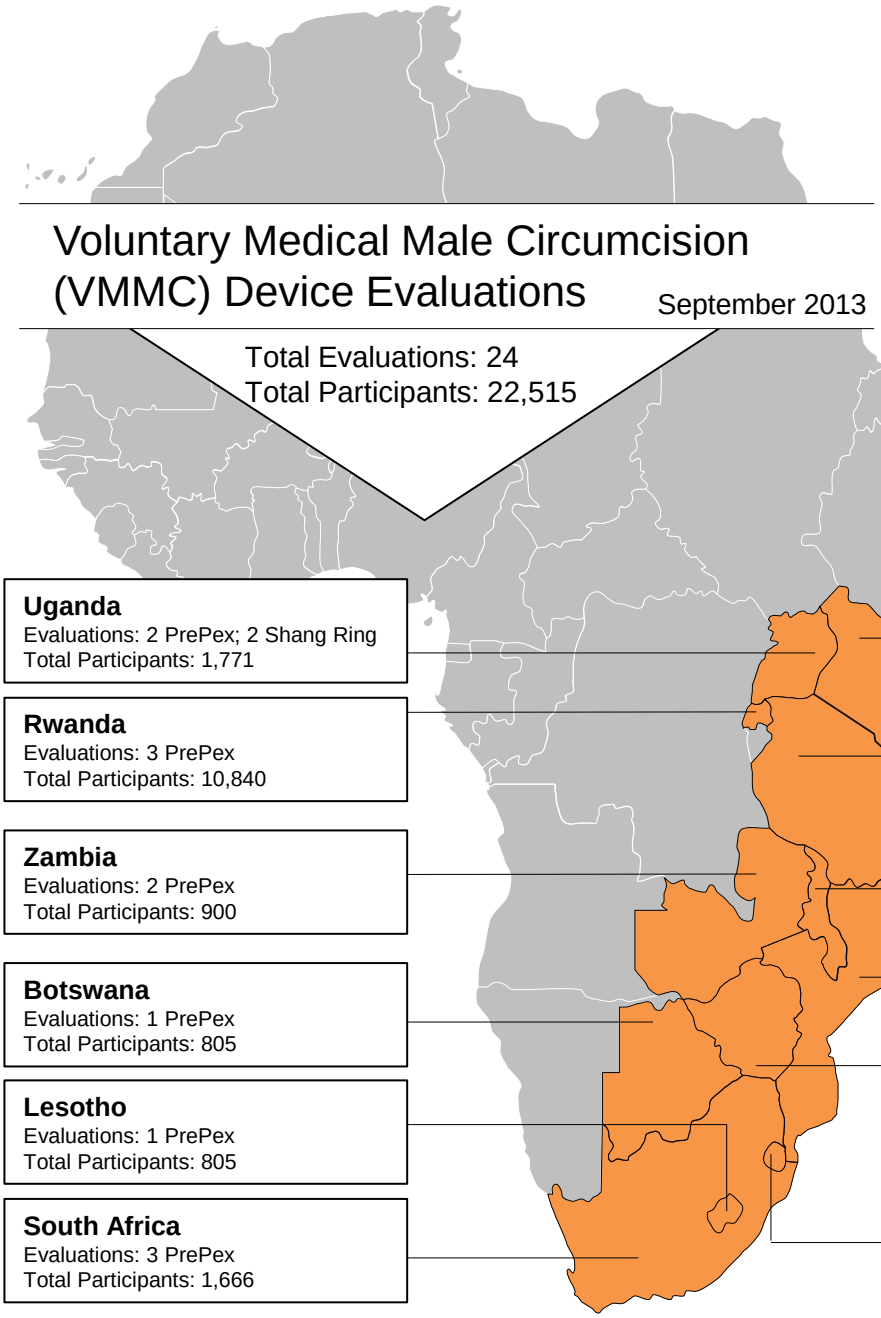
Voluntary Medical Male Circumcision (VMMC) Device Evaluations Map and Table

There are a range of evaluation studies underway to learn more about how non-surgical devices can be used for adult male circumcision. These evaluations, also called implementation pilots, are focused on questions about safety, feasibility and provider training. The World Health Organization has already determined that one device, known as PrePex, meets required standards of quality, safety and efficacy for international use. Evaluations of PrePex and other devices will provide information on how to use these strategies in the real world. Most evaluations are enrolling, ongoing or recently completed. Results can be expected within a year.



