

August 12th, 2015

"Offering VMMC Services with PrePex" - Summary of CHAPS & PSI dinner session

On July 21st, 2015 a professional dinner session was held in the framework of the IAS 2015 conference and was facilitated by Dr. Karin Hatzold, Global Deputy Director HIV, Biomedical and Clinical Interventions Population Services International and Dr. Dino Rech, Co-CEO, CHAPS South Africa. The session, named "Offering VMMC Services with PrePex", was attended by 26 participants. The goal of this session was to exchange updates, information and ideas with representatives from Sub-Saharan African countries implementing PrePex VMMC services and conducting operations research on PrePex. Researchers and implementers shared their most recent updates, experiences, successes and best practices. This summary contains the main points discussed and the issues raised during the session. Please also find attached in Annex A the list of attendees.

Main Discussion Points:

1. World Health Organization ("WHO") Technical Working Group - meeting report (September 2014)
 - Review of PrePex Safety Profile - safety is maintained at the level observed at the previous TAG meeting in 2013.
 - Recommendations for Adolescents - required active surveillance phase of at least 2,000 placements in 13-17 years old males from at least three countries. PEPFAR issued a notice to field offices confirming the funding of PrePex adolescent procedures under active surveillance phase.
 - PSI Zimbabwe, in collaboration with MOHCC, is planning Active Surveillance including a qualitative acceptability study for 1000 adolescents (13-17 years) with currently available device sizes. Start planned for end of August.
 - Device Displacements - Review of clinical management of the various cases of displacement, including early displacement with gross edema and skin blistering. Dr. Karin Hatzold informed that cases of displacement and edema occurred and SMC was done after 72 hours after the edema subsided without any adverse effects (in contrary to the 6-12 hours current requirement). Device displacement remains the most significant, although rare, AE related to PrePex.
 - Shang Ring has received WHO Pre-Qualification - it is important to note immediate surgical personnel and supplies must be available on site at time of device placement to manage ring slippage.
 - EIMC devices - WHO will not be managing PQ processes for EIMC devices, therefore other mechanisms must be sought if this is required

2. Upcoming Publications & Operational issues - presented by Dr. Karin Hatzold

- Approximately 10 PrePex related publications are expected to be published in JAIDS, expected prior to ICASA 2015 (November 29th-December 2nd). See selected list of articles below:

Safety, Feasibility

- **Safety and Acceptability of the PrePex™ Device when Used in Routine Male Circumcision Service Delivery during Active Surveillance in Zimbabwe:** Authors: Webster Mavhu, Karin Hatzold, Getrude Ncube, Sinokuthemba Xaba, Ngonidzashe Madidi, Jo Keatinge, Efison Dhodho, Christopher A. Samkange, Mufuta Tshimanga, Tonderayi Mangwiro, Owen Mugurungi, Emmanuel Njehumeli, Frances M. Cowan, to be published in JAIDS 2015
- **Safety profile of PrePex Male Circumcision Device and Client Satisfaction with Adolescent Males aged 13-17 years in Zimbabwe:** M. Tshimanga, K. Hatzold, O. Mugurungi, T. Mangwiro, G.Ncube, S. Xaba, P. Chatikobo, P Gundididza, C. Samkange, R. Dhlamini, M. Murwira, G. Gwinji1, to be published in JAIDS 2015

Costing

- **Evaluating opportunities for achieving cost efficiencies through the introduction of PrePex in Zambia and Zimbabwe:** L. Vandament, N. Yano, N. Chintu, O. Mugurungi, G. Ncube, S. Xaba, A. Samona, E. Muguza, T. Mangono, N. Madidi, B. Tambatamba, K. Hatzold to be published in JAIDS 2015
- **Comparative cost analysis of surgical and PrePex device male circumcision in Zimbabwe and Mozambique:** Authors: Schutte C, Tshimanga, M, Mugurungi O, Come J, Necochea E, Meheub M, Xaba S, Nyamukapa D, Bossemeyer D, Ferreira T, Macaringue L, ChatikoboP, Gundididza P, Hatzold K to be published in JAIDS 2015

Acceptability

- **Acceptability and satisfaction associated with the introduction of the PrePex™ circumcision device in Maputo, Mozambique:** Beverley Cummings, Edgar Necochea, Thais Ferreira, Benilde Soares, Meheub Mahomed, Humberto Muquingue, Leonel Nhambi, Debora Bossemeyer, Tigistu Adamu Ashengo to be published in JAIDS 2015
- **Perceptions of the PrePex device among men who received or refused PrePex circumcision and people accompanying them.** Minja Milovanovic et al to be published in JAIDS 2015

3. Pain Management - observations from Zimbabwe's practice at removal suggested the use of Ibuprofen 1 hour before removal and EMLA cream application 15 minutes before removal. However, Tigistu Ashengo (Jhpiego) and Dino Rech (CHAPS) reported mixed results from Rwanda and South Africa. It was agreed that further investigation is required to validate an effective method for pain reduction during removal. The importance of proper counseling and setting clients expectations accurately was emphasized as an effective way to reduce

perception of pain levels. For examples of PrePex Information for Clients materials prepared by different stakeholders please [visit this link](#).

