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Duet® for menstrual protection: a feasibility study in Zimbabwe☆

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Abstract

Background: Managing menses is a challenge for women in developing countries. Duet® is a cervical barrier being developed for contraception and STI prevention. We explored the hypothetical acceptability of using Duet as a menstrual cup, among Zimbabwean women.
Study Design: A survey and focus group discussions (FGD) were conducted with 43 women aged 18–45 years to gain information about their menstrual practices and attitudes regarding the use of Duet for menstrual protection.
Results: All 43 women reported that if Duet were available, they would "definitely" try it, and that it was "very important" that Duet is low cost and easy to clean; 86% reported that using it would make a difference in their lives. FGD findings highlighted unhygienic practices due to the lack of affordable options for menstrual management and a genuine interest in Duet, including its potential use for multiple purposes (contraception, disease prevention and menstrual protection).
Conclusions: Accessing affordable and hygienic menstrual protection was a problem for these Zimbabwean women. Duet appeared acceptable and it would be feasible to conduct a user-acceptability study of Duet as a menstrual cup in Zimbabwe.

Keywords: Cervical barriers; Menstrual protection; Duet; Menstrual practices; Zimbabwe; Prevention of HIV/STI

1. Introduction

Control of menstrual blood is a monthly reality faced by millions of women from menarche to menopause. While a wide array of commercial menstrual protection products are available and accessible in developed countries, this is not the case in many developing countries.

Virtually no peer-reviewed data are available on menstrual protection practices in sub-Saharan Africa. Anecdotal evidence and articles in the popular press have documented shortages in disposable sanitary pads across Zimbabwe and sub-Saharan Africa [1]. In Uganda, a report found that sanitary napkins for one girl cost one-tenth of a family's monthly income and that girls often stay home from school to avoid embarrassment during menses [2]. A small study in Zimbabwe suggested that there is a correlation between onset of menses and decreased school attendance [3]. Another survey amongst 380 poor women in New Delhi, India, highlighted the challenges of washing and drying menstrual cloths in a crowded urban setting with little privacy [4]. Lack of resources and affordable options for menstrual protection products are thus likely to have far-reaching implications on the quality of women's life in many developing country settings.

Duet® is an investigational cervical barrier device developed by ReProtect, Inc., currently being investigated for use as a contraceptive and for use in STI prevention [5]. Because Duet is worn over the cervix, it is also being investigated as a potential low-cost reusable menstrual cup to collect menstrual blood.

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The purpose of this study was to explore current menstrual practices, the effect of menses on daily life, unmet menstrual protection needs, and the hypothetical acceptability of the Duet as a new menstrual collection device among women of child-bearing age in Zimbabwe.

2. Materials and methods

2.1. Participants and study procedures

The study was conducted between October 2007 and March 2008, at the UZ-UCSF Programme in Women's Health, in Epworth, Zimbabwe. Epworth is a high-density suburb of the capital city of Harare. A convenience sample of 43 women was recruited by study staff at public clinics, markets and shopping centers. Eligibility criteria included being a female aged 18 to 45 years, having menstruated in the past 3 months, ever having had vaginal sex, currently living in the greater Harare region, being able to read and write in Shona or English, and willing and able to give informed consent.

Mixed methods were used for this study, including focus group discussions (FGD) and self-administered surveys. Following informed consent, and prior to the FGD, women completed a self-administered demographic questionnaire. For the comfort of participants, and to ensure age variability in the sample, FGD were stratified by age: two FGD were conducted with women aged 18–24 years (n=22) and two FGD with women aged 25–45 years (n=21). Duet was presented to women during the FGD group discussion. A self-administered attitude questionnaire about Duet was completed after the FGD. All data were collected in Shona, the local language.

Women in the study did not insert the device. They were shown a demonstration of Duet insertion and removal on a plastic pelvic model, and they were able to touch it and practice inserting the Duet onto the plastic pelvic model. Women in the study were read a script stating the following:

> "Duet is a cup-shaped device that is worn inside the vagina. It is being developed for contraception, to prevent sexually transmitted infections, and to collect menstrual flow. Today we are talking mostly about its use for collecting menses. Some women in the United States use cup-shaped devices similar to Duet for menstrual protection. Cup shaped devices like Duet are easy to clean and care for; they are fast to wash and dry because they are not absorbent and do not soak up water.
>
> Duet is worn inside the vagina. It covers the cervix, where the menstrual blood comes from. It collects menstrual flow inside the cup until Duet is emptied out, and put back in place to collect more. It can be reused for many menstrual periods, and can last at least a year, or more. It holds slightly more fluid than a tampon and needs to be emptied a few times a day, depending on the heaviness of the menstrual flow. This is a little less frequently than tampons or menstrual cloths would be changed. If not emptied often enough, it has more chance of leaking and spilling menstrual blood. It is convenient to empty it when going to the toilet. It can be worn throughout the day, or for whatever part of the day is wanted so long as it is emptied often enough to prevent leaking. It should be removed at least once a day, washed with soap and water, and rinsed with plain water then it can be reinserted immediately. When the menses are finished, after cleaning it, it can be stored in its covered storage tray for the next use."

The estimate that one Duet could be used for at least a year is based on preliminary laboratory data from the manufacturer, the intrinsic durability of polyurethane and the observed durability of implanted polyurethane medical devices in widespread clinical use.

This study was approved by the Committee on Human Research, the UCSF Institutional Review Board (IRB) that holds Department of Health and Human Services Multiple Assurance to involve humans as research subjects; and by the Medical Research Council of Zimbabwe, the Zimbabwean IRB.

2.2. Study device

Duet is a one-size-fits-all, diaphragm-like, intravaginal cervical barrier device with a 70-mm outside diameter. It is constructed entirely (both dome and rim) of polyurethane, a biocompatible polymer used for both male and female condoms, as well as for certain fully implantable medical devices. The device contains no latex. Duet is currently being investigated as a contraceptive and for STI/HIV prevention (with the vaginal microbicide BufferGel®). Duet can also be used intra-vaginally to collect menstrual blood, although it has not yet been clinically studied for this purpose. The expectation of Duet's utility for menses is based on its similarity to commercially available menstrual cups, and on anecdotal reports of diaphragm use for menstrual collection.

In a Phase I safety trial of the Duet in 30 healthy couples, 25 women successfully placed, and 28 women successfully removed, the device from the instructions alone. The product was equally acceptable to both men and women. Most users concluded that intercourse was the same or better with the device than with no product. About 73% would choose Duet over male condoms, and no one preferred the standard diaphragm. Colposcopic findings were noted at rates similar to a prior diaphragm study, and only one woman was found to have a breach in the vaginal epithelium. Most product-related adverse events were mild (10/11) and confined to the genitourinary tract [5].

2.3. Data management and analysis

Quantitative data from the self-administered questionnaires were double entered in an Excel database. Discrepancies were checked against the original questionnaires and corrected. Cleaned data were transferred into STATA software for analysis. Data were summarized using frequency tables for categorical variables, and means, medians and ranges for continuous variables. Some attitudinal questions