



Improving STD service delivery: Would American patients and providers use self-tests for gonorrhea and chlamydia?



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ABSTRACT

Chlamydia trachomatis (CT) and *Neisseria gonorrhoea* (GC) are the most frequently reported notifiable diseases in the United States and costs for diagnosis and treatment of these two infections are approximately \$700 million per year. A proposed new method for screening for these two infections is self-tests; similar to at-home pregnancy and HIV tests which do not include sending collected specimens to a laboratory for diagnosis. However, no such self-tests for sexually transmitted diseases (STD) have been approved by the Food and Drug Administration (FDA). To determine the acceptability of such a test, we used three surveys, conducted in 2017, including the American Men's Internet Survey, the SummerStyles survey, and the DocStyles survey to ask potential users about their interest in this type of test and how they might use it. Among our sampled population of men who have sex with men, 79.5% said they would prefer to take this type of test at home and 73.9% said they would be willing to pay at least \$20 for the test. Among young adults (18–29 years), 54.1% indicated that they would like to take this test at home and 64.5% were willing to pay more than \$10 for such a test. Among sampled physicians, 85.1% were “likely” or “very likely” to use an FDA-approved STD self-test in their office to screen for CT or GC. Self-tests for STDs are on our horizon and we need to be prepared to integrate these tests into our healthcare systems.

1. Introduction

Chlamydia trachomatis (CT) and *Neisseria gonorrhoea* (GC) are the two most frequently reported notifiable diseases in the United States (National Notifiable Diseases, 2018) and rates of these sexually transmitted diseases (STDs) are on the rise (CDC, 2017). If not appropriately diagnosed and treated, these infections can lead to serious sequela in women such as pelvic inflammatory disease and infertility (Stamm, 2008). Given that most CT and GC infections are asymptomatic, routine screening for at-risk populations is recommended by the Centers for Disease Control and Prevention (CDC) (CDC, 2015) in order to reduce the burden of disease and subsequent reproductive consequences of these infections.

Direct medical costs for CT and GC infections are estimated to be nearly \$700 million per year (Owusu-Edusei Jr. et al., 2013), and access to timely STD diagnostic and treatment services is limited due to shrinking budgets for STD clinics (Golden and Kerndt, 2010). Furthermore, cost and stigma have been identified as barriers to receiving STD services (Pearson et al., 2016). Therefore identifying efficient methods

for accessing care would be useful. One example of a more efficient service delivery is self-testing. The National Institutes of Health (NIH) has described point-of-care (POC) diagnostics, including self-collected specimens and self-testing, as ways to provide patients with lower cost methods of personalizing their healthcare and shortening the length of time between diagnosis and treatment (NIH, 2010). Two examples of at-home self-tests that are currently in use are home-based pregnancy and HIV self-tests. The introduction of similar tests for STDs may be helpful, but currently, no Food and Drug Administration (FDA) approved STD self-tests are available to consumers. However, POC STD tests that can be used outside of a clinical laboratory, including unsupervised tests by patients in their homes, are being developed (Cristillo et al., 2017) and the STD field is beginning to consider how these tests could be successfully integrated into and/or change the traditional testing, treatment, prevention, and surveillance paradigm (Peterman et al., 2018).

Self-tests, including those to detect pregnancy, glucose levels for diabetes, and HIV, are now being widely accepted and used by healthcare providers. Previous work has examined the acceptability of

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self-collected samples for STD testing among different populations, in different venues, and using different collection methods, and has shown that self-collected sampling is feasible and possibly a prelude to self-testing (Paudyal et al., 2015). Additional studies evaluating self-collected specimens suggest that this area is promising, but that more work is needed to assess the overall benefit to the population and to the healthcare system (Bernstein et al., 2016). In this current study, we set out to determine the willingness to use and preferences for use of these STD self-test kits by both patients and STD service providers.

2. Methods

We used data from three different surveys in order to capture broad perspectives on the acceptance and potential use of STD self-test kits. We analyzed data examining the public's acceptance of a self-test kit, as well as the setting in which they would like to use it, and how much they would be willing to pay for it, once they become available. We also analyzed data from healthcare providers about their willingness to accept these types of kits when brought in by patients.

