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Home versus clinic-based specimen collection for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

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Abstract

Sexually transmitted infections (STIs) are a major public health concern that must be addressed with innovative screening methods to supplement traditional approaches. Home-based screening with self-collected urine or vaginal specimens is a highly feasible and acceptable method, and shows promise in improving STI screening rates in both men and women. Home collection kits have been offered in a variety of settings, with results ranging from very modest improvements in screening rates to 100-fold increases beyond the rates observed with clinic-based screening. This article describes and evaluates the effectiveness and limitations of various home screening strategies used for the detection of STIs.

Keywords

Chlamydia trachomatis; home collection kits; home screening; postal specimens; self-collected specimens; sexually transmitted infections

Sexually transmitted infections (STIs) are a major public health concern, with *Chlamydia trachomatis* (CT) being the most prevalent STI, followed by genital warts, genital herpes and infection with *Neisseria gonorrhoeae* (GC) [1]. In the UK, 79,557 cases of chlamydia were diagnosed in young individuals 16–24 years of age who presented to genitourinary medicine clinics in 2007. From 2008–2009, the National Chlamydia Screening Programme (NCSP) found an additional 57,704 cases, for a 7% chlamydia positivity rate in index cases [2]. The rate of chlamydia has more than doubled in the UK over a 10-year period, from 447 per 100,000 in 1998 to 1102 per 100,000 in 2007 [1]. In the USA, reported cases of chlamydia exceeded one million for the first time in 2006, and rose by another 17.4% to

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1,210,523 by 2008. The increase is multifactorial, and is the result of increased screening, improved sensitivity of modern detection techniques and possibly an increase in disease burden [3]. CT infections are usually asymptomatic. For example, 95% of adolescents testing positive for chlamydia in the National Longitudinal Study of Adolescent Health in the USA were asymptomatic [4]. Thus, many infections are left undiagnosed and untreated, resulting in further transmission and adverse health outcomes, such as pelvic inflammatory disease (PID) [5]. The rate of infertility is 11% after one episode of PID and doubles with each subsequent infection. Even subclinical PID may disrupt fertility, with the result that tubal factor infertility accounts for nearly a third of infertility cases [6]. Other STI complications include ectopic pregnancy, chronic pelvic pain and neonatal infection [7].

In contrast to common sexually transmitted viral infections, such as genital warts and genital herpes, chlamydia and gonorrhea are bacterial infections that are easily treated and cured with antibiotics. The potential to cure these bacterial infections and prevent the associated long-term complications makes screening for these STIs in asymptomatic individuals an important public health priority. In fact, screening has been shown in several studies to reduce the rate of PID, and several regions throughout the world have reported declining PID rates after the introduction of chlamydia screening [8–11].

In England, the NCSP, introduced in 2003, uses a multipronged approach to encourage opportunistic chlamydia screening in primary care settings and through community contraceptive services, abortion services and pharmacies to increase the rate of screening outside of specialty clinics. In 2008/2009, screening rates for young individuals 15–24 years of age reached 16% through the NCSP, with three-times more women testing than men (24% of women vs 8% of men) [2]. In the USA, both the CDC and US Preventive Services Task Force recommend routine annual screening for chlamydia in women under 25 years of age and other women at high risk [3,10]. However, studies suggest that only 26–60% of at-risk women in the USA undergo annual screening [12–15].

Traditional STI screening requires a pelvic examination or urethral swab, which is an often cited barrier to screening, along with mistrust of the healthcare system, concerns about confidentiality, denial of STI risk and a sense of invulnerability [16,17]. The NCSP is one of several screening programs to acknowledge these barriers and offer noninvasive screening using urine specimens or self-obtained vaginal swabs for use with nucleic acid amplification tests (NAATs). These tests are the most sensitive and specific tests available to screen for chlamydia and gonorrhea [18,19]. NAATs include assays such as PCR, transcription-mediated amplification [20] and strand-displacement amplification [21]. Two systematic reviews found the use of NAATs for noninvasive STI screening to have high sensitivity and specificity for both CT and GC among women and men, and the results were nearly identical to invasively obtained samples [22,23].

