Comparative effectiveness and acceptability of home-based and clinic-based sampling methods for sexually transmissible infections screening in females aged 14–50 years: a systematic review and meta-analysis

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Abstract. **Background**: Home-based sampling is a strategy to enhance uptake of sexually transmissible infection (STI) screening. This review aimed to compare the screening uptake levels of home-based self-sampling and clinic-based specimen collection for STIs (chlamydia (\textit{Chlamydia trachomatis}), gonorrhoea (\textit{Neisseria gonorrhoeae}) and trichomoniasis) in females aged 14–50 years. Acceptability and effect on specimen quality were determined. **Methods**: Sixteen electronic databases were searched from inception to September 2012. Randomised controlled trials (RCTs) comparing the uptake levels of home-based self-sampling and clinic-based sampling for chlamydia, gonorrhoea and trichomoniasis in females aged 14–50 years were eligible for inclusion. The risk of bias in the trials was assessed. Risk ratios (RRs) for dichotomous outcomes were meta-analysed. **Results**: Of 3065 papers, six studies with seven RCTs contributed to the final review. Compared with clinic-based methods, home-based screening increased uptake significantly ($P = 0.001$–0.05) in five trials and was substantiated in a meta-analysis (RR: 1.55; 95\% confidence interval: 1.30–1.85; $P = 0.00001$) of two trials. In three trials, a significant preference for home-based testing ($P = 0.001$–0.05) was expressed. No significant difference was observed in specimen quality. Sampling was rated as easy by a significantly higher number of women ($P = 0.01$) in the clinic group in one trial. **Conclusions**: The review provides evidence that home-based testing results in greater uptake of STI screening in females (14–50 years) than clinic-based testing without compromising quality in the developed world. Home collection strategies should be added to clinic-based screening programs to enhance uptake.

**Additional keywords**: chlamydia, gonorrhoea, mass screening, trichomonas.

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Introduction

According to the 2011 report by the World Health Organisation, over 440 million new treatable cases of chlamydia (\textit{Chlamydia trachomatis}), gonorrhoea (\textit{Neisseria gonorrhoeae}) and \textit{Trichomonas vaginalis} sexually transmissible infections (STIs), occur annually in those aged 15–49 years.\textsuperscript{1} Due to physiological and social realities, higher burdens of these infections are recorded in female adolescents and young adults compared with their male counterparts.\textsuperscript{2–5} Over 50\% of infections occur asymptomatically. Many are untreated, resulting in severe complications with adverse outcomes on maternal and child health.\textsuperscript{8–19} In the developing world, with a greater burden, these infections and associated complications account for 17\% of economic losses caused by ill health.\textsuperscript{20–22} Mass screening of the at-risk population is one of several prevention and control strategies explored so far at local and international levels to stem the tide.\textsuperscript{23–28} Traditionally, the strategy utilised free clinic-based sampling and conventional culture methods for screening.\textsuperscript{3,12} Culture methods required specimen collection by a clinician in a pelvic examination,\textsuperscript{15} which is often cited as a barrier to screening.\textsuperscript{29–32} Where a pelvic examination was not otherwise indicated, specimen collection by less invasive methods is sometimes preferred by women to avoid the physical embarrassment associated with undressing.\textsuperscript{29–33} Following the incorporation of self-sampling (and molecular detection techniques) into clinic-based screening in several countries, access to clinic sites remains a major barrier.\textsuperscript{30}
Recent efforts to achieve greater control of STIs have centred on the use of home sampling to enhance uptake of screening.34–38 The home-based testing strategy utilises a variety of self-collected specimens (first void urine, vaginal swabs and tampons), molecular diagnostic systems, and self-pickup or mail delivery systems in screening for STIs.39,40 This method has been credited as having sensitivity and specificity levels that are on a par with clinic-based sampling utilising molecular detection techniques.34,41,42 With accepted delivery periods ranging between 2 and 7 days, it offers privacy and flexibility in site of collection and delivery time.40,43,44 Home sampling is thought to be minimally invasive, overcoming the barriers of unacceptability, fear and embarrassment associated with conventional screening methods.53,45–48 Research has, however, thrown light on challenges with this strategy.39,49 One such challenge is the use of mail delivery, which could result in specimen loss, spillage, damage, late delivery and a need for rescreening.49,49 Besides, mail delivery of specimens is currently prohibited in some countries.36,49

In two Danish studies, a home-based strategy was considered more effective than clinic-based testing in women.24,36 This finding contrasted with two other studies on effectiveness in Brazil and USA.31,49

The surge in the incidence of STIs over the past decade,39,37,50 has called into question the efficacy and perceived success of existing control strategies and brought to light the need for a focus on effective interventions.

