

Duet cervical barrier used continuously or precoitally for HIV prevention in Zimbabwean women: an acceptability and safety study

Presented by:

Elizabeth T. Montgomery, Ph.D

Microbicides 2010 Conference

Pittsburgh, PA, USA

May 24, 2010

Co-authors

- International Partnership for Microbicides
 - Cynthia Woodsong;
- University of Zimbabwe – University of California, San Francisco (UZ-UCSF) Collaborative Research Programme
 - Petina Musara
 - Tsungai Chipato
- ReProtect, Inc.
 - Thomas Moench
- RTI International
 - Helen Cheng
 - Ariane van der Straten

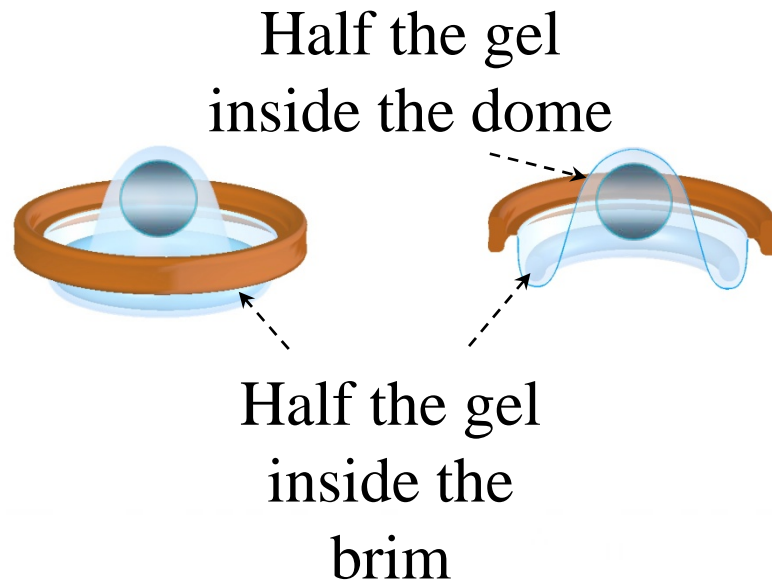
Background

- Duet[®] is a diaphragm-like cervical barrier that delivers microbicide gel on both its cervical and vaginal side, and is being investigated as a delivery mechanism for potential microbicides.
- A phase I study of the Duet in the US and Dominican Republic (n = 30 couples) concluded that further product development was warranted (Ballagh et. al., *Contraception*, 2008)

Study Objectives

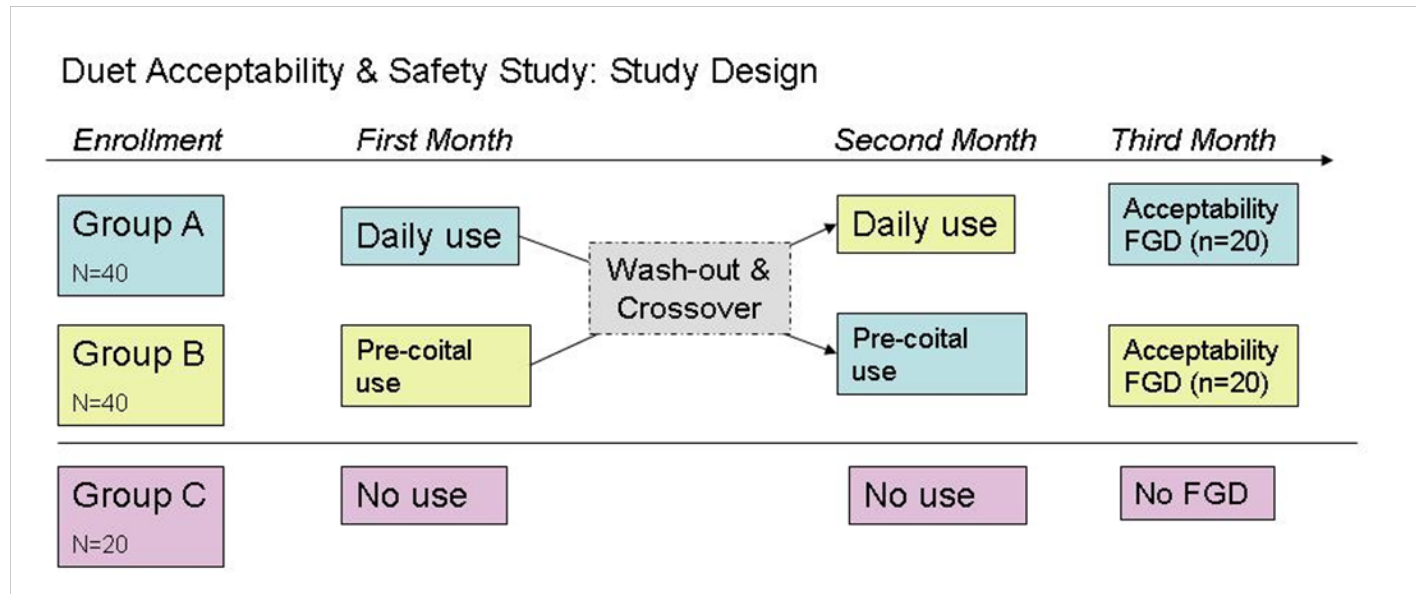
- To assess the **acceptability** and **safety** of the Duet for use among African women, when used continuously for 14 days or inserted pre-coitally for 14 days.
- This is the first study
 - Of the acceptability and safety of Duet in **African women**
 - To assess **continuous use (for 14 days)** of the device