The accepted use of noninvasive samples for STI detection raises an important question: must STI screening occur in a clinic? Urine and vaginal samples can be self-collected in the privacy of a patient's home and returned through the mail. This method has the potential to reach young individuals who are otherwise unlikely or unwilling to seek clinical services. In this article, we searched the literature for trials and observational studies of home-collected specimens for STI screening to determine if home-based screening is feasible and acceptable, whether it increases screening rates compared with clinic-based screening and whether partner management is enhanced by home collection. We compare several strategies for targeted screening of young individuals through clinical, community, regional and internet settings.

Methods

We searched the published literature using PubMed/MEDLINE and the following MeSH terms: sexually transmitted diseases; *Chlamydia trachomatis*; chlamydia infections; *Neisseria gonorrhoeae*; mass screening; home care services; self care; self-examination; postal service; specimen handling; and reagent kits, diagnostic. We also reviewed the bibliographies of key articles identified in this search for further references. We focused on articles from January 2005 to September 2010, but also drew information from earlier articles to describe the background and seminal trials in the field.

Results

Feasibility & acceptability of home-based collection for STI screening

When designing a screening program using home collection, there are several types of noninvasive specimens available for consideration. Urine specimens can be collected by men or women, simplifying the logistics in programs that screen both sexes. Nearly all (99%) men and women in an Australian study could safely and correctly pack urine test kits [24]. However, the transport of specimens is an important consideration in designing home screening programs. Swab and urine specimens are considered biohazardous materials in most countries, and are subject to packaging restrictions that can increase the cost and complexity of the testing process [25]. To our knowledge, kits incorporating the specimen collection system and appropriate packaging are not commercially available, and instead must be assembled by the researchers. Researchers have been creative in meeting these challenges; for instance, Australian researchers, restricted from mailing liquid urine samples, developed a gel-based medium that dessicates urine for dry transport [25].

There are little data available to evaluate the performance of the various NAAT assays on samples that have been sent through the mail prior to laboratory processing. Morre and colleagues mailed chlamydia-positive urine samples to a research laboratory. The researchers then used two different NAATs, PCR and ligase chain reaction, to retest these samples daily for 7 days following delivery. Each sample tested positive for chlamydia after mailing and results were consistent over 7 days [26]. These data are reassuring, but further research on the effects of temperature on specimen stability would be useful.

A comparison of vaginal swabs with urine samples in a large observational study found the two specimen collection methods to have similar sensitivities: 97.3% (95% CI: 93.1–99.2%) and 91.8% (95% CI: 86.1–95.7%), respectively [27]. However, another study detected more positive chlamydia cases from vaginal swabs compared with matched urine samples, and hypothesized that vaginal swabs may be the better specimen to detect chlamydial infections of either the cervix or urethra [20]. Compared with vaginal swabs, liquid urine samples are less stable and require more laboratory steps for processing [28]. Dry vaginal swab samples are also subject to fewer mailing restrictions, and yield identical PCR results compared with vaginal swabs immersed in a traditional transport medium [29].

In terms of acceptability, women find self-collection of vaginal swabs an acceptable, even preferable, alternative to traditional screening. Gaydos *et al.* conducted seven focus groups with American women aged 14–49 years to evaluate women's views on home-based screening for chlamydia. These women agreed that self-obtained vaginal swabs are comfortable and safe, and considered self-obtained vaginal swabs to be less invasive than a clinician-obtained cervical sample [30].

The focus groups also believed that privacy can be maintained with home collection, but emphasized that packaging should be discreet and lack any markings referring to sex or STIs

[30]. In a randomized trial of home versus clinic-based screening, packages were designed according to these recommendations, and only 5% of women responding to a satisfaction survey after testing had privacy concerns related to the testing process [31].

Women also consider self-obtained swabs to be very easy to use [31,32], regardless of age or level of education [32]. In fact, even teens prefer self-obtained vaginal swabs; Wiesenfeld *et al.* enrolled 228 female students between 15 and 19 years of age to self-collect a vaginal swab that was tested for GC, CT and trichomoniasis. These young women reported that self-collection was easy to perform (99%), preferable to a gynecologic examination (84%), and nearly all (97%) stated that they would undergo testing at frequent intervals if self-testing were available [16].

These positive perceptions of self-collected, home-based screening translate to decision-making: when available, women will choose home-based testing over clinic-based testing. In a trial of 462 women, women were three-times more likely to choose home screening over clinic screening (75.7% home screening vs 24.3% clinic screening) [33].

