PrePex™ Male Circumcision Device Study: Psychosocial Research Results

Danuta Kasprzyk, PhD, Daniel E. Montaño, PhD
Mufuta Tshimanga, MD, MPH

Update on STIs Workshop
Harare, Zimbabwe
2-4 May 2012
Male Circumcision: Impact

- WHO 2007 recommendations
- To have the largest impact on AIDS prevention, 80% of men aged 18-30 should be circumcised
- 20.3 million men need MCs by 2015
- By the end of 2010, 550,000 done (3% of need)
- Three major issues in implementation identified by Copenhagen Consensus (October 2011)
  - Medical capacity for surgical circumcisions
  - Uptake among men
  - Risk compensation after MMC
A Little Bit of History

• Early 2008: Gates Foundation approaches Battelle Medical Devices Group to review adult male circumcisions options and devices

• March 2008: Battelle Medical Devices (MD) lead scientist presents results of Battelle’s review to a WHO-sponsored meeting in Uganda

• Battelle Medical Devices group suggests two main approaches to increase efficiency with adult MCs
  – Task-shifting in the surgical suite
  – Use of a Non-surgical MC device

• September 2008: Visit to Battelle Columbus, MD group to see proposed Battelle prototype
Lead solution | O-Ring Concept

O-Ring Concept

- Condom filled topical anesthesia.
- Necrosing Ring with O-ring band.

Dev. Effort: LOW

1. Fill condom with anesthesia.
2. Place condom on the penis.
3. Leave condom in place for a period of time.
4. Retract the foreskin.
5. Mark the line of the circumcision.
6. Grasp foreskin with fingers and position.
7. Place necrosing ring over penis.
8. Align the bottom of the necrosing ring with the marked foreskin.
9. Roll foreskin back over the necrosing ring.
10. Using device, place O-ring over necrosing ring.
11. Make sure that the O-ring is placed in the necrosing ring track.
12. Cut foreskin below the O-ring using necrosing ring as a guide.
12. O-ring and necrosing ring are left on and bandaged.

Benefits:
- Minimal training required
- Relatively bloodless procedure
- Minimal development time
- Low Profile Necrosing ring
- Disposable device aids in cutting and sealing the wound
Medical Capacity Solutions

- Efficiency in medical surgical circumcisions
- Using the MOVE Model system
- Task shifting from physicians to nurses
- Task sharing, nurses team
- Orange Farm, South Africa example
- Zimbabwe adopts WHO MC recommendations
- MC added to HIV/AIDS Prevention Strategy using MOVE Model as basis
A Little Bit of History

- July 2009: Battelle MD group contacted by Israeli social entrepreneur, Dr. Oren Fuerst, about wanting to pursue the non-surgical device
- September 2009: Dr. Fuerst communicates with Battelle about interest in developing a device
- Zimbabwe suggested as a Trial site for testing a possible MC device
- February 2010: Battelle Scientists meet with Dr. Gwinji and Dr. Mugurungi and present Battelle’s report and MC device concept to MOHCW
- Dr. Gwinji says “We must bring this device to Zimbabwe”
A Little Bit of History

- Communication with the CircMedTech who say that the first trial of the MC Device will be held in Rwanda
- July 2010: Rwanda Safety Trial launched
- October 2010: STI Update Workshop presents us an opportunity to hear from CircMedTech about preliminary results to the Rwanda Trial
- October 2010: Zimbabwe team goes to Rwanda to observe PrePex™ being deployed
- Plans for conducting a Zimbabwe PrePex™ study are discussed
A Little Bit of History

• Mid 2011: Funding given by UNFPA to Zichire/MOHCW to conduct two Clinical Trials, a Safety Trial and a Comparative Trial with PrePex™

• July 2011: Funding given by Battelle to conduct two complementary Psychosocial studies in conjunction with the Clinical Trials of PrePex™

• October 2011: Safety Trial in Zimbabwe launched

• Companion Psychosocial study also launched

• November 2011: Comparative Trial in Zimbabwe launched

• Companion Psychosocial study also launched
Update on Device Approval

- WHO and other world health organizations have technical work groups (TWG) reviewing Adult Male circumcision devices
- PrePex™ being examined for approval
- Three phase trial completed in Rwanda:
  - Safety phase results showed device was safe
- WHO TWG found more evidence needed for non-surgical PrePex™ device approval
- Contingent approval for Rwanda 2011
- US FDA approval Jan 2012
Zimbabwe Clinical Trial

