Quarterly Research Digest On Voluntary Medical Male Circumcision for HIV Prevention

 Awori, Q. D., et al. Surgical outcomes of newly trained ShangRing circumcision providers. J Acquir Immune Defic Syndr 2016;72(Suppl 1):S13-7.

Online at: http://journals.lww.com/jaids/Fulltext/2016/06011/Surgical_Outcomes_of Newly Trained ShangRing.3.aspx

BACKGROUND: Devices can potentially accelerate scale-up of voluntary medical male circumcision in sub-Saharan Africa. Studies have demonstrated advantages of the ShangRing device over conventional circumcision. With the need to train providers rapidly for scale-up, concerns arise about the transferability of techniques and the expertise of new trainees.

METHODS: We compared outcomes of ShangRing circumcisions conducted in Kenya by experienced providers (experience with more than 100 ShangRing circumcisions) and newly trained providers (trained in Kenya by the experienced providers before the study began). During training, trainees performed at least 7 ShangRing circumcisions and 3 removals. Newly trained providers received intermittent clinical mentoring initially during the study but otherwise conducted circumcisions on their own.

RESULTS: Four hundred six and 115 ShangRing procedures were performed by the new trainees and the experienced providers, respectively. The mean duration of circumcisions was 6.2 minutes for both trained and experienced provider groups (P = 0.45), whereas the mean pain score (on an 11-point scale) was 2.5 and 3.2, respectively (P = 0.65). There was no difference in the proportion of participants healed by the day 42 visit (P = 0.13) nor in the incidence of moderate and severe adverse events observed (P = 0.16). Participants in both groups were equally satisfied with final wound cosmesis. **DISCUSSION:** Results demonstrate that the ShangRing circumcision technique is easy to learn and master. Newly trained providers can safely conduct ShangRing circumcisions in routine service settings. The ShangRing can facilitate rapid rollout of voluntary medical male circumcision for HIV prevention in sub-Saharan Africa.

 Barnabas, R. V., et al. Uptake of antiretroviral therapy and male circumcision after community-based HIV testing and strategies for linkage to care versus standard clinic referral: a multisite, open-label, randomised controlled trial in South Africa and Uganda. *Lancet HIV* 2016;3(5):e212-20. Online at: http://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(16)00020-5/abstract

BACKGROUND: Male circumcision decreases HIV acquisition by 60%, and antiretroviral therapy (ART) almost eliminates HIV transmission from HIV-positive people who are virally suppressed; however, coverage of these interventions has lagged behind targets. We aimed to assess whether community-based HIV testing with counsellor support and point-of-care CD4 cell count testing would increase uptake of ART and male circumcision.

METHODS: We did this multisite, open-label, randomised controlled trial in six research-naive communities in rural South Africa and Uganda. Eligible HIV-positive participants (aged >/=16 years) were randomly assigned (1:1:1) in a factorial design to receive lay counsellor clinic linkage facilitation, lay counsellor follow-up home visits, or standard-of-care clinic referral, and then (1:1) either point-of-care CD4 cell count testing or referral for CD4 testing. HIV-negative uncircumcised men (aged 16-49 years) who could receive secure mobile phone text messages were randomly assigned (1:1:1) to receive text message reminders, lay counsellor visits, or standard clinic referral. The study biostatistician generated the randomisation schedule via a computer-generated random number program with varying block sizes (multiples of six or three) stratified by country. Primary outcomes for HIVpositive people were obtaining a CD4 cell count, linkage to an HIV clinic, ART initiation, and viral suppression at 9 months, and for HIV-negative uncircumcised men were visiting a circumcision facility and uptake of male circumcision at 3 months. We assessed social harms as a safety outcome

throughout the study. We did the primary analyses by intention to treat. This trial is registered with ClinicalTrials.gov, number NCT02038582.

FINDINGS: Between June 6, 2013, and March 11, 2015, 15 332 participants were tested. 2339 (15%) participants tested HIV positive, of whom 1325 (57%) were randomly assigned to receive lay counsellor clinic linkage facilitation (n=437), lay counsellor follow-up home visits (n=449), or standard clinic referral (n=439), and then point-of-care CD4 cell testing (n=206, n=220, and n=213, respectively) or referral for CD4 testing (n=231, n=229, and n=226, respectively). 12 993 (85%) participants tested HIV negative, of whom 750 (6%) uncircumcised men were randomly assigned to receive clinic referral (n=230), text message reminders (n=288), or lay counsellor follow-up visits (n=232). 1218 (93%) of 1303 HIV-positive participants were linked to care, but only 488 (37%) participants initiated ART. Overall, 635 (50%) of 1272 HIV-positive individuals achieved viral suppression at 9 months: 219 (52%) of 419 participants in the clinic facilitation group, 202 (47%) of 431 participants in the lay counsellor followup group, and 214 (51%) of 422 participants in the clinic referral group, with no significant differences between groups (p=0.668 for clinic facilitation and p=0.273 for lay counsellor follow-up vs clinic referral). 523 (72%) of 734 HIV-negative men visited a circumcision facility, with no difference between groups. 62 (28%) of 224 men were circumcised in the male circumcision clinic referral group compared with 137 (48%) of 284 men in the text message reminder group (relative risk 1.72, 95% CI 1.36-2.17; p<0.0001) and 106 (47%) of 226 men in the lay counsellor follow-up group (1.67, 1.29-2.14; p=0.0001). No cases of study-related social harm were reported, including probing about partnership separation, unintended disclosure, gender-based violence, and stigma.

INTERPRETATION: All the community-based strategies achieved high rates of linkage of HIV-positive people to HIV clinics, roughly a third of whom initiated ART, and of those more than 80% were virally suppressed at 9 months. Uptake of male circumcision was almost two-times higher in men who received text message reminders or lay counsellor visits than in those who received standard-of-care clinic referral. Clinic barriers to ART initiation should be addressed in future strategies to increase the

proportion of HIV-positive people accessing treatment and achieving viral suppression.

FUNDING: National Institute of Allergy and Infectious Diseases, National Institutes of Health.

3. Barone, M. A., et al. Men's understanding of and experiences during the postcircumcision abstinence period: results from a field study of ShangRing circumcision during routine clinical services in Kenya and Zambia. *J Acquir Immune Defic Syndr* 2016;72 (Suppl 1): S18-23. Online at:

http://www.ncbi.nlm.nih.gov/pubmed/?term=%22Men%27s+Understandin g+of+and+Experiences+During+the+Postcircumcision+Abstinence+Period% 3A+Results+From+a+Field+Study+of+ShangRing+Circumcision+During+Rout ine+Clinical+Services+in+Kenya+and+Zambia%22

BACKGROUND: Men's understanding of counseling messages after voluntary medical male circumcision (VMMC) plays an important role in whether they follow them. Data on triggers for early resumption of sex may be useful as scale-up of VMMC for HIV prevention continues in sub-Saharan Africa.

METHODS: Data on understanding of post-VMMC abstinence recommendations, resumption of sex, condom use, and triggers for resuming sex were collected from participants during a follow-up interview 35-42 days after ShangRing circumcision in Kenya and Zambia.

RESULTS: Of 1149 men who had ShangRing circumcision, 1096 (95.4%) completed follow-up. Nearly all (99.2%) reported being counseled to abstain from sex post-VMMC; among those, most (92.2%) recalled the recommended abstinence period was 6 weeks. Most men (94.1%) reported that the counselor gave reasons for post-VMMC abstinence and recalled appropriate reasons. Few (13.4%) men reported resuming sex at 35-42 days' follow-up. Among those, 54.8% reported never using a condom post-VMMC. Younger participants (odds ratio 0.3, 95% confidence interval: 0.2 to 0.5, P < 0.0001) and those reporting at least some condom use at baseline (odds ratio 0.5, 95% confidence interval: 0.3 to 0.7, P = 0.0003)

were less likely to report resuming sex. Among men who reported some condom use, most (71.5%) said condoms were much easier or easier to use after circumcision. Men reported various reasons for early resumption of sex, primarily strong sexual desire (76.4%).