Screening strategies

Clinical recruitment

Noncontrolled trials have demonstrated the feasibility of recruiting individuals from clinical settings for home-based STI screening. In the UK, pharmacies offered chlamydia home-collection kits to women presenting for emergency contraception; fewer than half of the women accepted the kits, 18% submitted a urine sample and 9% of those screened were positive for CT [34].

Several controlled studies have also found that offering home-based screening to women results in increased rates of STI screening. The Detection Acceptability Intervention for STDs in Youth (DAISY) study randomized particularly high-risk young women in the USA to home or clinic screening, and found that home screening with self-obtained vaginal swabs improved screening rates. This study found that, compared with women assigned to traditional clinic screening, women who received home screening tests completed significantly more STI tests over 2 years of follow-up: 1.94 vs 1.41 tests per woman per year. While the incidence of STIs was high, there was no difference in infection rates between the intervention and control groups. This study demonstrates that home screening can successfully increase the rate of screening, but is limited in its general applicability by its population of very high-risk women [35,36].

Women with varying levels of STI risk, who may be more representative of a general screening population, have also experienced improved screening rates with home-based screening. A randomized trial in the USA recruited 558 women from the Contraceptive CHOICE Project, a large cohort study providing free contraception of a woman's choice for 2–3 years. The study population consisted of long-acting reversible contraceptive users (LARC; i.e., intrauterine devices and the contraceptive implant), with a mean age of 25.7 years, nearly equal proportions of black and white women, a wide distribution of education and income levels, and different degrees of STI risk. Home screeners were 1.7 times more likely to complete a test compared with self-reported clinic testers (56 vs 33%), and home screeners also rated testing as more convenient than women who had been tested at a clinic. The majority of home screeners would opt to continue home testing in the future (83%), compared with only 49% of women in the clinic group who preferred to continue with clinic-based testing [31].

A feasibility study in three general medical practices in Scotland randomized 600 women to usual care, opportunistic screening or postal screening for chlamydia. Usual care was not defined, but as no women in this group were screened, it suggests that chlamydia testing would only occur by patient request or in the presence of symptoms. Women in the opportunistic screening group were given home kits if they presented to the medical practice for care, while all women assigned to the postal screening arm were mailed home kits at the beginning of the study. Reminder letters were sent after 2 weeks to nonresponders in the postal screening group. None of the usual care women were tested for chlamydia, compared with 19% of the opportunistic screening group and 38% of the postal screening group. However, screening in the opportunistic and usual care groups was limited by the number of women who presented for care in the 4-month study period, a period that was determined arbitrarily. Only 59% of the opportunistic group presented for care during the study period, and the authors estimated that a larger proportion could be screened if the study period was extended, based on practice patterns. Interviews with office staff and physicians showed that the postal screening process was labor intensive and complicated by unreliable postal service. However, some providers were also hesitant to offer opportunistic screening in visits unrelated to sexual health, due to time constraints or difficulty in changing the focus of a visit [37].

Home screening for STIs has not yet been shown to improve screening rates in low-resource settings. However, self-collection can be an acceptable alternative to traditional screening in these communities. In Brazil, 818 women were randomized to home or clinic arms, and no clinically significant difference in screening rates was found between the groups at 6 weeks (93 vs 89%; one-sided p-value 0.03, two-sided p-value 0.07). However, home participants were required to hand-deliver their samples to the clinic, which did not eliminate barriers to screening such as transportation and time. Despite this, the study had impressively high response rates, suggesting that home screening was both acceptable and feasible in a low-resource setting, but also that the population may be very different from most screening populations [38]. In a South African study, young women were randomized to home or clinic screening. There was no difference in response rates (47 vs 42%) unless ‘partial responders’ who did not follow study protocol were excluded from the study. ‘Partial responders’ were women who mailed their specimens after the 6-week follow-up visit, or who did not mail in the kit but reported a positive result on a rapid trichomonas test included in the kit. In this subanalysis, women in the home group were 30% more likely to complete testing than the clinic group (54% home vs 42% clinic) [39]. Both of these studies recruited women mainly from clinics, which may have increased the proportion of women likely to complete clinic screening, thus biasing the results towards the null.

