



CAPRISA

CENTRE FOR THE AIDS PROGRAMME OF RESEARCH IN SOUTH AFRICA



CAPRISA IS A UNAIDS
COLLABORATING CENTRE
FOR HIV PREVENTION RESEARCH

Product Use End Visits

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On behalf of the eThekweni CRS
MTN Annual Meeting
15 March 2015

PUEV and SEV

- ❑ Product Use End Visits (PUEVs) for ASPIRE are taking place over the course of March-May 2015.
- ❑ PUEV's are conducted when the participant comes for her quarterly or semi-annual visit.
- ❑ Study Exit Visits (SEVs) will occur approximately 4 weeks after the PUEV.
- ❑ PUEV's and SEV's will continue until 25 June 2015, after which no further study visits will occur.

TRAINING

- ❑ Training was provided during the Protocol Team Call
- ❑ Training was also done at the site - review of SSPM, Operational Guidance #9, visit checklist and new CRF's.
- ❑ Visit checklist was revised following feedback received at this training – better clinic flow.
- ❑ Questions that arose during the training were forwarded to SCHARP for responses, feedback given to the team during team meetings



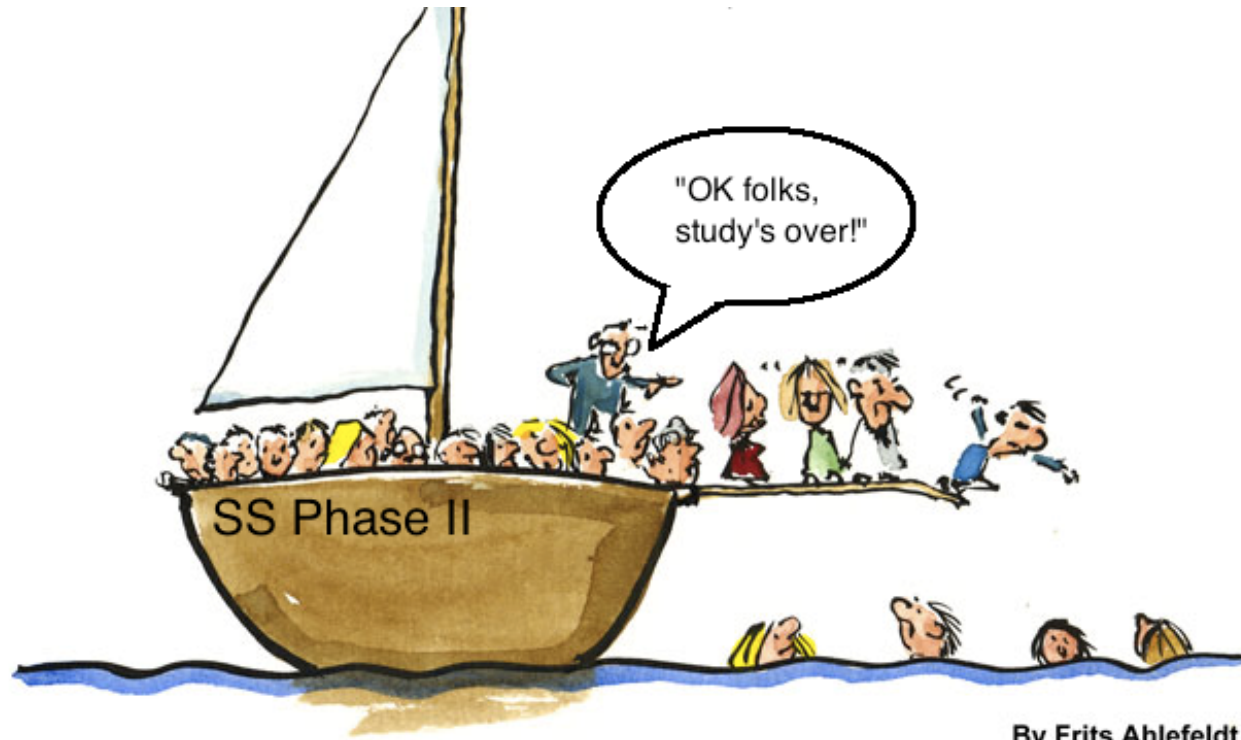
DISCUSSIONS WITH PARTICIPANTS

- ❑ PUEV discussed in daily group education sessions done in the waiting room:
 - Participants asked study staff when will it start?
 - Participants were concerned that they will seroconvert if they are not using the product
 - Participants were worried as they felt it increased sexual pleasure

DISCUSSIONS WITH PARTICIPANTS

- ❑ PUEV discussed in daily group education sessions done in the waiting room:
 - Participants asked if the ring would be rolled out into the public should it be found to be effective?
 - Will it be available for free like condoms and will it be collected monthly?
 - Will they be first to receive it since they have participated in ASPIRE?