CONCLUSIONS: Most men reported awareness of and adherence to the counseling recommendations for post-VMMC abstinence. A minority reported early resumption of sex, and, among those, condom use was low. Results could be used to improve post-VMMC counseling.

4. Bowa, K., et al. A review of HIV and surgery in Africa. Open AIDS J 2016;10:16-23.

Online at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4893540/

HIV has a significant impact on surgery in Africa. Its' influence has spanned a period of about 30 years. In the 1980s' Africa experienced a rise in the national prevalence of HIV spreading across East Africa through Southern Africa, and reaching peak prevalence in the Southern African region. These prevalence levels have affected four key areas of surgical practice; namely patient care, practice of surgery, surgical pathologies, the practitioner and more recently prevention. The surgical patient is more likely to be HIV positive in Africa, than elsewhere in the world. The patients are also more likely to have co infection with Hepatitis C or B and are unlikely to be aware of his or her HIV status. Surgical patients are also more likely to have impaired liver and renal function at the time of presentation. Therefore, HIV has affected the pattern of surgical pathologies, by influencing disease presentation, diagnosis, management and outcomes. It has also influenced the surgeon by increasing occupational risk and management of that risk. Recently in an ironic change of roles, surgery has impacted HIV prevention through the role of male circumcision as a significant tool in HIV prevention, which has traditionally focused on behavioural interventions. The story of surgery and HIV continues to unfold on the continent. Ultimately presenting a challenge which requires innovation, dedication and hard work in the already resource limited environments of Africa.

5. Bulled, N., et al. Making voluntary medical male circumcision a viable HIV prevention strategy in high prevalence countries by engaging the traditional sector. *Crit Public Health* 2016;26(3):258-268.

Voluntary medical male circumcision (VMMC) has been rapidly accepted by global HIV policy and donor institutions as a highly valuable HIV prevention strategy given its cost-effectiveness, limited interactions with a health facility, and projected long-lasting benefits. Many southern African countries have incorporated VMMC into their national HIV prevention strategies. However, intensive VMMC promotion programs have met with limited success to date and many HIV researchers have voiced concerns. This commentary discusses reasons behind the less-than-desired public demand and suggests how inclusion of the traditional sector—traditional leaders, healers, and circumcisers—with their local knowledge, cultural expertise and social capital, particularly in the realm of social meanings ascribed to male circumcision, may improve the uptake of this HIV prevention strategy. We offer Lesotho and Swaziland as case studies of the integration of universal VMMC policies; these are countries with a shared HIV burden, yet contrasting contemporary socio-cultural practices of male circumcision. The similar hesitant responses expressed by these two countries towards VMMC remind us that the incorporation of any new or revised and revitalized public health strategy must be considered within unique historical, political, economic, and socio-cultural contexts.

 Cummings, B., et al. Acceptability and satisfaction associated with the introduction of the PrePex circumcision device in Maputo, Mozambique. J Acquir Immune Defic Syndr 2016;72(Suppl 1): S56-62.
Online at: http://iournals.lww.com/iaids/Eulltext/2016/06011/Acceptability_and_Sati

http://journals.lww.com/jaids/Fulltext/2016/06011/Acceptability_and_Sati sfaction_Associated_With_the.10.aspx

BACKGROUND: Adult device circumcision may potentially reach more men in Sub-Saharan Africa, with fewer human resource and capacity needs than surgical procedures. Despite these advantages, little is known about device acceptability, including pain and maintaining the device in situ. **METHODS:** Healthy, HIV-negative men, between 18 and 49 years, in a Maputo clinic, were consecutively asked to participate in a circumcision device study that included assessing acceptability. Clinical forms and self-administered surveys were used to collect data at various times during the circumcision process for consenting men. Data were entered into a central database and analyzed using statistical software.

RESULTS: Between May and July, 2013, 504 men received device circumcision. Placement was painless for 98.2% of the male population, but the pain was more common during removal with 38.3% reporting severe or unbearable and 21.5% moderate pain. Satisfaction was high at both time points with 88.8% and 92.6% of men being very or somewhat satisfied at placement and removal, respectively. Half of the male population (50.2%) was very or somewhat comfortable with the device in situ; whereas, 36.8% were somewhat or very uncomfortable. Common device difficulties experienced were painful erections (38.5%) and difficult urination (21.8%) and hygiene (21.4%). By the final clinic visit at day 49, 90.4% of them were very or somewhat satisfied with the procedure.

DISCUSSION: High levels of satisfaction were reported for device circumcision, despite the pain noted during removal and some challenges with the device in situ. Given the advantages and acceptability among Mozambican men in this study, device circumcision could be offered, when clinically appropriate, as an alternative to surgery.

 Feldblum, P., et al. Safety and efficacy of the PrePex male circumcision device: results from pilot implementation studies in Mozambique, South Africa, and Zambia. J Acquir Immune Defic Syndr 2016;72(Suppl 1):S43-8. Online at:

http://journals.lww.com/jaids/Fulltext/2016/06011/Safety_and_Efficacy_of _the_PrePex_Male.8.aspx

BACKGROUND: Fourteen countries in East and Southern Africa have engaged in national programs to accelerate the provision of voluntary medical male circumcision (VMMC) since 2007. Devices have the potential to accelerate VMMC programs by making the procedure easier, quicker, more efficient, and widely accessible. **METHODS:** Pilot Implementation studies were conducted in Mozambique, South Africa, and Zambia. The primary objective of the studies was to assess the safety of PrePex device procedures when conducted by nurses and clinical officers in adults and adolescent males (13-17 years, South Africa only) with the following end points: number and grade of adverse events (AEs); pain-related AEs measured using visual analog score; device displacements/self-removals; time to complete wound healing; and procedure times for device placement and removal.

RESULTS: A total of 1401 participants (1318 adult and 83 adolescent males) were circumcised using the PrePex device across the 3 studies. Rates of moderate/severe AEs were low (1.0%; 2.0%; and 2.8%) in the studies in Mozambique, Zambia, and South Africa, respectively. Eight early self-removals of 1401 (0.6%) were observed, all required corrective surgery. High rates of moderate/severe pain-related AEs were recorded especially at device removal in South Africa (34.9%) and Mozambique (59.5%). Ninety percent of participants were healed at day 56 postplacement.

DISCUSSION: The study results from the 3 countries suggest that the implementation of the PrePex device using nonphysician health care workers is both safe and feasible, but better pain control at device removal needs to be put in place to increase the comfort of VMMC clients using the PrePex device.

 Feldblum, P. J., et al. Factors associated with delayed healing in a study of the PrePex Device for adult male circumcision in Kenya. J Acquir Immune Defic Syndr 2016;72(Suppl 1):S24-9.
Online at: http://journals.lww.com/jaids/Fulltext/2016/06011/Factors_Associated_Wi th_Delayed_Healing_in_a_Study.5.aspx

OBJECTIVES: To explore factors associated with healing requiring more than 6 weeks after placement of the PrePex device for adult medical male circumcision.

METHODS: We enrolled 427 men ages 18-49 years in an observational study of PrePex at 1 urban and 2 peripheral clinics in western Kenya. Participants were scheduled for device removal at day 7 and a follow-up visit at day 42 (allowable range, 40-44) at which the provider recorded wound status, with complete healing defined as a dry wound without any scab, later confirmed by site investigator review of digital penile photographs. We performed univariate and multivariate logistic regression to explore associations between selected demographic, surgical, and follow-up factors and delayed healing (not healed by day 42 visit).

RESULTS: Of the 427 men, 341 completing a day 42 visit with physical examination and recorded healing status were included. Fifty-four percent of included men were healed by day 42 visit. Factors associated with delayed healing in univariate analysis and remaining significant in the multivariate analysis were as follows: age 25 years or older [odds ratio (OR): 1.8; 95% confidence interval (CI): 1.4 to 2.4], an adverse event by day 44 (OR: 1.4; 95% CI: 1.03 to 2.0), and severe pain during device removal (protective association: OR: 0.7; 95% CI: 0.5 to 0.99).

