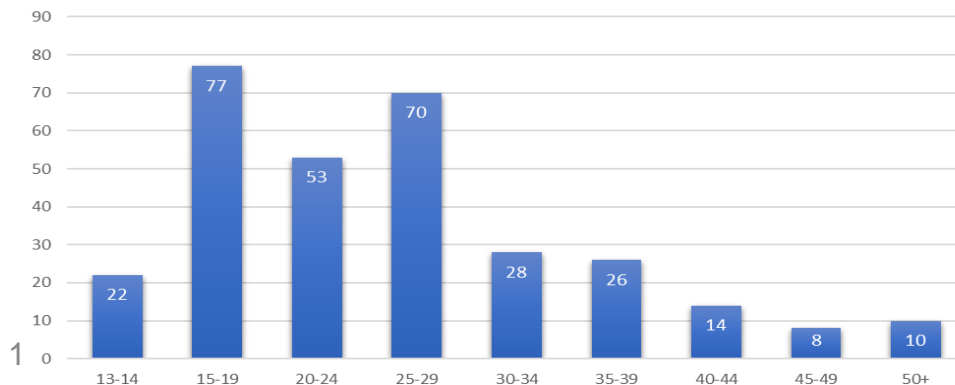


SAFETY NAMIBIA



- 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

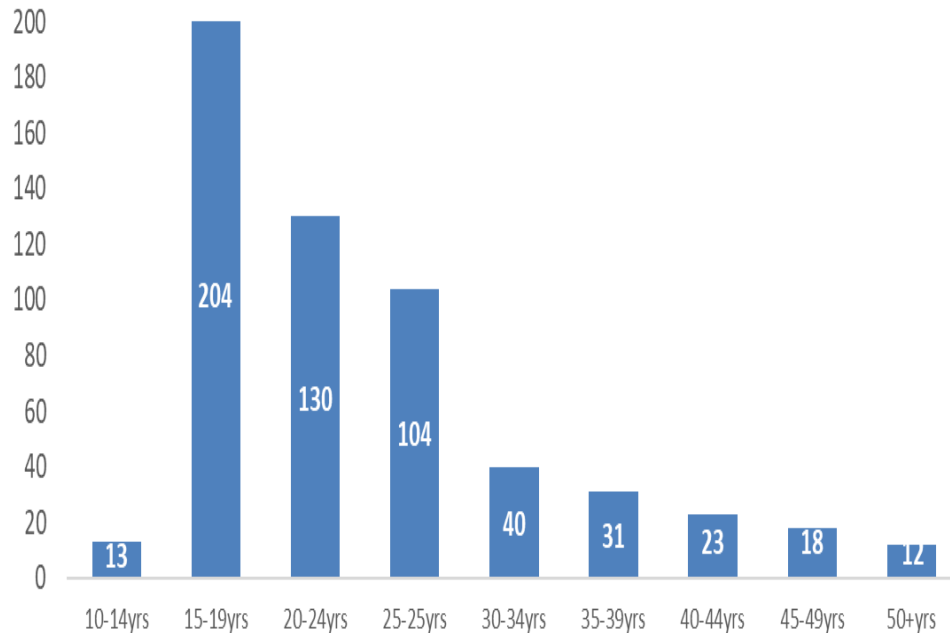
of Placement per Age group



- 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

SAFETY TANZANIA

- 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 \pm 3.98)
- Mean removal time - 6 min (SD \pm 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