Community-based recruitment

Expanded outreach to at-risk individuals who do not seek healthcare is important to increase screening rates in a population. Home-based screening with self-collected specimens has been offered in many different venues, including schools, correctional facilities and community centers [40–42]. For example, researchers in Australia distributed kits to youth groups, colleges, pharmacies and sports clubs, as well as making them available through the internet and via requests by phone. A pilot study of 100 returned urine test kits found a 7% prevalence of chlamydia infection. Participants preferred mobile phone or text message notification of test results. However, the authors did not report data on the characteristics of testers, such as gender or age distributions, or preferred locations for obtaining the test kits [24].

A recent study in Scotland compared several strategies for chlamydia screening in both clinical and community settings [43]. Home collection kits were available at record stores, pharmacies, local colleges and a youth sexual health clinic. Women made up the majority of

the 4475 testers (84.8%), all of whom were aged 13–25 years. Half of the tests were conducted using home kits, while 42.0% tested at the sexual health clinic and 6.7% at college clinics. Men strongly preferred home collection kits (80.2%), whereas women had nearly equivalent rates of testing using home and clinic methods. Supplying home collection kits to commercial venues is feasible and may be particularly attractive to men, who have lower rates of healthcare utilization compared with women [44].

A Danish randomized trial was the first to show the effectiveness of vaginal home screening kits to increase rates of STI screening among both women and men. Ostergaard *et al.* cluster-randomized 5487 female and 3422 male students at 17 high-schools to home sampling (intervention) or an invitation for physician screening (control) [45,46]. Of the sexually active teens who completed a baseline questionnaire, 93.4% of women in the home-sampling group completed chlamydia testing compared with 7.6% in the control arm (relative risk [RR]: 12.4), and 97.3% of men in the home-sampling group completed testing compared with only 1.6% in the control group (RR: 59.8). A strength of the study is that all chlamydia tests were objectively counted, either by receiving a home-collected specimen or by linking any clinic-based chlamydia testing performed in the county to the government registration number of each study participant. Results from 1 year after the screening offer showed that the women in the home sampling group had a significantly lower incidence of both chlamydia (2.9 vs 6.6%) and PID (2.1 vs 4.2%) compared with those in the clinic group.

Another Danish study randomized over 30,000 residents of one county to directly mailed home kits, mailed test-request card or usual care. Directly mailed home kits were four-times more effective in population screening of women compared with usual care (38.6 vs 9.4% tested; RR: 4.1), and also more effective than participant-requested kits (RR: 1.2). However, participant-requested home kits were still 3.5-times more effective than usual care. Men exhibited an even greater improvement in screening rates with directly mailed home kits (RR: 19.1) and participant-requested kits (RR: 11.8) compared with usual care. However, men in the usual care group had a very low rate of testing (1.4%) and, compared with women, men also had lower rates of testing in the intervention arms (16.5% participant-requested test group, 26.8% directly mailed home kit group) [47].

Using the same three-armed study design, Scholes *et al.* conducted a randomized trial to improve CT screening rates among 8820 men enrolled in a health plan in the USA [48]. Both interventions increased screening compared with routine care. Directly mailed kits produced twice as many screens as a test-request card (RR: 2.3); however, the response rate overall was low (3.6% for directly mailed home kits, 7.8% for requested kits). These studies demonstrate that, although the low baseline rate of screening in men can be improved with home collection of specimens, the rates of screening still remain low.

Population-level screening

Two countries have conducted large, uncontrolled pilot studies to evaluate the feasibility, acceptability and cost-effectiveness of national home-collected chlamydia screening programs. The Prevalentie en Interventie Landelijk Onderzoek Testen op Chlamydia trachomatis (PILOT CT; Prevention and intervention by country-wide testing for *Chlamydia trachomatis*) project in The Netherlands randomly selected 21,000 young men and women to receive home-screening urine collection kits. A total of 40% of kits were returned, with a greater response rate in women. The prevalence of CT was 2.0%, and treatment was confirmed in 91% of cases [49–51]. Dynamic modeling using this data showed that continuing this screening program could decrease the overall prevalence of CT in The Netherlands from 1.79 to 1.05%. A total of 10 years of screening would prevent 634 cases of PID, 125 cases of chronic pelvic pain, 86 ectopic pregnancies, 53 cases of

infertility, 75 neonatal complications and 3896 symptomatic infections in a simulated population of 100,000 heterosexual young men and women. While the program was not cost effective, a crude estimate showed that its cost is well below the cost–utility parameter of €20,000 per quality-adjusted life year accepted in The Netherlands [52].

