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Summary of scientific validation and ongoing use of prepex device for non-surgical adult male circumcision in Rwanda

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Abstract

Trials of the PrePex device for non-surgical MC were conducted using the WHO Evaluation Framework of Adult Male Circumcision Devices. Rwanda has completed the roadmap, validating the safety, efficacy, acceptability and superiority (over dorsal slit, on both time and safety) of PrePex. This report provides a meta analysis of all safety results accumulated in clinical trials and PrePex campaigns. Data was gathered from 4 trials and 3 campaigns including active reporting of Adverse Events (AEs). All AEs occurred up to day 8, treated and resolved see table 01

Study	Number of subjects/patients	Number Device Related Adverse Events
CR-CMT-01 – PrePex Safety & Efficacy Study	105	1 Related AE
RMC01 – Comparison Study .	144 PrePex / (73 Surgery)	0 PrePex related AE 4 unrelated AEs (7 surgery related AE)
RMC02 – Feasibility Study with Nurses	49	0 related AE 1 unrelated
RMC03 – Safety and Efficacy by Nurses	518 study + 72 study training	2 Related AEs 3 unrelated
Rwanda Military Hospital Ongoing campaign	818	3 Related AE 0 unrelated AEs
Byumba H&H campaign	1000	7 Related AEs 0 unrelated AEs
RMH campaign	1496	4 Related AEs 0 unrelated AEs
Summary	4,202	17 Related AE (all mild to moderate) 8 unrelated AEs (mild-moderate)

Over 90% of the 4,202 procedures were conducted by low cadre nurses. Studies confirmed that PrePex is safe when performed by physicians and by nurses, with a related AE rate of 0.4%, offering a bloodless procedure that requires no needles (no injection of anaesthesia), no knives, no sutures, no sterile settings.

Biography

He completed his doctoral studies in the National University of Rwanda. He has been charged with directing HIV Research Studies in Rwanda and currently he is the lead investigator of PrePex Clinical trials in Rwanda, working closely with the Male Circumcision Device Technical Advisory Group of the WHO. He also serves as an editorial board member for the Rwanda Medical Journal and the East African Epidemiological Bulletin.