CONCLUSIONS: Older age (25+ years), occurrence of an adverse event, and lesser self-reported pain at device removal were associated with delayed wound healing. If confirmed by larger surveillance studies, these results should be incorporated into the counseling given to male circumcision clients.

 9. Feldblum, P. J., et al. Randomized controlled trial of the ShangRing for adult medical male circumcision: safety, effectiveness, and acceptability of using 7 versus 14 device sizes. J Acquir Immune Defic Syndr 2016;72 (Suppl 1):S30-5.
Online at: <u>http://journals.lww.com/jaids/Fulltext/2016/06011/Randomized Controlle</u> <u>d Trial of the ShangRing for.6.aspx</u>

OBJECTIVES: To assess the safety, effectiveness, and acceptability of providing a reduced number of ShangRing sizes for adult voluntary medical male circumcision (VMMC) within routine service delivery in Lusaka, Zambia.

METHODS: We conducted a randomized controlled trial and enrolled 500 HIV-negative men aged 18-49 years at 3 clinics. Participants were randomized to 1 of 2 study arms (Standard Sizing arm vs Modified Sizing arm) in a 1:1 ratio. All 14 adult ShangRing sizes (40-26 mm inner diameter, each varying by 1 mm) were available in the Standard Sizing arm; the Modified Sizing arm used every other size (40, 38, 36, 34, 32, 30, 28 mm inner diameter). Each participant was scheduled for 2 follow-up visits: the removal visit (day 7 after placement) and the healing check visit (day 42 after placement), when they were evaluated for adverse events (AEs), pain, and healing.

RESULTS: Four hundred and ninety-six men comprised the analysis population, with 255 in the Standard Sizing arm and 241 in the Modified Sizing arm. Three men experienced a moderate or severe AEs (0.6%), including 2 in the Standard Sizing arm (0.8%) and 1 in the Modified Sizing arm (0.4%). 73.2% of participants were completely healed at the scheduled day 42 healing check visit, with similar percentages across study arms. Virtually all (99.6%) men, regardless of study arm, stated that they were very satisfied or satisfied with the appearance of their circumcised penis, and 98.6% stated that they would recommend ShangRing circumcision to family/friends.

CONCLUSIONS: The moderate/severe AE rate was low and similar in the 2 study arms, suggesting that provision of one-half the number of adult device sizes is sufficient for safe service delivery. Effectiveness, time to healing, and acceptability were similar in the study arms. The simplicity of the ShangRing technique, and its relative speed, could facilitate VMMC program goals. In addition, sufficiency of fewer device sizes would simplify logistics and inventory.

10. Fram, F., et al. Employing demand-based volumetric forecasting to identify potential for and roles of devices in scale-up of medical male circumcision in Zambia and Zimbabwe. *J Acquir Immune Defic Syndr* 2016;72 (Suppl 1): S83-9.

Online at:

http://journals.lww.com/jaids/Fulltext/2016/06011/Employing Demand B ased_Volumetric_Forecasting_to.15.aspx

INTRODUCTION: Devices for male circumcision (MC) are becoming available in 14 priority countries where MC is being implemented for HIV prevention. Understanding potential impact on demand for services is one important programmatic consideration because countries determine whether to scale up devices within MC programs.

METHODS: A population-based survey measuring willingness to undergo MC, assuming availability of surgical MC and 3 devices, was conducted among 1250 uncircumcised men, ages 10-49 years in Zambia and 1000 uncircumcised men, ages 13-49 years in Zimbabwe. Simulated Test Market methodology was used to estimate incremental MC demand and the extent to which devices might be preferred over surgery, assuming availability of: surgical MC in both countries; the devices PrePex, ShangRing, and Unicirc in Zambia; and PrePex in Zimbabwe.

RESULTS: Modeled estimates indicate PrePex has the potential to provide an overall increase in MC demand ranging from an estimated 13%-50%, depending on country and WHO prequalification ages, replacing 11%-41% of surgical procedures. In Zambia, ShangRing could provide 8% overall increase, replacing 45% of surgical procedures, and Unicirc could provide 30% overall increase, replacing 85% of surgical procedures.

CONCLUSIONS: In both countries, devices have potential to increase overall demand for MC, assuming wide scale awareness and availability of circumcision by the devices. With consideration for age and country, PrePex may provide the greatest potential increase in demand, followed by Unicirc (measured in Zambia only) and ShangRing (also Zambia only). These results inform one program dimension for decision making on potential device introduction strategies; however, they must be considered within the broader programmatic context.

Gorgens, M., et al. Potential impact of multiple interventions on HIV incidence in a hyperendemic region in Western Kenya: a modelling study. *PLoS Med* 2016;16(1):189.
Online at: http://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-016-1520-4

BACKGROUND: Multiple prevention interventions, including early antiretroviral therapy initiation, may reduce HIV incidence in hyperendemic settings. Our aim was to predict the short-term impact of various single and combined interventions on HIV spreading in the adult population of Ndhiwa subcounty (Nyanza Province, Kenya).

METHODS: A mathematical model was used with data on adults (15-59 years) from the Ndhiwa HIV Impact in Population Survey to compare the impacts on HIV prevalence, HIV incidence rate, and population viral load suppression of various interventions. These interventions included: improving the cascade of care (use of three guidelines), increasing voluntary medical male circumcision (VMMC), and implementing pre-exposure prophylaxis (PrEP) use among HIV-uninfected women.

RESULTS: After four years, improving separately the cascade of care under the WHO 2013 guidelines and under the treat-all strategy would reduce the overall HIV incidence rate by 46 and 58 %, respectively, vs. the baseline rate, and by 35 and 49 %, respectively, vs. the implementation of the current Kenyan guidelines. With conservative and optimistic scenarios, VMMC and PrEP would reduce the HIV incidence rate by 15-25 % and 22-28 % vs. the baseline, respectively. Combining the WHO 2013 guidelines with VMMC would reduce the HIV incidence rate by 35-56 % and combining the treat-all strategy with VMMC would reduce it by 49-65 %. Combining the WHO 2013 guidelines, VMMC, and PrEP would reduce the HIV incidence rate by 46-67 %.

CONCLUSIONS: The impacts of the WHO 2013 guidelines and the treat-all strategy were relatively close; their implementation is desirable to reduce HIV spread. Combining several strategies is promising in adult populations of hyperendemic areas but requires regular, reliable, and costly monitoring.

12. Haacker, M., et al. Effectiveness of and financial returns to voluntary medical male circumcision for HIV prevention in South Africa: an incremental cost-effectiveness analysis. *PLoS Med* 2016;13(5):e1002012. Online at:

http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.10 02012

BACKGROUND: Empirical studies and population-level policy simulations show the importance of voluntary medical male circumcision (VMMC) in generalized epidemics. This paper complements available scenario-based studies (projecting costs and outcomes over some policy period, typically spanning decades) by adopting an incremental approach-analyzing the expected consequences of circumcising one male individual with specific characteristics in a specific year. This approach yields more precise estimates of VMMC's cost-effectiveness and identifies the outcomes of current investments in VMMC (e.g., within a fiscal budget period) rather than of investments spread over the entire policy period.

