SAFETY NAMIBIA

- Pilot ongoing: 531 chose SR and screened for eligibility in six months
  - 512 successful ring placements
  - 10 clinical ineligible (short frenulum)
  - 9 unavailability of size A and B
- Removals: 500, 498 on time (day 6-8)
  - 2 early removals (day 3, 5)
  - 2 lost to follow up (1 self-removed would not return, and confirmed good healing by phone, 1 unreachable)
  - 10 in situ pending removal
- Most common placement time recorded 6-10 minutes
- Device removal time – 6 minutes
- 8 HIV positive (1 new & 7 known) – no AEs, all healed similarly to HIV negative participants
- Adverse events: 15 (3.0%) no age difference; all healed at day 49
  - 10 mild (2.0%)
    - 5 infection
    - 2 swelling
    - 2 scarring
    - 1 wound disruption
  - 5 moderate (1.0%)
    - 4 small laceration on frenulum discovered on removal
    - 1 day 3 self-removal
- Cause of lacerations unknown, suspect occurred during erections
- Day 3 self-removal after pain from erections; client withdrew from study but is confirmed completely healed
- Must educate clients on risks of self-removal
• Enrolled 575 clients in 30 days

• All devices were removed by day 8, all clients visited the health facility.
  – 539 (94%) removed on day 7
  – 29 (5%) day 4 to 6
  – 4 (0.7%) day 8
  – 1 (0.2%) self removal (day 3)
  – 1 (0.2%) self detachment (day 4)

• Mean placement time - 8 mins (SD ± 3.98)
• Mean removal time - 6 min (SD ± 4.5)
• Adverse Events: 9 (1.6%) - no age or provider cadre difference
SAFETY TANZANIA

- 6 mild (1.0%)
  - incomplete locking of the ring on placement; ring removed/wound sutured
  - inner skin slipped off the ring on placement; ring removed/wound sutured
  - Swelling
  - Displacement
  - Self detachment -1.8cm gaping at day 10
  - Self removal
- 3 moderate (0.5%)
  - Post-removal pain due to adhesions removed-topical cream was re-applied
  - bleeding- suturing was done
  - Infection- antibiotics were offered
- 6 of 9 AEs happened while wearing the device

- Post placement pain was not well tolerated in 2 clients (day 3 & 5)
- 2 didn’t respond to topical cream – injection used
- 99.5% of clients had healed by day 49
  - 3 clients had not healed due to poor personal hygiene
- 21 HIV+ (6 new & 15 known) – all healed similarly to HIV- 
- By day 10, >90% of the clients were back to routine work
- IDI clients self reporting:
  - 8 (16%) of 50 IDI participants resumed sex with main partner two weeks post removal
  - Intense pain starts on day 5 post placement