Study Products: Duet



Study Design

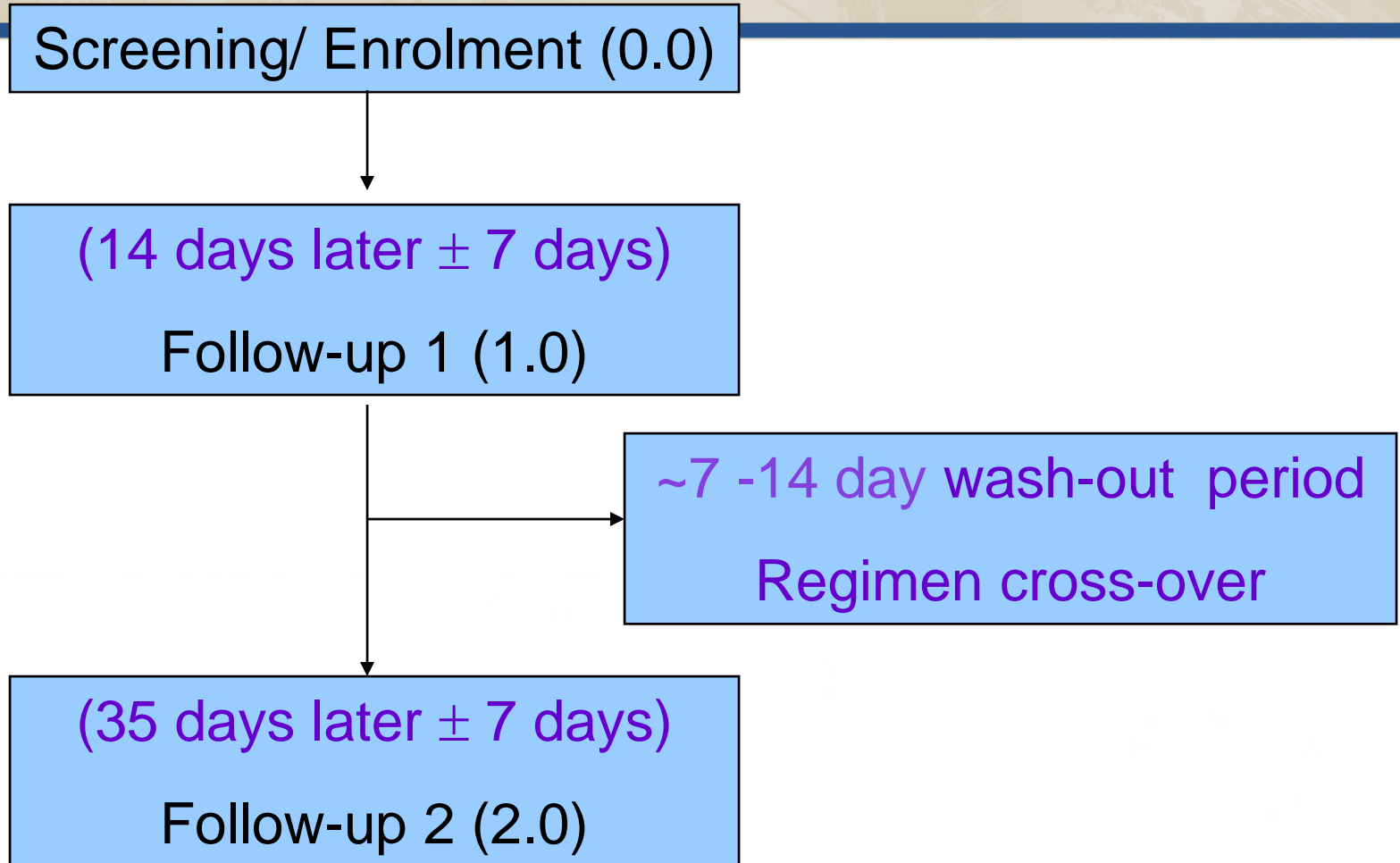
- Open-label, randomized cross-over design with 2 intervention arms and 1 observation arm