Voluntary Medical Male Circumcision (VMMC) Device Evaluations, August 2013					
Device and Evaluation Type	**Donor; Implementation Partners**	**Population**	**Country**	**Research Questions**	**Status**
PrePex Evaluations (WHO Prequalification-related evaluations not listed)					
PrePex Implementation Pilots					
PrePex Implementation Pilot	PEPFAR (CDC), BMGF; Jhpiego, ACHAP	805	Botswana	To evaluate the training of mid-level providers to learn PrePex technique; to describe and assess the safety of the PrePex device by the occurrence of clinical AEs, when circumcision is performed by trained nurses; and, to describe and assess male client and provider acceptability of VMMC with the PrePex device.	Enrolling as of May 2013
PrePex Implementation Pilot	BMGF; FHI 360	427	Kenya	To determine time to complete healing; to determine amount of training needed for proficiency; to determine costs of training and service delivery; to document proportion of men medically ineligible for the device; to document proportion of men who do not return for removal at 7 days and effort level needed for follow-up; and, to compare outcomes and acceptability in fixed sites vs. mobile.	Enrollment completed; follow-up continuing through Aug 2013
PrePex Implementation Pilot	PEPFAR (USAID); MCHIP (Jhpiego); HPP (Futures Institute)	805	Lesotho	To determine efficacy, healing time, training time (providers), procedure time and costing (incremental cost of adding PrePex to existing program; comparison of cost before vs. after introduction of PrePex; Comparison Unit cost of VMMC with PrePex vs. with forceps-guided surgery).	Estimated enrollment start date of Oct 2013
PrePex Implementation Pilot	PEPFAR (CDC), MSF; I-Tech, BLM/MSF	960	Malawi	To obtain cost data for the device, training, staff time, equipment and supplies; to observe application time and removal time; to observe client satisfaction: to observe time for the participants to return to normal activity including work, normal tasks and sexual activity; and, to assess client opinion of device-based circumcision including odor, cosmetic results and feedback shared with peers and families.	Estimated enrollment start date of Oct 2013
PrePex Implementation Pilot	BMGF; PSI	650	Mozambique	To study safety, training needs, acceptability and cost- effectiveness of device when used by mid- level providers.	Completed enrollment Aug 2013
PrePex Implementation Pilot	PEPFAR (USAID); CHAPS, Anova & HPP (for the costing component)	756	South Africa	To ascertain the training needs of mid-level providers and the level of skill required to safely and effectively use PrePex for VMMC procedures; describe and assess the acceptability and reasons for acceptability of PrePex male circumcision amongst male clients and providers; and describe and assess the safety of the PrePex device by the occurrence of clinical AEs, when trained nurses perform circumcision. Includes a costing component (incremental cost of adding PrePex to existing program; comparison of cost before vs. after introduction of PrePex; Comparison Unit cost of VMMC with PrePex vs. with forceps-guided surgery).	Estimated enrollment start date of Q1 2014

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PrePex Implementation Pilot	PEPFAR (CDC); Aurum	560	South Africa	To ascertain the training needs of mid-level providers and the level of skill required to learn PrePex procedures and use the devices; to assess the length of time to complete healing (*complete epithelial covering of wound* by visual inspection) post-PrePex removal; to assess the implementation of male circumcision services from mobile service setting.	Estimated enrollment start date of Q3 2013
PrePex Implementation Pilot	BMGF; PSI	350 (includes 50 adolescents)	South Africa	To determine safety and acceptability of PrePex device when used in adults and adolescents ages 13-17 years.	Estimated enrollment start date of Sept 2013
PrePex Implementation Pilot	PEPFAR (USAID); PSI/CHAPS (the study is implemented by CHAPS sub of PSI) & HPP (HPP for the costing component)	756	Swaziland	To ascertain the training needs of mid-level providers and the level of skill required to safely and effectively use PrePex for VMMC procedures; describe and assess the acceptability and reasons for acceptability of PrePex male circumcision amongst male clients and providers; and describe and assess the safety of the PrePex device by the occurrence of clinical AEs, when trained nurses in Swaziland perform circumcision. Includes costing component (incremental cost of adding PrePex to existing program; comparison of cost before vs. after introduction of PrePex; Comparison Unit cost of VMMC with PrePex vs. with forceps-guided surgery).	Estimated enrollment start date of Q1 2014
PrePex Implementation Pilot	PEPFAR (USAID); MCHIP (Jhpiego) & HPP (HPP for the costing component)	805	Tanzania	To determine efficacy, healing time, training time (providers), procedure time and costing (incremental cost of adding PrePex to existing program; comparison of cost before vs. after introduction of PrePex; Comparison Unit cost of VMMC with PrePex vs. with forceps-guided surgery).	Estimated enrollment start date of Oct 2013
PrePex Implementation Pilot	PEPFAR (NIH); Rakai Health Sciences	135 training; 350 study	Uganda	To determine safety, wound healing, acceptability and resumption of intercourse before certified healing and to assess microbiome at time of device removal.	Completed Nov 2012
PrePex Implementation Pilot	BMGF; PSI	500	Zambia	To assess safety, training needs, acceptability of the device when used by mid-level providers.	Estimated enrollment start date of Sept 2013
PrePex Active Adverse Event Surveillance					
PrePex Active AE Surveillance	BMGF; RBC	1,000	Rwanda	Assessment of the effectiveness of a Targeted Spontaneous Reporting (TSR) system for monitoring the safety of MC scale-up during an active surveillance phase.	TBD

