

31 May 2013

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

Product codes: DW0201, DW0202, DW0203, DW0204 and DW0205 (PQMC reference number 001-001-00)

Background:

1. HIV programmes in priority countries of East and Southern Africa are facing challenges in scaling up male circumcision as an additional prevention intervention, in particular due to the shortage of surgically trained and skilled providers to perform the current conventional surgical procedure.
2. In comparison to conventional surgical male circumcision, devices may have the potential to:
 - a. make the procedure safer (fewer complications), easier and quicker to perform;
 - b. allow other types of trained health workers (e.g. nurses) to perform the procedure;
 - c. improve the acceptability of the procedure.
3. While a number of devices for adult male circumcision are on the market, until recently scientifically robust and independent evidence on the quality and safety of these devices was not available.
4. In response, 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 adult male circumcision devices. At present applications for three such devices have been submitted to the WHO Prequalification Programme. These products are at various stages of the prequalification process. More information can be found at:

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

Update:

5. On 31 May, WHO prequalified the PrePex™ device for the purpose of adult male circumcision 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.
6. The use of the PrePex™ device was demonstrated to be efficacious in male circumcision and safe for use among healthy men 18 years and older when used by trained physicians and mid-level providers. Nonetheless, it is necessary that surgical backup facilities and skills are available to manage within a few hours events such as displacements and self-removals that could lead to serious complications.
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 systems to capture safety issues that allow for appropriate responses, including by the manufacturer.
8. Male circumcision using the PrePex™ :
 - 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 effective education and counselling in line with the WHO minimum service package for male circumcision.
 - More information on male circumcision is available <http://www.who.int/hiv/topics/malecircumcision/en/>