Study sample: n = 103

- Main Inclusion criteria:
 - Women aged 18 – 40
 - Sexually-active (=>1 times/week in past 3 months)
 - Non-pregnant and on effective contraception
 - Asymptomatic for genital infections
- HIV status was not an eligibility criteria

Visit Schedule



Methods

- Acceptability and Adherence
 - Self-reported at 2 follow-up periods
- Safety
 - Adverse events:
 - assessed by participant self-report and clinician exam at follow up visits

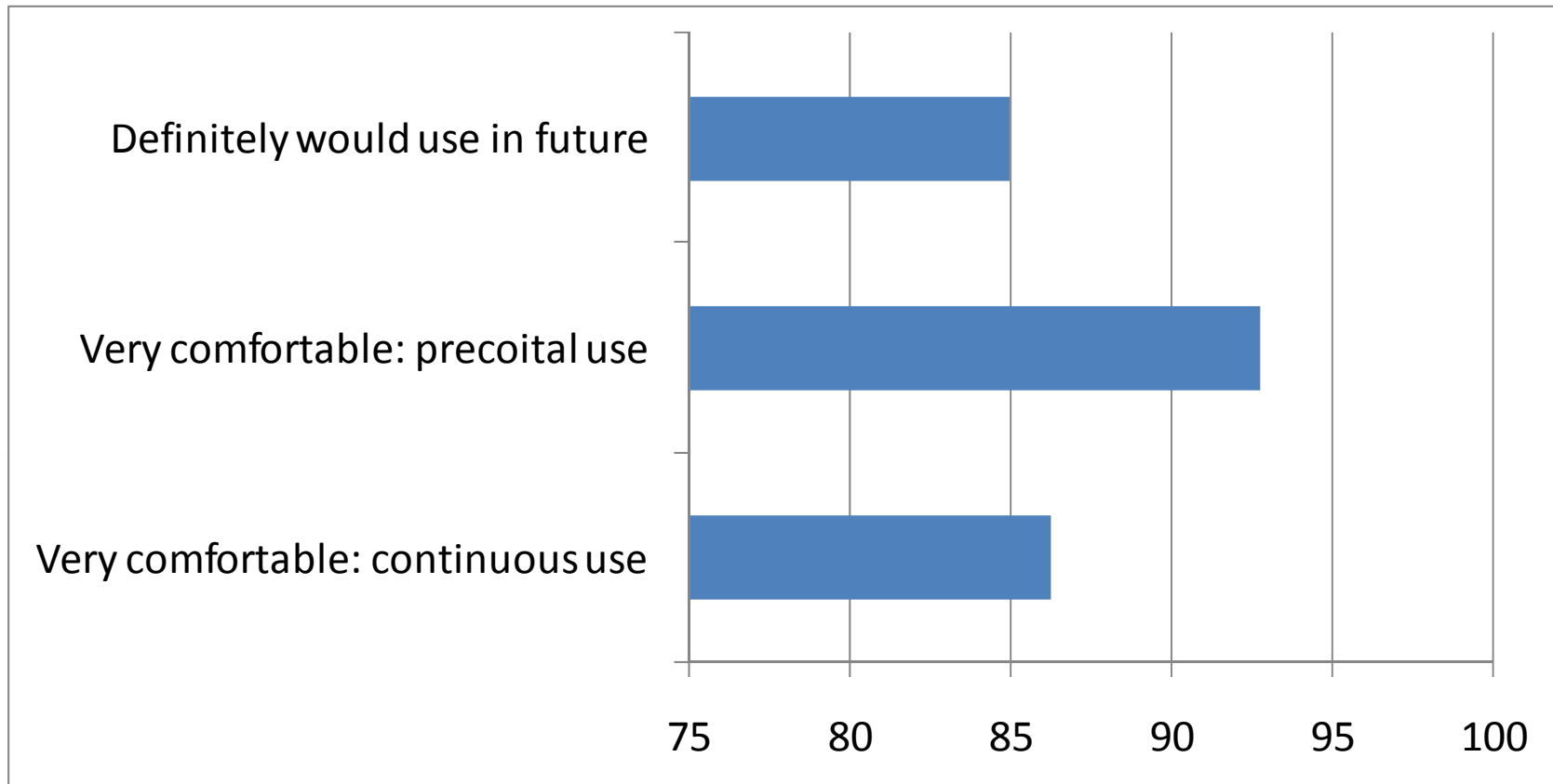
Results

- 103 women enrolled
 - 100 (97%) completed study as scheduled;
 - 1 woman discontinued for unresolved symptomatic genital infection
 - 2 withdrew for personal reasons
- Mean and median age 30
- All married and monogamous
- 65% Shona
- All had at least 1 child
- 12 had used diaphragm in the past 3 months

Product Use, by regimen period

Adherence level	Continuous Use	Pre-coital Use
Worn 100% of days	81.0	NA
Worn 80% of days	89.9	NA
Used during 100% of sex acts	88.6	89.0
Used during 80% of sex acts	93.7	93.9

Acceptability: overall



Regimen Preference

Preferred regimen

Continuous	31	38.8
Precoital	41	51.3
Same	8	10.0

Preferred regimen of partner

Continuous	30	37.5
Precoital	41	51.3
Same	9	11.3

See also Poster # 326 Monday, van der Straten et. al.

Most and least favored characteristics

- Most favored
 - Does not interfere with normal/ natural sex
 - Reusable
 - Can insert herself
- Least favored
 - Might come out during sex
