

# Inferility

## Prevention Program

Region II

Summer 2004

Newsletter

## Self Administered Vaginal Swabs (SAS)

By Charlotte A. Gaydos, Dr.P.H., Associate Professor, Johns Hopkins University

### Synopsis of SAS Issues

Self administered vaginal swabs offer advantages over traditional methods and **yield similar prevalence rates** for chlamydia and other STDs ...

The need to develop acceptable and easily available techniques for diagnosing sexually transmitted diseases for all high-risk populations is significant. Self administered vaginal swabs (SAS) yield similar prevalence rates for chlamydia and other STDs compared with standard diagnostic tests, when they are tested by the highly sensitive nucleic acid amplification tests (NAATs). This method offers advantages over traditional testing methods in that an adolescent could pick up a test kit, sample herself at home, and mail in the swab for testing. Privacy, often very important to adolescents, can be enhanced, since the patient does not have to visit a clinician. Since adolescents are at the highest risk for chlamydia infection, this is encouraging news.

Because physical examinations are not required for the collection of SAS, use of these specimens has expanded the venue in which individuals can seek screening for chlamydia. Routine approaches to STD diagnosis require gynecologic pelvic examination among women. Previously, symptomatic persons or contacts of infected patients would be the only persons seeking care for STDs, usually at a STD clinic or family planning clinic. Since chlamydia infections are mostly asymptomatic, traditional approaches

to clinic-based diagnosis of chlamydia leaves a whole segment of the population that would not ordinarily get tested. Thus, use of self-obtained specimens for chlamydia testing, which employ NAATS, has enhanced the use of non-traditional sites for screening programs because a clinician is not required to obtain the specimens.

SAS have performed as well as or better than clinician-obtained endocervical swabs to diagnose either chlamydia or gonococcal infections using DNA amplification assays. There appears to be no difference in detection rates whether the patient or the clinician collects the vaginal swab. One study demonstrated that self-collected tampons could be used in addition to SAS. Use of self-sampling also detected a higher prevalence of pathogens than conventional microscopy and culture, while another reported a sensitivity of 91.8% for patient-obtained vaginal swabs compared to 89.8% for clinician-obtained cervical swabs for detection of chlamydia by LCR. A higher prevalence of pathogens was detected in military women using a single SAS than did convention STD clinic protocols in military women. A vaginal swab that was transported to the laboratory in a "dry" state was demonstrated to be as accurate for the detection of

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Screening on the basis of age **(less than 25 years)** appears to be effective even in areas where the prevalence of chlamydia is low to moderate **(3-6%)**

## Clinical Review of Chlamydia Screening Issues

*Summarized by Erica Schachne, MPA, Program Associate, Cicatelli Associates Inc.*

There continues to be uncertainty regarding whom to screen for chlamydia and how frequently to do so. There is little evidence of the effectiveness of screening in asymptomatic women who are not in high-risk groups. Screening on the basis of age (less than 25 years) appears to be effective even in areas where the prevalence of chlamydia is low to moderate (3-6%). In a longitudinal cohort study of screening in 3,202 high-risk, inner-city young women, chlamydia was detected in 24.1%; the median time to new infection was slightly more than 7 months, and the median time to a repeated positive test was 6.3 months. On the basis of these results, it was recommended that all young, sexually active women be screened every six months.<sup>1</sup> Evidence from randomized trials is lacking regarding the effectiveness of screening and treatment of pregnant women in populations with a low prevalence of chlamydia.

Given the high prevalence of asymptomatic infections in the population, some experts advocate for the routine screening of young men as the next important step toward reduced rates of prevalence and complications. Although there is strong evidence that treatment can eradicate chlamydia in men, there are no studies demonstrating that screening asymptomatic men can reduce the rates of acute infection and adverse outcomes in men or women. While cost-effectiveness

analyses have suggested that there is an economic benefit to society in screening high-risk women, the cost effectiveness of screening men and low-risk women is debatable and will depend upon factors such as the ease and cost of specimen collection, the cost of testing, and the short- and long-term adverse outcomes that are prevented. Additional research is needed to determine the optimal interval between screenings and to compare the universal screening of all sexually active women younger than 24 years old with screening based upon the presence of additional risk factors in populations with a range of prevalence rates.

