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REPLY

An evidence-based analysis of voluntary medical male circumcision devices

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With regard to our Review (Voluntary medical male circumcision in resource-constrained settings. *Nat. Rev. Urol.* **12**, 661–670 (2015))¹, we would like to thank Peter Millard and Norman Goldstuck for their correspondence (The Unicirc[®] instrument enables rapid, single-visit, convenient and safe medical male circumcision, *Nat. Rev. Urol.* <u>http://dx.doi.org/10.1038/</u><u>nrurol.2016.77</u> (2016))². The WHO recommends voluntary medical male circumcision (VMMC) to reduce heterosexual HIV acquisition³, and VMMC devices should help accelerate scale-up of VMMC in Eastern and Southern Africa.

Although VMMC utilizing the Unicirc® (Unicirc, South Africa) device does not require a follow-up visit for device removal, the data presented in Table 1 in our Review¹ follows current WHO recommendations of at least one follow-up visit within a week of VMMC⁴, even when a surgical method is used that does not require any devices. The follow-up visit enables assessment of healing, detection and management of adverse events, reinforcement of risk reduction counselling messages, and reiterating an offer of HIV testing to those who initially declined. The follow-up visit would be as - if not more important for men undergoing VMMC with the Unicirc® device, because of the limited number of VMMC procedures performed with the Unicirc® device to date, and because of concerns regarding the cyanoacrylate adhesive owing to its exposure to body fluids and use in areas of high skin tension, especially during penile erection⁵.

Table 1 in our Review¹ refers to a surgical setting, not an operating theatre. Consultation rooms — even tents — can be made to be appropriate surgical settings for minor surgical procedures. Thus, the scoring on this point would remain unchanged.

Our Review¹ was based on the best available evidence when evaluating the surgical procedures and available devices. The two available Unicirc[®] articles published in peerreviewed journals by Millard and colleagues did not include complete circumcision as a study outcome and did not explicitly state the level of efficacy of the Unicirc[®] method^{6,7}. Thus, we could not ascertain whether the device alone was successful at removing the foreskin, although we noted that frenulectomies were performed in some men circumcised with the Unicirc[®] device.

The WHO extensively evaluates VMMC devices based on efficacy, clinical safety, quality manufacturing, acceptability, and feasibility, and grants prequalification status to permit procurement by United Nations agencies, WHO member states, and other public-sector purchasers⁸. Although WHO prequalification decisions include data on device efficacy, such data are only available for

the two devices that have been prequalified by the WHO to date, PrePex[™] (Circ MedTech, Israel) and ShangRing[®] (Wuhu Snnda Medical Treatment Appliance Technology Company, China). We would like to encourage the manufacturers of the Unicirc[®] device to devote additional effort to completing the WHO prequalification requirements.

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Competing interests statement The authors declare no competing interests.