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TITLE: Intervention to Decrease Risk for Sexually Transmitted Diseases (STDs) and the Associated Negative Reproductive Health Outcomes in Women Aboard Ships: A Biopsychosocial Approach

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13. ABSTRACT *(Maximum 200 Words)*

Unintended pregnancies (UIPs) and STDs with their sequelae of ectopic pregnancy continue to be epidemic among active duty enlisted women. Such reproductive health problems result in major morbidity among affected women as well as posing a potential threat to combat readiness. UIPs and STDs result from complex interactions between biological and behavioral factors in military women. The ultimate control in preventing such morbidities must rely on both behavioral and biologic strategies. The primary aim of the project is to develop, implement, and evaluate an intervention which emphasizes correct information, motivation and behavioral skills building (IMB Model) coupled with non-invasive screening using urine-based amplified DNA techniques to detect C. trachomatis and N. gonorrhoeae and urine based pregnancy testing. A pre-test, post-test experimental design was employed to evaluate the impact of the behavioral intervention on the experimental group using both self-report questionnaires (UIP/STD psychosocial and behavioral risk factors) and results from the STD and pregnancy screening tests as measures. The control intervention will consist of a prevention program focusing on nutrition, breast cancer, fitness and injury prevention. Questionnaires and urine testing will be done at pre-test, mid-study, and post-test 6-12 months later. Subjects will include junior enlisted Marine women with N=1000 in the experimental group and N=1000 in the control group.

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3. INTRODUCTION

Overall Goal: To prevent sexually transmitted diseases (STDs) and unplanned pregnancies (Focus curriculum) and to promote good nutritional habits and reduce sports/training injuries (Fitness-for-Life curriculum) through the provision of information, communication and problem-solving skills training, use of program-specific videos, and group discussions which emphasize prevention of risk behaviors and negative peer influences. The curricula for both components are implemented in 4, two-hour sessions that occur during Recruit Training (Parris Island, SC). Screening for pregnancy and prevalent STDs, including chlamydia, gonorrhea, and trichomonas is also included.

Participants: Junior, enlisted women Marine Recruits who voluntarily agreed to participate in the program were randomly assigned by platoons to either the Focus (Study condition) or Fitness-for-Life (Control condition) Curricula at arrival at recruit training.

Assessments: All participants complete a self-report questionnaire of their knowledge, attitudes, beliefs, and behaviors regarding STDs, unplanned pregnancies, nutrition and fitness at T-1 baseline (prior to participation in the Program at Recruit Training Regimen-RTR, Parris Island, SC), at T-2 after completing Marine Combat Training (MCT at Camp LeJeune, NC, approximately 5 weeks from graduation from recruit training) which was preceded by boot leave, and at T-3 which is 9-11 months post-MCT at their first duty assignment or MOS School. These individuals are also screened for pregnancy and STDs at each of the three assessment periods.

Program Evaluation: The primary goal of the program evaluation is to determine the feasibility and effectiveness of the Focus curriculum for preventing unplanned pregnancies and STDs and the Fitness-for-Life curriculum for promoting good nutritional habits and reducing sports/performance injuries in junior enlisted women Marines.

Specific Aims:

(A) Develop, implement, and evaluate a reproductive health educational and cognitive-behavioral skills-building intervention (behavioral intervention) designed to modify knowledge, psychosocial and behavioral risk factors associated with UIPs and STD acquisition.

(B) Test the relevance of the Information, Motivation, and Behavioral Skills (IMB) Model in explaining the determinants of behaviors linked with UIPs and STDs.

(C) Define the prevalence of UIPs and STDs, emphasizing the most common bacterial agents, such as C.trachomatis and N.gonorrhoeae, and their sequelae of PID and ectopic pregnancy.

(D) Utilize pregnancy and STD diagnostic screening tests as biological markers to validate self-reported behaviors and to evaluate the impact of the behavioral intervention.

(E) Assess the performance of non-invasive, non-culture-base screening tests for the detection of as C.trachomatis and N.gonorrhoeae by ligase chain reaction (LCR) technique on first void urine compared to standard tests applied to (invasive) endocervical and urethral specimens by the presence or absence of urogenital symptoms.

4. BODY

Overview

The research methods, results, and discussion are described below in relation to the Statement of Work for the grant period August 7, 1999-August 6, 2000. Overall plans for the extension for Year 5 of the project included the following tasks: a) completion of the recruitment of all women Marines to participate in the project and the completion of the actual implementation of the intervention during the recruit training period (curriculum for FOCUS/FITNESS FOR LIFE); b) completion of the baseline clinical/biological and self-reported questionnaire assessments for the initial intervention phase of the project (T-1); c) hiring and training of all additional staff needed to implement the data collection for the initial follow-up period at MCT (T-2); d) completion of 60% of the follow-up assessments (clinical/biological and questionnaire assessments) of participants at T 2; e) hiring and training of the additional staff needed to implement the assessments for the final assessment period (T 3) at the participants' first duty station; f) begin the actual T-3 assessments at the 3 geographic sites)clinical/biological and questionnaire assessments); and g) initiation of the baseline clinical/biological data including early descriptive data analyses.

STATEMENT OF WORK (SOW)

The following summarizes progress on the SOW activities:

(A) Select a group of surface destroyer and submarine tender ships to focus initial data collection of which two ships will be targeted as study ships for the current study.

1. The target population for implementation of the project is US Marine Corps Recruits from the Marine Corps Recruiting Depot (MCRD), Recruit Training Regimen (RTR) on Parris Island, SC. To date, we have approached 2,282 women Marine recruits to participate in the *FOCUS-Fitness for Life* intervention. Of these women 95% voluntarily consented to participate in the program (N=2,157). Of these women, 49%w ere assigned to the *FOCUS* program and 51% were assigned to the *Fitness for Life* program. The intervention component (T-1) of the program is finished with 1916 women completing the intervention and graduating from recruit training (89% of those enrolled). (213) have been discharged from Recruit Training.)

2. The Marine Combat Training (MCT)component of data collection (T-2) at Camp LeJeune, NC. At this initial follow-up, the participants were screened for pregnancy and STDs (chlamydia, gonorrhea, trichomonas) and completed a short interim behavioral questionnaire. A total of 1748 women completed T-2 which represents 81% of those originally enrolled at T-1 (91% of those who completed T-1).

3. A second follow up (T-3) of the participants is just being completed (begun July 1, 2000). We have established follow-up sites on Okinawa, Japan (Camp Hansen, Camp Lester and others), in Jacksonville NC (Camp LeJeune, Camp Geiger, and others), and southern California (Camp Pendleton, 29 Palms, San Diego) to reach the women Marine participants who are assigned to duty stations in and around these regions. The women are screened for pregnancy, STDs (chlamydia, gonorrhea, trichomonas), and complete a self-reported behavioral questionnaire. In addition to these locations, MCRD at Parris Island, SC will serve as the coordinating site to reach women who are stationed in other regions of the country and abroad beyond our formal established research sites. These women will only complete a second-follow-up questionnaire. This phase of the study was launched in July 2000 and has resulted in 1299 follow-ups to date: 838 with both STD/pregnancy screening and questinnaires; and 461 questionnaires alone.

(B) Brief the Commanding Officers (COs) of the target populations.

