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HIV is the primary exclusion criterion in a PrePex™ male circumcision device introductory study in Mozambique

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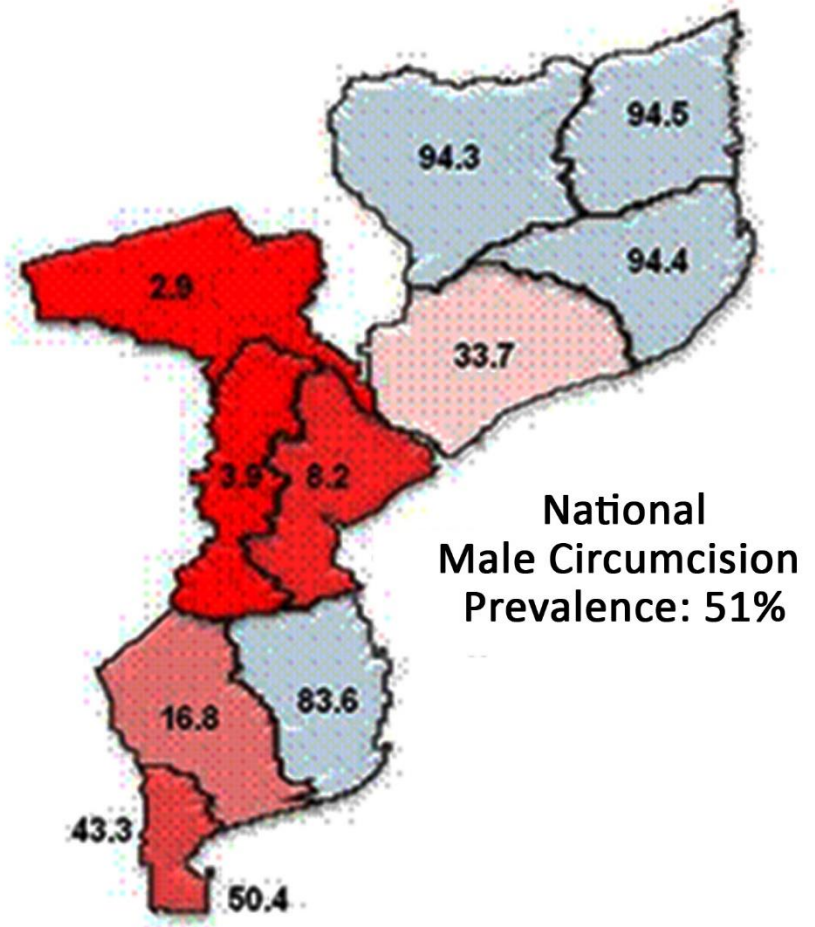
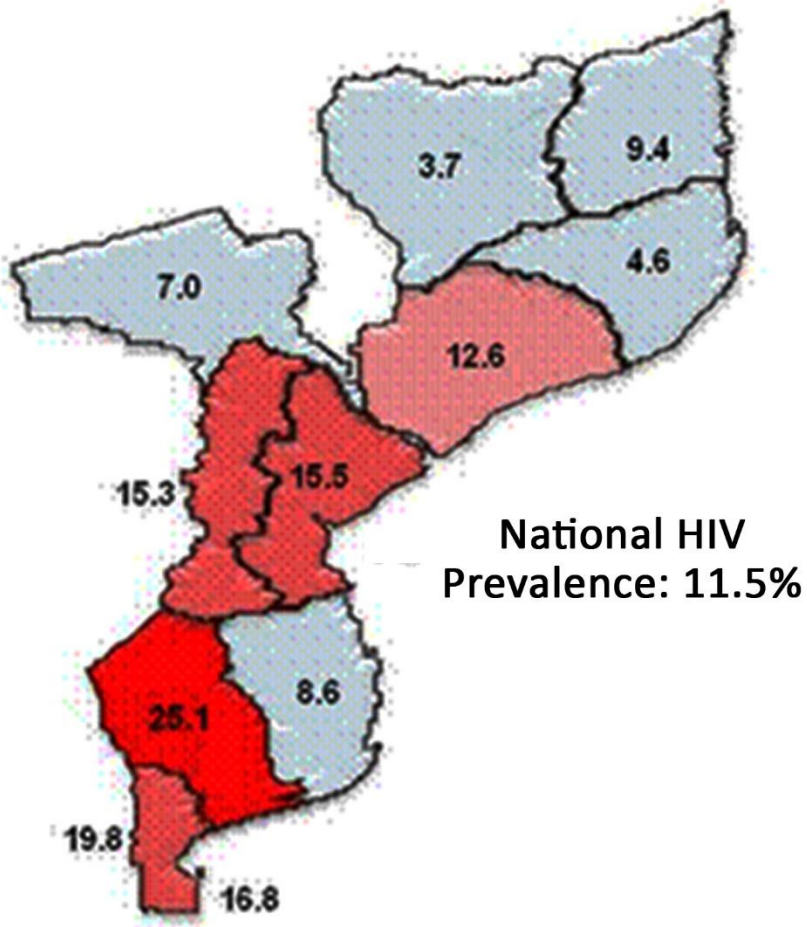
Background