This study examined the effectiveness of home-based sampling strategies on increasing the uptake of STI screening programs in females aged 14–50 years and their impact on specimen quality compared with traditional clinic screening. It was undertaken to inform population-level screening programs in both industrialised and developing countries, as well as to contribute to the pool of research evidence on effectiveness.

Methods
Sixteen electronic bibliographic databases comprising biomedical, scientific (e.g. Cochrane Library, MEDLINE, EMBASE, CINAHL, ASSIA, PSyc INFO, Web of Science, CRD and ongoing clinical trial registries) and grey literature sources were searched from inception to September 2012.

The search strategy utilised thesaurus and free text terms representative of both population and intervention (e.g. STI, chlamydia, gonorrhoea, trichomoniasis, venereal disease, home-based sampling, screening) with Boolean operators to ensure the maximal yield of all relevant articles.51 These were then combined with validated RCT filters. Electronic searches were further supplemented with hand searches of STI journals. A reference manager (RefWorks ver. 2.0, ProQuest LLC, Ann Arbor, MI, USA) was used to identify and eliminate duplicates. Citations were sifted by title, abstract and full text. A description of the search strategy and potentially relevant studies excluded from the review are depicted in a flowchart.52

Inclusion and exclusion criteria
Study selection was undertaken by two reviewers using the following inclusion criteria:51 RCTs were chosen to limit confounding and bias that could mask the true measure of effect of an intervention.39 RCTs comparing home-based self-sampling (by mail or self-pickup delivery) and clinic-based testing strategies (by clinician or self) for the selected STIs: chlamydia (Chlamydia trachomatis), gonorrhoea (Neisseria gonorrhoeae) or trichomonas in females aged 14–50 years were considered eligible for review. All eligible trials utilised validated molecular detection methods for diagnosing STIs.

The primary outcome of interest was uptake or non-uptake of screening, defined as the number of females screened as a proportion of all those that should have been screened.53 Secondary outcomes were number of rejected samples, preference for and ease of self-sampling. RCTs utilising other populations (males, children or animals), and non-English and non-randomised studies were excluded.

Data abstraction
Data relating to study design, quality and results were extracted directly to customised electronic data extraction forms in a bid to avoid transcription errors. Where multiple publications of a study existed, data were extracted and reported as one study.

Quality assessment strategy
Two reviewers assessed the quality of trials utilising the Cochrane risk of bias tool.51 The mode of sequence generation, allocation concealment, blinding of participants and assessors, incomplete outcome data and selective reporting, as well as other study specific forms of bias, were assessed.51 Quality assessors were not blinded to author, institution or journal.

Data synthesis
For each study, relevant data were highlighted by means of descriptive tables.54,55 A meta-analysis was achieved with Review Manager ver. 5.1.2 (Java 6, The Cochrane Collaboration, Copenhagen, Denmark) for dichotomous outcomes providing the number of events per number of participants in each trial arm.51 A random effect model was assumed for all analysis accounting for between-study variation, and providing wider and more conservative estimates than the fixed effect model.51,56

Uptake was reported as a risk ratio (RR) and a 95% confidence interval (CI).51 An assessment of heterogeneity was performed on studies utilised in a meta-analysis using the $I^2$ method as described in the Cochrane Handbook.51 The $I^2$ test is designed to quantify inconsistency across studies as well as to assess the impact of such heterogeneity on the meta-analysis.51,56 Substantial levels of heterogeneity ($I^2$ levels $>50\%$) were explored with a sensitivity analysis assessing the effect of bias and study design.51,56

It was hypothesised that mode of assessment (medical records ver. medical records plus self-report), organisational factors in the health systems of developed versus developing countries and study duration ($\leq 12$ months and $>12$ months) may impact on outcome.55,55 A subgroup analysis was achieved by mode of assessment, study duration and continent. Where a meta-analysis was considered inappropriate (e.g. unit of analysis...
issues in cluster trials, insufficient data or type of outcome), a narrative synthesis was done to present results.