- Current three phase trial being conducted in Zimbabwe
  - First independent (of manufacturer) test of the PrePex™
  - Trained physicians to deploy device
- Three phases:
  - **Safety Trial**: to determine safety of the device
  - **Comparative Trial**: to compare outcomes between men who got Device circumcisions to men getting Surgical circumcisions
  - **Field Trial**: to determine whether trained nurses can implement the device in district/provincial hospital settings and to assess how the device can be incorporated into clinical practice
The PrePex Device – Core Elements

1. Measure under coronal sulcus
2. Mark circumcision line
3. Place Delivery Ring
4. Insert Inner Ring
5. Deploy Elastic Ring
Zimbabwe Three Phase Trial

• **I: Safety Phase conducted**
  – 52 men

• **II: Comparative Phase conducted**
  – 160 randomized to Device circumcisions
  – 80 randomized to current standard Surgical circumcisions

• **III: Field Study, currently being implemented**
  – Train clinicians to deploy PrePex™ device in local hospital settings
  – Circumcisions provided by nurses, physicians, trained in device deployment with about 100 – 150 men
  – Implement in 3 settings
  – 500-600 men total
Zimbabwe Trial

Trial Overall Psychosocial Goals:

• Phase I, Phase II and Phase III: To assess psychosocial aspects of device deployment among:
  – Male patients and Female partners

• Phase III: To assess effect of PrePex™ device deployment:
  – Among clinicians deploying PrePex™
  – On other clinicians in the clinic setting
Psychosocial Study Objectives and Methods – Men

• To evaluate psychosocial effects of device deployment among men to determine:
  – Device acceptability,
  – Attitudes towards and experiences with Device circumcision,
  – Effects on activities of daily living
  – Attitudes towards protection from HIV, and
  – Effects on sexual expectations and sexual behavior
  – To improve counselling around deployment if possible

• Measures collected at three points in time:
  – Pre-deployment
  – Two weeks post-deployment
  – About 90 days post-deployment
Psychosocial Study Objectives and Methods – Female Partners

• To evaluate psychosocial effects of device deployment among female partners of men to determine:
  – Attitudes towards male partner’s MC, experience
  – Effect on activities of daily living
  – To determine what messages to impart to female partners to increase deployment if possible

• Measures collected at two points in time:
  – Pre-circumcision of male partner
  – About 90 days post-circumcision of male partner
Psychosocial Study Objectives and Methods – All Clinicians

• To evaluate psychosocial effects among clinicians deploying the device to determine:
  – Attitudes toward and satisfaction with training and deployment
  – Barriers and facilitators to deployment
  – Impact on services in clinical setting
  – To improve training and deployment methods

• Measures collected at three points in time:
  – Pre-deployment
  – Two weeks post-deployment
  – About 90 days post-deployment
# Overall Psychosocial Study Design

<table>
<thead>
<tr>
<th>Group</th>
<th>Time Frame</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MEN</strong></td>
<td></td>
</tr>
<tr>
<td>Pre-procedure</td>
<td>2 weeks post procedure</td>
</tr>
<tr>
<td>90 days post procedure</td>
<td></td>
</tr>
<tr>
<td><strong>WOMEN</strong></td>
<td></td>
</tr>
<tr>
<td>Pre-procedure</td>
<td>90 days post procedure</td>
</tr>
</tbody>
</table>
PHASE I SAFETY STUDY: PSYCHOSOCIAL RESULTS
Safety Phase: Psychosocial Methods

- **Study design**
  - Pre-procedure interview: Males and Female partners if available
  - Two week post-procedure interview: Males
  - 90 day post-procedure interview: Males and Female partners if available

- **Face-to-face private interview**

- Collected data on demographics, expectations about MC, and actual experience post MC, attitudes, social support, effect on activities of daily living, sexual behavior
## Safety Phase: Psychosocial Results

