Cohort Field Study on Safety and Efficacy of PrePex Performed by Physicians &Nurses on Adolescents Male Population

M. Tshimanga[1,2], TI.Mangwiro[1], E. Fusire[4], K. Hatzold[3], C. Samkange[1], S.Xaba[4], P.Chatikobo[2], P.Gundidza[2]

1- University of Zimbabwe, College of Health Sciences, Harare, Zimbabwe, 2 - ZICHIRE Project, Department of Community Medicine, College of Health Sciences, University of Zimbabwe, Harare, Zimbabwe, 3 –PSI Zimbabwe, Gates Partnership,Harare, Zimbabwe, 4 - Ministry of Health and Child Welfare, Harare, Zimbabwe

Background

It is well known from a range of observational and epidemiological studies that the lifetime risk of acquiring HIV among males can be significantly reduced via circumcision by 53%-60% [1-3]. Numerous papers on the topic have been published over the past two decades to promote HIV prevention awareness, especially in sub-Saharan countries.
A new male circumcision (MC) device called the PrePex has shown great promise in transforming the MC landscape. The PrePex is an innovative circumcision device requiring no injected anesthesia, sutures or sterile setting. An earlier phase of the PrePex clinical trial in Zimbabwe has demonstrated that the device can be potentially used by low-level health care professionals like registered general nurses (RGN) and primary care nurses (PCN) in addition to surgeons.

WHO recommended that Zimbabwe study the PrePex for use on its adolescent population, starting withages 15-17 and thereafter ages 13-14 and 10-12.
In line with the recommendations from the WHO Framework for Clinical Evaluation of Devices for Male Circumcision (February 2011), the safety and efficacy of the device should be assessed in a healthy adolescent male population scheduled for voluntary male circumcision.

The primary objectives of this study were:

1. To determine the statistical distribution of sulcus size and foreskin flexibility in adolescent boys aged10 to 17
2. Safety of the device when used inthe adolescent population
3. Eligibility rate based on screening.

Research Method:

The study was approved by the Medical Research Council of Zimbabwe (MRCZ) (1628) and was conducted in adherence to the ICH-GCP guidelines. A cohort field study assessed the safety and efficacy of the PrePex device on the adolescent population. The study site was located at ZNFPC Spilhaus Center, Harare, Zimbabwe.Thestudy was divided into 3 phases:

1. Phase I: The sizing phase - by physicians: Completed
2. Phase II: The procedure phase by physicians:
   a. Adolescents age 15-17 years– 50 subjects
   b. Adolescents age 13-14 years– 50 subjects

   } Completed
3. Phase III: the procedure phase by nurses:
   c. Adolescents age 15-17 years– 150 subjects
   d. Adolescents age 13-14 years– 150 subjects

   } Completed ~~Ongoing~~

Findings:

The sizing phase: 402~~162~~ adolescents aged 10-17 were sized to determine the size distribution. The sizes which were tested included standard sizes of PrePex, and additional new smaller sizes. The most popular size was B, whichsuited 89~~44~~ subjects (22.1~~27~~%).

The diagram below show the device size distribution of phase II,conducted by physicians with assistance from trained nurses,using 134 devices that were placed(14 is the smallest size and E is the biggest):

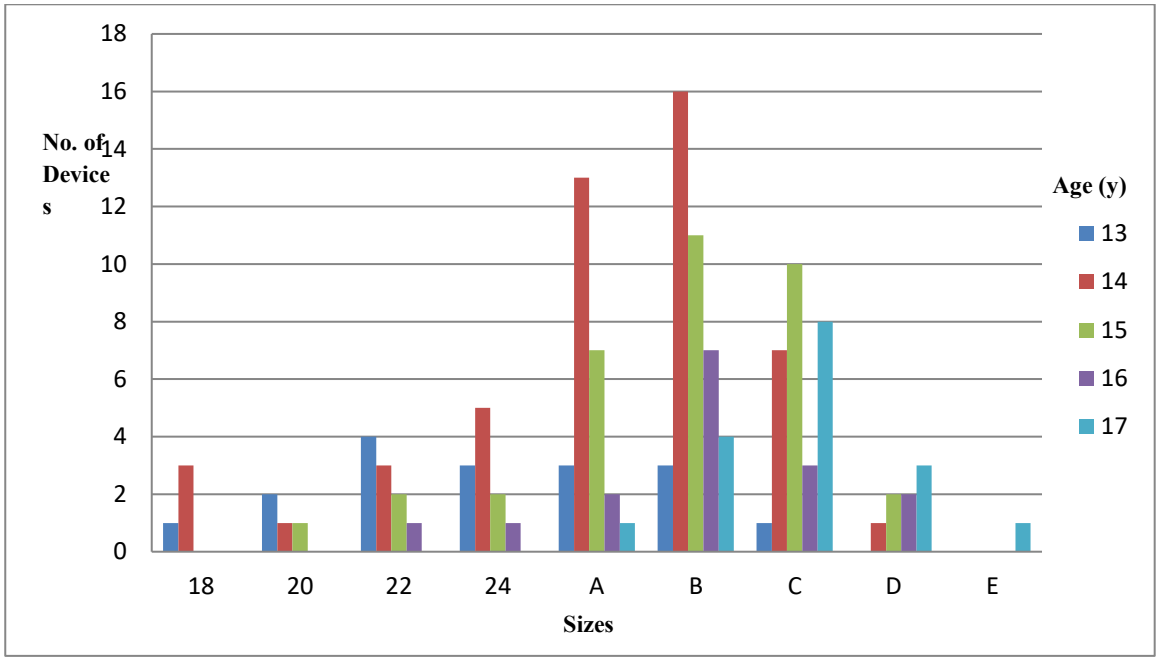

Diagram 01 – Size Distribution of PrePex in Adolescents Population

Safety: There were no adverse events (AEs) or serious AEs. Healing duration was documented for several subjects on day 28 and all subjects achieved complete circumcision (glans fully exposed).

Most subjects (94%) felt no pain at all or just a little (pain VAS 02) during erection when the device was on (the VAS scale ranges between 0 -10, where 10 is the highest). 44.1% of subjects reported that they did notwake up during the night due to pain and 53.5% of subjects felt pain very seldomto the point that it woke them at night.

Eligibility: 70% of subjects were not eligible due to challenges in obtaining parental consent and some chose not to participate in the study.

Interpretation:

The safety objective was achieved at zero AE rate which demonstrated that the procedure was very safe for this age group (ages 13-17). The findings regarding the behavior of adolescents also demonstrated that the boys would not tamper with the device. This is not significantly different from similar data for the earlier adult PrePex trial. The studyresults presentthe size distribution for adolescents (ages 13-17) in Zimbabwe, which will help other neighboring countries to estimate their population device distribution. The study proved that the PrePex device can be used to circumcise adolescents age 13-17years old.

References:

1. Gray RH, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomized controlled trial. Lancet. 2007; 369:657–666.

2. Bailey RC, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomized controlled trial. Lancet. 2007; 369:643–656.

3.Auvert B, Taljaard D, Lagarde E, et al. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 trial. PLoS Med. 2005; 2:e298.