**Results**

A PRISMA flow chart\(^5\) depicting the process of identifying relevant RCTs is depicted in Fig. 1. Six RCTs of long- and short-term duration were included in the study. A summary of each study is presented in Table 1.

All RCTs were published between 1998 and 2011 (Table 1). In total, 5475 females between the ages of 14 to 45 years\(^5\) (mean age: 21.6 years) were enrolled in the trials. The number of participants in each trial ranged from 420\(^6\) to 1761.\(^6\) The home and clinic groups had 2774 (50.7%) and 2701 (49.3%) females allocated to each respectively.\(^5\)–\(^7\) Four of the six trials were conducted in developed countries.\(^5\)–\(^6\) Recruitments of participants were from both the clinic and the community in four studies,\(^4\)–\(^6\) one from multiple clinics\(^5\) and another from schools.\(^6\) Females were either sexually active,\(^5\)–\(^6\) on long-acting contraceptives,\(^5\) had a prior history of an STI screen or had completed a baseline screen as a prerequisite for enrolment\(^6\) in four studies. Literacy was used as a criterion for enrolment in two studies.\(^4\),\(^5\)

Baseline demographic characteristics (age, marital status, socioeconomic status, ethnicity) were well balanced for both groups across the trials, with few exceptions. One trial\(^6\) did not supply information on age, and two did not provide information on the comparability of ethnic groups between intervention and control groups.\(^5\),\(^6\) The trial by Graseck et al.\(^5\) had more never married people in the clinic group, whereas Lippman et al.\(^4\) had more single women in the home group.

**Quality assessment**

All trials documented the mode of sequence generation and had an at low risk for bias\(^4\),\(^5\)–\(^6\) (Fig. 2). Randomisation was achieved at the cluster level in one trial.\(^5\) Four of the trials utilised a parallel RCT design,\(^4\),\(^5\),\(^6\) one used a factorial group \((2\times2\) design.\(^6\) Four trials reported adequate methods of allocation concealment and were graded as having a low risk of bias.