The first survey included data gathered from the American Men's Internet Survey (AMIS). This online survey aims to recruit approximately 10,000 men who have sex with men (MSM) in the US annually. The survey, which is not incentivized, includes questions regarding sexual behaviors and beliefs, as well as health seeking behaviors. The present analysis includes data from the 2017 cycle. Convenience sampling was used to recruit participants via web-banner advertisements through the period of July 28 through November 7, 2017. Participants were also recruited by emailing participants from the previous cycle of AMIS (AMIS-2016) who consented to be re-contacted for future studies. The survey screened for participants who were at least 15 years of age, were not transgender, were US residents and who reported ever having either oral or anal sex with another man. The analysis sample was further restricted to those who reported oral or anal sex with another man in the past 12 months. The survey was hosted on a secure server that met all requirements of the Health Insurance Portability and Accountability Act. This survey was approved by the Institutional Review Board at Emory University and is protected by a federal certificate of confidentiality that prevents legal action which would force release of the data. A more detailed description of the survey methodology has been previously provided (Sanchez et al., 2015).

We examined two questions in AMIS. The first question asked "Researchers are developing self-tests for gonorrhea and chlamydia that would allow people to test themselves with self-collected swabs or urine and read the results by themselves, much like women can read the results of a pregnancy test. If such a test were available to you, where would you prefer to take the test?" The second question was "If such a test became available, how much would you be willing to pay for this test?" Frequencies for the responses to each of these questions were calculated overall and stratified by demographic and health services characteristics of the respondents.

The second set of data that was gathered from two different surveys that are part of the Porter Novelli's annual Styles survey series. The CDC licensed access to data from SummerStyles, a survey of consumers from GfK's KnowledgePanel®, and DocStyles, a survey of health care providers from SERMO's Global Medical Panel. No personal identifying information is collected in these surveys and secondary analysis of these data are considered to be exempt from CDC IRB review. Further information about SERMO and KnowledgePanel® can be found on their respective websites (KnowledgePanel®, 2018, SERMO, 2018).

The SummerStyles data was collected June 7 through July 2 of 2017. The survey was sent out to a sample of 5586 panelists aged 18 years or older. Respondents received cash-equivalent reward points (worth approximately \$5) for participating. Although 4107 adults answered the survey, we limited our analyses to respondents who were 18–29 years of age (n = 590).

We examined three questions in the SummerStyles survey to

determine young adults' willingness to use an STD self-test. Three questions were asked. "Chlamydia screening is recommended annually for sexually active females age 24 and younger, for older women at increased risk, and for some men. Have you ever been tested for the sexually transmitted infection chlamydia?" "If a chlamydia test became available that you could do on your own (like a pregnancy test) where would you prefer to take the test?" "If you could do your own chlamydia test (like a pregnancy test), how much would you be willing to pay for the test?" Responses to each of these questions were tabulated and were stratified by sex.

We then examined data that was taken from the DocStyles web-based survey which was conducted June 8 through August 9 of 2017. This survey collected data from 1000 primary care physicians, 250 pediatricians, 250 OB/GYNs, 250 nurse practitioners, 250 oncologists, 150 retail pharmacists, and 100 hospital pharmacists. Respondents were paid up to \$85 for completing the survey with incentives varying based on the number of questions their specialty was asked to complete.

For this survey, we focused our analyses on the four provider types that would be most likely to treat STDs in their practice, including Family Practitioners, Internists, Pediatricians and Obstetricians/Gynecologists. For this analysis we focused on one survey question: "How likely would you be to screen for chlamydia or gonorrhea if there was an FDA-approved test you could perform in your office (similar to a pregnancy test) using a patient-collected swab?" The responses to this question were based on the Likert scale and ranged from "Very likely" to "Very unlikely". We calculated frequencies of responses overall and stratified these frequencies by provider type. Responses to these questions were tabulated and stratified by physician specialty.

3. Results

For the AMIS survey of MSM, there were a total of 7929 respondents to the first question. The vast majority (79.5%) said that if a self-test kit became available, they would prefer to take this test at home, compared to 15.5% who would prefer taking this test at the doctor's office and 4.0% at an STD clinic (Table 1). When asked how much they would be willing to pay for the self-test, 73.9% were willing to pay at least \$20, 18.3% were willing to pay \$10, and 7.8% were not willing to pay anything. Stratification by age and by type of insurance coverage showed that there were no discernable differences in preferences among age groups or insurance status; most respondents regardless of age or insurance status preferred to take the test at home and were willing to pay for the test (Table 1).