- Mozambique has a generalized HIV epidemic with a prevalence of 11.5% in the adult population
- High HIV prevalence is associated with low circumcision rates
- Voluntary Medical Male Circumcision (VMMC) started as a pilot in November 2009
- Since then more than 350,000 clients had been surgically circumcised

2009, INSIDA

2013, MOH. Strategic National Expansion Plan for VMMC, 2013-2017

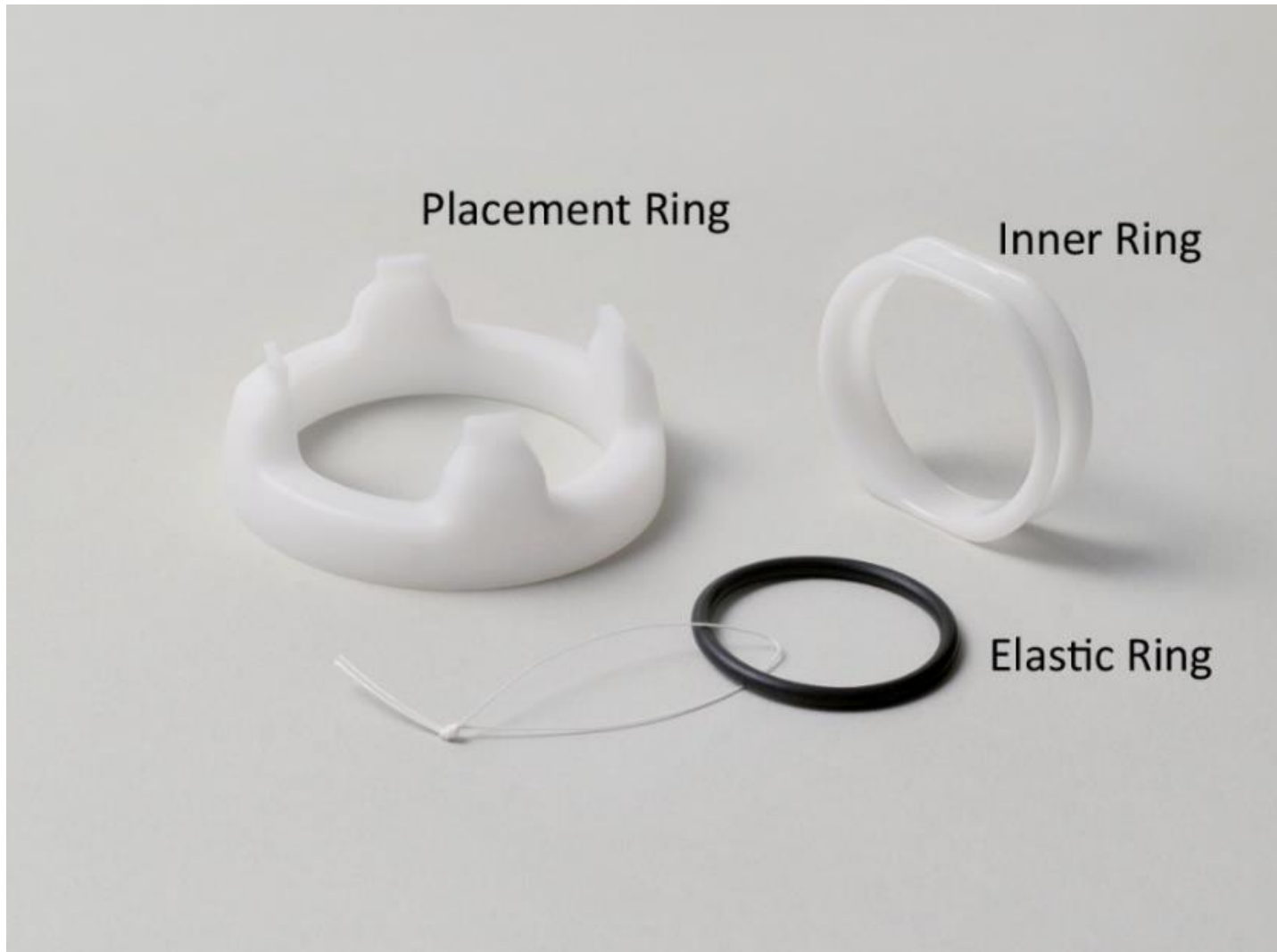
Mozambique HIV and MC Prevalence



PrePex™ - Mozambique Study

- Progress scaling up the intervention in Mozambique has been slower than expected and MOH aims to circumcise 2 million males by 2017
- Recent technological advances, such as circumcision devices, provide viable options for achieving national targets
- PrePex™ is a non-surgical circumcision device that could potentially reduce procedure time and increase acceptability for VMMC
- In 2013, an introductory study of the PrePex™ device was conducted in Maputo, to assess the acceptability of the PrePex™ device among providers and clients

PrePex™ device: the parts



Source: PrePex website

Methods

- Adult clients presenting for VMMC at the study site in Maputo were offered a choice of conventional surgery (forceps-guided technique) or PrePex™
- Those who preferred PrePex™ were screened for inclusion criteria. Exclusion criteria were recorded