1. To date, all COs at the participating sites have been briefed. In order to establish sites to conduct the second follow-up of the study, the following briefs were conducted in the last year (see Appendix 1 for a sample copy of the most current briefing packet):

   Jacksonville, NC: Mr. George Reynolds, Chief of STD Control and Mr. Donald Neil, STD/HIV Disease Intervention Specialist for the Naval Hospital at Camp LeJeune provided access to all Branch Medical Clinics and Battalion Aide Stations (BAS) for all bases in the Jacksonville, NC area. The initial brief was conducted in March 1999. The last briefing was conducted by Drs. Boyer and Shafer in September, 2001.

   Southern California: CMDR Sainten, USN, MC, CO for all Branch Medical Clinics and BAS on Camp Pendleton was briefed in April 2000. A similar brief has taken place with LCDR Cruz and LT Sonders, USN, MC at 29 Palms, the points of contact at 29 Palms. The last team visit to Camp Pendleton by Drs. Boyer and Shafer was March, 2001 accompanied by LT Heidi Kraft, NHRC. Dr. Shafer and Boyer worked with the site coordinators Alison Reade and Brenda Zepeda who is now in charge of coordinating the mailings and follow-up of all the "questionnaire-only" women who fall outside the 4 catchment areas for the T-3 collections.

   Okinawa, Japan: CAPT Schall, USN, MC, Directorate of Branch Clinics was briefed to gain access to all Branch Medical Clinics and BAS on the bases on Okinawa, Japan where women Marines are stationed (June 2000).

(C) Conduct elicitation research (focus groups) in order to develop a self-report question to assess knowledge, attitudes, and beliefs, and behaviors of the target population and to develop a military-specific behavioral intervention to reduce risk or UIPs and STDs in the target population, including development, implementation, and evaluation of the intervention.

1. All program materials, including videos, training exercises, training materials, and evaluation (assessment) instruments have been developed.

2. All study participants have been enrolled into the *FOCUS-Fitness for Life* intervention program as described above in section A-1 (T-1). All but 16%% of the participants have successfully completed the program. These remaining participants are still in their 13-week Recruit Training period and are scheduled to complete the program by September 15, 2000.

3. MCT follow-up phase (T-2) of the study was completed in January 2001. This phase includes 1,748 women as described in section A-2 above.

4. The second follow-up (T-3) of the women Marine participants at their first duty station was initiated in July 2000 and is scheduled to be completed by November 2001 as described above in sections A-3 above.

5. From the initial analyses of the T-1 baseline questionnaire risk assessment data and STD screening results from the 2,157 women, it is shown that this largely single (92%), diverse (C-58%, L-20%, AfAm 16%, O-6%), young (19.2 years mean age), were engaging in risky sexual behaviors: 85% were sexually experienced, 82% had 2 or more partners ever, 16% had a history of pregnancy and 13% had current STDs. Using risk markers and factors in a regression analysis to determine their relationship with current STD status at baseline showed that age, partner's race at last sex, perception that their sexual partners had other partners, birth control use and STD related symptoms at baseline screening were found to be associated with an STD diagnosis at baseline (See Appendix 2).

(D) Review STD logs and clinical records to establish the prevalence of reproductive health outcomes in the target population.

1. All activities related to this task were completed prior to this fiscal year.

2. We determined the baseline prevalence for C.trachomatis, N.gonorrhoeae, and T.vaginalis in the target population (See Appendix 3, text of the poster of baseline STD screening results presented at the Chlamydia 2000 International meeting in Helsinki, Finland August, 2000). We found an overall 13% rate of STD infections among entering Marine recruits including 11% infected with chlamydia, 2% with gonorrhea and 2% with trichomonas.

(E) Test the feasibility of non-invasive STD screening tests (urine) for chlamydia and gonorrhea in comparison to standard invasive tests.

1. All activities related to this task were completed prior to this fiscal year.

2. We also determined the performance profiles for the 3 different collection methods to detect C.trachomatis and N.gonorrhoeae by nucleic acid amplification tests applied to endocervical, first catch urine, and self-administered vaginal swab specimens.(See Appendix 1, Focus Brief for specific information).

(F) Test the acceptability of screening for pregnancy in the target population.

1. All activities related to this task were completed prior to this fiscal year.

5. KEY RESEARCH ACCOMPLISHMENTS TO DATE

(A) Designed and successfully implemented an intense 8 hour training program within a complex recruit training schedule to decrease STDs and IUPs.
(B) Determined the feasibility of follow-up of individual participants over 3 different time periods during their first enlistment.
(C) Described basic reproductive health behaviors including sexual activity, sexual partner information, contraceptive use, among others.
(D) Determined the prevalence rates for common STDs among Marine women recruits: C.trachomatis (11%), N.gonorrhoeae (2%), and T.vaginalis (2%).
(E) Evaluated the performance profiles of 3 different techniques for collecting STD specimens (endocervical, first part urine and self-administered vaginal swabs) and determined that vaginal or a combination of endocervical and vaginal detect the most infections and showed that the self-administered vaginal swabs had the highest performance for identifying chlamydia compared to the endocervix and urine specimens.
(F) Determined that self-administered vaginal swabs are acceptable to these young women.
(G) Determined that 92% of the Papanicolaou smears were entirely normal and 8% had evidence of HPV (human papillomavirus infection) with no cancer identified.
(H) Age, partner's race at last sex, perception that sexual partners had other partners, birth control use and STD related symptoms at baseline screening were associated with a STD diagnosis at baseline analyzing the data using logistic regression techniques.

6. REPORTABLE OUTCOMES

(A) Developed and produced a complete manual describing "how to" implement the FOCUS/FITNESS FOR LIFE interventions.

(B) Produced a skills building teaching video, "GOOD TO GO" as a part of this project which is used in the intervention training.

(C) Developed a computerized and manual system for tracking recruits throughout their first enlistment.

(D) Publications and presentations during past 12 months: (See Appendix 2):

Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. ISSTDR: Sexually Transmitted Infections 241-246, 2001.

Boyer CB, Shafer MA, Pollack L, Kraft H: Sexually transmitted disease acquisition in a national, non-clinical, diverse sample of young women: associations of sociodemographic, behavioral, and clinical factors. Proceedings of The Society of Behavioral Medicine's 22nd Annual Meeting, Seattle, Washington, March 21-24, 2001.

Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. ISSTDR: Sexually Transmitted Infections, Berlin, Germany, June 24-27, 2001.

Boyer CB, Shafer MA, Betsinger K, Shaffer RA, Brodine SK, Kraft H, Schachter J: Preventing HIV, STDs, and unplanned pregnancies in young women entering the US military: A cognitive-behavioral approach. 2001 National HIV Prevention Conference, Atlanta, Georgia, August 12-15, 2001.

7. CONCLUSIONS TO DATE:

(A) Implementation of an intense cognitive-behavioral intervention to decrease acquisition of STDs and unplanned pregnancy is possible within a military setting.

(B) Implementation of a universal STD and pregnancy screening program is possible within a military setting over time.

(C) Asymptomatic and undetected STDs especially C.trachomatis are common among young women Marines.

(D) Young women Marines are placing themselves at risk for acquisition of STDs and unplanned pregnancy by engaging in risky sexual behaviors including having unprotected sexual intercourse, having sexual intercourse with multiple partners, among other risky behaviors.