It remains uncertain whether the routine use of urine specimens or patient-collected specimens would improve compliance with testing and treatment. In addition, it is unclear whether the empirical treatment of the sexual partners of positive patients is preferable to the screening of these partners. Some experts suggest that providing patient-delivered therapy for their partners will reduce the rate of re-infection, but this hypothesis remains unproven.

### Conclusions and Recommendations

Chlamydia screening is indicated in sexually active women with risk factors for this infection, including:

- Age of less than 25 years;
- Inconsistent use of barrier contraceptives;

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- A new sexual partner;
- More than one sexual partner;
- Cervical ectopy; and
- A history of or coexisting sexually transmitted disease.

Annual screening is reasonable, although more frequent testing may be indicated in areas of high prevalence or in women with several risk factors.

Information on prevalence can often be obtained from microbiology laboratories, and the use of barrier contraception such as condoms should be discussed with all patients. Re-screening is recommended when patients present for care within a year after a positive test.

Timely treatment of the patient's sexual partners is also essential in order to reduce the risk of re-infection. The sexual partners should be evaluated, tested and treated if they have had sexual contact with the patient during the 60 days preceding the diagnosis. Treatment for sexual partners that is delivered by the patient for the prevention of repeated infection has efficacy similar to that of self-referral and is a reasonable approach.<sup>2</sup>

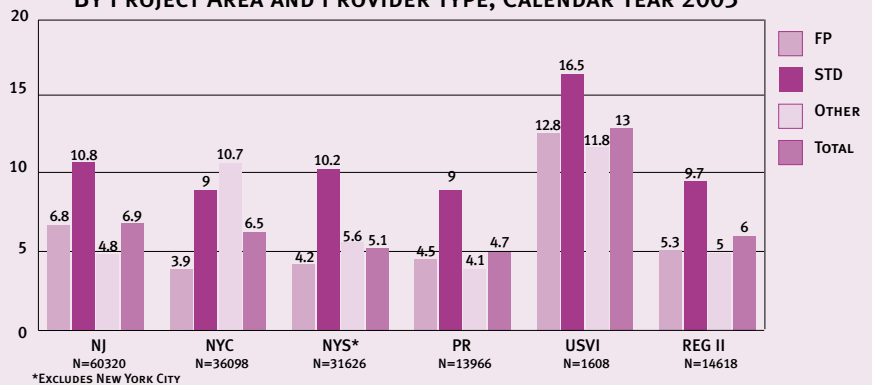
To read this article in its entirety, please visit: [www.cicatelli.org/ipp/resource.htm](http://www.cicatelli.org/ipp/resource.htm)

1. It is unclear, however, whether these findings can be generalized to populations with a lower prevalence of infection.

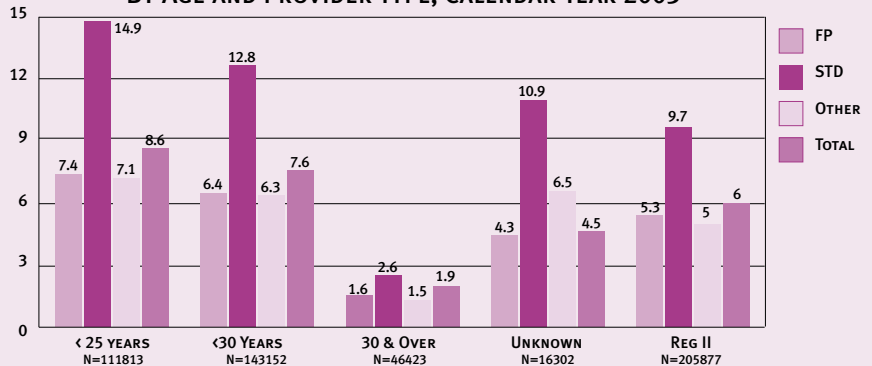
2. However, partner-delivered therapy is not legal in all fifty states, and is in fact illegal in all states and territories in Region II.

