ 800 adolescent males (circumcised, uncircumcised)
- ~ 400 adolescent females
- Observation: baseline, 12, and 24 months
- Observation: 6 weeks (circumcised men/boys)
- Ages: 18 – 29 adults; 13 – 17 adolescents
- Audio-CASI for sensitive questions
- 40 qualitative interviews
Potential OR Studies:

• Fixed versus mobile MC services: Assess the quality and cost
• Physicians versus non-physicians: Evaluate the quality and cost
• Assess the optimal post-op visit schedule
  - single visit vs. multiple visits
  - comparison of follow-up and AE rates
• Improving Informed consent: Assess whether self-instruction via an interactive technology is better for informed consent comprehension than a standard video
Operational Challenges

- Human resource constraints - within existing public sector sites and for recruiting staff for dedicated services
- Educating/informing public of site locations w/out creating unmet need
- Dealing with unknowns around client behavior post-MC and how to effectively "counsel" them w/o sufficient data
- Supply chain management to sites across all sectors