The Chlamydia Screening Studies (ClaSS) Project in the UK offered postal screening to 19,733 men and women, 16–39 years of age, randomly selected from general practice lists. Of these, 73% were successfully contacted and 25% of these accepted the initial invitation to screen. Additional efforts, including repeated mailed invitations, phone reminders and flagged patient charts, increased the response rate to 34.5% [53]. Men used urine screening kits, and women were asked to provide urine and vaginal swab samples [54]. The overall incidence of infection was 3.2%, but a higher incidence (5.8%) was observed among individuals aged 16–25 years [53].

Internet recruitment

Recently, investigators of home-based screening have turned to the internet to recruit participants. A total of 60% of American adults have searched for health information online, including information on STIs [55,102]. Given the increasing relevance of the internet in day-to-day life, this may be the ideal method to reach at-risk young individuals, particularly those who do not seek clinical services. A website created by Gaydos *et al.* received 3774 requests from American women for chlamydia test kits, of which one-third were returned [56]. In the pilot phase, the website also listed locations where kits were available, such as pharmacies, hospital emergency departments and recreation centers. However, 87.5% of kits requested during the pilot phase were requested through an email link on the website, showing a clear preference for direct mailing [57]. This preference continued throughout the study, with internet requests accounting for 97.1% of all requested collection kits since 2005. Respondents ranged in age from 14–63 years, with a median age of 23 years, and most women were black (64.0%). Over 90% of women who completed the kits found self-collection preferable, safe and easy. Women in focus groups were split over the preferred method to disclose results, with similar numbers preferring disclosure via mail, email, telephone call or by request through a toll-free number. Receiving results through a website was not preferred by most women [30]. The website was recently expanded to include men, who were tested using both urine and penile swab specimens [58]. A third of requested kits were returned, the same proportion returned by women in the previous study. Men also considered self-collection easy and acceptable. A high rate of STI positivity was noted, with 21% of participants testing positive for at least one STI (CT, GC or trichomoniasis).

All inhabitants of one Swedish county in 2004–2005 were eligible to request home collection kits through the internet. The researchers relied mostly on word of mouth to inform residents of the website, and one poster was sent to each school and youth health center in the county. Other advertising methods included one video advertisement at a sporting event, an internet advertisement and a press conference at the beginning of the study. While the website received nearly 20,000 visits, only 1450 kits were requested, of which 62% were returned. The kits were used by both men (40%) and women (60%), and the 20–24-year-old age group had the highest rates of screening. Among all individuals who returned a test kit, the chlamydia prevalence was 4.6% in women and 6.0% in men, which was not significantly different. Although 38% of requested test kits were unused in this study, the authors argued that this method of internet-based screening still resulted in fewer unreturned test kits than systematic postal screening. However, they admit that it is unknown whether members of all social classes can equally access the internet to request testing [59].

Similarly, a recent 2010 study in The Netherlands invited over 250,000 men and women under 30 years of age, cluster-randomized by neighborhood, to request a home collection kit

through the internet. The study was planned after the completion of the PILOT CT trial described earlier [49–52]. Of those invited, 20% ordered a free test kit and 79% of requesters returned a kit. While the kit request rate seems low, not all of the invited participants were eligible for testing. For instance, those who were not sexually active were not permitted to test, but the proportion of sexually active individuals was not reported. Respondents from one lower-risk region were also required to prove their higher risk status on a website questionnaire before ordering a kit. A total of 63% of those who completed the questionnaire met high-risk criteria [60].

As seen in the aforementioned trials, a low rate of completed testing is a common problem for internet-based screening programs. Martin *et al.* compared several strategies for providing STI screening in nonclinical settings in Australia. Kits were provided to 413 young men and women through a variety of avenues, such as outreach events, via email or by phone. While email and outreach events were equally popular methods of obtaining a kit, kits obtained in person at outreach events were more likely to be returned than those requested via email (odds ratio: 9.6) [61].

Partner screening

Individuals with chlamydia and gonorrhea are at high risk for reinfection due to re-exposure from untreated partners or repeated contact with individuals at high risk of infection. Studies suggest that repeat chlamydial infection occurs in 7–30% of women in the 4–6 months following initial diagnosis [62–65]. Recurrent infection, especially among women, increases the risk for severe sequelae such as PID, infertility and chronic pelvic pain [6,7].

