World Health Organization

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Information update on the PrePex device for male circumcision for HIV prevention

PrePex™ (PQMC reference number 001-001-00) with the following product codes **DW0201, DW0202, DW0203, DW0204, DW0205** was prequalified by WHO on 31 May 2013, and added to the WHO list of prequalified male circumcision devices. On 2 March 2016, the prequalification status was amended to include an expanded intended use.

Background:

1. Since 2007, programmes in priority countries of East and Southern Africa are scaling-up voluntary medical male circumcision (VMMC) as an additional HIV prevention intervention.

2. Innovations in male circumcision methods have emerged that promise to make the procedure simpler, less resource intensive, usable by non-physician health care providers, acceptable to clients and providers, and have the potential to expand coverage thus maximizing prevention.

3. While a number of devices for VMMC are on the market, until recently scientifically robust and independent evidence on the quality and safety was not available. In response:
    a. WHO established the Prequalification of Male Circumcision Devices programme to provide Member States and other agencies with technical information about the quality and safety of specific medical devices for VMMC. The status for products undergoing WHO prequalification assessment can be found at:

http://www.who.int/diagnostics_laboratory/evaluations/PQMCdevices_list/en/index.html

    b. In 2013 WHO issued the "*Guideline on the use of devices for adult male circumcision for HIV prevention"* which recommends the use of WHO prequalified devices given the assurance that the device meets global standards of quality, safety and efficacy.

Update:

4. On 31 May 2013, WHO prequalified PrePex™ for the purpose of VMMC for HIV prevention. The term "prequalified" means the device has been assessed and meets international standards for three components: (1) the review of the regulatory dossier of the device, (2) the inspection of the quality management system under which the product is manufactured, and (3) clinical studies on efficacy and safety in settings of intended use, have been satisfactorily completed.

5. On 2 March 2015, the prequalification status was amended to reflect a change notification submitted in support of use of PrePex™ in eligible males aged 13 to 17 years of age for sizes A-E. The device should not be used if the foreskin cannot be easily and fully retracted.

6. The use of the PrePex™ device was demonstrated to be efficacious in male circumcision and safe for use among healthy males 13 years and older when used by trained physicians and mid-level providers. Nonetheless, it is necessary that skills and surgical facilities should be available, at the time of placement or soon after, to safely convert failures of device placement, such as displacements and self-removals, to conventional procedures.

7. Introduction of a new device into public health HIV programmes should be implemented in a phased manner with careful monitoring of the type and frequency of complications outside of controlled study settings. It must also be accompanied by **post-market surveillance as part of monitoring** to capture safety issues such as rare adverse events that must be identified, recorded, and reported to national regulatory authorities and to WHO, as well as to the manufacturer as part of ongoing risk management. The extension of use to this lower age range (13 – 18 years) must be undertaken with active post market surveillance until further data is available.

8. Male circumcision using PrePex™ , an elastic collar compression device:
   - does not routinely require injectable anaesthesia or suturing, however, some pain may occur (albeit less than with conventional surgery), during the first few hours to days after device placement and at removal;
   - required less time to perform than conventional surgery, but must be worn for one week and requires two visits to a provider - one for placement and a second for removal;
   - takes about one to two weeks longer to heal than by conventional surgery as healing is by secondary intention
   - must include:
     a. standard surgical skin preparation and good instructions on personal hygiene
     b. effective education and counselling in line with the WHO minimum service package for male circumcision for HIV prevention, and the risks and benefits of this specific method.

More information on voluntary medical male circumcision is available at
http://www.who.int/hiv/topics/malecircumcision/en/

The amended WHO Prequalification Public Report for PrePex™ is available at
http://www.who.int/diagnostics_laboratory/evaluations/160308_prepex_amended_final_public_report.pdf?ua=1