HIV/AIDS Programme

FRAMEWORK FOR CLINICAL EVALUATION OF DEVICES FOR MALE CIRCUMCISION

World Health Organization

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ABBREVIATIONS AND ACRONYMS

AE	adverse event
CFR	Code of Federal Regulations
EU	European Union
FDA	US Food and Drug Administration
GHTF	Global Harmonization Task Force
HIV	human immunodeficiency virus
HPV	human papillomavirus
HSV-2	herpes simplex virus-2
ISO	International Organization for Standardization
MDD	Medical Device Directive (European Union)
PMA	pre-market approval
SFDA	State Food and Drug Administration (People's Republic of China)
UNAIDS	Joint United Nations Programme on HIV/AIDS
VMMC	Voluntary medical male circumcision
WHO	World Health Organization

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EXECUTIVE SUMMARY

Male circumcision has been shown to reduce the risk of heterosexually acquired HIV infection in men. The World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) recommend male circumcision as a priority intervention in countries and settings with a high incidence of HIV and a low prevalence of male circumcision.

Male circumcision devices have the potential to accelerate delivery of male circumcision programmes in resource-limited settings by reducing the time to perform the operation, by simplifying the procedure so that providers can perform it more easily and in some circumstances by making the procedure more acceptable to clients than a surgical approach. Devices are widely used for circumcision in infants and young boys, but experience in post-pubertal boys and adults is limited, particularly in the countries in the African region where rapid expansion of male circumcision programmes for HIV prevention is most urgent.

Regulations governing approval of medical devices require clinical evaluation but may only require limited clinical trials for devices that are used as aids to surgery or remain external to the body. This includes male circumcision devices. As male circumcision programmes for HIV prevention are a public health intervention and involve large numbers of healthy men, a more rigorous assessment of the clinical safety, efficacy, acceptability and cost-effectiveness of male circumcision devices is required. *The Framework for clinical evaluation of devices for male circumcision* is intended to be used by (a) product developers seeking to develop new male circumcision devices or to modify existing devices for use in adult male circumcision programmes in resource-limited settings; (b) clinicians involved in testing devices for acceptability and suitability for use in resource-limited settings, particularly by mid-level providers; (c) regulators responsible for overseeing the development, testing and evaluation of male circumcision devices; and (d) programme managers and sponsors supporting expansion of programmes for male circumcision to prevent HIV infection.

The framework focuses mainly on clinical requirements for assessing the suitability of a device for male circumcision within public health HIV prevention programmes in resource-limited settings and, secondarily, on regulatory and manufacturing considerations. A series of steps and clinical studies is described to evaluate the clinical performance, safety and acceptability of a new male circumcision device, as are the minimum sizes of these different studies. These studies include clinical studies in