(E) It is critical to develop an annual universal STD screening program for STDs to be implemented immediately among young military women.

(F) Early findings of high rates of STDs and risky behaviors linked to STD acquisition and IUPs dictate that the implementation of an STD/IUP prevention program for young women Marines is essential to support combat readiness.

PROPOSED PROJECT ACTIVITIES: AUGUST 2001-JUNE 30, 2002

Description of the Proposed Extension of Contract Activities To Be Completed:

(A) Complete a second follow-up (T-3) on all of the participating women Marines.

1. All participants will be followed at their first duty station. Based on preliminary tracking assessments, we anticipate that we will be able to locate 100% study participants who are still enlisted in the Marine Corps. We estimate that 60% of the women will be in our three primary targeted sites (Jacksonville, NC, Southern CA, Okinawa, Japan). These women are contacted by the Site Coordinators (Brenda Zepeda and Alison Reade, CA, Richelle Balazs, NC, and Chrissie Ojeda, Japan) via telephone and scheduled for a follow-up clinic appointment to screen them for STDs, pregnancy, and to complete a self-report questionnaire (see Appendix 2 for a copy of the extensive protocol manual which describes these activities in detail).

2. Participants who are stationed at commands other than our three primary target sites, are contacted via a letter and are asked to complete a self-reported questionnaire. An attempt to also have them mail in a self-administered vaginal swab for chlamydial and gonococcal testing is also planned.

   This follow-up phase (T-3) of the study will be completed by November 2001 (see section "SOW" A-3 above, page 6).

(C) Evaluate the efficacy of the experimental (*FOCUS*) and control (*Fitness for Life*) intervention programs to prevent STDs and unplanned pregnancies.

1. Baseline Data (T-1)

   To date, all data related to the baseline STDs (chlamydia, gonorrhea, trichomonas, bacterial vaginosis), Well-Women's clinic visits records (e.g., cytopathology, STD-related symptoms), and self-reported questionnaires (e.g., knowledge, attitudes, beliefs and behavior related to reproductive health) have been collected, entered with initial analysis completed (see Brief, Appendix 1 and Abstracts of presentations, Appendix 2). A projected timeline for completion of all the clinical and biological data analysis is December 31, 2000.

2. Initial Follow-up Data (T-2)

   Collection of the initial follow-up data from MCT graduates is (T-2) is 100% complete. Data cleaning and descriptive statistics will be completed by December, 2001. Logistic regression statistical models that evaluate the 'short-term' efficacy of the *FOCUS-Fitness for Life* intervention program will be completed by February, 2002. Scientific, peer-reviewed journal articles and paper presentations will be written concurrently which describes these interim data.

Progress reports to the Department of the US Army will be written and disseminated concurrently. See Brief, Appendix 1 for initial descriptive T-2 data.

(3) Second Follow-up Data (T-3)

The second follow-up data collection completed. The data entry and statistical cleaning will be ongoing and will be completed by March 2002. Descriptive data analyses will also be ongoing and will be completed in April 2002. Evaluation of the 'long-term' efficacy of the *FOCUS-Fitness for Life* intervention program will require complex statistical comparisons of the baseline and second follow-up data, comparisons between intervention and control groups, and clustering effects by original platoons. These analyses will be completed by May 2002. Scientific, peer-reviewed journal articles, paper presentations, and progress reports to the US Department of the Army will be written and disseminated by June 30, 2002.

We anticipate that we will have reached approximately >70% of the women who completed T-1 with our T-3 follow up. Most of the women who will not be followed will have been discharged from the Marine Corps and some will have declined further participation in the study. This will include those women who completed both the questionnaire and clinical STD collection as well as those outside our "catchment" area study sites who filled out the questionnaire only by mail. This means that we will have reached our target population by December 30, 2001.

Most of the time from Janury 1, 2002-June 30, 2002 will be spent in the entering, cleaning, analysis and preparation of abstracts and manuscripts describing the findings from the entire study.

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Publications to Date from the Project

1. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. ISSTDR: Sexually Transmitted Infections 241-246, 2001.

2. Boyer CB, Shafer MA, Pollack L, Kraft H: Sexually transmitted disease acquisition in a national, non-clinical, diverse sample of young women: associations of sociodemographic, behavioral, and clinical factors. Proceedings of The Society of Behavioral Medicine's 22nd Annual Meeting, Seattle, Washington, March 21-24, 2001.

3. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. ISSTDR: Sexually Transmitted Infections, Berlin, Germany, June 24-27, 2001.

4. Boyer CB, Shafer MA, Betsinger K, Shaffer RA, Brodine SK, Kraft H, Schachter J: Preventing HIV, STDs, and unplanned pregnancies in young women entering the US military: a cognitive-behavioral approach. 2001 National HIV Prevention Conference, Atlanta, Georgia, August 12-15, 2001.

Appendices

Appendix 1: FOCUS Brief, 2001

Appendix 2: Publications and Presentations During the Past 12 Months

a. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. ISSTDR: Sexually Transmitted Infections 241-246, 2001.

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Appendix 1

FOCUS Brief, 2001

FOCUS

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BACKGROUND AND SIGNIFICANCE

- Sexually experienced women, ages 15-24 years, have higher rates of *C. trachomatis* and *N. gonorrhoeae* than any other age group.
- These infections pose serious health concerns for young women because of their association with adverse reproductive health outcomes such as pelvic inflammatory disease, tubal infertility, ectopic pregnancy, and increased risk of exposure to HIV.
- The risk of exposure to STDs is the result of complex interrelationships among sociodemographic risk markers and behavioral risk factors.
- Much of what is known about these factors is reported from STD and family planning clinics. Such groups may overestimate the prevalence of STDs in young women.
- Women entering recruit training for military service represents a more ideal national, non-clinical cross-section to assess the prevalence of STDs in young women.

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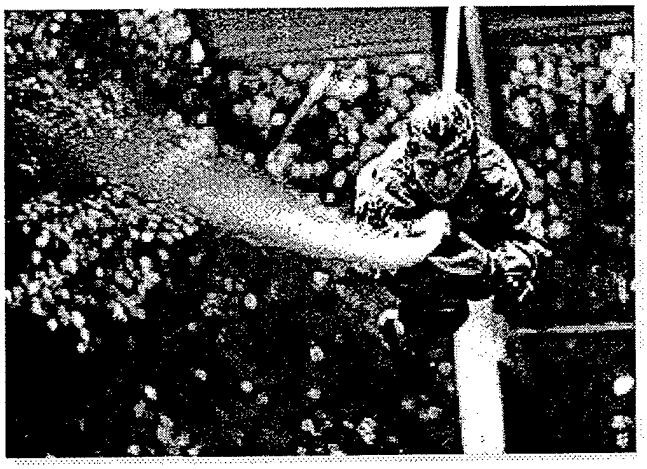
Until now, the Marine Corps has taught only two methods of contraception...

FOCUS

...on the choices you make now that will effect your future and career



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PROGRAM OBJECTIVE

To evaluate the feasibility and effectiveness of a cognitive-behavioral intervention to prevent and reduce the risk of HIV/STDs and unplanned pregnancies (UIPs) in young women from throughout the United States entering recruit training for the military.

