PEC234

Experience with Introduction of PrePex™ Device for Medical Male Circumcision for HIV Prevention in Kenya (2013–2017)

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Introduction

- Since 2008, approximately 1.8 million males have been circumcised in Kenya through its voluntary medical male circumcision (VMMC) program for HIV prevention.
  - Most of these circumcisions were performed using conventional surgical approaches.
- Complexities of conventional surgery, coupled with long procedure times (15–30 minutes) and the need for suturing, have led to the development of simpler circumcision methods.
  - Since 2013, Kenya's VMMC programs have evaluated the PrePex™ device.
  - PrePex achieves circumcision by compressing the foreskin between an elastic ring and a hard surface to occlude circulation and produce tissue ischaemia, devitalization, and necrosis.
  - After placement, the device is left in position for 1 week to allow for complete foreskin necrosis—the foreskin is then excised in a bloodless procedure.

Geographic Scope of Kenya's VMMC Program

- Kenya's VMMC program targets communities that traditionally do not circumcise their males.
  - These communities are in 10 priority counties—i.e., counties with the highest HIV prevalence in the country (see Figure 1).
  - Most counties are in the western region.
  - National HIV prevalence rate is 5.9.

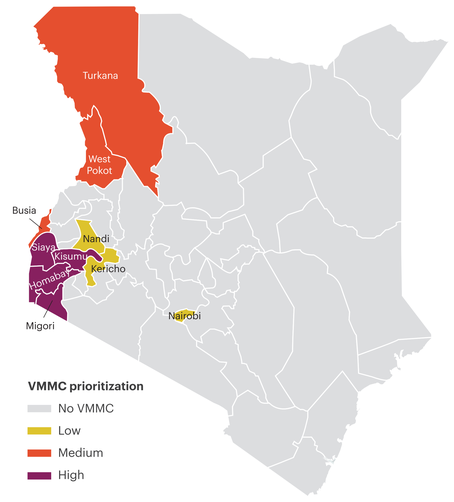
County name	HIV prevalence (%)
Kisumu	19.9
Siaya	24.8
Homabay	26.0
Migori	14.3
Busia	6.7
Turkana	4.0
West Pokot	1.5
Nairobi	6.1
Kericho	3.5
Nandi	2.4

Source: National AIDS Control Council (NACC). 2016. Kenya HIV county profiles. NACC website. http://nacc.or.ke/wp-content/uploads/2016/12/Kenya-HIV-County-Profiles-2016.pdf. Accessed June 1, 2018.

Conventional or Device-Based Surgical Circumcision Methods Used in Kenya's VMMC Programs

- Dorsal slit method is used for all age groups.
- Forceps-guided method was suspended for safety reasons in 2018.
- Use of the PrePex device is in a passive—i.e., routine—rollout stage, while the use of the ShangRing device is in an active adverse event (AE) surveillance stage.

Figure 1. Prioritization of VMMC programs



Note: voluntary medical male circumcision (VMMC)

Methods for Evaluating the Safety of PrePex

Device introduction stage	Objective	Timeframe	Number of circumcisions performed
Pilot	Assess effectiveness, safety, and acceptability	February–August 2013	427
Active AE surveillance	Evaluate safety and operational requirements in routine health care settings	August 2015–May 2016	2,195
Passive (routine) AE surveillance	Endorsed an open-ended, passive rollout	July 2016	76

Note: adverse event (AE)

Evaluation Results

Device introduction stage	Results	Remarks
Pilot	• Moderate/severe AE rate: 5.9% (N: 417 male circumcisions) • 1–2 weeks longer healing time than conventional surgical circumcision	• Higher AE rate than conventional surgical methods, which is 1%–2% • Effective and well accepted
Active AE surveillance	• Moderate/severe AE rate: 0.3% (N: 2,195 male circumcisions)	• Lower AE rate than conventional surgical methods, which is 1%–2% • Well accepted
Passive (routine) AE surveillance (open-ended)	• 1 AE (nonfatal tetanus)	• Higher risk for tetanus than conventional surgical methods • Demand has reduced because of requirement for two tetanus toxoid-containing vaccine immunizations prior to device placement

Note: adverse event (AE), toxoid-containing vaccination (TTCV)

Conclusions

- Although the use of PrePex was initially shown to be effective, safe, and well accepted in Kenya, the new requirement for full protective tetanus toxoid-containing vaccine (TTCV) immunization before device placement has hampered the device's rollout.
  - Most Kenyan males do not have documentary evidence of having received TTCV; therefore, they find it difficult to return to the clinic multiple times for immunization before device placement.
  - PrePex introduction in Kenya has revealed a gap in TTCV immunization coverage among males.
  - Therefore, PrePex circumcision should only be rolled out in settings with high-TTCV coverage among eligible males or in settings where provision of full protective doses of TTCV is feasible before each procedure.

Next Steps in Kenya

- Use PrePex for routine VMMC service delivery as long as TTCV is provided according to Kenya's new tetanus mitigation policy, which is aligned with World Health Organization's recommendations.
- Consider the use of PrePex among schoolboys, as it may be feasible to provide repeat TTCV doses before male circumcision.
- Pilot the use of PrePex in early infant male circumcision programs to eliminate the risk of glans injuries associated with the Mogen clamp.
- Work with global, regional, and national stakeholders to increase TTCV coverage for males.
- Assess the level of immunity to tetanus among VMMC clients in Kenya.

PrePex male circumcision at Siaya County Referral Hospital. Photo by Siaya County Referral Hospital.

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