- **Highlights for men:**

<table>
<thead>
<tr>
<th></th>
<th>Pre-procedure (n=38)</th>
<th>2-wk Post-procedure (n=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hear about MC: Media</td>
<td>60-83%</td>
<td>40-64%</td>
</tr>
<tr>
<td>Hear about MC: Clinics</td>
<td>36%</td>
<td>27%</td>
</tr>
<tr>
<td>Hear about MC: VCTs</td>
<td>41%</td>
<td>17%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Talk about MC</td>
<td>92%</td>
<td>96%</td>
</tr>
<tr>
<td>Talk with 1-2 people</td>
<td>47%</td>
<td>13%</td>
</tr>
<tr>
<td>Talk with 3-4 people</td>
<td>14%</td>
<td>25%</td>
</tr>
<tr>
<td>Talk with 10+ people</td>
<td>10%</td>
<td>45%</td>
</tr>
<tr>
<td>Know someone with MC in past month?</td>
<td>36%</td>
<td>56%</td>
</tr>
</tbody>
</table>
**Safety Phase: Psychosocial Results**

- **Highlights:**

<table>
<thead>
<tr>
<th>Beliefs:</th>
<th>Pre-procedure</th>
<th>2-wk Post-procedure</th>
<th>90-day Post procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure was painful</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agree</td>
<td>16%</td>
<td>41%</td>
<td>25%</td>
</tr>
<tr>
<td>Not sure</td>
<td>30%</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Disagree</td>
<td>50%</td>
<td>58%</td>
<td>75%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>% “Agree”</th>
<th>% “Agree”</th>
<th>% “Agree”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healing was painful</td>
<td>20%</td>
<td>33%</td>
</tr>
<tr>
<td>Took too long to heal</td>
<td>14%</td>
<td>27%</td>
</tr>
<tr>
<td>Disfigurement</td>
<td>17%</td>
<td>2%</td>
</tr>
<tr>
<td>Doctor made mistake, may disfigure</td>
<td>45%</td>
<td>7%</td>
</tr>
<tr>
<td>Too much bleeding</td>
<td>36%</td>
<td>4%</td>
</tr>
</tbody>
</table>
## Safety Phase: Psychosocial Results

### Highlights for men:

<table>
<thead>
<tr>
<th>Activities of daily living</th>
<th>Pre-procedure</th>
<th>2-wk Post-procedure</th>
<th>90-day post procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take time off work</td>
<td>All employed expected to</td>
<td>6 took time off</td>
<td></td>
</tr>
<tr>
<td>Being able to go to work</td>
<td>70% disagree</td>
<td>60%</td>
<td>78%</td>
</tr>
<tr>
<td>Bathing</td>
<td>92% disagree</td>
<td>72%</td>
<td>84%</td>
</tr>
<tr>
<td>Ability to urinate</td>
<td>76% disagree</td>
<td>76%</td>
<td>87%</td>
</tr>
<tr>
<td>Walk as much as need</td>
<td>79% disagree</td>
<td>85%</td>
<td>84%</td>
</tr>
<tr>
<td>Able to sit as long as needed</td>
<td>87% disagree</td>
<td>80%</td>
<td>93%</td>
</tr>
<tr>
<td>Able to sleep</td>
<td>79% disagree</td>
<td>74%</td>
<td>80%</td>
</tr>
</tbody>
</table>
## Safety Phase: Psychosocial Results

<table>
<thead>
<tr>
<th>Activities of daily living</th>
<th>Pre-procedure</th>
<th>2-wk Post-procedure</th>
<th>90-day post procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do work around house responsible for</td>
<td>82% disagree</td>
<td>80%</td>
<td>82%</td>
</tr>
<tr>
<td>Use public transport</td>
<td>84% disagree</td>
<td>83%</td>
<td>89%</td>
</tr>
<tr>
<td>Wanting to have sex with wife</td>
<td>21% disagree</td>
<td>39%</td>
<td>24%</td>
</tr>
<tr>
<td>Socialize with friends</td>
<td>90% disagree</td>
<td>87%</td>
<td>89%</td>
</tr>
<tr>
<td>Going to shops, bottle store, beer hall</td>
<td>90% disagree</td>
<td>87%</td>
<td>87%</td>
</tr>
</tbody>
</table>
Safety Phase: Psychosocial Results

- Highlights for men:

<table>
<thead>
<tr>
<th>Likelihood of HIV infection</th>
<th>Pre-procedure</th>
<th>Post-procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very unlikely</td>
<td>56%</td>
<td>55%</td>
</tr>
<tr>
<td>Somewhat unlikely</td>
<td>14%</td>
<td>10%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>22%</td>
<td>20%</td>
</tr>
<tr>
<td>Somewhat likely</td>
<td>6%</td>
<td>10%</td>
</tr>
<tr>
<td>Very likely</td>
<td>2%</td>
<td>3%</td>
</tr>
</tbody>
</table>

Did not decrease perception of risk of HIV acquisition
Sexual Behavior

• At Baseline 30 men had sexual partners
• Very few men admit to masturbation (n=2)
• No men had sex at 2-week post-procedure
• 90-day follow-up 35 men had sexual partners
  – 30 had 1; 5 had 2-4
• At 90-day post-procedure interview:
  – 1 had sex within 28-34 days
  – 3 had sex at 35-41 days
  – 11 had sex at 42-48 days
  – 14 had sex at 49-55 days
  – 6 men had sex at 56+ days

Nurses counselled men to wait for 8 weeks (56 days) post-device removal to have sex
Sexual Behavior

- Condom use behavior and motivation

<table>
<thead>
<tr>
<th>Condom Use Behavior</th>
<th>Pre-procedure</th>
<th>90 days Post-procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not use condoms</td>
<td>50%</td>
<td>40%</td>
</tr>
<tr>
<td>Used condoms less than half the time</td>
<td>11%</td>
<td>20%</td>
</tr>
<tr>
<td>Used condoms between half to three fourths time</td>
<td>3%</td>
<td>14%</td>
</tr>
<tr>
<td>Used condoms all the time</td>
<td>13%</td>
<td>14%</td>
</tr>
<tr>
<td>No intention to use condoms</td>
<td>60%</td>
<td>40%</td>
</tr>
<tr>
<td>Intention to use condoms all the time</td>
<td>8%</td>
<td>14%</td>
</tr>
</tbody>
</table>
Safety Phase: Psychosocial Results

• High acceptability and positive attitudes towards device circumcision
• Expectations of minimal effects on activities of daily living
• Differences found between pre-procedure interviews to post-procedure interviews
• Results likely due to actual experience – particularly perceived vs. expected pain
• Expectations for less effect prior to actual procedure
• These results show that messages conveyed in pre-procedure counselling must manage men’s expectations
Safety Phase: Psychosocial Results

- Most men are not waiting for the recommended time to start having sex
- Pre-procedure condom use rates are low
- Likely due to the fact that these are main partners
- Pre-procedure motivation to use condoms after the circumcision is lower than current condom use
- Post-procedure condom use rates for intermittent condom use actually go up
- It may be that men start to have sex, use condoms initially, and then drop the use of condoms when they feel completely healed
Psychosocial Study Conclusions

• Management of specific expectations for nurses in terms of counselling messages
  – Messages men were getting made them expect little pain
  – Psychosocial results showed men thought it was more painful than they expected
  – Refraining from sex needs reinforcement; with emphasis on condom use
  – Condom use messages need reinforcement

• Men showed 100% satisfaction with device MCs
• Men disseminate their experience to friends and family
Psychosocial Study: Next Steps

• Will provide data for better messaging around uptake

• Kippax paper on psychosocial factors in successful HIV prevention programs
  – Successful interventions are integrated into social relations and practices
  – Need to better understand psychosocial factors to design successful evidence-based behavior change interventions
Psychosocial Study: Next Steps

• Leverage natural diffusion occurring via personal communication about the device circumcisions
• Opportunity to deliver effective communication to maximize uptake
• Use findings to develop strategies for more effective recruitment of men for MC
• The psychosocial component of Zimbabwe Field Study is critical:
  – To examine in a more ‘natural’ implementation what the effects will be on attitudes, expectations, sexual behavior
  – For design of evidence-based strategies to maximize uptake of PrePex™ MC
Acknowledgements

• UNFPA for funding the Zimbabwe PrePex™ Clinical Trial
• Battelle for funding the Psychosocial Study
• Study clinicians for deploying PrePex™
• Participants at Spilhaus for volunteering to be part of the first two Trial phases
• Zichire team for data collection and data entry
• Deven Hamilton for data analyses