METHODS/FINDINGS: The model has three components. We adapted the ASSA2008 model, a demographic and epidemiological model of the HIV epidemic in South Africa, to analyze the impact of one VMMC on HIV incidence over time and across the population. A costing module tracked the costs of VMMC and the resulting financial savings owing to reduced HIV incidence over time. Then, we used several financial indicators to assess the cost-effectiveness of and financial return on investments in VMMC. One circumcision of a young man up to age 20 prevents on average over 0.2 HIV infections, but this effect declines steeply with age, e.g., to 0.08 by age 30. Net financial savings from one VMMC at age 20 are estimated at US\$617 at a discount rate of 5% and are lower for circumcisions both at younger ages (because the savings occur later and are discounted more) and at older ages (because male circumcision becomes less effective). Investments in male circumcision carry a financial rate of return of up to 14.5% (for circumcisions at age 20). The cost of a male circumcision is refinanced fastest, after 13 y, for circumcisions at ages 20 to 25. Principal limitations of the analysis arise from the long time (decades) over which the effects of VMMC unfold-the results are therefore sensitive to the discount rate

applied, and more generally to the future course of the epidemic and of HIV/AIDS-related policies pursued by the government.

CONCLUSIONS: VMMC in South Africa is highly effective in reducing both HIV incidence and the financial costs of the HIV response. The return on investment is highest if males are circumcised between ages 20 and 25, but this return on investment declines steeply with age.

 Howard-Payne, L., et al. Citizenship in a time of HIV: Understanding medical adult male circumcision in South Africa. J Health Psychol 2016 Jun 12. pii: 1359105316651709. [Epub ahead of print]

Medical adult male circumcision has been shown to offer men significant protection against HIV infection during peno-vaginal sex. This has resulted in calls for a national roll-out of medical adult male circumcision in South Africa, a rights-based constitutional democracy. This article explores the ways that the potential tensions between this call to circumcise as a practice of good health citizenship and the guaranteed right to bodily integrity are negotiated in interviews with 30 urban-based men in Johannesburg. The results suggest that despite its demonstrable biological efficacy, these tensions may paralyse decision- and policy-makers in grappling with the potential scaling up of medical adult male circumcision for HIV prevention in South Africa.

14. Jenness, S. M., et al. Effectiveness of combination packages for HIV-1 prevention in sub-Saharan Africa depends on partnership network structure: a mathematical modelling study. *Sex Transm Infect* 2016 Jun 9. pii: sextrans-2015-052476. [Epub ahead of print]

OBJECTIVES: Combination packages for HIV prevention can leverage the effectiveness of biomedical and behavioural elements to lower disease incidence with realistic targets for individual and population risk reduction. We investigated how sexual network structures can maximise the effectiveness of a package targeting sexually active adults in sub-Saharan Africa (SSA) with intervention components for medical male circumcision (MMC) and sexual partnership concurrency (having >1 ongoing partner).

METHODS: Network-based mathematical models of HIV type 1 (HIV-1) transmission dynamics among heterosexual couples were used to explore how changes to MMC alone and in combination with changes to concurrency impacted endemic HIV-1 prevalence and incidence. Starting from a base model parameterised from empirical data from West Africa, we simulated the prevalence of circumcision from 10% to 90% and concurrency was modelled at four discrete levels corresponding to values observed across SSA.

RESULTS: MMC and concurrency could contribute to the empirical variation in HIV-1 disease prevalence across SSA. Small reductions in concurrency resulted in large declines in HIV-1 prevalence. Scaling up circumcision in low-concurrency settings yields a greater relative benefit, but the absolute number of infections averted depends on both the circumcision coverage and baseline incidence. Epidemic extinction with this package will require substantial scale-up of MMC in low-concurrency settings.

CONCLUSIONS: Dynamic sexual network structure should be considered in the design and targeting of MMC within combination HIV-1 prevention packages. Realistic levels of coverage for these packages within southern Africa could lead to a reduction of incidence to the low levels observed in western Africa, and possibly, epidemic extinction.

 Johnson, L. F., et al. Prospects for HIV control in South Africa: a modelbased analysis. *Glob Health Action* 2016;9:30314.
Online at: http://www.globalhealthaction.net/index.php/gha/article/view/30314

BACKGROUND: The goal of virtual elimination of horizontal and mother-tochild HIV transmission in South Africa (SA) has been proposed, but there have been few systematic investigations of which interventions are likely to be most critical to reducing HIV incidence.

OBJECTIVE: This study aims to evaluate SA's potential to achieve virtual elimination targets and to identify which interventions will be most critical to achieving HIV incidence reductions.

DESIGN: A mathematical model was developed to simulate the populationlevel impact of different HIV interventions in SA. Probability distributions were specified to represent uncertainty around 32 epidemiological parameters that could be influenced by interventions, and correlation coefficients (r) were calculated to assess the sensitivity of the adult HIV incidence rates and mother-to-child transmission rates (2015-2035) to each epidemiological parameter.

RESULTS: HIV incidence in SA adults (ages 15-49) is expected to decline from 1.4% in 2011-2012 to 0.29% by 2035 (95% CI: 0.10-0.62%). The parameters most strongly correlated with future adult HIV incidence are the rate of viral suppression after initiating antiretroviral treatment (ART) (r=-0.56), the level of condom use in non-marital relationships (r=-0.40), the phase-in of intensified risk-reduction counselling for HIV-positive adults (r=0.29), the uptake of medical male circumcision (r=-0.24) and the phasein of universal ART eligibility (r=0.22). The paediatric HIV parameters most strongly associated with mother-to-child transmission rates are the relative risk of transmission through breastfeeding when the mother is receiving ART (r=0.70) and the rate of ART initiation during pregnancy (r=-0.16).

CONCLUSIONS: The virtual elimination target of a 0.1% incidence rate in adults will be difficult to achieve. Interventions that address the infectiousness of patients after ART initiation will be particularly critical to achieving long-term HIV incidence declines in South Africa.

 Kagaayi, J., et al. Self-selection of male circumcision clients and behaviors following circumcision in a service program in Rakai, Uganda. *AIDS* 2016 May 19. [Epub ahead of print]

OBJECTIVES: Sub-Saharan African countries have substantially scaled-up safe male circumcision (SMC) services. However, it is unclear whether services are reaching men most at risk of HIV and whether there is behavioral disinhibition after SMC. We compared characteristics of SMC acceptors and non-acceptors in Rakai, Uganda.

DESIGN: Cohort design. METHODS: Through the Rakai Community Cohort Study, baseline characteristics of 587 non-Muslim men who subsequently

accepted SMC were compared to those of 4,907 uncircumcised non-Muslim men. Behaviors after SMC were compared with those of men who remained uncircumcised. Poisson multivariable regression was used to estimate adjusted prevalence rate ratios (aPRR) of behaviors in circumcised versus uncircumcised men.

RESULTS: At baseline (pre-SMC), men subsequently circumcised were younger (mean = 26.1 years), compared to the uncircumcised (mean = 28.5 years, p < 0.001), more likely to live in urban areas (21.1% versus 12.4%, p < 0.001), less likely to have been currently or previously married (36.5 % versus 45.8%, p < 0.001) and more likely to report multiple sexual partners (48.3% versus 41.6%, p = 0.05) and genital discharge (7.4% versus 4.4%, p = 0.03). At follow up (post-SMC), behaviors and genital discharge did not differ between the groups. Genital ulcers were less reported among circumcised (6.8%) compared to uncircumcised men (10.5%) (aPRR = 0.60, 95% CI = 0.42-0.87, p = 0.007).

CONCLUSION: In Rakai district, Uganda, the circumcision service program is attracting sexually active men at higher risk of HIV and we find no evidence of behavioral disinhibition following circumcision. The SMC program in this setting has the potential to reduce the HIV epidemic among men.

17. Kohler, P. K., et al. **Safety, feasibility, and acceptability of the PrePex device for adult male circumcision in Malawi**. *J Acquir Immune Defic Syndr* 2016;72(Suppl 1):S49-55.

Online at:

http://journals.lww.com/jaids/Fulltext/2016/06011/Safety, Feasibility, an d Acceptability of the.9.aspx

INTRODUCTION: Nonsurgical adult male circumcision devices present an alternative to surgery where health resources are limited. This study aimed to assess the safety, feasibility, and acceptability of the PrePex device for adult male circumcision in Malawi.