STUDY DESIGN

Recruit Training Baseline T1	MCT Initial Follow – up T2	First Duty Station Second Follow-up T3
Recruitment Questionnaire STD/Pregnancy Screen Programs "FOCUS" "Fitness for Life"	Questionnaire STD/Pregnancy Screen	Questionnaire STD/Pregnancy Screen

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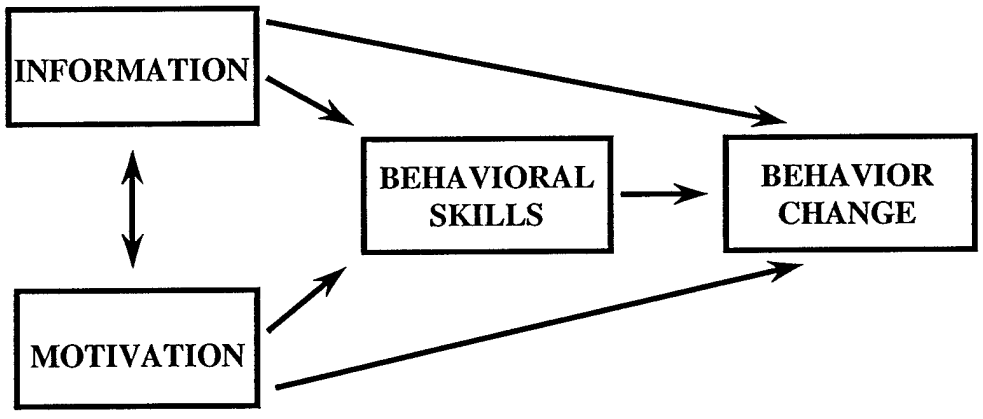
PROGRAM OVERVIEW

- Approach
  - Information
  - Cognitive-Behavioral Processes
  - Skills-Building Techniques
- Strategies
  - Didactic Slides
  - Interactive Group Exercises
  - Military-Specific Videos
- Format (Small Groups)
  - 4, Two-hour Sessions

IMB MODEL



Fisher and Fisher, 1992; 1996

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EXPERIMENTAL INTERVENTION: "FOCUS" CURRICULUM GOALS

- Educate participants about the risk and impact of unplanned pregnancies, STDs and HIV.
- Provide participants with factual information about effective methods of contraception and STD outcomes.
- Familiarize participants with the basics of a GYN exam and the female reproductive anatomy.

"FOCUS" CURRICULUM GOALS

- Develop participants' communication and decision-making skills regarding sexual behaviors and use of contraception.

- Provide participants with information about the effects of alcohol use.

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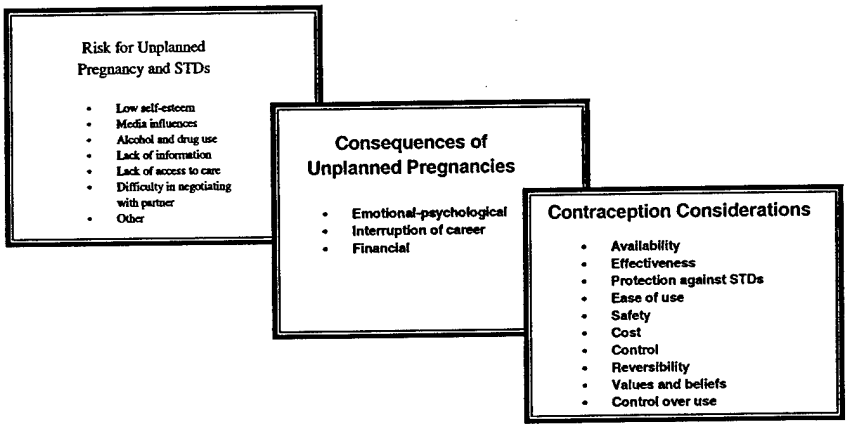
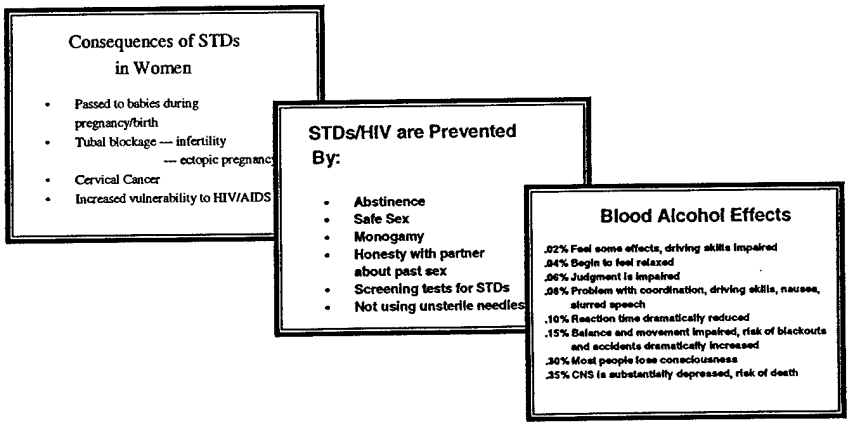
"FOCUS"

EXAMPLES OF DIDACTIC INFORMATION



"FOCUS"

EXAMPLES OF DIDACTIC INFORMATION



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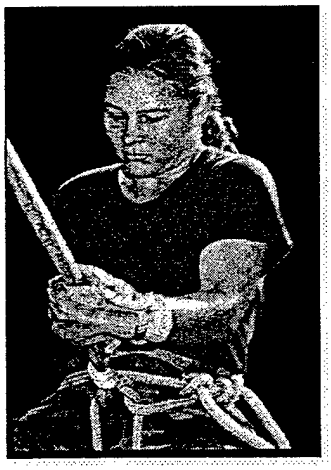
"FOCUS"
EXAMPLE OF A ROLE-PLAY EXERCISE

"Let's talk about sex and contraception"

"Imagine that you are in the beginning weeks of a new relationship. You really like this guy a lot and think this relationship has the potential to develop into something special. But you want it to be different than previous relationships. You've promised yourself that in any new relationship you will start off by being open and honest in talking about sex before you're in the heat of the moment. You also realize that beginning the conversation is difficult and a little scary. What do you say?"

CONTROL INTERVENTION
"FITNESS FOR LIFE" CURRICULUM GOALS

- Improve participants' physical performance through healthier food choices.
- Reduce participants' risk of sports/physical training injuries.
- Examine the risk and prevention of cervical and breast cancer.



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METHODS

- All women recruits between June 1999 and June 2000 were approached to participate in the study.
- 95% of women voluntarily agreed to participate either in the cognitive-behavioral, skills-building intervention (FOCUS) to prevent unplanned pregnancies and STDs or a nutrition and fitness program (Fitness for Life). Assignments to the programs were random.
- The participants completed a self-administered questionnaire and were screened for asymptomatic *C. trachomatis*, *N. gonorrhoeae*, *T. vaginalis* and pregnancy at baseline, and two follow-up periods.