Among our sample of 18–29 year old respondents to the SummerStyles survey, 63.1% had never been tested for chlamydia, and 26.3% had ever received a chlamydia test (Table 2). The remaining respondents (10.3%) answered "Don't know". Among all respondents, 54.1% indicated that if a self-test STD kit were available, they would want to take this type of test at home, 23.9% wanted to take the test at a doctor's office, 18.1% at an STD clinic, 1.9% at a family planning clinic, and 1.5% at a pharmacy. When asked how much they were willing to pay for the self-test, 64.5% were willing to pay \$10 or more for this test and 32.9% were willing to pay \$20 or more. When stratifying by sex, differences were noted for responses to each of the questions. Females were more likely to report a past chlamydia test (42.9%) than males (9.0%). A greater percentage of females preferred to take this type of test at home (57.1%), compared to males (50.9%). Also, a greater percentage of females were more likely to be willing to pay at least \$10 for the test (70.5%) compared to males (59.8%).

Among our sample of healthcare providers from the DocStyles survey, we found that the majority (85.1%) were either "likely" or "very likely" to use an FDA-approved test in their office to screen for CT or GC (Table 3). When stratifying these responses by provider type, nearly three-quarters of each specialty were either "likely" or "very likely" to use this test to screen for CT or GC. Pediatricians had the lowest percentage of respondents (73.6%) indicating that they were

Table 1
Self-testing preferences among men who have sex with men, American Men's Internet Survey, 2017.

Question #1: If such a test were available, where would you prefer to take the test?					
	Home	Doctor's office	Family planning clinic	Pharmacy	STD clinic
Total, N = 7929	6304 (79.5%)	1227 (15.5%)	44 (0.6%)	35 (0.4%)	319 (4.0%)
Age group (years)					
15–24	1688 (77.5%)	345 (15.8%)	19 (0.9%)	11 (0.5%)	115 (5.3%)
25–29	780 (80.2%)	151 (15.5%)	5 (0.5%)	5 (0.5%)	52 (5.3%)
30–39	1014 (80.2%)	192 (15.2%)	6 (0.5%)	7 (0.6%)	46 (3.6%)
≥ 40	2822 (80.8%)	539 (15.4%)	14 (0.4%)	12 (0.3%)	106 (3.0%)
Insurance coverage					
Private employer	3728 (81.5%)	664 (14.5%)	13 (0.3%)	21 (0.5%)	149 (3.3%)
Private exchange	364 (77.8%)	74 (15.8%)	3 (0.6%)	2 (0.4%)	25 (5.3%)
Medicaid/Medicare	654 (74.1%)	173 (19.6%)	8 (0.9%)	2 (0.2%)	45 (5.1%)
Other or multiple	748 (75.9%)	182 (18.5%)	11 (1.1%)	1 (0.1%)	44 (4.5%)
No insurance	539 (80.7%)	79 (11.8%)	6 (0.9%)	7 (1.0%)	37 (5.5%)
Prefer not to answer	67 (78.8%)	11 (12.9%)	1 (1.2%)	2 (2.4%)	4 (4.7%)
Don't know	204 (77.0%)	44 (16.6%)	2 (0.8%)	0 (0%)	15 (5.7%)

Question #2: If such a test became available, how much would you be willing to pay for the test?					
	Nothing	\$10	\$20	\$30	≥ \$40
N = 7279	571 (7.8%)	1329 (18.3%)	2160 (29.7%)	1580 (21.7%)	1639 (22.5%)
Age (years)					
15–24	146 (7.0%)	345 (16.5%)	641 (30.7%)	504 (24.1%)	454 (21.7%)
25–29	55 (6.0%)	166 (18.1%)	279 (29.6%)	212 (23.2%)	203 (22.1%)
30–39	83 (7.1%)	232 (20.1%)	350 (30.3%)	233 (20.1%)	259 (22.4%)
≥ 40	287 (9.2%)	586 (18.8%)	890 (28.6%)	631 (20.2%)	723 (23.2%)
Insurance coverage					
Private employer	206 (4.9%)	712 (16.9%)	1269 (30.2%)	969 (23.1%)	1047 (24.9%)
Private exchange	29 (6.8%)	76 (17.8%)	137 (32.1%)	85 (19.9%)	100 (23.4%)
Medicaid/Medicare	123 (15.2%)	191 (23.7%)	223 (27.6%)	145 (18.0%)	125 (15.5%)
Other or multiple	124 (13.7%)	158 (17.4%)	260 (28.7%)	178 (19.6%)	186 (20.5%)
No insurance	59 (9.8%)	119 (19.7%)	169 (27.9%)	144 (23.8%)	114 (18.8%)
Prefer not to answer	12 (15.2%)	18 (22.8%)	22 (27.8%)	8 (10.2%)	19 (24.1%)
Don't know	18 (7.1%)	55 (21.8%)	80 (31.7%)	51 (20.2%)	48 (19.0%)

either “likely” or “very likely” to use this test.

