



MEN DON'T NEED TO KNOW EVERYTHING (“GASON PA BEZWEN KONNEN TOUT BAGAY”): IMPLEMENTING A PILOT STUDY ON THE ACCEPTABILITY OF A CONTRACEPTIVE CERVICAL CAP AMONG HAITIAN-AMERICAN WOMEN

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Abstract - Objectives: To evaluate early results of a pilot study among Haitian-American women

Methods: Cervical barrier research on US women at high HIV risk is rare. A pilot study in Miami assesses the feasibility/short-term acceptability of the *Femcap* among 30 Haitian-American women aged 18-45 yrs. After a 45', small-group, educational peer counseling session in Créole, women are fitted, and asked to try the cap for 1-2 weeks and return to the clinic for an interviewer-administered questionnaire and focus group discussion

Results: Nine women have completed follow-up. Most were married, two-thirds had children. Two-thirds were unemployed; 8/9 had no health insurance. None reported prior use of female barriers, or tampons. All women inserted the cap (4-8 hrs); 1 used it during intercourse. 6 of 9 liked/very much, 1 neutral, 1 disliked. Overall complaints were few. 4 women had minor difficulty in removal. All women elected to continue cap use; all would recommend the method to other women. Method attributes mentioned frequently include: (1) comfortable, (2) covert use and (3) reusable device. Women appreciated study sessions: "It's a training that will help me cope with poverty...something I can share with other women." The cap was liked, "Because it's convenient and easy to insert and you don't have to take pills and have an operation" Recruitment is slower than anticipated due in part to scheduling conflicts (insecure employment, childcare, medical problems) and limited study resources

Conclusions: Enrolled women with no prior cervical barrier experience liked the cap. Recruitment challenges include helping women overcome initial hesitancy with female barrier, and facilitating women's attendance at 2-3 h initial session.

The Femcap as a Multipurpose Prevention Technology:

- **Contraceptive:** FDA-approved; effectiveness in same class as diaphragm, male condom, female condom.
- **HIV/STI Prevention:** by analogy, covers cervix with seal, and should reduce risk of some STI; research program urgently needed to assess level of disease prevention. Microbicide delivery device.
 - ✓ Primary prevention of HIV/STI, and prevention of vertical transmission together is potentially reduced via a single method that is compatible with male condoms, hormonal contraceptive methods, IUD.
 - ✓ Offset increased risks of STI/HIV with hormonal methods (Depo, OC) .
- **Menstrual cup:** akin to other barriers used for menstrual collection safely
- **Fertility enhancement:** Original cervical caps had this clinical usage, published data

Background: Gaps in Cervical Barrier Research

- Cervical barrier research in the HIV/AIDS era has been conducted predominantly among women in resource-poor settings (low-risk couples, FP clinic attendees, women with multiple sex partners, and sex worker populations).
- Research has targeted either new (Silcs) diaphragm or traditional diaphragms. Scarce research on cervical caps historically, including currently approved and marketed *FemCap*.
- Nevertheless cervical caps, as a class, have theoretical advantages over new and traditional diaphragms; these may bring significant increases in observed protection from HIV/STI. Inference from dp studies may substantially underestimate actual cap protection.
 - a *suction fit* around cervix and conical shape a conforming *seal* around the cervix – spermicide is not thought to contribute significantly to contraceptive efficacy (observational studies show non spermicide cap users have equivalent pregnancy rates)
 - *long-term wear* (48h -72 hr), *insertion long before sex, use for multiple sex acts without removal* or spermicide reapplication, covert use
 - the cap is *small, simple, highly portable, durable, and resistant to temperature* and other environmental conditions (*Femcap is silicone*).

- Research on cervical barriers among Haitians or Haitian-Americans is lacking, although this population constitutes a high-HIV prevalence/incidence group worldwide and in key US cities most affected by the HIV/AIDS epidemic (e.g. Miami, New York)

Methods

- A waiting room survey was administered to 36 women at the Center for Haitian Studies, a free clinic in "Little Haiti:" section of Miami, summer 2010. 24% had < HS education; 91% born in Haiti ; 86% reported Créole as first language. Two-thirds were unemployed and had children (61%), most reported prior male condom use (73%). 90% of women indicated interest in *female barriers and specifically a cervical barrier method study*.
- First and second generation Haitian–American women ages 18-45 were then recruited, enrolled per eligibility criteria, and completed 2 study visits.