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Device and Evaluation Type	**Donor; Implementation Partners**	**Population**	**Country**	**Research Questions**	**Status**
PrePex Passive Adverse Event Surveillance					
PrePex Passive AE Surveillance	BMGF; RBC	9,000 (embedded operational research will have specific sample sizes TBD)	Rwanda	Assessment of the effectiveness of a Targeted Spontaneous Reporting (TSR) system for monitoring the safety of MC scale up during the passive surveillance phase; assessment of the safety and efficacy of PrePex operators performing device removal procedure without an assistant; assessment of the infection rates and efficiency gain in using different sterilization procedures (autoclaves and alternative methods); and cost-effectiveness analysis comparing PrePex and Surgical MC.	TBD
PrePex Bridging Studies					
PrePex Bridging Study (adolescents)	BMGF; RBC	240 sizing phase; 600 safety phase	Rwanda	Determine the statistical distribution of sulcus size and foreskin flexibility in ages 10 to 17 to establish required sizes of PrePex devices for adolescents; determine the proportion of genital deformities as part of screening inclusion/exclusion criteria (proportion of phimosis, paraphimosis, warts under the prepuce, torn or tight frenulum, narrow prepuce, hypospadias, epispadias); assess the safety of the non-surgical PrePex device, when performed by physicians and nurses on adolescent male population.	TBD
PrePex Bridging Study (military)	PEPFAR (DOD); DOD	300	Swaziland	To study odor prevention and time back to work.	Estimated enrollment start date of Q1 2014
PrePex Bridging Study (military)	PEPFAR (DOD); DOD	400	Uganda	To study odor prevention and time back to work.	Estimated enrollment start date of Jan 2014
PrePex Bridging Study (military)	PEPFAR (DOD); DOD	400	Zambia	To study odor prevention and time back to work.	Estimated enrollment start date of Jan 2014
PrePex Bridging Study (adolescents)	BMGF; PSI	200, ages 16-17; 200, ages 13-15	Zimbabwe	To determine safety and acceptability of PrePex device when used with adolescents, ages 13-17. (Sizing study in 240 adolescents, ages 10-17, first to determine appropriate sizes needed for this group.)	Sizing study completed; main study enrollment start date of Aug 2013
PrePex Bridging Study (lowest nurse cadres/lower level health facilities)	BMGF	780	Zimbabwe	To determine safety and feasibility of PrePex device at lower level health care facility and when used by Primary Care Nurses (lower cadre than Registered General Nurse).	Enrolling as of June 2013

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Shang Ring Evaluations (PQ-related evaluations not listed)					
Shang Ring Implementation Pilots					
Shang Ring Implementation Pilot	PEPFAR (NIH); Rakai Health Sciences	621 total	Uganda	To determine safety, wound healing, acceptability and resumption of intercourse before certified healing.	Completed Oct 2011
Shang Ring Bridging Studies					
Shang Ring Bridging (adolescents)	PEPFAR (NIH); Rakai Health Sciences	400, ages 13-17	Uganda	To determine safety, wound healing, acceptability and resumption of intercourse before certified healing	Completed May 2013
AccuCirc Evaluations					
AccuCirc PQ Studies					
AccuCirc Early Infant Male Circumcision Comparison (Mogen/AccuCirc)	BMGF; PSI	150	Zimbabwe	Comparison study (Mogen clamp/AccuCirc), safety, acceptability and costing.	Completed June 2013
AccuCirc Early Infant Male Circumcision and Field Study	BMGF; PSI	500	Zimbabwe	Providing the comparative study demonstrates that AccuCirc is safe for further roll out of EIMC, an introductory field study using nurses/midwives will be conducted in order to assess safety and acceptability of using nurses/midwives for roll out; explore operational issues relating to timing of procedure and integration into existing health delivery systems at each level of service delivery and; explore costing issues.	Enrolling as of July 2013