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**Fig. 1.** PRISMA flow diagram showing screening process (adapted).\(^5\) RCT, randomised controlled trial.
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants’ recruitment criteria</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Assessment of primary outcome (uptake)</th>
<th>Study size</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lippman et al. 2007;</td>
<td>RCT, parallel</td>
<td>Females aged 18–40 years from clinic and community sites who are literate enough to self-test</td>
<td>Home screening (vaginal swab) using self-pickup and delivery mechanism. Cobas</td>
<td>Clinic screen with clinician-obtained specimens (ECS) and self-collection kits; (n = 408)</td>
<td>Medical records for trichomonas, chlamydia and gonorrhoea screen</td>
<td>818</td>
<td>8 months</td>
</tr>
<tr>
<td>Brazil(^6)</td>
<td></td>
<td></td>
<td>Cobas AmpLi-Cor; (n = 410)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jones et al. 2007;</td>
<td>RCT, parallel</td>
<td>Females aged 14–25 from clinic and community sites who are literate (Grade 5 education)</td>
<td>Home screening (vaginal swab) using mailed self-collection kits. Cobas</td>
<td>Clinic screen with clinician-obtained specimens and self-collection kits; (n = 313)</td>
<td>Self-report and medical records for trichomonas, chlamydia and gonorrhoea screen</td>
<td>626</td>
<td>12 months</td>
</tr>
<tr>
<td>South Africa(^7)</td>
<td></td>
<td></td>
<td>AmpLi-Cor and in-house PCR. (n = 313)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graseck et al. 2010;</td>
<td>RCT, parallel</td>
<td>Females aged 14–45 years from multiple clinic sites who are sexually active, English- or Spanish-speaking, enrolled in the CHOICE study and who completed a baseline screen</td>
<td>Home screening (vaginal swab) using mail delivery mechanism. BD probe Tec</td>
<td>Clinic screen with self-collection kits; (n = 285)</td>
<td>Self-report and medical records for chlamydia and gonorrhoea</td>
<td>558</td>
<td>3 years</td>
</tr>
<tr>
<td>USA(^8)</td>
<td></td>
<td></td>
<td>ET. (n = 273)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cook et al. 2007;</td>
<td>RCT, parallel</td>
<td>Females aged 15–24 years from clinic and community sites who are sexually active, and completed the baseline screen with a recent history of STI, (&gt;2) risk factors for STI ((\leq 20) years, Black race, monthly douching, (&gt;1) sexual partner in past 1 year or living in a neighbourhood with a top 33% of chlamydia)</td>
<td>Home screening (vaginal swab) using mail or self-delivery mechanisms. BD probe</td>
<td>Clinic screening using clinician-obtained specimens (ECS); (n = 209)</td>
<td>Medical records for chlamydia and gonorrhoea screen</td>
<td>420</td>
<td>2 years</td>
</tr>
<tr>
<td>USA(^9)</td>
<td></td>
<td></td>
<td>Tec ET. (n = 211)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ostergaard et al. 1998;</td>
<td>Cluster RCT</td>
<td>Females aged 17–20 years from multiple school sites, and sexually active baseline questionnaire responders</td>
<td>Home screening (vaginal flush) using mailed self-collection kit. Gene Probe.</td>
<td>Clinic screen with clinician-obtained specimens (ECS); (n = 833)</td>
<td>Medical records for chlamydia screen</td>
<td>1761</td>
<td>4 months</td>
</tr>
<tr>
<td>Denmark(^6)</td>
<td></td>
<td></td>
<td>(n = 928)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Xu et al. 2011; USA(^{10})</td>
<td>RCT, factorial ((2 \times 2) design (STI and FPC arms)</td>
<td>Females aged (&gt;16) years (from multiple clinics and community) who completed baseline screen with a confirmed laboratory history of chlamydia infection</td>
<td>Home screening (vaginal swab) using mail or self-delivery mechanisms. Aptima combo 2 assay. (n = 441)</td>
<td>Clinic screening using clinician-obtained specimens (ECS); (n = 439)</td>
<td>Medical records for chlamydia screen</td>
<td>STI 880</td>
<td>18 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aptima combo 2 assay. (n = 441)</td>
<td></td>
<td></td>
<td>FPC 412</td>
<td></td>
</tr>
</tbody>
</table>
The cluster trial by Ostergaard et al.\textsuperscript{60} was at high risk for other forms of bias such as recruitment bias in that recruitment and consent were only obtained from participants after randomisation.\textsuperscript{60} Furthermore, the lack of documentation of an intracluster correlation coefficient and power size calculation did not permit judgement as to whether a power size calculation was fulfilled.\textsuperscript{60}

Figs 3–6 show the forest plot with risk ratio for each study and pooled data. In two trials (1184 females) assessing uptake by a combination of self-report and medical records, a home-based self-sampling strategy significantly (RR: 1.55; 95% CI: 1.30–1.85; \(P=0.00001\)) increased uptake of STI screening among females compared with clinic-based testing. Moderate but acceptable levels of heterogeneity (\(I^2=49\%\); \(\chi^2=1.96\); \(P=0.16\)) were observed between the two trials (Fig. 3).

In three trials (with 1987 females) assessing uptake via medical records (and providing sufficient data for a meta-analysis), no significant difference (RR: 1.37; 95% CI: 0.90–2.08; \(P=0.14\)) was observed in the uptake of screening between women in the home and clinic groups. A high degree of heterogeneity (\(I^2=96\%\); \(\chi^2=44.50\); \(P=0.00001\)) was, however, observed between these trials (Fig. 3). The test for heterogeneity was insignificant (\(I^2=0\%\); \(\chi^2=0.23\); \(P=0.63\)) when the trial by Graseck et al.\textsuperscript{58} (utilising only clinic recruitment and a study duration of >12 months) was excluded from the analysis (Fig. 4). The subgroup analysis was based on study duration (>12 months and ≤12 months) and continent, with the test for subgroup differences being significant (\(P<0.0001\)). In the subgroups ≤12 months and developing country (measured by medical records), no significant difference (RR: 1.07; 95% CI: 1.00–1.14; \(P=0.06\)) was observed in uptake of screening between women in the home and clinic groups (Fig. 4).