SELF-REPORTED QUESTIONNAIRE

Sociodemographic Risk Markers

- Age
- Race/Ethnicity
- Marital Status
- Education
- Geographic Residence
- Sexual partner's age
- Sexual partner's race/ethnicity

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SELF-REPORTED QUESTIONNAIRE

Behavioral Risk Factors

- Age at sexual debut
- Number of sexual partners
- Number of casual partners
- Frequency of birth control
- Frequency of condom use
- Frequency of alcohol and substance use
- Frequency of sex under the influence of alcohol and substance use
- Frequency of contraception use at last sex
- Perception that sex partners had a history of STDs
- Perception that sex partners had other partners

UCSF

SELF-REPORTED QUESTIONNAIRE

Clinical Risk Factors

- History of pregnancy
- History of STDs
- Vaginal symptoms at screening

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STD SCREENING

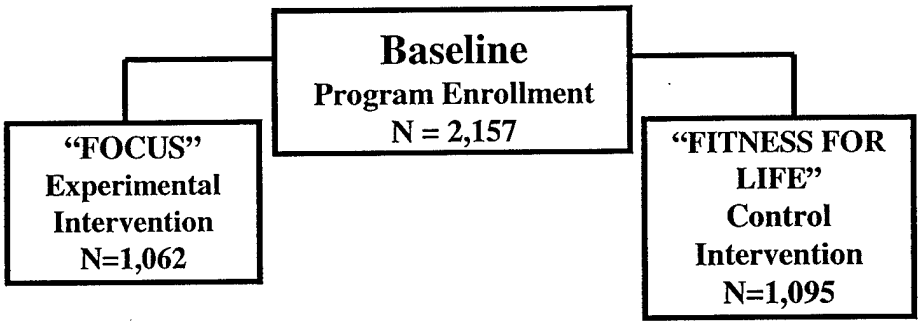
C. trachomatis and *N. gonorrhoeae*

- Participants provided 20-25 ml of first catch urine (FCU), self-administered vaginal swabs, and clinician collected cervical swabs for LCx tm processing (Abbott Laboratories).

T. vaginalis

- A self-administered vaginal swab was processed using In-Pouch TV tm (Biomed Laboratories).

GROUP ASSIGNMENT



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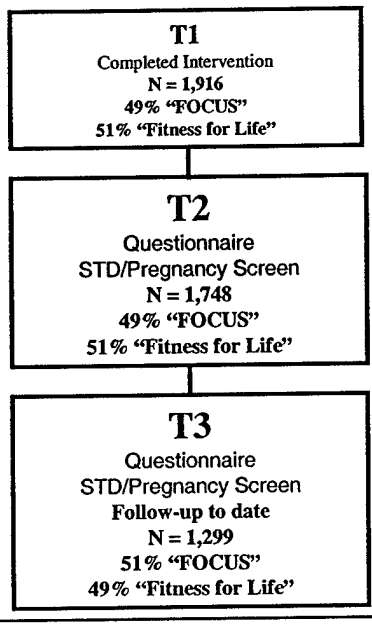
INTERVENTION & FOLLOW-UP



BASELINE RESULTS

Sociodemographic Markers

Age	
17-18	52%
19-20	32%
≥ 21	16%
Race/Ethnicity	
Caucasian	57%
Latina	20%
African American	17%
Asian/PI/Native American	6%

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SOCIODEMOGRAPHIC MARKERS

Marital Status	
Single	92%
Married	8%
Level of Education	
High School Diploma/GED	73%
College/Vocational School	27%
Geographic Residence	
Urban	78%
Rural	22%
Years of sexual experience	
≤1	26%
≥2	74%

SOCIODEMOGRAPHIC MARKERS

Age of Last Sexual Partner	
≤20	49%
21-23	25%
≥24	26%
Sexual Partner's Race/Ethnicity	
Caucasian	58%
Latino	19%
African American	19%
Asian/PI/Native American	4%

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BEHAVIORAL RISK FACTORS (LIFETIME)

Sexual Partners	
1	18%
> 2	82%
Casual Partners	
1-2	34%
>3	66%
Frequency of Birth Control	
Never/Almost Never	20%
Sometimes	13%
Usually/Always	67%
Condom Use	
< 100%	78%
100%	22%

BEHAVIORAL RISK FACTORS (PRIOR 3-MONTHS)

Sexual Partners	
1	88%
≥ 2	12%
Casual Partners	
0-1	89%
≥2	11%
Frequency of Birth Control	
Never/Almost Never	30%
Sometimes	9%
Usually/Always	61%
Condom Use	
Never	26%
< Always	47%
Always	27%

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BEHAVIORAL RISK FACTORS (PRIOR 3-MONTHS)

Heavy Drinking	
Yes	14%
No	86%
Substance Use	
Yes	6%
No	94%
Sex Under the Influence of Alcohol/Substances	
Never	43%
Almost Never/Sometimes	46%
Usually/Always	11%

BEHAVIORAL RISK FACTORS (PRIOR 3-MONTHS)

Sexual Partner's Risk	
Perception of STD history	25%
Perception of other partners	18%
Do not perceived partner to be at risk	57%

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CLINICAL RISK FACTORS

History of Pregnancy	16%
History of STDs	11%
Vaginal Symptoms at Screening	24%

PROGRAM SUMMARY TO DATE

- Although it is too soon to evaluate the effectiveness of the intervention, our baseline findings of a high prevalence of sexual risk factors and STDs in this national, non-clinical sample of young women suggest the need for ongoing comprehensive interventions that integrate STDs, HIV, and UIPs into a single program.
- Such programs should include STD screening and behavioral risk reduction and should also target young women recruits.

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AFTER YEARS OF FITTING IN, MAYBE IT'S TIME TO STAND OUT.

BASELINE STD SCREENING

Source	Microbe	Processed
Urine	CT, GC	UCSF
Vaginal	CT, GC, TV	UCSF, Navy
Cervical	CT, GC	UCSF, Navy
Pap smear	HPV	Navy

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BASELINE STD PREVALENCES

STD	Source	
Chlamydia*	Cx, Ur, Vag	11%
Gonorrhea*	Cx, Ur, Vag	2%
Trichomonas**	Vag	2%
Total	**Any**	**13%**

* by LCx^{R}
** by Trich-In-Pouch^{R} (self-swab)

PREVALENCES OF CHLAMYDIA* BY SPECIMEN

Any positive	11 %
Endocervix	7 %
Urine	8 %
Vagina*	9 %

* Self-administered vaginal swab

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CHLAMYDIA SENSITIVITY BY SPECIMEN

Endocervix	66 %
Urine	73 %
Vagina*	82 %
Endocervix or urine	87 %
Endocervix or vagina*	93 %
Vagina or urine	94 %

* Self-administered vaginal swab

PREVALENCES OF GONORRHEA BY SPECIMEN

Any positive	2 %
Endocervix	1 %
Urine	0.5 %
Vagina*	2 %

* Self-administered vaginal swab

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GONORRHEA SENSITIVITY BY SPECIMEN

Endocervix	49 %
Urine	27 %
Vaginal*	74 %
Endocervix or urine	57 %
Endocervix or vagina*	100 %
Vagina* or urine	79 %

* Self-administered vaginal swab

PAP SMEAR DIAGNOSES*

Normal**	92 %
Abnormal	8 %

* 3% unsatisfactory or no cells
** inflammation, repair, etc.

