Key issues Prepex Study Zimbabwe

SESSION II: CLINICAL EFFICACY, SAFETY AND ACCEPTABILITY OF DEVICES:

PANELIST
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Enrolment into the Prepex study

Inclusion criteria all phases

- Above 18 years
- HIV sero-negative
- Agreed to be circumcised by any of the study methods, PrePex or Surgical
- Accepted study procedures and requirements
  - Agreed to return to the healthcare facility for follow-up visits (or as instructed) for up to 10 weeks post-procedure
  - Agreed to anonymous video and photographs of the procedure
  - Agreed to in-depth psychosocial interviews.
  - Abstain from sexual intercourse and directly rubbing circumcised area (e.g. masturbation),

Sample size

- Phase 1: 53
- Phase 2: 160
- Phase 3:603
- Extended phase for PCN : 600

Eligibility for the Device

- The majority of men in Zimbabwe were eligible for the device
- 6% of men above 18 not eligible for the device.
- Main reason were:
  - Phimosis
  - Penile size bigger than available sizes. This was not significant issue as only 3 men could not be placed with the device .

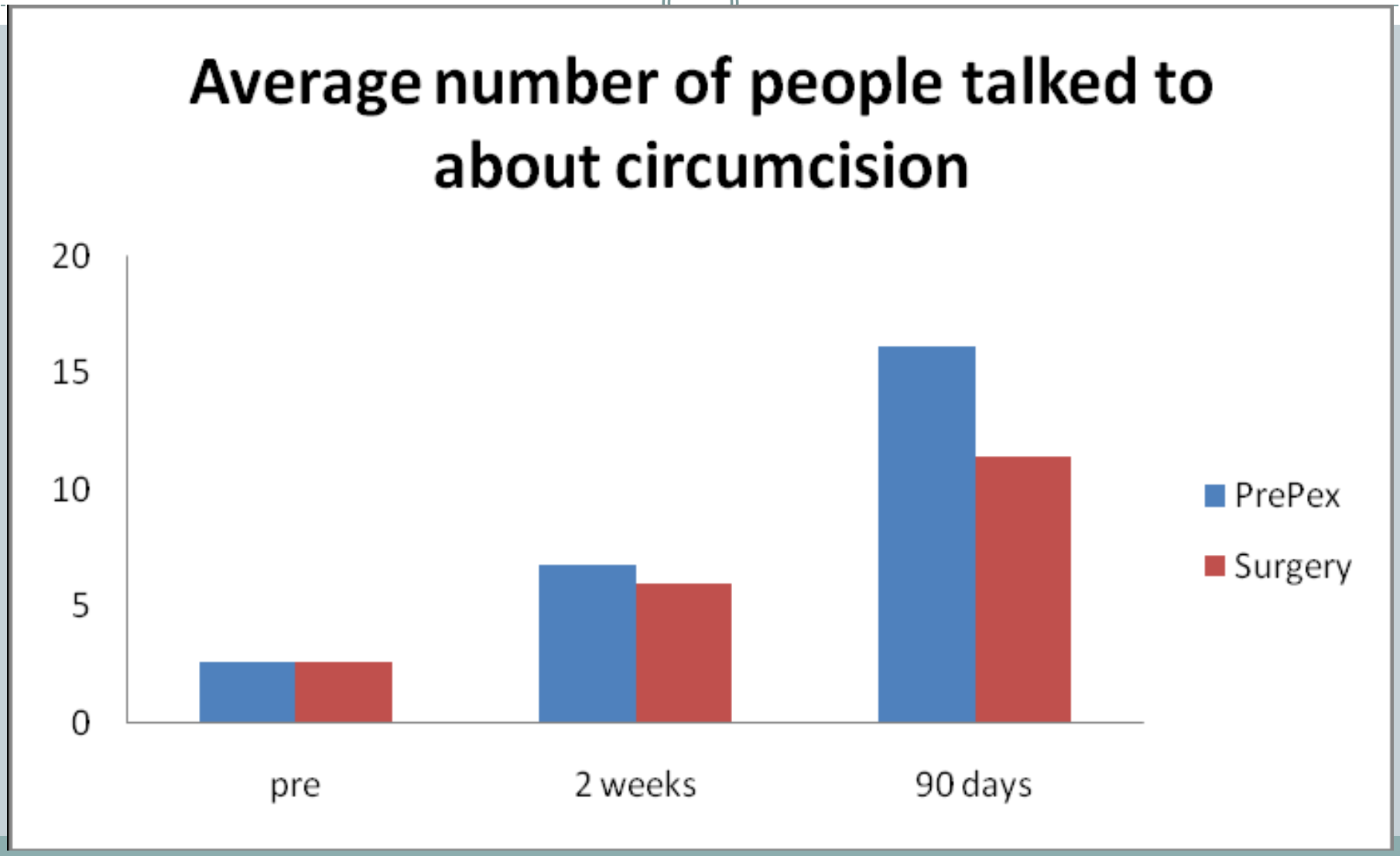
Adverse events

- Through the different phases of the study there were no severe adverse events, however acknowledge that TAG classified some as SAE.
- Below 1% of clients experienced mild to moderate adverse events
- Odour was not systematically documented
- Client behaviour was a contributing factor to some adverse events especially those that related to device displacement and early removal

Acceptability

- Interviews conducted before placements at 2weeks and 90 days post device placements.
- Men who had the device reported to have talked to about 20 people about the device circumcision compared to 10 in the surgical arm.(proxy)
- Device was also **preferred by service providers** as there were less calls compared to the surgical arm.
- Preference for device over surgery is apparent. More men currently not taking MC till device is available especially in sites that have provided device before
- Over 90% of Men reported being extremely satisfied with device and also reported they **believed their sexual partners were also very satisfied**
- The device did not affect the activities of daily living through all the phases of the study.

Men in device arm told more friends



Effects on ADL

- Generally No effect on daily activities

Activity	Strongly disagree	Perception pre placement	2 week Post placement	Strongly Agree
Work		73%	88%	
Bath		84%	87%	
Socialise		92%	95%	
Home Chore		90%	98	
Sex with wife		48%	52%	38%/36
Urinate		85%	95%	

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- Thank you