The result from the subgroup analysis of ≤12 months was not in keeping with two other studies that measured outcome by medical records, but could not be meta-analysed due to insufficient data.\textsuperscript{59,60} The study by Cook et al.\textsuperscript{59} assessed the proportion of women who completed at least one STI test within a 2-year period (three screen points) and found a significant increase (\(P=0.001\); 82.2% v. 61.3%) in uptake of screening in favour of women in the home group compared with clinic group.\textsuperscript{59} In that same study, more women in the home group were found to complete at least two tests in the 2-year period when compared with the clinic group (\(P=0.001\); 55.9% v. 37.2%).\textsuperscript{59}

Ostergaard et al.’s study,\textsuperscript{60} a cluster trial analysed as an individual trial (unadjusted for clustering), also observed a statistically significant difference in the level of uptake in favour of females using home-based tests (\(P=0.01\); 867 out of 928 v. 63 out of 833).\textsuperscript{60} Without an intracluster correlation coefficient, the results could not be adjusted for clustering and utilised in a meta-analysis.

Two studies measured the uptake of screening after the introduction of reminder calls. Figs 5, 6 shows the forest plots depicting the RR for each study and the pooled data. Following the introduction of reminders to encourage response in females, no significant difference (RR: 1.41; 95% CI: 0.81–2.44; \(P=0.22\)) in uptake was observed between women in the home group and those in the clinic group. The trial by Lippman et al.\textsuperscript{59} differed in methodology (parallel RCT) delivery mechanisms (self-pickup alone), study duration
Fig. 3. Forest plot depicting the overall effect of the comparison between home- and clinic-based screening in relation to uptake. CI, confidence interval; M-H, Mantel–Haenszel.

Fig. 4. Forest plot depicting the overall effect of the comparison between home- and clinic-based screening in relation to uptake (subgroup analysis). CI, confidence interval; M-H, Mantel–Haenszel.
Applying a sensitivity analysis approach (Fig. 6) to the study design still resulted in substantial levels of heterogeneity ($I^2 = 64\%$; $c^2 = 2.76$; $P = 0.10$), with subgroup analysis resulting in significant levels of uptake in favour of females in the home group (RR: 1.64; 95% CI: 1.17–2.30; $P = 0.004$).

The study by Xu et al.\textsuperscript{61} limited the analysis to only participants reached by reminders. The meta-analysis resulted in a significant increase in uptake of screening in the home group (RR: 1.42; 95% CI: 1.18–1.70; $P = 0.0002$). The test for heterogeneity was not significant ($P = 0.36$). In the trial by Lippman et al.,\textsuperscript{49} introduction of reminder calls did not result

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Table: Screening for STI in females aged 14–50 years

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Home</th>
<th>Clinic</th>
<th>Risk ratio</th>
<th>Risk ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
<td>Total</td>
</tr>
<tr>
<td>Lippman 2007</td>
<td>381</td>
<td>410</td>
<td>359</td>
<td>403</td>
</tr>
<tr>
<td>XU 2011 FPC</td>
<td>80</td>
<td>196</td>
<td>43</td>
<td>208</td>
</tr>
<tr>
<td>XU 2011 STI</td>
<td>109</td>
<td>408</td>
<td>77</td>
<td>403</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>1014</td>
<td>1014</td>
<td>100.0%</td>
<td>1.41 [0.81, 2.44]</td>
</tr>
<tr>
<td>Total events</td>
<td>570</td>
<td>479</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity, $\tau^2 = 0.22$; $\chi^2 = 43.34$, df = 2 ($P &lt; 0.00001$); $I^2 = 95%$</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: $Z = 1.22$ ($P = 0.22$)</td>
<td></td>
<td></td>
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</tbody>
</table>

Fig. 5. Forest plot depicting the overall effect of the comparison between home- and clinic-based screening in relation to uptake following the introduction of reminders. CI, confidence interval; M-H, Mantel–Haenszel; FPC, family planning clinic arm of the study; STI, sexually transmissible infection arm of the study.

