Hello. I wanted to submit the following update on our latest studies with the ShangRing in Kenya in case it is helpful to the TAG during the 12 August consultation. Please let me know if you have any questions. The information is not considered confidential as unfortunately we don’t have any actual data to include at this time. Thank you.

EngenderHealth, Weill Cornell Medical College, the Kenya Ministry of Health, and the Kenya National AIDS & STI Control Program (NASCOP) recently completed two studies to examine procedural and clinical outcomes, as well as participant and provider acceptability, of several variations of the current ShangRing male circumcision technique for boys and men that would simplify the procedure. The studies were conducted at two sites in Kenya; one in Homa Bay County (Homa Bay County Hospital) and the other in Kilifi County (Vipingo Health Center). Participants in both studies were boys and men 10 years of age and older seeking voluntary medical male circumcision at the study sites. Data collection is now complete in both studies and the data are currently being analyzed.

The first study explored a modification of the original ShangRing technique, which is referred to as the no-flip technique, as well as spontaneous detachment of the device. All participants underwent the no-flip ShangRing technique, with participants randomized to ring removal at 7 days after circumcision as per the instructions for use vs. spontaneous detachment, where the ring was left in place until it fell off on its own. 230 participants were randomized 1:1 in this study.

The second study explored the use of topical anesthesia for the ShangRing procedure. It was a randomized study comparing topical anesthesia (2.5% lidocaine, 2.5% prilocaine cream) vs. injectable anesthesia (1% lidocaine). 344 participants were randomized (2 topical: 1 injectable) in this study. During the second study, we are collaborating with Johns Hopkins to gather microbiome data on men and boys undergoing ShangRing circumcision (they have previously gathered similar data for conventional and PrePex VMMC). We collected three swabs per participant (before circumcision, at 7 days post-MC before the ShangRing was removed, and at 42 days post-MC when participants came for their final follow-up visit). A total of 33 participants agreed to the collection of swabs. We have the full set of three swabs from 29 participants, in addition to the swabs prior to circumcision and at day 7 in three participants. We are still waiting for permission from the Kenya MOH to export the samples, which will be analyzed in the US, so unfortunately the results will not be available in time for the upcoming consultation.

We are not aware of any reported cases of tetanus among boys or men recently circumcised with the ShangRing in either China or Africa. The ShangRing has been commercially available in China (where it is manufactured) since 2006 and has been used to circumcise probably upwards of one million young boys, adolescents and men (exact figures are unavailable). Childhood immunization rates, including tetanus, are reported to be high in China, with nearly universal coverage. In Africa, the ShangRing has been studied in Kenya, Malawi, Uganda, and Zambia (approximately 4,100 boys and men 10 years of age and older). Presumably the TAG has whatever data are available on tetanus immunizations rates in these countries.

The ShangRing is a collar clamp device, with removal of the foreskin at the time of placement, which seems unlikely to result in an environment conducive to growth of anaerobes or issues with odor. We have not previously had reports of odor from the circumcision wound by either those who have been circumcised or providers removing rings in our studies in Kenya and Zambia.