

# Letter to the Editor

## PREPEX: THE POTENTIAL OF SCALING UP NON SURGICAL CIRCUMCISION IN RWANDA

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To the Editor,

Randomized controlled studies have shown that male circumcision (MC) can reduce the risk of transmission of Human Immunodeficiency Virus (HIV) by 53%–60% [1-3], and meta-analyses of available data have confirmed the effectiveness of MC in reducing the risk of HIV transmission [4-7]. The World Health Organization (WHO) and Joint United Nations Program on HIV/AIDS have recommended that MC be considered as a means of HIV prevention [8]. Over 38 million adolescent and adult males in Africa could benefit from MC for HIV prevention [9,10], and WHO estimates that at least 20 million MC procedures must be performed to achieve the desired impact on HIV prevention [11]; however, the only method of adult MC currently approved by WHO is surgery.

The Government of Rwanda plans to implement a nation-wide circumcision program with the objective of facilitating voluntary circumcision of 2 million adult men within 2 years to achieve a goal of decreasing HIV incidence rate by 25% in the fifth year from scale-up initiation, calculated by a national task force. However, given current resource limitations, such a goal is unattainable using standard surgical methods, the only approved method by the WHO.

The Government has sought to investigate solutions for non physicians in non sterile settings, thus minimizing the burden on the existing health care system, which is already strained handling life-saving procedures. Among the devices considered, the PrePex<sup>TM</sup> device seemed most suitable, as the procedure is bloodless and requires no injected anesthesia, suturing, or sterile setting. Therefore, a formal program under the guidelines of WHO was initiated to assess safety, effectiveness, and the feasibility of task shifting and scale up.

The PrePex device applies controlled radial elastic pressure to the foreskin between a rigid Inner Ring and an Elastic Ring to cut off distal blood flow. After 7 days, the necrotic foreskin and the device are removed.

Three clinical studies in Rwanda, guided by the WHO draft Framework for Evaluation of Adult Circumcision Device, were conducted in 2010 and 2011 to assess the safety profile of PrePex. The first study enrolled 105 men and assessed safety, time to healing and days lost from work. The second study randomized 180 men to MC via PrePex versus surgical MC in a 2:1 ratio and evaluated procedure time as well as safety, time to healing and satisfaction. The third study enrolled 590 men and assessed safety and efficacy when MC is done by nurses under conditions of intended use.

Rwanda has completed the roadmap, scientifically validating the safety, efficacy, acceptability and superiority (over dorsal slit, on both measures of time and safety) of the PrePex device and has approved the device for use in Rwanda in March 2011, and on February 2012 WHO approved the PrePex for MC scale up in Rwanda.

Overall, more than 4,200 PrePex procedures were conducted by October 2012 in Rwanda, where 888 procedures were performed in the frame work of clinical studies.

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# Lettre pour l'éditeur

## PREPEX: LE POTENTIEL D'AUGMENTER LA CIRCONCISION NON CHIRURGICALE AU RWANDA

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Pour l'éditeur,

Les études contrôlées et randomisées ont montré que la circoncision masculine peut réduire le risque de transmission du virus d'immunodéficience humaine (VIH) de 53-60%, et les meta-analyses des données disponibles ont confirmé l'efficacité de la circoncision masculine dans la réduction du risque de transmission du VIH. L'Organisation Mondiale de la Santé (OMS) et le Programme intégré des Nations Unies sur le VIH/SIDA ont recommandé de considérer la circoncision masculine comme un moyen de prévention du VIH. Plus de 38 millions d'adolescents et hommes adultes en Afrique pourraient bénéficier de la circoncision masculine pour la prévention du VIH, et l'OMS estime qu'au moins 20 millions d'actes de circoncision masculine doivent être exécutés pour réaliser l'impact souhaité sur la prévention du VIH. Cependant, la seule méthode de circoncision masculine adulte actuellement approuvée par l'OMS est la chirurgie.

Le Gouvernement du Rwanda envisage de mettre en œuvre un programme national de circoncision avec l'objectif de faciliter la circoncision volontaire de 2 millions d'hommes adultes au cours des 2 ans à venir afin de diminuer le taux d'incidence du VIH à 25% dans les 5 ans à partir de l'initiation du programme. Cependant, étant donné des limites des ressources actuelles, un tel objectif est difficile à atteindre en utilisant la méthode chirurgicale standard, seule méthode approuvée par l'OMS.

Ainsi, le Gouvernement a cherché à explorer des solutions utilisables par des non-médecins dans des conditions non-stériles, minimisant ainsi le poids sur le système de soins de santé existant, qui est déjà surchargé par les activités visant à sauver des vies humaines. Parmi les dispositifs considérés, le PrePex<sup>TM</sup> a semblé être le plus approprié, étant donné que la procédure est non sanglante et n'exige aucune injection d'anesthésie, sutures ou environnement stérile. C'est pourquoi un programme formel suivant les directives de l'OMS a été introduit pour évaluer les risques, l'efficacité et la faisabilité du transfert des tâches et de l'implémentation à large échelle.

Le PrePex exerce une pression élastique radiale contrôlée sur le prépuce entre un anneau intérieur rigide et un anneau élastique pour stopper le flux sanguin distal. Après 7 jours, le prépuce nécrosé et le dispositif sont enlevés. Trois études cliniques, guidées par le projet du cadre d'évaluation de dispositifs de circoncision adulte de l'OMS, ont été conduites en 2010 et 2011 au Rwanda pour évaluer l'absence de risque du PrePex. La première étude a enrôlé 105 hommes et a évalué le risque, le temps de guérison et les jours perdus au travail. La deuxième étude a randomisé 180 hommes pour la circoncision via PrePex contre la circoncision chirurgicale avec un ratio de 2:1 et a évalué le temps de la procédure aussi bien que le risque, le temps de guérison et la satisfaction. La troisième étude a inscrit 590 hommes et a évalué le risque et l'efficacité quand la circoncision masculine est faite par des infirmiers dans les conditions d'usage prévues.

Le Rwanda a achevé la feuille de route, validant scientifiquement l'absence de risque, l'efficacité, l'acceptabilité et la supériorité (par rapport à l'incision dorsale, pour les deux mesures de temps et de risque) du dispositif PrePex et a approuvé le dispositif pour l'utilisation au Rwanda en mars 2011. En février 2012, l'OMS a approuvé l'utilisation du PrePex dans la circoncision masculine à large échelle au Rwanda.

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