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ABNORMAL PAP SMEAR DIAGNOSES*

HPV-related	
• atypia, koilocytes	6%
• SIL, low grade	2%
SIL High grade	0.4%
Cancer (in situ)	0%

* Abnormal Paps = 8% of all Paps

FACTORS ASSOCIATED WITH ABNORMAL PAP SMEAR DIAGNOSES

- 4 or more lifetime partners
- < 20 years old
- Condom use < 100 %
- Positive chlamydia test

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T2 CLINICAL RESULTS MCT

Any positive STD	4.0 %
Chlamydia	3.0 %
Gonorrhea	0.5 %
Trichomonas	0.4 %
Pregnancy Test (+)	0.4 %

T2 STD RESULTS MCT

FOCUS	20 (4 %)
FITNESS	31 (6 %)

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T2 PREGNANCY RESULTS MCT

FOCUS	4 (0.8 %)
FITNESS	4 (0.8 %)

T1 CLINICAL FINDINGS

- Feasible to screen for CT and GC by urine
- STDs are epidemic among recruits (13%)
- Pap smears do not yield major pathology

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RECOMMENDATIONS AND FINDINGS TO DATE

- Continue WWC STD screening
- Repeat urine STD screening at end of MCT
- Reassess the utility of universal Pap smear screening
- FOCUS program shows promise for decreasing STDs and pregnancy between recruit training and MCT

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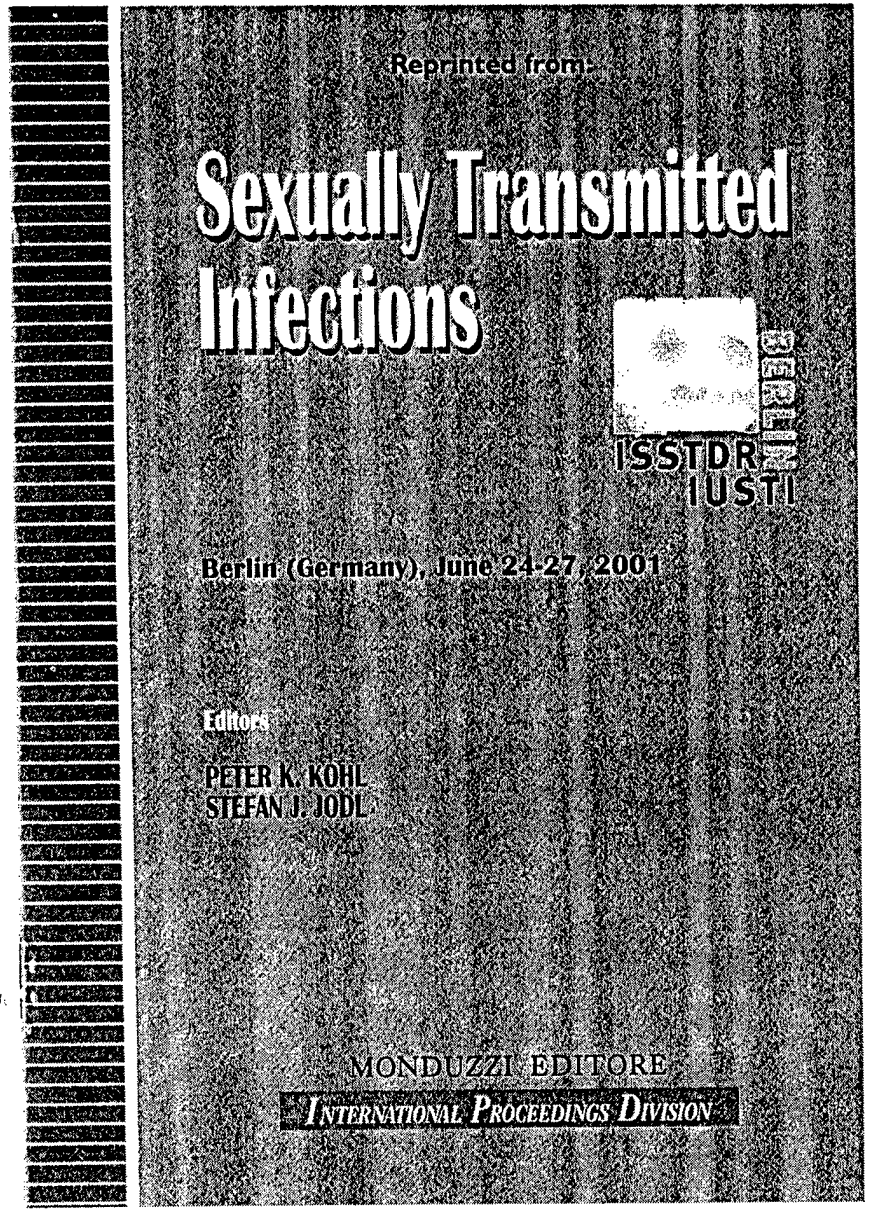
Appendix 2

Publications and presentations during the past 12 months

a. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. ISSTDR: Sexually Transmitted Infections 241-246, 2001.



Sociodemographic, Behavioral, and Clinical Factors Associated With STDs in a National Sample of Women Entering the US Military

C.B. Boyer[1,2], M.A. Shafer[1,2], J. Moncada[1,3], J. Schachter[1,3], R.A. Shaffer[4] and S.K. Brodine[4,5]

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Summary

STDs are epidemic among sexually active young women in the U.S.[1,2] Although research exists linking risk factors to STDs in young women, most studies were conducted in clinic-based samples of women seeking reproductive health care.[3,4,5] The purpose of this study was to determine the role of sociodemographic risk markers, behavioral risk, and clinical factors to acquisition of STDs in women from throughout the U.S. entering military recruit training. Risk factors (in the 3 months prior to the study) that were significantly associated with acquisition of STDs included age, geographic location of residence, ràce/ethnicity of the most recent sexual partner, inconsistent use of birth control, and vaginal symptoms. The high prevalence rates of STDs in this national, non-clinical sample of young women suggest the need for ongoing prevention interventions including STD screening and behavioral risk reduction programs that target non-college students.

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Introduction

Sexually experienced women, ages 15-24 years, have higher rates of chlamydia (CT) and gonorrhea (GC) than any other age group.[1] These infections pose serious health concerns for young women because of their association with adverse reproductive health outcomes such as pelvic inflammatory disease, tubal infertility, ectopic pregnancy, and increased risk of exposure to HIV.[1,2] The risk of exposure to STDs is the result of complex interrelationships among sociodemographic risk markers and behavioral risk factors. Much of what is known about these factors is reported from STD and family planning clinics.[3,4,5] These data may overestimate the prevalence of STDs in young women. Women entering recruit training for military service represents a more ideal national, non-clinical cross-section to assess the prevalence of STDs in this group.

Methods

Procedures

All women recruits (N= 2288) between June 1999 and June 2000 were approached to participate in the study. A total of 2157 (95%) women voluntarily agreed to participate either in a cognitive-behavioral, skills-building intervention to prevent unplanned pregnancies and STDs or a nutrition and fitness program. Assignments to the programs were random. At baseline, prior to the intervention, the participants completed a self-administered questionnaire and were screened for asymptomatic CT, GC, and trichomonas vaginalis (TV).