DISCUSSIONS WITH PARTICIPANTS



- ❑ A depiction of what some participants felt, but it was explained that this is not the case

DISCUSSIONS WITH PARTICIPANTS

- ❑ PUEV discussed in daily group education sessions done in the waiting room:
- Participant informed study staff that she overheard discussions in the waiting room that some participants may keep the ring and report it as “lost” at their PUEV – this topic was thereafter addressed as part of the ongoing waiting room education sessions

DISCUSSIONS WITH PARTICIPANTS

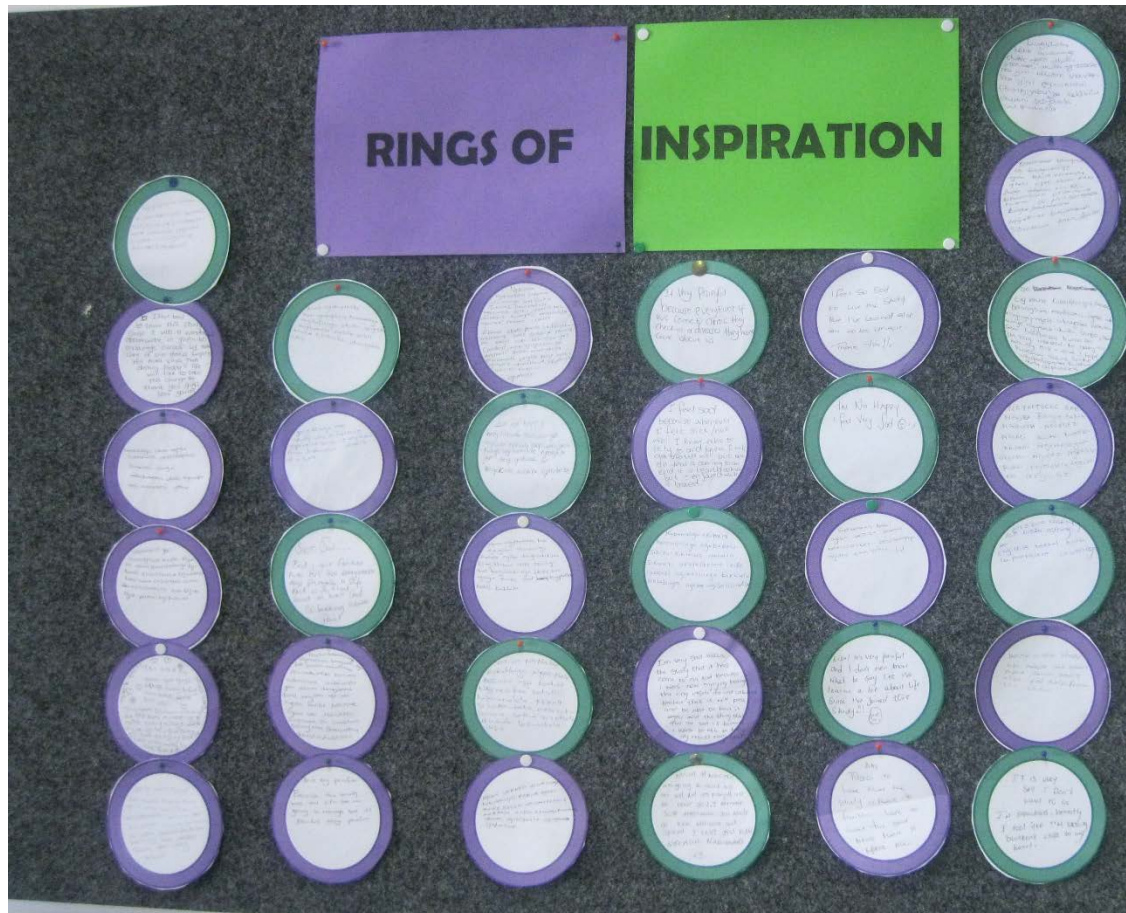
- ❑ PUEV discussed one on one with study staff:
 - Some participants did seem fatigued and were more accepting that the study is coming to an end.
 - Some said that they have been finding it difficult coming for study visits.
 - Some reported increased sexual pleasure.
 - Some said that they enjoyed the clinic atmosphere ie movies, music, air conditioning, meals.

DISCUSSIONS WITH PARTICIPANTS

- ❑ PUEV discussed one on one with study staff:
 - Participant enquired why she needed to come back for termination visit as she was no longer using a ring - purpose of termination visit explained
 - Some participants unhappy that they will no longer be receiving medical care.
 - On reminding 1 participant that she can still return for VCT, she indicated that it is "not the same", as she will forget or not be motivated enough to come in if she does not have a scheduled appointment every month.

DISCUSSIONS WITH PARTICIPANTS

- ❑ PUEV discussed during participant events – milestone event.



DISCUSSIONS WITH PARTICIPANTS

I'm very Sad about the study that it has come to an end because I was now enjoying having the ring inside me and I always believe that it will pass and be able to have it again and the thing that had me sad it because I won't be able to know my result every month

I Feel bad to leave this study cause it was a wonderful opportunitie in youth to encourage ourself by take care of our status beyond Hiv Aiad virus that will like to take this change to thank you guys love you all.

PUEV

- ❑ 44 PUEV's done to date (as at 09 March 2015)
- Both ACASI laptops are available for use due to the number of PUEV's done daily.
- After the first day of PUEV visits, the site team met to iron out any kinks / common errors being made on forms / clinic flow issues.
- QC's - Skip patterns were being missed as staff were familiar with old practices, re-emphasised changes on those CRFs.



PUEV

- Participant had her PUEV on 25 February 2015 and then reported about a week later that she is leaving Durban – re-location – on 13 March 2015. Decision taken to bring her in for SEV/Term Visit before she leaves, 2 weeks after PUEV.
- What would be done if it was less than 2 weeks? SEV/Term Visit?

PUEV

- Participant had an abnormal blood result – grade 1 ALT at PUEV, a new AE that is highly likely to resolve. Under normal circumstances this would be followed up at the next visit, however the site has opted to repeat the test in 2 weeks rather than at the SEV/Term Visit.
- How would other sites handle this?

Questions?



ACKNOWLEDGEMENTS

- CAPRISA ASPIRE study team for their efforts in identifying and working through challenges associated with PUEV.
- FHI for training and training materials.
- SCHARP for the flurry of queries from the site.