METHODS: A prospective single-arm cohort study was conducted at 3 sites (1 urban static, 1 rural static, 1 rural tent) in Malawi. Adverse event (AE)

outcomes were stratified to include/exclude pain, and confidence intervals (CIs) were corrected for clinic-level clustering.

RESULTS: Among 935 men screened, 131 (14.0%) were not eligible, 13 (1.4%) withdrew before placement, and 791 (84.6%) received the device. Moderate and severe AEs totaled 7.1% including pain [95% CI: 3.4-14.7] and 4.0% excluding pain (95% CI: 2.6 to 6.4). Severe AEs included pain (n = 3), insufficient skin removal (n = 4), and early removal (n = 4). Among early removals, 1 had immediate surgical circumcision, 1 had surgery after 48 hours of observation, 1 declined surgery, and 1 did not return to our site although presented at a nearby clinic. More than half of men (51.9%) reported odor; however, few (2.2%) stated they would not recommend the device to others because of odor. Median levels of reported pain (scale, 1-10) were 2 (interquartile range, 2-4) during application and removal, and 0 (interquartile range, 0-2) at all other time points.

CONCLUSIONS: Severe AEs were rare and similar to other programs. Immediate provision of surgical services after displacement or early removal proved a challenge. Cases of insufficient skin removal were linked to poor technique, suggesting provider training requires reinforcement and supervision.

 Kufa, T., et al. Delivering PrePex medical male circumcision services through a mobile clinic: the experience from a pilot project in North West Province, South Africa. J Acquir Immune Defic Syndr 2016;72(Suppl 1):S69-72.

Online at:

http://journals.lww.com/jaids/Fulltext/2016/06011/Delivering_PrePex_Me dical_Male_Circumcision.12.aspx

We describe the implementation of a pilot project to demonstrate the safety and feasibility of providing PrePex circumcision from a mobile clinic. We analyzed available project diary entries and staff meeting minutes to identify challenges encountered. The main challenges identified were (1) daily time constraints because of setting up procedures, (2) transportation logistics for clients when the mobile clinic had moved to a different location, (3) integration and coordination of staff responsibilities, and (4)

recruitment for PrePex services in the mobile clinic. The provision of PrePex device circumcision through a mobile clinic was feasible but careful planning and review of operational procedures were needed to resolve the implementation challenges.

 Mavhu, W., et al. Safety and acceptability of the PrePex device when used in routine male circumcision service delivery during active surveillance in Zimbabwe. J Acquir Immune Defic Syndr 2016;72(Suppl 1):S63-8.
Online at: http://journals.lww.com/jaids/Fulltext/2016/06011/Safety_and_Acceptabil ity_of_the_PrePex_Device_When.11.aspx

BACKGROUND: Male circumcision devices have the potential to accelerate voluntary medical male circumcision roll-out, with PrePex being one promising device. Here, we present findings on safety and acceptability from active surveillance of the implementation of PrePex among 1000 males circumcised in Zimbabwe.

METHODS: The first 1000 men consecutively circumcised using PrePex during routine service delivery were actively followed up. Outcome measures included PrePex uptake, attendance for postcircumcision visits, and adverse events (AEs). A survey was conducted among 500 consecutive active surveillance clients to assess acceptability and satisfaction with PrePex.

RESULTS: A total of 2156 men aged 18 years or older were circumcised across the 6 PrePex active surveillance sites. Of these, 1000 (46.4%) were circumcised using PrePex. Among them, 4 (0.4%) self-removals that required surgery (severe AEs) were observed. Six (0.6%) removals by providers (moderate AEs) did not require surgery. A further 280 (28%) AEs were mild or moderate pain during device removal. There were also 12 (1.2%) moderate AEs unrelated to pain. All AEs resolved without sequelae. There was high adherence to follow-up appointments, with 97.7% of clients attending the scheduled day 7 visit. Acceptability of PrePex was high among survey participants, 93% indicated willingness to recommend the device to peers. Of note, 95.8% of respondents reported experiencing pain when the

device was being removed. Additionally, 85.2% reported experiencing odor while wearing the device or during removal.

CONCLUSIONS: Active surveillance of the first 1000 men circumcised using PrePex suggests that the device is both safe and acceptable when used in routine service delivery.

20. Milovanovic, M., et al. Perceptions of the PrePex device among men who received or refused PrePex circumcision and people accompanying them. J Acquir Immune Defic Syndr 2016;72(Suppl 1):S78-82. Online at: http://journals.lww.com/jaids/Fulltext/2016/06011/Perceptions_of_the_Pr

ePex_Device_Among_Men_Who.14.aspx

BACKGROUND: The PrePex medical male circumcision (MMC) device has been approved for MMC scale-up. However, the WHO has recommended that a country-specific situation analysis should be carried out before MMC device rollout.

METHOD: A cross-sectional survey was conducted over 12 months in 3 MMC clinics, by trained nurses and researchers, to ascertain attitudes toward PrePex MMC in 3 groups: men consenting for PrePex MMC (PrePex recipients), people accompanying men, and adolescents coming for either PrePex or surgical circumcision (MMC escorts) and men refusing the PrePex device MMC (PrePex rejecters). All participants received information on surgical and the PrePex device MMC methods.

RESULTS: A total of 312 PrePex recipients, 117 MMC escorts, and 21 PrePex rejecters were recruited into the study. Ninety-nine percent of PrePex recipients thought that their expectations (safe, convenient, minimal pain) were met, and they were pleased with cosmetic outcome. Fifty-nine percent of PrePex rejecters opted for surgical circumcision because they perceived PrePex to be novel and risky. All 3 groups of participants were concerned about odor, dead skin, discomfort, healing time, and wound care. Ninety-eight percent of MMC escorts, 99% of PrePex recipient, and 81% of PrePex rejecters perceived PrePex circumcision as an acceptable option for South African MMC programmes.

CONCLUSIONS: This acceptability study suggests that PrePex MMC is considered safe and convenient and could be incorporated into existing MMC programmes. Concerns about odor, pain, wound care, and healing time suggest that the need for more research to further optimize methods and that MMC clients should be counseled on available methods to enable them to choose among options based on their preferences.

21. Morris, B. J., et al. Circumcision is a primary preventive against HIV infection: critique of a contrary meta-regression analysis by Van Howe. *Glob Public Health* 2016 April 4: 1-11. [Epub ahead of print]

A meta-analysis by Van Howe of 109 populations confirms the well-known association of male circumcision (MC) with reduced HIV prevalence. He then performed meta-regression adjusting for location, risk and MC prevalence. When one or two of these adjustments in combination were applied MC appeared protective, but when all three were introduced the association remained significant in high-risk populations, but not in general populations within Africa with a hypothetical MC prevalence of <25% or elsewhere with hypothetical MC prevalence of <75%. However, many MC prevalence values given differed from those reported in references cited (including all US studies). This and other problems invalidate his adjustments for MC prevalence, undermining most of his meta-regression results. Meta-regression is a highly sophisticated statistical tool and is prone to error if not applied correctly. The study contained a high risk of bias arising from confounding. We also question his use of crude, rather than adjusted, odds ratios and his inclusion of unpublished data, so precluding replication by others. Flawed statistics, opaque presentation of results and inclusion of previously repudiated arguments downplaying a role for MC in HIV prevention programmes should lead readers to be sceptical of the findings and conclusions of Van Howe's study.

22. Mukudu, H., et al. A cross sectional study of the prevalence of preputial and penile scrotal abnormalities among clients undergoing voluntary medical male circumcision in Soweto, South Africa. *PLoS One* 2016;11(6):e0156265.

Online at: <u>http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0156265</u>

OBJECTIVE: Medical device use is currently approved for males without preputial or major penile scrotal abnormalities for voluntary medical male circumcision (VMMC). We determined the prevalence of preputial abnormalities at a busy VMMC centre in Soweto, South Africa.

METHODS: This was a cross-sectional record review at a high-volume VMMC centre in South Africa. We collated pre-circumcision demographic and genital examination findings from clients 8 years and older who had undergone VMMC from 01 May 2013 to 30 April 2014. Logistic regression was used to determine factors associated with preputial abnormalities.