Questionnaire

The questionnaire included queries on sociodemographic risk markers (age, race/ethnicity, marital status, education, geographic residence, sexual partner's age and race/ethnicity); behavioral risk in 3 months prior to the survey (number of primary and casual sexual partners, frequency of birth control use, condom use, alcohol/substance use, sex under the influence of alcohol/substance use, perceived STD risk of sexual partners; and clinical risk factors (history of pregnancy, STDs, and vaginal symptoms at screening).

STD Screening

C. trachomatis and *N. gonorrhoeae* were tested applying LCx™ to FVU samples and self-administered vaginal swabs. Specimens were frozen to –70°C within 24 hours of collection and transported to an author's research laboratory (Schachter) while maintaining the cold chain. Specimens were processed as previously described.[6] A self-administered vaginal swab for *T. vaginalis* was immediately inoculated into the In-Pouch TV™ (Biomed Laboratories) and read at 2 and 5 days.

Data Analyses

All statistical analyses were performed using data from study participants who self-reported as having had sexual intercourse (n=1826). Conventional descriptive statistics were used to assess the characteristics of the participants. Bivariate comparisons between participants who were STD positive and STD negative were made using X^2 test of differences in proportions. To determine the best model for predicting an STD diagnosis, the variables (based on the prior 3 months) that were significantly associated with diagnosis of an STD at the bivariate level ($p \leq .10$) were entered into a logistic regression equation then subjected to a backward stepwise procedure, using an iterative process. Criterion for retention in the model was a likelihood ratio test with a p-value ≤ 0.05.

Results

The participants were young women (mean age = 19.2 years) of diverse racial/ethnic background (58% Caucasian, 20% Latina, 17% African American, 6% Other) who were largely from urban settings (78%). These women were primarily single (92%), sexually experienced (85%) and at risk for STDs; 16% had a history of pregnancy and 11% had a history of STDs. In the 3 months prior to the study, 12% had ≥2 primary partners, 11% had ≥2 casual partners, 57% used alcohol/substances before/during sex, 39% rarely or never used birth control and 73% did not use condoms consistently; 18% perceived their partners had other partners. At screening, 24% had vaginal symptoms, and 13% were positive for an STD (11% *C. trachomatis*, 2% *N. gonorrhoeae*, 2% *T. vaginalis*).

Conclusions

This cohort of young women entering the military commonly reported

Table 2. Significant Factors Associated with an STD Diagnosis: A 3-Month Model

Variable	Odds Ratio	95% C.I.
Age (19-20)^		
17-18 years	1.53	1.05-2.23
21+	1.97	1.21-3.21
Geographic Residence (Urban)^		
Rural	1.61	1.12-2.32
Race/Ethnicity Last Sex Partner (Caucasian)^		
Latino	1.47	0.94-2.33
African Americans	4.73	3.29-6.79
Asian/PI	2.02	0.44-9.30
Native American	2.20	0.87-5.60
Birth Control Use (Usually/Always)^		
Never/Almost Never	1.25	0.88-1.78
Sometimes	1.99	1.21-3.26
Perception that Sex Partner Had Other Partners (No)^		
Yes/Possible	1.40	1.02-1.93
Vaginal Symptoms At Screening (No)^		
Yes	1.50	1.07-2.11

^Reference Group

Table 1. Bivariate Associations Between Sociodemographic, Behavioral, and Clinical Factors with STD Diagnosis

Risk Variable	3-Month Model X^2
Age	6.92*
Race/Ethnicity	63.76***
Marital Status	2.79*
Education	0.00
Geographic Location	3.89*
Sexual Partner's Age	1.91
Sexual Partner's Race	87.30***
Sexual Partners	4.32*
Casual Partners	0.52
Birth Control Use	8.78*
Condom Use	2.39
Heavy Alcohol Use	1.17
Substance Use	1.26
Sex Under the Influence Of Alcohol/Substances	1.74
Perception that Sex Partner Had Other Partners	9.32**
Perception that Sex Partner Had STDs	5.14*

***p<0.001; **p<0.01; *p<0.05

risky sexual behaviors. A high prevalence of STDs (CT, GC, TV) was diagnosed among these women, including 76% asymptomatic infections. The risk factors associated with STD infections identified in this study are consistent with those reported in the current literature.[3,4,5] The 3-month STD risk model provide insight into factors that place these young women at risk for STDs including having an African American sexual partner, having the perception that their sexual partner have/may have other concurrent sexual partners, and inconsistently using birth control. Our findings on the association of African American race and STDs are consistent with current national surveillance data on STDs.[1] Recent research suggest that African Americans' increased risk of STDs may be, in part, related to a higher prevalence of STDs among their sexual partners who are older and at higher risk, and who may be a part of geographic "core groups" within which there is a high prevalence of STDs.[7] Many of these young women are engaging in risky sexual behaviors that may lead to major STD-related reproductive morbidity such as ectopic pregnancy and infertility. Ongoing STD prevention interventions are needed to address risk factors that are amenable to change such as choice of sexual partners, use of effective birth control, and seeking appropriate reproductive health care, especially for detection and treatment of asymptomatic STDs.

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1. Division of STD Prevention. Sexually Transmitted Disease Surveillance, 1999. Department of Health and Human Services. Atlanta: Centers for Disease Control and Prevention (CDC), September 2000;1-133.
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b. Boyer CB, Shafer MA, Pollack L, Kraft H: Sexually transmitted disease acquisition in a national, non-clinical, diverse sample of young women: associations of sociodemographic, behavioral, and clinical factors. Proceedings of The Society of Behavioral Medicine's 22nd Annual Meeting, Seattle, Washington, March 21-24, 2001.

Sexually transmitted disease acquisition in a national, non-clinical, diverse sample of young women: Associations of sociodemographic, behavioral, and clinical factors

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[1]University of California, San Francisco, [2]Department of Pediatrics, Division of Adolescent Medicine, 3333 California Street, San Francisco, CA 94143-0503;
[3]Center for AIDS Prevention Studies; [4]Naval Health Research Center, San Diego, CA

Purpose: To determine the relationship of sociodemographic risk markers, behavioral risk, and clinical factors to acquisition of sexually transmitted diseases (STDs) in a national sample of women entering recruit training for the military.

Methods: 2,157 women (mean age = 19.2 years) of diverse racial/ethnic background (Caucasian 58%, Latino 20%, African American 16%, Other 6%) voluntarily participated in a cognitive-behavioral intervention to prevent unplanned pregnancies and STDs. At baseline, participants were screened for STDs and completed a self-reported questionnaire to assess sociodemographic risk markers (age, race/ethnicity, marital status, education, sexual partner characteristics), behavioral risk (age of sexual debut, number of sexual partners, casual sex, use of birth control), and clinical factors (history of pregnancy and STDs, STD-related symptoms).

Results: Participants were primarily single (90%), sexually experienced (85%), and at risk for STDs: 82% had ≥ 2 sexual partners, 16% had a history of pregnancy and 12% had STDs. Many participants used alcohol/substances during/before sex (57%), and did not consistently use birth control (56%) or condoms (73%); 48% perceived their partners had other partners and 18% believed their partners had STDs. At screening, 24% had vaginal symptoms, and 13% were positive for an STD (11% chlamydia). Variables assessed in the three months prior to the study that were associated ($p < .10$) with an STD diagnosis at the bivariate level entered into a backward, stepwise logistic regression equation ($p < .05$). The results indicate that age [$\leq$18 years (OR=1.53, CI =1.05-2.24) or $\geq$21 years (OR = 1.81, CI = 1.11-2.95)], partner's race at last sex [African American (OR= 4.44, CI = 3.11-6.34)], perception that their sexual partners had other partners (OR = 1.43, CI =1.04-1.97), birth control (OR = 1.92, CI = 1.17-3.15), and STD-related symptoms at screening (OR = 1.51, CI = 1.07-2.12) were associated with an STD diagnosis.