Home-based screening has been proposed as a method to identify infected partners and prevent disease transmission. In most studies, home-based screening resulted in similar numbers of treated partners compared with conventional partner tracing, or patient-delivered partner therapy. Apoola and Beardsley randomized 200 women with CT to notify partners using contact slips, or using a urine home sampling kit plus contact slip. No difference in the number of treated partners was found (0.67 vs 0.62 partners treated per index case). However, both arms were required to visit a clinic to hand-deliver urine samples, which reduces the convenience of home collection [66]. In another UK-based study of partner notification among 330 index cases, Cameron *et al.* compared three different partner testing strategies: postal testing kits, patient-delivered partner therapy and patient referral. There were no significant differences in partner testing or reinfection rates among the three methods [67].

However, one study has demonstrated improved partner testing with home kits. In Denmark, 1826 men and women diagnosed with CT were randomized to home versus office screening of partners. Index cases were provided with sample collection kits to give to their partners, which could be used at home or in a clinical setting, depending on the randomization group. Both sexes had improved partner testing rates with home testing (26.1 vs 11.8% in women, RR: 2.2; 14.8 vs 3.3% in men, RR: 4.4). In addition, more infected partners were found in the home testing group [68].

Discussion

Is home screening feasible & acceptable?

Home-collected screening for chlamydia and gonorrhea is both feasible and acceptable to men and women. Qualitative data from focus groups and surveys, mostly of women, show that respondents believe self-collecting samples is easy, comfortable and preferable to a pelvic examination. Privacy is a concern when STI screening takes place outside of a clinical setting, but an acceptable level of privacy can easily be achieved by discreet

packaging. Multiple controlled studies showing uptake rates as low as 7.8% but as high as 97.3% prove that men and women are willing to participate in home-based screening (Table 1). Most studies had uptake rates in the range of 40–60%.

This article encompasses studies conducted in multiple countries with different approaches to healthcare. For instance, studies in countries with nationalized healthcare systems, such as The Netherlands, Sweden, Denmark and the UK, tended to be broad, population-level studies of interventions that could be conducted by the healthcare system itself. Examples include studies conducted at a national (ClaSS and Pilot CT) [49,53], county [47,59] or city-wide level [43,60]. Only one study was conducted in a general practice [37]. However, these healthcare systems may choose to provide incentives to increase chlamydia screening within a practice. Such incentives could encourage innovation, including home-based screening.

By contrast, several studies were conducted in the USA, where the private insurance markets may influence physician behavior through reimbursement. Home-based screening is a labor-intensive process, particularly if home collection kits must be assembled from scratch. This was emphasized by Senok *et al.* in their study offering home-based screening in Scottish medical practices [37]. Thus, research in the USA has focused on strategies that could be used by public health agencies, health insurance companies and academic institutions interested in reducing the incidence of STIs. Traditional STI testing can be prohibitively expensive for uninsured women and men in the USA, making affordable options for STI screening vitally important for these high-risk individuals. Eliminating a clinician visit through home collection and/or subsidizing the cost of testing itself could be useful public health strategies.

Two studies evaluated the use of home-collection in low-resource settings. These studies showed that home-based testing is acceptable to women living in underdeveloped countries, although clinically significant improvements in testing rates were not observed. In particular, the Brazilian study required home kits to be dropped off at a study site, rather than through the mail, thus negating many of the benefits of home screening [38]. However, these studies suggest that home screening can be one of many satisfactory strategies to provide STI screening in low-resource communities.

Does home screening increase screening rates?

Multiple studies in developed countries, including several randomized controlled trials, showed increased screening rates with home-based screening. The controlled studies were well designed, with adequate power to show a difference in screening rates. The current STI screening rates for women are estimated to be 42% of screening guideline-eligible women in the USA, and 24% of young women in the UK [2,12]. Home screening in controlled studies resulted in higher screening rates, ranging from 38 to 65%, compared with control groups. An outlier was the outstanding 93.4 and 97.3% home screening rates achieved in Ostergaard *et al.*'s study of female and male high school students, respectively [46]. However, these screening rates were calculated based upon the number of individuals who responded to an initial survey, which comprised only 43% of women and 26% men who were offered testing. Thus, the actual rate of screening among the total study population is probably much lower.

