

Poster presentation

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## **P14-07. Offering new prevention modalities in HIV vaccine trials: experience with male circumcision in the Phambili trial**

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### **Background**

New prevention options will be added to the 'standard of prevention' offered in HIV vaccine efficacy trials as new methods prove effective. The HVTN503/Phambili trial was initiated in January 2007, shortly after results from 3 randomized controlled trials of male circumcision (MC) demonstrated that MC reduces the risk of HIV acquisition. Thus, HVTN503 investigators made plans to offer MC at no cost to enrolled male participants.

### **Methods**

All participants were informed of the benefits of MC as a component of HIV risk reduction counseling, including how and where MC could be accessed. One site offered on-site MC and the others provided referral to local services for men who requested MC. We present data on uptake of MC post-enrollment.

### **Results**

Prior to discontinuation of enrolment, 441 men joined the trial, of whom 312 (70.7%) were uncircumcised. Of these, 82 (26.3% of uncircumcised men) requested MC after enrolment. Uptake varied by site, being lower (<15%) at the Medunsa and KOSH sites, intermediate at Soweto and Cape Town sites, and high (>70%) at the eThekweni site, the site with lowest baseline MC prevalence. Among 3 sites with intermediate baseline MC prevalence,

uptake varied from 3.3 to 37.6%, being highest at the site providing MC on site. Uptake was similar in vaccine and placebo arms of the trial [42 (26.1%) vs. 40 (26.5%)]. There was no significant difference by arm in the timing of circumcision relative to randomization assignment being provided to participants following release of the STEP trial results [post-unblinding, vaccine 18 (42.9%) vs. placebo 13 (32.5%),  $p = 0.37$ ].

### **Conclusion**

MC, a new prevention modality, was offered as part of HIV prevention services in HVTN503. Uptake varied by provision of care model and inversely with baseline MC prevalence, but did not differ between treatment arms, and remained similar even after provision of treatment.