 - Might change the feeling of sex for partner
 - Might change feeling of sex for her

Safety I

- No SAEs reported
- 90 AEs reported among 57 individuals
 - 68% classified as “mild”
 - 32% classified as “moderate”

Safety II

- No statistically significant differences between Duet and observation groups in:
 - Overall number of AEs, number of reproductive-tract (RT) or urinary-tract (UT) related AEs;
 - AE severity
- No statistically significant differences between AEs reported during continuous use and precoital use in:
 - Overall number of AEs, number of reproductive-tract (RT) or urinary-tract (UT) related AEs;
 - AE severity
 - Relatedness to study product

Conclusions

- Duet was highly acceptable and safe for use both continuously and precoitally in this African setting, when used for 14-day periods.
- Further research should explore the safety of the device with alternative microbicide candidates as a potential disease prevention option.
- Assignment to continuous use of the Duet did not equate to more Duet use during sex acts

Acknowledgements



INTERNATIONAL
PARTNERSHIP for
MICROBICIDES



Safety II

- 31 events (among 28 women) were classified as related to study products:
 - 13 “possibly”
 - 10 “probably”
 - 8 “probably not”
 - 0 “definitely”
- Most were RT- or UT-related; however, a few physiological/neurological discomfort associated with squatting
- 3 cases of abnormal physical exam findings at each of two follow-up visits
- No reports of epithelial disruption