While it is encouraging to see improvements in STI screening rates with home-based screening, screening rates are still fairly low considering the fact that, in many studies, screening kits were made immediately accessible by direct mailing to the participant's home. So why are screening rates not even higher? The authors of the randomized trial within the contraceptive CHOICE Project interviewed 67% of women in both the home and clinic arms who did not complete testing. The most commonly cited reason for not testing

was that women simply forgot (32%). This response was twice as frequent in the home group compared with the clinic group [31]. While it appears that home collection makes it simple to complete screening, inertia and lack of basic organizational skills may play a role in the low response rate. Although home collection removes barriers such as access, high cost, inconvenience and discomfort associated with traditional testing, there are still many known and unknown reasons why people fail to comply with preventive health behaviors.

Is screening effective in both men & women, & for partner testing?

In almost all studies that screened both sexes, women exhibited higher rates of screening than men (Figure 1). A study that enrolled only American men exhibited the lowest rate of home testing uptake (7.8%) [48]. Given that women are more likely to suffer the complications of chlamydial infection, such as PID, infertility and chronic pelvic pain, the motivation for women to be screened is probably higher than for men.

Partner screening with home collection has had mixed results, with only one study finding an increase in the number of treated partners [68]. By contrast, Cameron *et al.* examined three strategies for partner treatment, including home testing, partner notification and patient-delivered partner therapy, and found no differences between the approaches [67]. Compared with patient-delivered partner therapy, where the index case both notifies and treats all partners, home-based testing requires the extra step of collecting and returning a specimen before a partner is treated. This increases the cost, time and potential for loss to follow-up.

Does home collection target the highest-risk groups?

Most studies were conducted in young individuals under the age of 25 years, the population with the highest rates of STIs [3]. We know that young people find self-testing acceptable based on survey data and the high rates of testing observed in most studies described in this article. However, studies with the newest internet-based recruitment approaches are limited since it is difficult to identify which subpopulations do not access the internet. While internet use is high among young people, this may not be true across all socioeconomic groups.

High-risk individuals include those who do not seek health-care, but little data are available to evaluate the value of providing STI test kits in nonclinic community venues, such as pharmacies, schools and community centers. Williamson *et al.* reported that 2200 collection kits were picked up from non-clinic locations, with men strongly preferring to pick up a collection kit rather than test at a college or sexual health clinic [43]. By contrast, another study found that only 12.5% of collection kits were obtained from community sites advertised on a website; the majority of website visitors chose to have a directly mailed kit [57]. However, neither of these studies had control groups, making it difficult to evaluate whether community availability of home kits captured individuals who would not otherwise be tested by the healthcare system. Unfortunately, most studies that made home kits available in the community gave little information that could be useful in planning future interventions, such as the most popular home collection kit pick-up locations.

Expert commentary & five-year view

Continuing a trend that has been steady over the previous 5 years, we believe the chlamydia incidence will continue to rise over the next 5 years. This will result from the identification of more asymptomatic cases through increased screening efforts, as well as an overall increase in the actual disease burden.

Home-based specimen collection for STIs should be an important component of a multipronged strategy to improve screening rates. First, both traditional and noninvasive testing in clinician offices will remain essential in screening individuals who present for healthcare. We should encourage healthcare providers to integrate chlamydia screening into the regular care of their patients, making screening nonjudgmental and not linked to a pelvic exam. Secondly, home collection kits should be made available through multiple venues. Future research is needed to determine the best community locations at which subsidized collection kits can be provided. However, such locations will probably vary by the particular community being served, and local studies may be the most useful.

The most innovative method for offering home screening is through the internet, and we anticipate future research and public health efforts moving towards internet-based testing. This strategy offers the benefits of convenience and privacy inherent to postal testing, while not restricting the target population by geography or use of healthcare services.

Chlamydia tests, both rapid tests and those that are sent to a laboratory for testing, are currently available commercially on the internet. However, many of these websites and the tests they sell appear to be unreliable. Owens *et al.* reviewed 27 of these websites, finding few that responded to repeated survey requests and several that had invalid contact information. Of the seven specimens sent by the authors, results were never received for two, two rapid tests produced false-negative results and only three laboratory-performed tests had true-positive results, including one from the authors' own website [69]. Michel *et al.* also studied the poor performance of rapid tests available on the internet, and found that sensitivity can be as low as 12% [70].