FINDINGS: During the review period, 6861 circumcisions were conducted and 37.1% (n = 2543) were 8-13 year olds. Median age was 15 years (IQR: 12-23 years). Fifteen percent (n = 1030) had preputial abnormalities or major penile scrotal abnormalities. Age-specific prevalence of preputial or major genital abnormalities were 27.3%, 10.6% and 6.0% in 8-13, 14-18 and > 18 year olds respectively. The odds of preputial or major penile scrotal abnormality were higher in younger clients aged 8-13 years (OR = 5.9; 95% CI = 4.8-7.1) and 14-18 years (OR = 1.9; 95% CI = 1.5-2.4) compared to older clients above18 years and in those testing for HIV outside our clinic network (OR = 1.9; 95% CI = 1.4-2.7).

CONCLUSION: The high prevalence of preputial and penile scrotal abnormalities observed suggests a need for VMMC sites to provide for both open surgical and devices methods in the provision of VMMC services. This is especially so among young male subjects presenting themselves for VMMC services at the various sites being developed in sub Saharan African countries.

23. Musiige, A. M., et al. Participant experiences and views of odor and PrePex device removal pain in a VMMC pilot study in Botswana. *J Acquir Immune Defic Syndr* 2016;72 (Suppl 1):S73-7. Online at:

http://journals.lww.com/jaids/Fulltext/2016/06011/Participant Experience s_and_Views_of_Odor_and.13.aspx

OBJECTIVE: To assess participant experiences and perceptions of removal pain and odor associated with the PrePex device procedure.

METHODS: We analyzed data from a PrePex device pilot implementation study of 802 male participants aged 18-49 years at 2 clinics in Botswana, 2013. Study staff administered survey questions on device-related odor and assessed pain using visual analog scale scores categorized as no pain (0), mild (1-4), moderate (5-7), or severe pain (8-10).

RESULTS: Mean participant age was 27.7 (range = 18-48) years. Of the 802 participants, 751 (94%) reported to have noticed an unusual or unpleasant odor while wearing the device. Of these, 193 (26%) participants tried something to combat the odor. A total of 84 (10%) participants reported no pain, 655 (82%) mild pain, 48 (6%) moderate pain, and 15 (2%) severe pain at 2 minutes after device removal. Pain reports at 15 minutes after removal were 553 (69%) no pain, 247 (31%) mild pain, and 2 (0.25%) moderate pain, with no report of severe pain at this time point. Of 740 participants interviewed on day 42 after device placement, 678 (92%) were satisfied with the procedure and 681 (92%) would recommend it to another man considering circumcision, including 488 (66%) who would recommend it strongly.

CONCLUSIONS: An unusual or unpleasant odor while wearing the PrePex device and mild self-limiting pain at device removal were common, but overall, these did neither seem to impair satisfaction nor deter participants from recommending PrePex to others, which could suggest good prospects for uptake of the device in this setting.

24. Qian, H. Z., et al. Lower HIV risk among circumcised men who have sex with men in China: interaction with anal sex role in a cross-sectional study. *J Acquir Immune Defic Syndr* 2016;71(4):444-51.

BACKGROUND: Voluntary medical male circumcision reduces the risk of HIV heterosexual transmission in men, but its effect on male-to-male sexual transmission is uncertain.

METHODS: Circumcision status of men who have sex with men (MSM) in China was evaluated by genital examination and self-report; anal sexual role was assessed by questionnaire interview. Serostatus for HIV and syphilis was confirmed.

RESULTS: Among 1155 participants (242 were seropositive and 913 with unknown HIV status at enrollment), the circumcision rate by self-report (10.4%) was higher than confirmed by genital examination (8.2%). Male circumcision (by examination) was associated with 47% lower odds of being HIV seropositive [adjusted odds ratio (aOR): 0.53; 95% confidence interval (CI): 0.27 to 1.02] after adjusting for demographic covariates, number of lifetime male sexual partners, and anal sex role. Among MSM who predominantly practiced insertive anal sex, circumcised men had 62% lower odds of HIV infection than those who were uncircumcised (aOR: 0.38; 95% CI: 0.09 to 1.64). Among those whose anal sex position was predominantly receptive or versatile, circumcised men have 46% lower odds of HIV infection than did men who were not circumcised (aOR: 0.54; 95% CI: 0.25 to 1.14). Compared to uncircumcised men reporting versatile or predominantly receptive anal sex positioning, those who were circumcised and reported practicing insertive sex had an 85% lower risk (aOR: 0.15; 95% CI: 0.04 to 0.65). Circumcision was not associated clearly with lower syphilis risk (aOR: 0.91; 95% CI: 0.51 to 1.61).

CONCLUSIONS: Circumcised MSM were less likely to have acquired HIV, most pronounced among men predominantly practicing insertive anal intercourse. A clinical trial is needed.

25. Ridzon, R., et al. VMMC devices-introducing a new innovation to a public health intervention. J Acquir Immune Defic Syndr 2016;72(Suppl 1):S1-4. Online at: http://journals.lww.com/jaids/Fulltext/2016/06011/VMMC_Devices_Introd ucing a New Innovation to a.1.aspx 26. Samuelson, J., et al. Innovative methods of male circumcision for HIV prevention-getting the right evidence. J Acquir Immune Defic Syndr 2016; 72(Suppl 1):S5-s12. Online at: http://journals.lww.com/jaids/Fulltext/2016/06011/Innovative_Methods_of_Male_Circumcision_for_HIV.2.aspx

World Health Organization recommends that countries with hyperendemic and generalized HIV epidemics implement voluntary medical male circumcision programs for HIV prevention. Innovative methods of male circumcision including devices have the potential to simplify the procedure, reduce time and cost, increase client acceptability, enhance safety, and expand the numbers of providers who may perform circumcision. We describe work led by World Health Organization and supported by global partners to define a pathway for the evaluation of efficacy and safety of male circumcision devices, to set priority criteria, and to establish a process to guide the use of devices in publicly funded voluntary medical male circumcision programs for HIV prevention. A device classification scheme, an expert Technical Advisory Group on Innovations in Male Circumcision, and a formal pregualification program have also guided considerations on safe use of devices. A rigorous approach was deemed appropriate given the intervention is for use among healthy men for public health purposes. The pathway and processes led to coordinated research, better standardization in research outcomes, and guidance that informed the research, introduction and implementation phases. The lessons learnt from this case study can inform evaluation and use of future public health innovations.

27. Schutte, C., et al. Comparative cost analysis of surgical and PrePex device male circumcision in Zimbabwe and Mozambique. *J Acquir Immune Defic Syndr* 2016;72(Suppl 1):S96-s100.

Online at:

http://journals.lww.com/jaids/Fulltext/2016/06011/Comparative_Cost_An alysis_of_Surgical_and_PrePex.17.aspx

BACKGROUND: The PrePex device has proven to be safe for voluntary medical male circumcision (VMMC) in adults in several African countries.

Costing studies were conducted as part of a PrePex/Surgery comparison study in Zimbabwe and a pilot implementation study in Mozambique.

METHODS: The studies calculated per male circumcision unit costs using a cost-analysis approach. Both direct costs (consumable and nonconsumable supplies, device, personnel, associated staff training) and selected indirect costs (capital and support personnel costs) were calculated.

RESULTS: The cost comparison in Zimbabwe showed a unit cost per VMMC of \$45.50 for PrePex and \$53.08 for surgery. The unit cost difference was based on higher personnel and consumable supplies costs for the surgical procedure, which used disposable instrument kits. In Mozambique, the costing analysis estimated a higher unit cost for PrePex circumcision (\$40.66) than for surgery (\$20.85) because of higher consumable costs, particularly the PrePex device and lower consumable supplies costs for the surgical procedure using reusable instruments. Supplies and direct staff costs contributed 87.2% for PrePex and 65.8% for surgical unit costs in Mozambique.