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Table: Screening for STI in females aged 14–50 years (at 7 week window end of study) limited to those reached by reminders

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Home</th>
<th>Clinic</th>
<th>Risk ratio</th>
<th>Risk ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
<td>Total</td>
</tr>
<tr>
<td>XU 2011 FPC</td>
<td>77</td>
<td>130</td>
<td>42</td>
<td>111</td>
</tr>
<tr>
<td>XU 2011 STI</td>
<td>104</td>
<td>239</td>
<td>68</td>
<td>206</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>369</td>
<td>317</td>
<td>100.0%</td>
<td>1.42 [1.18, 1.70]</td>
</tr>
<tr>
<td>Total events</td>
<td>181</td>
<td>110</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heterogeneity, $\tau^2 = 0.00$; $\chi^2 = 0.84$, df = 1 ($P = 0.36$); $I^2 = 0%$</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: $Z = 3.76$ ($P = 0.0002$)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig. 6. Forest plot depicting the overall effect of the comparison between home- and clinic-based screening in relation to uptake following the introduction of reminders (sensitivity analysis) CI, confidence interval; M-H, Mantel-Haenszel; FPC, family planning clinic arm of the study; STI, sexually transmissible infection arm of the study.

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(6 weeks) and enrolment criteria from the other two trials.\textsuperscript{61}
in a significant difference in uptake between participants in the home and clinic groups (RR: 1.4; 95% CI: 0.81–2.44). In two studies, young age, being a student or having a high school education were important predictors of uptake. This contrasted with findings from a South African trial, where higher levels of uptake were observed among older women with a lack of education and multiple sexual partners. Low socioeconomic status, being of African–American descent and a less frequent utilisation of clinics were other notable predictors of uptake. Similar treatment follow-up rates were observed among women with positive tests allocated to either group.  

### Secondary outcomes

Three trials considered secondary outcomes of interest: specimen quality, number of rejected specimens, ease of self-sampling and a preference for home sampling. In two trials, no significant difference was noted in response to a questionnaire on the ease of self-sampling in both the clinic and home groups, with all (100%) women reporting it as being easy. An exception was the trial by Jones et al. where a significantly higher number of women (P < 0.01) in the clinic group (96.2% v. 85.8%) rated self-sampling as being easy.

A preference for home sampling (measured via questionnaire or interviews) was strongly associated with group allocation in the three trials. In two trials, statistically significant differences were observed in favour of the home group (P = 0.05, 61% v. 26% in Lippman et al.; P = 0.001 in Graseck et al.; P = 0.001, 57.6% v. 27.3% in Jones et al.).

### Discussion

This is the first systematic review comparing levels of screening uptake associated with home self-sampling and clinic-based sampling modalities of specimen collection for STI among females.

Home sampling resulted in an increased uptake of screening in five out of six studies. This evidence was further substantiated in a meta-analysis of two trials measuring uptake by self-report and in another involving trials measuring uptake (by medical records for >12 months) after the introduction of reminder calls. A statistically significant effect demonstrated in one trial was found to vary with the mode of assessment of uptake. The exclusion of self-report in the assessment in that trial resulted in an insignificant difference in uptake of screening between females in the home and clinic groups. This trial was conducted in South Africa, where postal systems are not fully developed. Consequently, considerable numbers of specimens submitted by women in the home group were reported as lost in the mail.

A similar finding was observed in another study in a low income country (Brazil). In this study, no significant difference in uptake of screening was observed between women in the clinic and home group before and after the introduction of reminder calls (following a missed screen at Week 2) to enhance response rates. A possible explanation for the insignificant effect observed in the Brazilian trial may be because it utilised only self-pickup and delivery systems for kits between participants and clinic. Where participants have to attend the clinic twice to complete a screen (i.e. to pick up and drop off a kit), home sampling may not offer much advantage compared with the traditional clinic screen. Issues of privacy, distance and transport may have also contributed to the insignificant response rates observed between groups.