The US FDA has not approved any chlamydia/gonorrhea assay for home-collected samples. Recently, the FDA issued a warning letter to a company selling a urine collection kit for chlamydia and gonorrhea at a major US pharmacy chain [103]. Given the poor performance of some nonapproved tests, FDA approval of home specimen collection kits is a prudent regulatory step, but also a major impediment to expanded STI screening in the USA.

US healthcare reform opens the door to new incentives for private physicians to improve health outcomes. Outcomes-based payment systems are promising experiments that may gain new emphasis in the near future. Chlamydia screening may be an area of scrutiny, as it has been identified as one of the top seven priorities in preventive health, based on health impact, cost-effectiveness and current low uptake [71]. Home-based screening may be an excellent strategy to improve screening rates for chlamydia within a medical practice, a community or an entire population.

Health insurance plans have traditionally been the stakeholders with the greatest incentives to reduce costs in the American healthcare system. It is surprising that only one US health insurance plan has published a study evaluating the effects of a postal chlamydia screening program [48]. Curiously, this study focused on men, who do not suffer the serious and expensive complications of chlamydial infection. Preventing PID, chronic pelvic pain and infertility in women through expanded home screening could result in cost savings, and further research is necessary to determine if health insurance plans could use postal screening to improve outcomes and save money. Cost-effectiveness studies should evaluate all costs associated with traditional clinic-based screening as well as the downstream adverse reproductive outcomes of untreated infections (e.g., PID, chronic pelvic pain, ectopic pregnancy and infertility) to assess the utility of home-based STI screening.

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Figure 1.
Comparison of screening uptake in men and women in studies screening both sexes.

Table 1
Comparison of controlled trials of home-based screening for sexually transmitted infections.

Study (year)	Description	Sample size (n)	Control arm	Home testing rate	Control testing rate	RR (95% CI)	Ref.
Graseck <i>et al.</i> (2010)	Randomized study of American long-acting contraceptive users	558	Invitation for clinic-based screening with self-swabs at clinics or screening using the usual method practiced by the participant's physician	56%	33%	1.7 (1.4–2.0)	[31]
Graseck <i>et al.</i> (2010)	Observational study of American women choosing home- or clinic-based screening	462	Invitation for clinic-based screening with self-swabs at clinics or screening using the usual method practiced by the participant's physician	65%	32%	2.0 (1.5–2.8)	[33]
Cook <i>et al.</i> (2007)	Randomized study of high-risk, young American women	420	Invitation for clinic-based screening	1.94 tests/year	1.41 tests/year	1.4 (1.2–1.6)	[35]
Lippman <i>et al.</i> (2007)	Randomized study of Brazilian women recruited from a clinic	818	Appointment for clinic-based screening with self-swabs	93%	89%	1.04 (1.00–1.09)	[38]
Jones <i>et al.</i> (2007)	Randomized study of South African women recruited from a clinical trial research site	626	Appointment for clinic-based screening with self-swabs	47%	42%	1.3 (1.1–1.5)	[39]
Scholes <i>et al.</i> (2007)	Randomized study of male enrollees in an American health plan	8820	Mailed test-request card or usual care	7.8%	3.6% (mailed test request card), 0.8% (usual care)	Compared with usual care: 11.1 (7.3–16.9)	[48]
Senok <i>et al.</i> (2005)	Randomized study of Scottish women belonging to one of three medical practices	600	Opportunistic clinic screening (home kit offered to those presenting for medical care) or usual care	48%	21% opportunistic; 0% usual care	Compared with opportunistic: 2.3 (1.6–3.4)	[37]
Andersen <i>et al.</i> (2002)	Randomized study of male and female residents of a Danish county	30,439	Mailed test-request card or usual care	Women: 38.6% Men: 26.8%	Women: 33% test-request card and 9.4% usual care Men: 16.5% test-request card and 1.4% usual care	Compared with usual care: women: 4.1 (3.8–4.4) Men: 19.1 (16.0–22.8)	[47]
Ostergaard <i>et al.</i> (1998)	Cluster-randomized study of male and female students at 17 high schools in Denmark Eligible subjects responded to a questionnaire and were sexually active	8909 offered screening; 2449 eligible	Invitation for physician screening	Women: 93.4% Men: 97.3% (of eligible subjects)	Women: 7.6% Men: 1.6% (of eligible subjects)	Women: 12.4 (9.7–15.7) Men: 59.8 (22.6–158.1)	[45]

RR: Relative risk.