DISCUSSION: PrePex device male circumcision could potentially be cheaper than surgery in Zimbabwe, especially in settings that lack the infrastructure and personnel required for surgical VMMC, and this might result in programmatic cost savings. In Mozambique, the surgical procedure seems to be less costly compared with PrePex mainly because of higher consumable supplies costs. With reduced device unit costs, PrePex VMMC could become more cost-efficient and considered as complementary for Mozambique's VMMC scale-up program.

28. Thornton, R., et al. Medical male circumcision: How does price affect the risk-profile of take-up? *Prev Med* 2016 Jun 7. pii: S0091-7435(16)30128-1. [Epub ahead of print]

OBJECTIVE: The benefit of male circumcision is greatest among men who are most at risk of HIV infection. Encouraging this population of men to get circumcised maximizes the benefit that can be achieved through the scaleup of circumcision programs. This paper examines how the price of circumcision affects the risk profile of men who receive a voluntary medical circumcision.

METHODS: In 2010, 1649 uncircumcised adult men in urban Malawi were interviewed and provided a voucher for a subsidized voluntary medical male circumcision, at randomly assigned prices. Clinical data were collected indicating whether the men in the study received a circumcision.

RESULTS: Men who took-up circumcision with a zero-priced voucher were 25 percentage points less likely than those who took-up with a positive-price voucher, to be from a tribe that traditionally circumcises (p=0.101). Zero-priced vouchers also brought in men with more sexual partners in the past year (p=0.075) and past month (p=0.003). None of the men who were most at risk of HIV at baseline (those with multiple partners and who did not use a condom the last time they had sex) received a circumcision if they were offered a positive-priced voucher. Lowering the price to zero increased circumcision take-up to 25% for men of this risk group. The effect of price on take-up was largest among those at highest risk (p=0.096).

CONCLUSIONS: Reducing the price of circumcision surgery to zero can increase take-up among those who are most at risk of HIV infection.

29. Tobian, A. A., et al. An evidence-based analysis of voluntary medical male circumcision devices. *Nat Rev Urol* 2016;13(5):295.

Throughout East and Southern Africa, the WHO recommends voluntary medical male circumcision (VMMC) to reduce heterosexual HIV acquisition. Evidence has informed policy and the implementation of VMMC programmes in these countries. VMMC has been incorporated into the HIV prevention portfolio and more than 9 million VMMCs have been performed. Conventional surgical procedures consist of forceps-guided, dorsal slit or sleeve resection techniques. Devices are also becoming available that might help to accelerate the scale-up of adult VMMC. The ideal device should make VMMC easier, safer, faster, sutureless, inexpensive, less painful, require less infrastructure, be more acceptable to patients and should not require follow-up visits. Elastic collar compression devices cause vascular obstruction and necrosis of foreskin tissue and do not require sutures or injectable anaesthesia. Collar clamp devices compress the proximal part of the foreskin to reach haemostasis; the distal foreskin is removed, but the device remains and therefore no sutures are required. Newer techniques and designs, such as tissue adhesives and a circular cutter with stapled anastomosis, are improvements, but none of these methods have achieved all desirable characteristics. Further research, design and development are needed to address this gap to enable the expansion of the already successful VMMC programmes for HIV prevention.

 30. Tshimanga, M., et al. Safety profile of PrePex male circumcision device and client satisfaction with adolescent males aged 13-17 years in Zimbabwe. J Acquir Immune Defic Syndr 2016;72(Suppl 1):S36-42.
Online at: http://journals.lww.com/jaids/Fulltext/2016/06011/Safety_Profile_of_PreP ex Male Circumcision Device.7.aspx

BACKGROUND: The safety and efficacy of the PrePex device for voluntary medical male circumcision (VMMC) has been demonstrated in studies in Rwanda, Uganda, and Zimbabwe, leading to the conditional prequalification of the device for use in adults. Because the majority of VMMC clients in the 14 priority countries are adolescents under 18 years, research to establish the safety and efficacy of the device for males <18 years is required.

METHODS: One-arm, prospective study included 402 adolescents, aged 13-17 years, using PrePex device between August 2013 and January 2014 at a VMMC centre in Harare. Endpoints are number and grade of adverse events associated with device circumcision, time to complete wound healing, client satisfaction with the procedure, and outcome.

RESULTS: The rate of medical ineligibility among adolescent males was high; 237/402 (35.9%) of study participants had to be excluded based on medical reasons. The severe/moderate adverse event rate was low at 2/402 (0.5%). No device displacements/self-removals were observed. Time to complete wound healing was shorter than in adults; 367/398 (92.2%) adolescents had completed wound healing by day 35, whereas 90% of adults had completed wound healing by day 56 as demonstrated in

previous studies. Overall, adolescents were highly satisfied with the results of their circumcision.

CONCLUSIONS: The study demonstrates that the PrePex device can be safely used in adolescents aged 13-17 years. The significant proportion of males opting for surgical circumcision and the high medical ineligibility suggest that surgical circumcision needs to be provided alongside PrePex services in programs targeting young age groups.

31. Tshimanga, M., et al. A Phase II randomized controlled trial comparing safety, procedure time, and cost of the PrePex device to forceps guided surgical circumcision in Zimbabwe. *PLoS One* 2016;11(5):e0156220. Online at:

http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0156220

BACKGROUND: The World Health Organization (WHO) and the Joint United Nations Program on HIV/AIDS promote MC (male circumcision) as a key HIV prevention strategy where HIV prevalence and incidence are high and MC prevalence is low. In Zimbabwe, to achieve the 1.26 million circumcisions needed to be performed by 2015 to achieve optimal MC coverage, a new approach was needed. The primary objective of the current trial was to assess the performance (safety, procedure time, and cost) of the PrePex device compared to forceps-guided surgical circumcision.

METHODS AND FINDINGS: This Phase II, randomized, open-label trial in Zimbabwe involved healthy, non-circumcised adult male volunteers who were randomly assigned to the PrePex device (n = 160) or surgical arm (n = 80). Three doctors and 4 nurses, all certified on both circumcision methods, performed the procedures. The PrePex device procedure involves a plastic ring with a rubber O-ring that necrotizes the foreskin to facilitate easy and minimally invasive removal. Total procedure time was the primary endpoint. Adverse event (AE) data were also gathered for 90 days postprocedure. All 80 participants in the surgical arm and 158 participants in the PrePex arm achieved complete circumcision. The total procedure time for the PrePex device was approximately one-third of the total surgical procedure (4.8 minutes, Standard Deviation [SD]: 1.2 versus 14.6 minutes; SD: 4.2; p<0.00001). There were 2 AEs for 2 participants (rate of 1.3%, 95% Confidence Interval: 0.0025-4.53%), which were resolved with simple intervention. The AEs were device related, including 1 case of pain leading to device removal and 1 case of removal of the device.

CONCLUSIONS: The trial supports previous studies' conclusions that the PrePex procedure is safe, quick, easy to apply, and effective in terms of procedure time as an alternative to traditional surgical circumcision. The PrePex device has great potential for use in overburdened health systems and in resource-limited settings and is recommended for use in rapid scale-up of adult MC in Zimbabwe.

TRIAL REGISTRATION: ClinicalTrials.gov NCT01956370.

32. Vandament, L., et al. Evaluating opportunities for achieving cost efficiencies through the introduction of PrePex device male circumcision in adult VMMC programs in Zambia and Zimbabwe. J Acquir Immune Defic Syndr 2016;72(Suppl 1):S90-5. Online at: http://journals.lww.com/jaids/Fulltext/2016/06011/Evaluating_Opportuniti es_for_Achieving_Cost.16.aspx

BACKGROUND: Results from recent costing studies have put into question potential Voluntary Medical Male Circumcision (VMMC) cost savings with the introduction of the PrePex device.