4. Discussion

Our findings suggest that both patients and providers are open to using this new type of self-testing kit when it becomes available. Convenience and privacy appear to be important factors in using this type of test, as indicated by the large percentages of respondents reporting that they would like to use this test at home compared to other settings. Furthermore, our results indicate that potential purchasers of

this test would be willing to pay for it, albeit at values differing by population. Differences in preferences for the test were noted between males and females. Among physicians, our results indicate that most providers, who would potentially treat STDs, were open to using this type of test in their office, if it were FDA-approved.

Numerous studies have used self-collected specimens for STD testing in different venues and among different populations and this method has been promoted as a more convenient and private way of collecting specimens for STD testing. One study showed that a home testing intervention for chlamydia and gonorrhea could save money when taking

Table 2
Self-testing preferences among a convenience sample of male and female 18–29 year olds, SummerStyles Survey, 2017.

Question #1: Chlamydia screening is recommended annually for sexually active females age 24 and younger, for older women at increased risk, and for some men. Have you ever been tested for the sexually transmitted infection chlamydia?				
	Yes	No	Don't Know	Missing
Total, N = 590	156 (26.3%)	372 (63.1%)	61 (10.3%)	2 (0.3%)
Male	26 (9.0%)	238 (82.4%)	24 (8.3%)	1 (0.4%)
Female	129 (42.9%)	134 (44.5%)	37 (12.3%)	1 (0.3%)

Question #2: If a chlamydia test became available that you could do own your own (like a pregnancy test) where would you prefer to take the test?							
	At Home	Doctors Office	Fam Planning Clinic	Pharmacy	STD Clinic	None of these	Missing
Total, N = 590	319 (54.1%)	141 (23.9%)	11 (1.9%)	9 (1.5%)	107 (18.1%)	3 (0.5%)	0 (0%)
Male	147 (50.9%)	58 (20.1%)	1 (0.3%)	6 (2.2%)	74 (25.6%)	3 (1.0%)	0 (0%)
Female	172 (57.1%)	83 (27.6%)	10 (3.3%)	3 (1.0%)	33 (5.6%)	0 (0%)	0 (0%)

Question # 3: If you could do your own chlamydia test (like a pregnancy test) how much would you be willing to pay for this test?							
	\$50	\$40	\$30	\$20	\$10	Nothing	Missing
Total, N = 590	13 (2.1%)	12 (2.0%)	50 (8.5%)	123 (20.9%)	187 (31.7%)	201 (34.1%)	4 (0.7%)
Male	7 (2.4%)	6 (2.1%)	16 (5.5%)	46 (15.9%)	98 (33.9%)	115 (39.8%)	1 (0.4%)
Female	6 (2.0%)	6 (2.1%)	34 (11.3%)	77 (29.6%)	89 (29.6%)	86 (28.6%)	3 (1.0%)

Table 3
Acceptance of STD self-testing by provider type, DocStyles Survey, 2017.

Question: How likely would you be to screen for chlamydia or gonorrhea if there was an FDA-approved test you could perform in your office (similar to a pregnancy test) using a patient-collected swab?				
	Very likely	Likely	Unlikely	Very unlikely
Total, N = 1504	814 (54.1%)	466 (31.0%)	144 (9.6%)	80 (5.3%)
Provider type				
Family practitioner n = 494	300 (60.7%)	147 (29.8%)	34 (6.9%)	13 (2.6%)
Internist n = 509	214 (42.0%)	200 (39.3%)	61 (12.0%)	34 (6.7%)
Pediatrician n = 250	116 (46.4%)	68 (27.2%)	37 (14.8%)	29 (11.6%)
Obstetrician/ gynecologist n = 251	184 (73.3%)	51 (20.3%)	12 (4.8%)	4 (1.6%)

into account both direct and indirect costs of care, but that the decision to implement this type of program would be complicated by other factors including clinic capacity and limited budgets (Smith et al., 2007). Wiesenfeld and colleagues found that the use of self-collected vaginal swabs was easily implemented in a group of high school students and that using the self-collected swabs increased the likelihood of detecting STDs (Wiesenfeld et al., 2001). Chernesky and colleagues found that women in seven different North American cities were successfully able to collect vaginal swabs for NAAT testing (Chernesky et al., 2005). More recently, Gaydos and colleagues have demonstrated the benefits of using at-home, self-collected specimens paired with internet based sexual health programs (Gaydos et al., 2009). However, each of these examples demonstrate the feasibility of self-collected specimens that involve a laboratory for diagnosis and are not self-tests that can be conducted in a person's home or other location allowing for immediate diagnosis.