Nurses during PrePex training

Eligibility: Exclusion Criteria

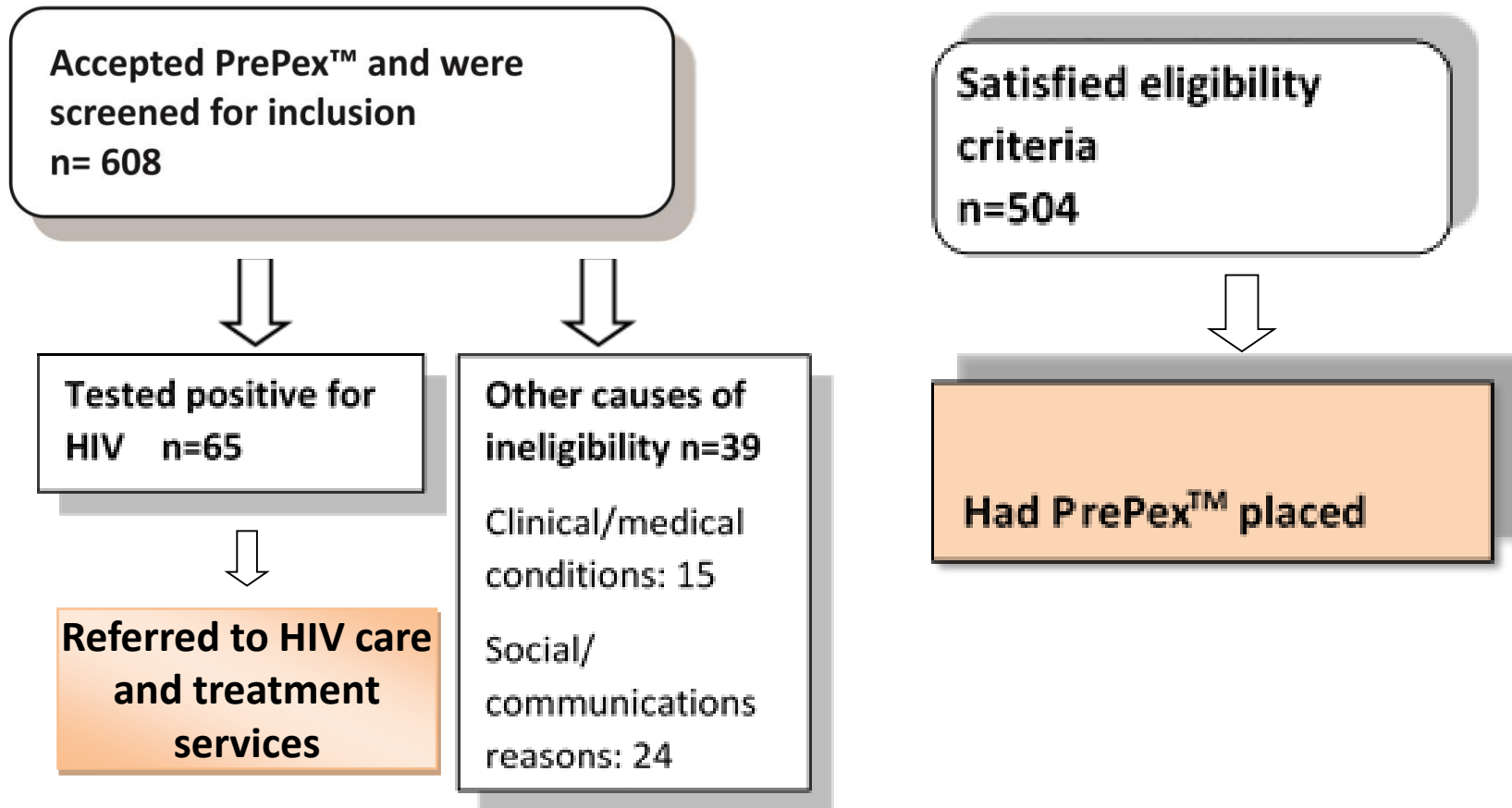
Clinical medical conditions

- Bleeding issues or abnormal coagulation
- Anatomical abnormalities
- Active genital infections
- Narrow foreskin or foreskin with limited flexibility
- Warts in the foreskin
- Torn or tight foreskin frenulum (adhesion below the glans)
- Phimosis
- Paraphimosis
- Hypospadias
- Epispadias
- Positive HIV test result

Social Communication requirements

- Able to understand the study procedures and requirements
- Lives within 25 kilometers of the health center
- Has a working mobile phone
- Able to communicate in Portuguese
- Able and willing to provide informed consent in writing

Recruitment Flow



Findings

Ineligibility reasons for circumcision with PrePex™ device

Reason	n	%
HIV+	65	62.5%
Phimosis	11	10.6%
No cell phone	8	7.7%
Poor communication in Portuguese	7	6.7%
Ineligible age*	6	5.8%
Lack of understanding of the study	2	1.9%
Genital infection	2	1.9%
Sexual dysfunction	1	1%
Narrow foreskin	1	1%
Mental disorder	1	1%
Total	104	100%

* Clients excluded after re-verification of age.

Discussion

- Of the 608 clients assessed, 104 were determined to be ineligible, representing 17% of those who opted for PrePex™
- HIV sero-positivity was the main cause for ineligibility (62.5% of the ineligible)
- 10.7% of HIV prevalence during the study was much higher than that found in surgical circumcision clients at José Macamo HC (3.4%) - This could be related to the fact that PrePex™ clients were older, aged 18 to 49 years, than the average client for surgical circumcision.

Conclusions

- An integrated program offering both device and surgical VMMC is the best service delivery option to ensure that HIV positive clients receive VMMC and to expand choices for prospective VMMC clients
- A positive HIV test should not exclude for PrePex: in fact, once bridging (safety) studies of PrePex in HIV positive men are complete presumably testing positive for HIV will not be an exclusion criteria to PrePex.

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