METHODS: We evaluated the cost drivers and the overall unit cost of VMMC for a variety of service delivery models providing either surgical VMMC or both PrePex and surgery using current program data in Zimbabwe and Zambia. In Zimbabwe, 3 hypothetical PrePex only models were also included. For all models, clients aged 18 years and older were assumed to be medically eligible for PrePex and uptake was based on current program data from sites providing both methods. Direct costs included costs for consumables, including surgical VMMC kits for the forceps-guided method, device (US \$12), human resources, demand creation, supply chain, waste management, training, and transport.

RESULTS: Results for both countries suggest limited potential for PrePex to generate cost savings when adding the device to current surgical service delivery models. However, results for the hypothetical rural Integrated PrePex model in Zimbabwe suggest the potential for material unit cost savings (US \$35 per VMMC vs. US \$65-69 for existing surgical models).

CONCLUSIONS: This analysis illustrates that models designed to leverage PrePex's advantages, namely the potential for integrating services in rural clinics and less stringent infrastructure requirements, may present opportunities for improved cost efficiency and service integration. Countries seeking to scale up VMMC in rural settings might consider integrating PrePex only MC services at the primary health care level to reduce costs while also increasing VMMC access and coverage.

33. Wang, Z., et al. Prevalence and associated factors of behavioral intention for risk compensation following voluntary medical male circumcision among male sexually transmitted diseases patients in China. *AIDS Care* 2016: 1-6. [Epub ahead of print]

Risk compensation was an important concern of voluntary medical male circumcision (VMMC) promotion campaigns. No study investigated risk compensation following VMMC among male sexually transmitted diseases patients (MSTDP). A cross-sectional survey interviewed 308 uncircumcised MSTDP in Shenzhen, China. 26.9% of them intended to perform at least one of the five types of risk compensation behaviors following VMMC. In the summary stepwise model, provision of incorrect response to HIV/sexually transmitted diseases knowledge items (multivariate odds ratios (ORm) = 2.30), genital herpes infection (ORm = 3.19), Risk Reduction Score for Unprotected Sex, and Negative Condom Attitudes Scale (ORm = 1.13) were significantly associated with behavioral intention to perform at least one type of risk compensation behavior following VMMC. The results provided a framework for developing related interventions. Prevention of risk compensation should be an essential component of VMMC promotion for all MSTDP, irrespective of their intention for VMMC.

34. Ware, N. C., et al. How home HIV testing and counselling with follow-up support achieves high testing coverage and linkage to treatment and

prevention: a qualitative analysis from Uganda. *J Int AIDS Soc* 2016 19(1): 20929.

Online at: http://www.jiasociety.org/index.php/jias/article/view/20929

INTRODUCTION: The successes of HIV treatment scale-up and the availability of new prevention tools have raised hopes that the epidemic can finally be controlled and ended. Reduction in HIV incidence and control of the epidemic requires high testing rates at population levels, followed by linkage to treatment or prevention. As effective linkage strategies are identified, it becomes important to understand how these strategies work. We use qualitative data from The Linkages Study, a recent community intervention trial of community-based testing with linkage interventions in sub-Saharan Africa, to show how lay counsellor home HIV testing and counselling (home HTC) with follow-up support leads to linkage to clinic-based HIV treatment and medical male circumcision services.

METHODS: We conducted 99 semi-structured individual interviews with study participants and three focus groups with 16 lay counsellors in Kabwohe, Sheema District, Uganda. The participant sample included both HIV+ men and women (N=47) and HIV-uncircumcised men (N=52). Interview and focus group audio-recordings were translated and transcribed. Each transcript was summarized. The summaries were analyzed inductively to identify emergent themes. Thematic concepts were grouped to develop general constructs and framing propositional statements.

RESULTS: Trial participants expressed interest in linking to clinic-based services at testing, but faced obstacles that eroded their initial enthusiasm. Follow-up support by lay counsellors intervened to restore interest and inspire action. Together, home HTC and follow-up support improved morale, created a desire to reciprocate, and provided reassurance that services were trustworthy. In different ways, these functions built links to the health service system. They worked to strengthen individuals' general sense of capability, while making the idea of accessing services more manageable and familiar, thus reducing linkage barriers.

CONCLUSIONS: Home HTC with follow-up support leads to linkage by building "social bridges," interpersonal connections established and developed through repeated face-to-face contact between counsellors and prospective users of HIV treatment and male circumcision services. Social bridges link communities to the service system, inspiring individuals to overcome obstacles and access care.

35. Zamawe, C. O., et al. What are the social and individual factors that are associated with undergoing male circumcision as an HIV prevention strategy? A mixed methods study in Malawi. *Int Health* 2016;8(3):170-8.

BACKGROUND: There is compelling evidence that medical male circumcision (MMC) decreases transmission of HIV. Nevertheless, the uptake of MMC is generally very low. Understanding the characteristics of individuals who choose MMC could inform future strategies for scaling-up MMC. The main objective of this study was to explore the social and individual characteristics of men that are associated with the uptake of circumcision as an HIV prevention strategy.

METHODS: A mixed-methods study, comprising a cross-sectional survey and an exploratory qualitative study, was conducted in Malawi. A total number of 1644 men, of at least 18 years old, participated in this study. A multistage sampling approach was used in the survey while convenience sampling was adopted in the qualitative study. Descriptive statistics, bivariate analyses and multivariable logistic regression were performed to analyze the cross-sectional data and thematic content approach to analyze the qualitative data.

RESULTS: Individuals who chose MMC were more likely to be unemployed (AOR=1.65; 95% CI: 1.30-2.11), to be married (AOR=3.16; 95% CI: 2.21-4.52) and to have had exposure to MMC promotions (AOR=1.81; 95% CI: 1.41-2.33). They were also more likely to reside in rural areas (AOR=1.85; 95% CI: 1.44-2.38), to perceive themselves as more vulnerable to HIV (AOR=1.60; 95% CI: 1.19-2.15) and to be more knowledgeable about the benefits of MMC (AOR=1.51; 95% CI: 1.16-1.97).

CONCLUSIONS: The findings suggest that men who had certain social and individual characteristics (for example better knowledge of the benefits of MMC, greater perceived vulnerability to HIV, married and unemployed) were more likely to choose circumcision as a prevention strategy for HIV than those who lacked those characteristics. Strategies for increasing MMC take-up should recognize the current social/individual landscape of MMC uptake and ensure that deliberate efforts targeting marginalized categories of men are available.

36. Zungu, N. P., et al. HIV risk perception and behavior among medically and traditionally circumcised males in South Africa. BMC Public Health 2016;16(1):357.
Online at:

http://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-016-3024-y

BACKGROUND: In South Africa, voluntary medical male circumcision (VMMC) has recently been implemented as a strategy for reducing the risk of heterosexual HIV acquisition among men. However, there is some concern that VMMC may lead to low risk perception and more risky sexual behavior. This study investigated HIV risk perception and risk behaviors among men who have undergone either VMMC or traditional male circumcision (TMC) compared to those that had not been circumcised.

METHODS: Data collected from the 2012 South African national population-based household survey for males aged 15 years and older were analyzed using bivariate and multivariate multinomial logistic regression, and relative risk ratios (RRRs) with 95 % confidence interval (CI) were used to assess factors associated with each type of circumcision relative no circumcision.

RESULTS: Of the 11,086 males that indicated that they were circumcised or not, 19.5 % (95 % CI: 17.9-21.4) were medically circumcised, 27.2 % (95 % CI: 24.7-29.8) were traditionally circumcised and 53.3 % (95 % CI: 50.9-55.6) were not circumcised. In the final multivariate models, relative to uncircumcised males, males who reported VMMC were significantly more likely to have had more than two sexual partners (RRR = 1.67, p = 0.009),

and males who reported TMC were significantly less likely to be low risk alcohol users (RRR = 0.72, p < 0.001).

CONCLUSION: There is a need to strengthen and improve the quality of the counselling component of VMMC with the focus on education about the real and present risk for HIV infection associated with multiple sexual partners and alcohol abuse following circumcision.