## REGION II INFERTILITY PREVENTION PROJECT WOMEN TESTING POSITIVE FOR CHLAMYDIA

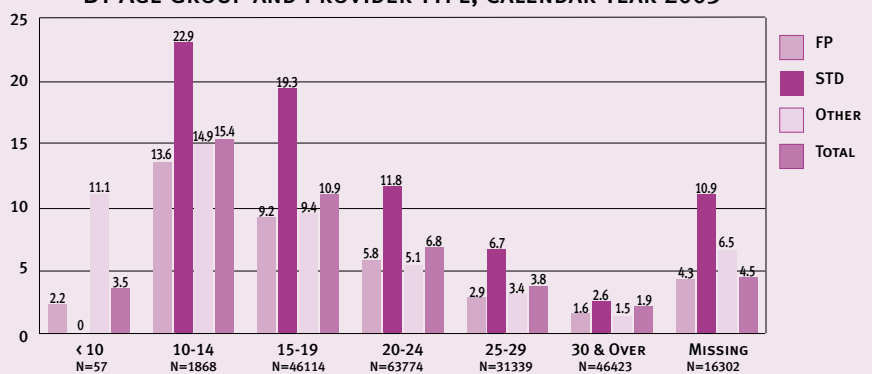
### BY PROJECT AREA AND PROVIDER TYPE, CALENDAR YEAR 2003



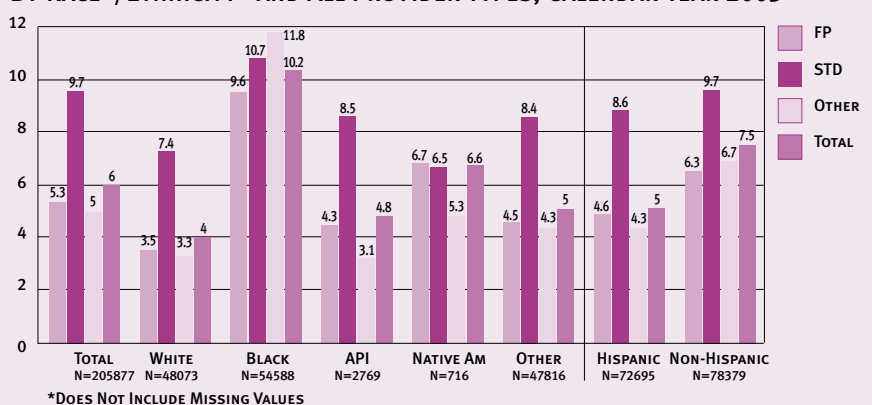
### BY AGE AND PROVIDER TYPE, CALENDAR YEAR 2003



### BY AGE GROUP AND PROVIDER TYPE, CALENDAR YEAR 2003



### BY RACE\*/ETHNICITY\* AND ALL PROVIDER TYPES, CALENDAR YEAR 2003





## The ABCs of Chlamydia: A Region II Online Educational Resource

We are excited to present The ABCs of Chlamydia, an e-learning tool developed by the Region II Infertility Prevention Project and the New York/New Jersey STD Prevention Training Center. The tool is expected to be online in September of 2004, and is an easy-to-use, quick reference for clinicians to augment their knowledge on this important issue. There are several downloadable powerpoint presentations and articles, along with links to other STD-related websites.

Continuing education credits will be available!

The course is divided into six interactive, user-friendly modules:

1. Need for Chlamydia Tests
2. Chlamydia Screening
3. Approaching Clients
4. Lab Technologies
5. Treatment
6. Client Interaction

*Visit:* [www.cicatelli.org/ipp](http://www.cicatelli.org/ipp) for updates on the tool and how to access it once it is online!

The ABCs of Chlamydia is an easy-to-use, **quick reference tool** ...for clinicians to augment their knowledge and earn continuing education credits.

## Screening Considerations: Understanding Predictive Value

Predictive value is an expression of the likelihood that a given test result correlates with the presence or absence of disease. A positive predictive value is the ratio of patients with the disease who test positive to the entire population of individuals with a positive test result; a negative predictive value is the ratio of patients without the disease who test negative to the entire population of individuals with a negative test (source: On-Line Medical Dictionary at <http://cancerweb.ncl.ac.uk/omd/>).

Predictive value can vary greatly depending upon the prevalence rates in a given population. When used in low prevalence settings, even excellent tests may have poor positive predictive value.

The issue for clinicians and patients is determining the accuracy of tests results. A false positive may result in unnecessary treatment and personal distress, while a false negative prevents an infected person from receiving needed medical treatment.