Conclusions: These findings from a national, non-clinical sample of young, ethnically diverse women suggest the need ongoing prevention interventions, including behavioral risk reduction programs and STD screening which target non-college bound students.

c. Boyer CB, Shafer MA, Moncada J, Schachter J, Shaffer RA, Brodine SK: Sociodemographic, behavioral, and clinical factors associated with STDs in a national sample of women entering the US military. ISSTDR: Sexually Transmitted Infections, Berlin, Germany, June 24-27, 2001.

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Abstract Number
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Abstract Submittal Form

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- ☐ Track D. Prevention strategies
- ☒ Track E. Behavioural science

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PART 3

Type Abstract within the rectangle on this form.

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SOCIODEMOGRAPHIC, BEHAVIORAL, AND CLINICAL FACTORS ASSOCIATED WITH STDS IN A NATIONAL SAMPLE OF WOMEN ENTERING THE US MILITARY

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Objective: To determine the relationship of sociodemographic risk markers, behavioral risk, and clinical factors to acquisition of STDs in women from through out the United States entering recruit training for the military. **Methods:** Participants were screened for chlamydia and gonorrhea using LCx™ applied to urine, vaginal swabs, and cervical specimens, and trichomonas using InPouch TV™. Participants also completed a self-reported questionnaire to assess sociodemographic risk markers (age, race/ethnicity, marital status, education, sexual partner characteristics), behavioral risk (e.g., number of sexual partners, casual sex, use of birth control), and clinical factors (history of pregnancy and STDs, STD-related symptoms). **Results:** The participants were 2,157 women (mean age = 19.2 years) of diverse racial/ethnic background (Caucasian 58%, Latino 20%, African American 16%, Other 6%) who were primarily single (90%), sexually experienced (85%) and at risk for STDs, 16% had a history of pregnancy and 12% had STDs. In the three months prior to the study, 29% had ≥2 partners, 57% used alcohol/substances before/during sex, 56% did not use birth control and 73% did not use condoms consistently; 48% perceived their partners had other partners. At screening, 24% had vaginal symptoms, and 13% were positive for an STD (11% chlamydia, 2% gonorrhea, 2% trichomonas). Sociodemographic risk markers, behavioral risk in the three months prior to the study, and STD-related symptoms were entered into a backward stepwise logistic regression. Age [≤18 vs. 19-20 (OR=1.53, CI =1.05-2.24); ≥21 vs. 19-20 (OR = 1.81, CI = 1.11-2.95)], partner's race at last sex [African American vs. White (OR= 4.44, CI = 3.11-6.34)], perception that their sexual partners had other partners (OR = 1.43, CI =1.04-1.97), frequency of birth control [Usually/Always vs. Almost Never/Never (OR = 1.92, CI = 1.17-3.15)], and presence of STD-related symptoms at screening (OR = 1.51, CI = 1.07-2.12) were significantly associated ($p<.05$) with an STD diagnosis. **Conclusions:** The high prevalence of STDs in this national, non-clinical sample of young women suggest the need for ongoing prevention interventions, including STD screening and behavioral risk reduction programs that target non-college students.

PART 4

The author affirms that the material submitted has not been previously published at any national or international meeting; any experimentation has been conducted according to a protocol approved by the institutional committee on ethics or, if no such committee exists, that it conforms with the principle of the Declaration of Helsinki of the World Medical Association (Clinical Research 14:193; 1966). The undersigned also certifies that all authors named in the abstract have agreed to its submission for presentation at the International Congress of Sexually Transmitted Infections, June 24 – 27, 2001.

Author's Signature Cherie Boyer, PhD Date 1/12/01

d. Boyer CB, Shafer MA, Betsinger K, Shaffer RA, Brodine SK, Kraft H, Schachter J: Preventing HIV, STDs, and unplanned pregnancies in young women entering the US military: A cognitive-behavioral approach. 2001 National HIV Prevention Conference, Atlanta, Georgia, August 12-15, 2001.

Title: Preventing HIV, STDs, and unplanned pregnancies in young women entering the U.S. Military: A cognitive-behavioral approach

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Issues: Young, single, sexually experienced women are at risk for HIV/STDs, and unplanned pregnancies (UIPs). Research has shown that HIV/STD prevention interventions based on cognitive-behavioral principles are effective strategies for building skills and/or modifying behaviors associated with these health outcomes.

Setting: The goal is to evaluate the feasibility and effectiveness of a cognitive-behavioral intervention to prevent and reduce the risk of HIV/STDs and UIPs in young women from throughout the United States entering recruit training for the military.

Project: A randomized control trial assessing pre- and post-intervention measures of sexual behavior, STDs, and UIPs, is utilized to evaluate the intervention. The intervention's development was guided by the Information, Motivation, and Behavioral Skills (IMB) Model (Fisher and Fisher, 1992). It consisted of 4, 2-hour interactive and didactic group sessions that focused on: information about the prevention and risk factors associated with HIV/STDs, and UIPs, female anatomy, effective contraceptive methods, and use of alcohol and other substances; psychosocial factors (motivation) such as peer norms, self-efficacy, behavioral intentions; and skills-building strategies to enhance communication and problem-solving skills. The control condition was conducted in a similar manner and focused on improving the participants' physical performance through promoting healthier food choices and preventing physical training injuries.

Results: Of the 2288 women approached, 2157 (94%) voluntarily agreed to participate; 1062 (49%) and 1095 (51%) were assigned, by platoons (groups of 50-60 women), to the intervention and control conditions, respectively. The participants were primarily young, (mean age=19.2 years), single (90%), of diverse racial/ethnic backgrounds (Caucasian 58%, Latino 20%, African American 16%, Other 6%), and sexually experienced (85%). At baseline, the participants were at risk for STDs: 59% initiated sex at $\leq$16 years of age, 82% had $\geq$ 2 sexual partner; 16% had a history of pregnancy and 12% had STDs. In the three months prior to the study, 29% had $\geq$2 partners, 57% used alcohol/substances before/during sex, 56% did not use birth control, and 73% did not use condoms consistently; 48% perceived their partners had other partners. At screening, 24% had vaginal symptoms and 13% were positive for an STD (11% chlamydia, 2% gonorrhea, 2% trichomonas). To date, we have followed 803 (51% intervention) participants at 9-11 months post intervention. This number reflects 42% of the 1912 individuals who completed the program; 49 (3%) have declined further participation and 95 (5%) have been lost to follow-up.

Lessons Learned: Although it is too soon to evaluate the effectiveness of the intervention, our baseline findings of a high prevalence of sexual risk factors and STDs in this national, non-clinical sample of young women suggest the need for ongoing comprehensive interventions that integrate STDs, HIV, and UIPs into a single program. Such programs should include STD screening and behavioral risk reduction and should also target non-college populations.