4. PrePex Demand Creation - the most successful tool generating demand for PrePex during studies was Word-of-Mouth thanks to the device's unique features. Methods from the successful PrePex campaign held in Zimbabwe were shared, where PrePex was branded as "The Ring" (due to difficulties with saying "PrePex"). Radio shows and posters focused on the easy availability of PrePex thanks to the fact that it enables men to go on with their daily life while wearing "The Ring". Please find the PSI-Zim PrePex Campaign presentation together with other countries' examples of PrePex demand creation materials [in this link](#).
5. PrePex Training Program & Classification of Trainers - Augustine Hellar shared highlights from the Jhpiego PrePex training workshop held in Rwanda during last May. Dino Rech (CHAPS) and Karin Hatzold (PSI) informed that a joint CHAPS/PSI facilitated workshop to standardize the training materials and trainer's certification requirement is planned this September in Zimbabwe, involving stakeholders from different countries and organizations with experience in PrePex implementation and training.
6. Supply Chain Issues - Eddy Horowitz, Circ MedTech's CEO, proposed CMT would help with the procurement of accessories since many countries are facing difficulties obtaining supplies. The successful procurement, and on time delivery, of close to 300,000 PrePex units including all required accessories by the Rwanda Health Ministry was presented as example of CMT's ability to deliver the necessary commodities.
 - CMT will become a one-stop shop for planning and executing procurement of PrePex's accessories for the implementers.
 - Priontex presented their PrePex kit/ box which includes all kits and accessories in an easy to use format for PrePex procedures. This represents a possible solution for solving logistical problems.
 - Jason Reed clarified that per OGAC guidelines – PEPFAR funds allow direct purchasing from the manufacturer as countries are not obligated to procure through SCMS.
7. Device forecast research - Lindsey Vandament (CHAI) shared highlights from the device forecast research done by IPSOS. IPSOS performed Market Research for VMMC in Zambia and Zimbabwe, including a device forecast to assess if devices could generate incremental demand for VMMC. The device segment was a projection, survey based, cohort study. Data from study suggest that PrePex could potentially create incremental demand for men opting for VMMC (up 59% in Zambia and up to 45% in Zimbabwe, dependent on age group). Results are expected to be published in the JAIDS supplement.

8. WHO Recommendation on Tetanus - presented by Dr. Tim Farley on behalf of WHO (PPT slides by Julia Samuelson)

- Final report of March consultation meeting is expected to be published shortly. Key points from WHO draft report on the tetanus consultation include:
 - Overview of reported cases
 - Review of potential risks for Surgical MC, PrePex & Shang Ring
 - Mitigation of Risk – WHO suggest a dual approach, relevant to all VMMC methods, clean care & booster according to risk considerations
 - Overview of the TTC vaccination practice in SSA. Major challenges were: antibody level is low in early adolescents & older; only females get a routine booster due to vaccination policy during pregnancy; poor documentation of vaccine history.

Responses from attendees:

- Jhpiego, Kelly Curran: It feels the TTC booster on MC day is a strategy to improve population immunization using rather than ensuring immediate client safety.
- Jhpiego, Hally Mahler: What is WHO doing to communicate the meeting results with relevant ministries in SSA? As an implementing partner, they are unable to push for reinstating PrePex.
- Jhpiego, Jason Reed: OGAC determined that each MoH must decide its own course of action, however where OGAC is of the opinion that country guidance is not addressing recommendations from WHO in mitigating Tetanus risk, funds may be withheld at OGAC discretion
- Zimbabwe MoHCC, Getrude Ncube: The MoH reviewed TTC national coverage, at 67%, and after consultation decided not to incur a TTC booster requirement. Improved counseling, IEC material and training on tetanus risk mitigation were recommended instead.
- CHAPS, Dino Rech: The SA NDoH did a similar in-country evaluation and determined that in SA it was not necessary to embrace TTC into the VMMC program but rather efforts to focus on clean care and proper sterilization were to be augmented

For any questions or inquiries please contact Dr. Karin Hatzold at khatzold@psi.org/khatzold@psi-zim.co.il or Dr. Dino Rech at dino@chaps.za.

Best regards,

Dr. Karin Hatzold (PSI Zimbabwe) & Dr. Dino Rech (CHAPS South Africa)

Annex A- List of participants

	Name	Affiliation
1.	Dino Rech	CHAPS SA
2.	Karin Hatzold	PSI Zimbabwe
3.	Tsitsi Apollo	MoHCC Zimbabwe
4.	Getrude Ncube	MoHCC Zimbabwe
5.	Harry Hausler	TBVIH
6.	Tony Healy	Priontex
7.	Mike Hyslop	Priontex
8.	Elya Tagar	CHAI and global resources
9.	Lyndsey Vandament	CHAI and global resources
10.	Kathie Callahan	CHAI and global resources
11.	Madidi Ngonidzashe	CHAI and global resources
12.	Frances Cowan	Director CESSHAR
13.	Sheppard Maphisa	Maphisa and Partners private clinics
14.	Mitchell Warren	AVAC: Global Advocacy for HIV Prevention
15.	Tigistu Adamu	Jhpiego
16.	Jason Reed	Jhpiego
17.	Kelly Curran	Jhpiego
18.	Hally Mahler	Jhpiego
19.	Augustine Hellar	Jhpiego
20.	Nina Hasen	Director HV/TB PSI
21.	Tim Farley	Sigma3
22.	Tajudeen Oyewale	UNICEF
23.	Eddy Horowitz	Circ MedTech
24.	Ron Goldwasser	Circ MedTech



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25.	Adi Kadussi	Circ MedTech
26.	Lior Levert	Circ MedTech