Visit 1 (Baseline)

- Clinical visit - speculum exam to rule out signs of infection; cap fitting to determine size
- Brief (45') interactive counseling and post counseling assessment
- Baseline data collected (demographics, sexual history)

Visit 2 (Week 1-2). Women return to the clinic after 1-2 weeks

- Acceptability assessed interviewer administered questionnaire
- Focus Group in Créole -recorded

Study sample (n=9)
 Average age 35 yrs (19-45)
 1st generation immigrants
 9 Creole first language
 57% unemployed
 9/9 had children



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**** References - upon request**

Results

Acceptability -

- High acceptability of *Femcap*. All women chose to keep the cap and indicated interest in a future study.
- 8 of 9 women would recommend the device:
 - ❖ "paske si fanm gen lide pa fe timoun fo yo proteje tet yo" – Because if women don't want to have children they have to protect themselves
 - ❖ "pou planin" – Because it is a good birth control method/family planning
 - ❖ "paske si ligen yon marili fe konfyans yo kapa kontrole pou yopa fe pitit" – Because if she has a husband she trusts, they can take control over not having more children
 - ❖ "paske li fasil pou mete, epi ou pa beswen operasyon ni lowe grenn" – Because its convenient and easy to insert and you don't have to take pills or have an operation
- Easy Insertion, minor difficulty with removal; any difficulties were not linked to rejection of cap as method.
 - ❖ 8 reported easy insertion and removal of the cap : "li fasil pou mete" – quick to insert

Other Findings -

- **Body Knowledge:** Women had low knowledge and use of tampons (16%). Following brief counseling session, body knowledge increased, however, there was still room for improvement:
- **Discreet Use:** Discreet use was demonstrated to be possible and of interest to women. Several women tried the cap without informing their partner.
- **Fitting cap via obstetrical history/size determination:** Parity did not predict clinically – determined cap size
 - ❖ 9 women had children and would have received large cap based on history. Of the nine women who were parous, 6 were found by clinical (visual) sizing to fit for a medium cap, and 3 clinically for a large cap
- **Counseling :** Women appreciated the educational experience of participating in the study, and shared the information widely among their network.
 - ❖ "Participating in educational training is part of the integration process into a society. This is what I was missing - to participate in an educational training about family planning"
- **Relevance of project expansion to Haiti:** Women expressed an urgent need to bring the method to the island of Haiti.
 - ❖ "If you could bring this method to Haiti, it would be very great; after the earthquake, pregnancies are out of control. After the earthquake, many young people are having babies. It would be very useful to offer this method in Haiti, especially in the temporary shelters. After the earthquake, there is no sexual education; people don't find enough condoms. All they do is eat and have sex."

Conclusions

- Despite little experience with barrier methods, women of Haitian descent in Miami were interested in the *Femcap* as a contraceptive and potential MPT. Those in this small sample reported no cultural or other barriers to their use, and were enthusiastic for additional choices in contraception since hormonal methods are not popular among an important number. Interest in method with both contraceptive and disease-reduction activities was high.
- Community–based organizations in Little Haiti are enthusiastic about partnering in such research, and are referring women to our study. Haitian radio station ("Radio Mega") donated air time for program on women-controlled protection.
- Further research regarding fitting approach needed; can large cap size be used for all women? Should clinical fitting be required? Etc...these are basic questions that could be addressed with even a small resource base for research.
- HIV continues to be an urgent, and unattended, priority in US populations of minority women. Given potential benefits of existing contraceptive devices/barriers, research to define STI/HIV prevention efficacy is clear next step. Such research would also respond to the US Strategic Plan, is cost-effective, ethical. Local barrier protection for women either combined with hormonal contraception, or used alone consistently, could minimize STI/HIV risk and maximize contraceptive protection. Women have a right to know the disease-reducing potential of existing devices.