The new NAATs for gonorrhea and chlamydia screening have

very high specificity. Their routine application to screen women at low to zero risk for gonorrhea or chlamydia may lead to false positive test results. This is much more of a potential problem in communities where prevalence of disease is low (less than 2%). The positive predictive value (PPV) of a screening test tells what proportion of all screening positive results are actually true positives (PPV = true positive results/all screen positive results). For tests with less than 100% specificity, the

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### Q&A

### Questions for the Experts

**My partner told me that 4 days ago, he was diagnosed with chlamydia and his doctor gave him a prescription for something to take for 7 days. Two days ago, I came to this clinic and was given a “drink” to take for the chlamydia. We had unprotected sex last night – am I still protected against the chlamydia?**

The history should ascertain if the patient has any symptoms of PID (fever, abdominal pain, etc), if there was vaginal, oral or anal intercourse and if she knows what medication the partner was prescribed and if he is still on the medication. In this scenario, the partner could be on a 7 day course of Doxycycline 100 mg po bid, Orfloxacin 300 mg po bid, Levofloxacin 500 mg po qd, Erythromycin base 500 mg po qid, or Erythromycin ethylsuccinate 800 mg qid. This patient was probably given Azithromycin 1 gm po (reconstituted from a powder form). An exam should be offered to elicit any signs of PID (elevated temperature, abdominal tenderness/rebound, cervical motion/adnexal tenderness, etc). If lab testing was not performed on the visit 2 days ago, then the patient can be offered to have chlamydia and any other appropriate tests done but the goal is to presumptively (re)treat.

Patients are advised to abstain from sexual intercourse for 7 days after single dose therapy or until completion of a 7-day regimen. It is prudent to retreat this patient and to advise abstinence, recommend that partners within the last 60 days get treated, that she gets a rescreening in 3-4 months and to remember to offer emergency contraception.

*Jennifer Howard, MD, MPH  
Medical Director  
Planned Parenthood  
Greater Northern New Jersey*

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**cont'd from page 1** *Self Administered Vaginal Swabs (SAS)*

chlamydia and gonorrhea as shipping the swab in the “wet” liquid transport medium recommended by the manufacturer. The ability to transport swabs in a “dry” state to the laboratory extends the utility of the vaginal swab to be easily mailed in a pre-addressed mailing packet from a distant site to a central laboratory for testing.

In addition, certain studies have demonstrated that under selected situations, women will use the SAS. One study verified that of adolescents screened by SAS, 99% reported the SAS was easy to use and 83% of the 113 patients who had experienced a pelvic examination preferred the SAS method. About 97% stated they would test themselves more often if self-testing were widely and easily available. From 1216 newly pregnant women from 32 general practices and 5 family planning clinics in London, 1161 provided both swab and urine samples yielding the following results: 47% preferred urine, and 48% preferred both equally.

To read this article in its entirety, please visit: [www.cicatelli.org/ipp/resource.htm](http://www.cicatelli.org/ipp/resource.htm)

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**cont'd from page 4** *Understanding Predictive Value*

PPV will be impacted by the prevalence of the condition in the population undergoing screening. Even if one uses published excellent NAAT test performance characteristics (e.g., sensitivity = 98.2% and specificity = 99.3%), a low chlamydia or gonorrhea prevalence (less than 1%) negatively impacts the PPV. Because of the low prevalence, the predictive value of a positive screening test is less than 70%. This means that less than 70% of women in this population testing positive using a NAAT will actually be infected.

STD screening of asymptomatic women over age 25 may therefore do more harm than good. According to a recent evaluation of FamilyPACT services\*, providers are screening too many women over the age of 25 for chlamydia and gonorrhea infections. Not only is this practice wasting valuable resources, but it may actually do more harm to patients by reporting more false positive results than true positive results.

\* Family PACT is California's innovative approach to provide comprehensive family planning services to eligible low income men and women. This clinical program increases access to services by expanding the provider network to include medical providers, pharmacies and laboratories.

## Check out the Region II IPP Website!

Cicatelli Associates Inc. (CAI) is the Region II Title X Training Center as well as the coordinating agency for the Region II Infertility Prevention Project. Please visit CAI's consistently updated Region II IPP website, which includes a national and regional overview of the project, project area contact information, data reports and resources, at: [www.cicatelli.org/ipp](http://www.cicatelli.org/ipp)

## Websites of Interest

### [www.ahrq.gov/](http://www.ahrq.gov/)

The Agency for Health Care Quality and Research, the federal agency that sponsors the US Preventive Services Task Force recommendations on preventive services, has now listed appropriate preventive services for women and men.