The four other trials that reported a significant increase in uptake were all conducted in the developed world. The factorial trial explored the use of reminders alongside the intervention home sampling and observed significant increases in uptake when the analysis was conducted among all participants and limited to those reached by reminder calls. It is, however, difficult to say whether it was the reminders that resulted in an increased response rate (as more calls were delivered to the women in the home group) or the strategy alone.

Three studies which reported on the number of rejected specimens found no statistically significant difference by allocation. With two trials in the developing world and one in USA, the implication is that, if well instructed, women are able to collect as adequate a specimen as clinicians for diagnosis by molecular techniques. In relation to ease of self-sampling, more women in the home group rated self-sampling as being easy compared with the clinic group (in two trials). These contrast with the trial by Jones et al. where more females in the clinic group rated self-sampling as easy when compared with those in the home group. One possible reason for the difference observed was that participants allocated to the clinic group in this trial self-collected specimens under supervision of the nurse. This assistance may have biassed the ratings obtained in favour of the clinic group.

When asked by questionnaire and interview methods, more women in the home group were observed to exhibit a preference for resampling at home in three trials. Exposure to home screening may have affected the response rate to be in favour of the home group. This may also infer that the strategy is acceptable to women.

The studies included in this review were judged as moderate in quality, with each having a low risk of bias in at least four domains. Although the review consisted of studies from different parts of the world, not all regions, cultural and ethnic groups were represented. Most of the studies were conducted in America only one in Africa and none in Asia. The effect of the intervention may differ elsewhere. The recruitment of participants from only the clinic in one study and the use of a baseline screen as a criterion for enrolment in three studies may have introduced selection bias into the study. There is the possibility that those that consented and participated in the study may be systematically different from
those that did not, thus questioning the generalisability. Furthermore, increases in uptake observed in the home sampling group may have been influenced by prior contact of study subjects with researchers at enrolment in which the screening process was described and procedural instructions provided. Hence, lower uptake levels may be observed in real-life settings where researcher–patient relationships may be nonexistent and where health care delivery mechanisms differ. For instance, a report on a 3-year registry-based screening for chlamydia in the Netherlands by van den Broek et al.\textsuperscript{62} indicated that the use of home-based screening may not necessarily result in increased uptake over time. In that study, uptake dropped from 16% in the first year to 9% by the third year, indicating inconsistency, as opposed to the clinic group, which maintained 13% uptake levels.\textsuperscript{62} The researchers suggested that declining participation may have been due to logistical challenges, since participants needed to log on to websites to access kits.\textsuperscript{62}

The findings in this review are similar to those observed in two traditional reviews on home-based sampling. In the review by Graseck et al.\textsuperscript{30} and Shih et al.,\textsuperscript{46} home-based screening strategies were associated with higher utilisation rates of STI screening facilities in both sexes.

The strengths of this review include its conduct (in line with Cochrane guidance) and its choice of the RCT study design for the evaluation of screening programs. Studies are representative of recently published evidence with the majority being adequately powered and having reasonable lengths of follow-ups. The incorporation of self-report and medical record into the assessment of outcomes in some of the trials and the grouping of outcomes as such was also another strength, making for improved STI screening rates in females. There is a need for further research on the effectiveness and cost-effectiveness of this strategy and to justify its use at population-level screening, as the evidence on effectiveness of this strategy appears to be dominated by trials in the developed world, it may serve as an alternative for women who shy away from clinics. The data are important for informing evidence-based decisions to add a home collection strategy to existing clinic-based control programs as part of a multipronged approach to enhance screening uptake in these regions. However, to further elucidate the effectiveness of this strategy and to justify its use at population-level screening, further research on the effectiveness and cost-effectiveness of the strategy is required. High quality trials with larger sample sizes and longer study durations are required both in the industrialised and developing world.

**Conflict of interest**

None declared.

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