Self-tests for STDs (of unknown quality) are available outside of the United States. Two studies examining the use of these tests have been conducted in the Netherlands. In one study that included a panel of Internet users collected through the University of Maastricht, participants were asked about their previous use of a list of 25 different self-tests including chlamydia and syphilis. Among the group of 1263 respondents who had reported ever using a self-test, 9% reported having used a self-test for chlamydia and 5% reported having used a self-test for syphilis (Ronda et al., 2009). A more recent study was conducted among individuals in Amsterdam and found that usage of self-tests for HIV, chlamydia and syphilis was low, but increased over time and that usage was higher among individuals who were at greater risk of contracting an STD (Bil et al., 2017). As self-tests become available in the U.S., studies will be needed to guide how they can best be distributed to those who would benefit most from their use as well as how the use of these tests could be best integrated into the continuum of care for STDs.

As mentioned earlier, two tests in the U.S. that would be most analogous to an STD self-test are home pregnancy and HIV self-tests. Home pregnancy tests were FDA-approved for sale to the general public > 40 years ago in the United States, and these tests are widely used for the early detection of pregnancy, while offering the benefits of privacy and convenience (Cole et al., 2004). Currently, these devices use urine samples to qualitatively assess human chorionic gonadotropin levels to determine if a pregnancy has occurred, but questions about the accuracy of many of these tests still exist (Grenache, 2015). Therefore, many at-home pregnancy tests are a first step in the diagnostic process, as many women still seek confirmatory testing by a clinician (Childerhose and MacDonald, 2013). Similar issues of accuracy may be encountered if these STD self-tests are urine based (Schacter et al., 2005).

Self-tests for HIV are a relatively newer technology that received FDA approval in 2012 (New York Times, 2012), but along the way to development and implementation, these tests were met with mixed reviews regarding their cost and accuracy (Walensky and Paltiel, 2006; Paltiel and Walensky, 2012). Studies on the acceptability among potential users showed that many potential users were enthusiastic (Myers et al., 2014), and studies performed after the release of these tests have shown that use of the HIV self-test has been positive, but that concerns about test sensitivity during early infection and linkage to care after diagnosis are still issues that need to be resolved (Krause et al., 2013; Witzel and Rodger, 2017).

The results of our present study need to be considered in the light of its limitations. Firstly, we did not determine the socioeconomic status (SES) of potential users of the STD self-tests. Demographic variables, that may be related to socioeconomic status, have been shown to affect the willingness to purchase HIV self-tests (Nunn et al., 2017), and similar effects would be expected for STD self-tests as well. However, our data suggest that people are willing to pay for privacy and convenience of these tests. Secondly, questions posed to healthcare providers did not specifically ask about their acceptance of self-tests that were performed outside of a supervised clinical environment and that were brought to them by a patient, although work by Tat and colleagues demonstrated that clinicians were willing to accept the use of self-collected, extra-genital specimens from patients in an HIV clinic where routine STD testing was necessary (Tat et al., 2018). Thirdly, our questions did not ask about different collection techniques. Previous studies have found that different collection methods can produce different results in detection capability (Fang et al., 2008) and that men and women do have different preferences when it comes to how specimens for STDs are collected (Schacter et al., 2005; Shoveller et al., 2010). However, the questions used for our analyses of young adults were framed using the phrase “like a pregnancy test” which implies a urine sample. Finally, our study asked about the use of a product that is not yet available in the US.

5. Conclusion

Our analyses suggest that there will be acceptance for the use of STD self-tests. The healthcare system needs to be prepared to integrate these tests into systems of care. Approaches to covering the costs of these tests should be considered in order to remove some of the barriers to efficient care for those at highest need. Cost considerations for these STD self-tests could be made based on costs of currently available home pregnancy tests and HIV self-tests. Insurance companies and governments might consider providing these tests to at-risk populations as an alternative to screening in clinics. Sexually transmitted disease self-tests are on our horizon, and we should be prepared to use them.

Conflict of interest statement

All authors declare no conflicts of interest in this work.

Disclaimer

The findings and conclusions of this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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