For a summary of the CT screening guidelines in English: [www.ahrq.gov/clinic/uspstf/uspchlsm.htm](http://www.ahrq.gov/clinic/uspstf/uspchlsm.htm)

For a fact sheet about CT screening in English: [www.ahrq.gov/clinic/prev/chlamwh.htm](http://www.ahrq.gov/clinic/prev/chlamwh.htm)

For a fact sheet about preventive services for women in Spanish, including CT screening: [www.ahrq.gov/ppip/healthywomsp.htm](http://www.ahrq.gov/ppip/healthywomsp.htm)

### [www.cdc.gov/std/chlamydia2002/default.htm](http://www.cdc.gov/std/chlamydia2002/default.htm)

The Chlamydia Prevalence Monitoring Project Annual Report for 2002 can now be ordered at this site.

### [www.cdc.gov/std/commdata](http://www.cdc.gov/std/commdata)

Houses the STD Communications Database, designed to help public health practitioners create specialized STD health communication prevention interventions. Provides access to disease- and population-specific communication information, as well as behavioral and communication theory, design principles, and best practices and lessons learned from other documented STD campaigns and communication efforts.

Also houses a library of more than 200 HIV- and STD-specific media materials and a subset of the consumer marketing tool, PRIZM, which includes password-protected zip codes for every non-business community

in the US. State and local health department communication staff can obtain a password by attending regional CDC STD Communication Database/CDCynergy sponsored trainings. For more information, please visit the database's FAQ or contact Angela Bland (866-855-8155 or [avb8@cdc.gov](mailto:avb8@cdc.gov)).

### [www.cdc.gov/std/gisp/](http://www.cdc.gov/std/gisp/)

Site of the Gonococcal Isolate Surveillance Project, which monitors trends in antimicrobial susceptibilities of strains of *N. gonorrhoeae* in the United States in order to establish a rational basis for the selection of gonococcal therapies. GISP is a collaborative project between selected sexually transmitted diseases (STD) clinics, five regional laboratories, and CDC.

### [www.cdc.gov/yrbss](http://www.cdc.gov/yrbss)

Contains the 2003 Youth Risk Behavior Survey (YRBS) Surveillance Summary. This system monitors six categories of priority health-risk behaviors among youth and young adults. Included among the categories are sexual behaviors that contribute to unintended pregnancy and sexually transmitted diseases (STDs).

### [www.cmap.nypirg.org/](http://www.cmap.nypirg.org/)

CMAP has helped more than 300 nonprofit organizations improve services, win policy reforms, better communication, and secure funding for valuable programs. The site serves as an excellent resource for obtaining maps for various IPP purposes.

### [www.lab-education.org/review\\_ed\\_mod/modo1\\_slide01.htm](http://www.lab-education.org/review_ed_mod/modo1_slide01.htm)

Spotlights an educational program funded by GenProbe on the introduction of nucleic acid amplified testing (NAATs) in the laboratory. The slide set emphasizes tests commonly used for the diagnosis of chlamydia and gonorrhea, which include those marketed by GenProbe, BD Biosciences, and Roche.

### [www.state.nj.us/health/cd/2003stdclinicdirectory.pdf](http://www.state.nj.us/health/cd/2003stdclinicdirectory.pdf)

Features the updated statewide directory of clinical services in New Jersey.

### [www.stdhivtraining.org/pdf/chlamydia\\_screen.pdf](http://www.stdhivtraining.org/pdf/chlamydia_screen.pdf)

The California PTC has just reissued the paper-based Chlamydia CME booklet, "Sexually Transmitted Chlamydia Infections – A Primary Care Clinician's Guide to Diagnosis, Treatment and Prevention." This 26-page color booklet can be viewed at this site. Providers can receive up to 2 CMEs or 2.4 CEUs for completing the course exam and evaluation online. Info on ordering large quantities of the booklets can be found on page 3 of the booklet; contact [captc@dhs.ca.gov](mailto:captc@dhs.ca.gov) for individual copies, or download directly from the website.

## IPP Contact Info

For more information about the Region II Infertility Prevention Project, please contact your respective project manager listed below:

#### New Jersey

Jerry Carolina  
STD Program  
NJDOH&SS  
(609) 588-7526

#### New York

Martha Newcomb  
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#### New York City

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STD Program  
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#### Puerto Rico

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