**Horizon Scan Report 0003** **20 February 2009**

# Diagnostic Technology:
Testing for *Chlamydia trachomatis* in Primary Care using self-taken swabs

**Clinical Question:** In patients screened for *Chlamydia trachomatis* infection, do self-taken swabs accurately detect chlamydia infection compared to clinic-based screening and is it cost effective.

**Advantages over Existing Technology:**
Vulvovaginal swab samples remove the need for a speculum investigation for many patients, and have been suggested as an alternative to combined cervical/urethral swabs (1). This improves clinical efficiency and thereby access to services, and allows high risk individuals to be tested in primary care (or at home) without visiting a specialist clinical service.

**Details of Technology:**
Vulvo-vaginal swabs (VVSs) are used as a non-invasive sample type for nucleic acid amplification testing for *Chlamydia trachomatis*.

**Patient Group and Use:**
- Patients and contacts of patients with suspected *Chlamydia trachomatis* infection
- Screening of asymptomatic patients concerned that they may have contracted *Chlamydia trachomatis*

**Importance:**
Genital *Chlamydia trachomatis* infection is the sexually transmitted infection diagnosed most frequently in English genitourinary medicine (GUM) clinics (www.chlamydiascreening.nhs.uk). Prevalence of infection is highest in young sexually active adults, especially aged <25 years. Untreated infection can have serious long-term consequences, particularly for women, in whom it can lead to pelvic inflammatory disease, ectopic pregnancy and tubal factor infertility. In both men and women it may lead to Reiter's syndrome. Since many infections are asymptomatic, a large proportion of cases remain undiagnosed. Treatment of early stage chlamydia using oral antibiotics is very effective. Cure rates are 97% for azithromycin and 98% for doxycycline (12).

**Previous Research:**
In 2003 the National Chlamydia Screening Programme (NCSP) in England for men and women aged 16-24 was established with the objective of improving the early detection and treatment of asymptomatic infection, thus preventing the development of sequelae and reducing onward disease transmission. National roll-out was completed in March 2008. However, a systematic review undertaken in 2008 reported an absence of evidence supporting opportunistic chlamydia screening in the general population <25 years (2). This review concluded that randomized trials of multiple rounds of screening with biological outcome measures are still needed to determine the balance of benefits and harms of chlamydia screening.

An HTA report entitled "Epidemiological, social, diagnostic and economic evaluation of population screening for genital chlamydial infection" was published in February 2007 (3). This report concluded that home-based specimen collection could be offered by post as an alternative to clinic-based screening, and general practice would be the best setting for opportunistic screening. Furthermore, they reported that Practice Nurse-led partner notification was as effective a strategy for ensuring treatment of sexual partners of people diagnosed with chlamydia in primary care as referral to a GUM clinic. The strategy was no more expensive than referral to a specialist GUM clinic and was preferred by patients.

In this programme, postal kits were available, where female patients were asked to provide a self-taken vulvovaginal swab along with a urine sample. They reported that female VVS specimens are likely to become more popular for screening

women, as they had high sensitivity and specificity, and lower levels of inhibition than with urine specimens. A validation study comparing VVSs with endocervical swabs from 267 women showed that 255/267 (96%; 95% CI 92 to 98%) sets of samples gave concordant results, indicating VVSs to be suitable samples for detecting *C. trachomatis* (4). A multicentre study demonstrated that a self-taken VVS was at least as good as a clinician-taken cervical swab (5). A recent study on the feasibility of using self-taken swabs as an alternative to physician-assisted cervical swabs reported that self-taken swabs had a sensitivity of 91% (95% CI = 60% to 99%), specificity of 99% (95% CI = 95% to 99%), positive likelihood ratio of 91, and negative likelihood ratio of 0.09 in diagnosing STIs (13). None of the patients reported difficulty or discomfort using this technique.

Urine samples are also an accurate method of diagnosing chlamydia, however, the presence of inhibitory substances in urine from women, both pregnant and non-pregnant, has been a cause for concern, with 3.9–11.0% of samples displaying inhibition depending on the DNA test used (8,9). Regarding acceptability to patients, studies have shown that women find it easy to provide a VVS and have no objections to this type of sample (6,7), however some anecdotal evidence reported by the NCSP and by Skidmore et al. indicates reluctance amongst some women. This could possibly be attributed to lack of information about the requirements for this type of sample. An Australian study showed that combining chlamydia and Pap screening increases the rate of chlamydia screening in general practice.

A US study evaluating the cost-effectiveness of chlamydia screening strategies that use different methods of specimen collection, namely cervical swabs, urines, and self-obtained vaginal swabs, showed that sensitivities of vaginal, urine, and cervical samples were 97.2%, 91.7%, and 91.7%, respectively. The study showed that the self-obtained vaginal swab strategy was the least expensive and the most cost-effective, preventing 17 more cases of pelvic inflammatory disease than the next least expensive strategy (14).

**Cost-effectiveness and economic impact:**
One HTA report and three published papers report on the costs and cost-effectiveness of testing for *Chlamydia trachomatis* in a primary care setting using self-taken swabs. A US decision analytic modelling study (14) found use of the self-obtained vaginal swabs more cost-effective (in fact cost saving) when compared with urine or cervical specimens. Cost savings were also found in a relatively small US RCT study comparing home and clinic based testing (16) and results from a dynamic Monte Carlo model assessing home versus clinic based testing found that once the model reached 4-years into the programme the accumulated indirect costs offset the direct costs – cost-saving from a Danish societal viewpoint (17). The HTA report published in 2007 (3) documents a population-based survey of adult men and women invited to collect urine and (for women) vulvovaginal swab specimens at home, the resource use and healthcare and patient costs were calculated (18) and used in the cost-effectiveness modelling. The transmission and cost-effectiveness of screening was assessed using a transmission dynamic model. The incremental cost-effectiveness ratio (2003 prices) comparing screening men and women annually to no screening in the base case was £27,000/major outcome averted at 8 years (not deemed cost-effective). If estimated screening uptake and pelvic inflammatory disease incidence were increased, the cost-effectiveness ratio fell to £3,700/major outcome averted.
The report highlighted the need for future research to be concentrated on undertaking a systematic review of studies comparing the performance of female urine and vulvovaginal specimens for *C. trachomatis* diagnosis to determine whether the increase in yield with vulvovaginal specimens is clinically important. Studies about quality of life associated with chlamydia, and its long-term consequences in women, men and newborn children, are required so that cost-effectiveness studies can use cost per QALY as the outcome.

**NICE Guidelines:**
A recent NICE guideline (PH3 Prevention of sexually transmitted infections and under 18 conceptions: guidance; February 2007) (11) recommended that for chlamydia infection, health professionals working in general practice, GUM and community health services should consider providing a home sampling kit.

**Ongoing trials:**
The NCSP website reports two ongoing studies on chlamydia screening in primary care:

1. "*Chlamydia trachomatis*: How have general practices overcome the barriers to testing and opportunistic screening? A qualitative study." Principal investigator: Dr Cliodna McNulty; End date: December 2008.
2. "A randomised controlled trial to determine the value of a complex intervention in general practice to increase chlamydia screening." Principal investigator: Dr Cliodna McNulty; End date: June 2011.

**Research Questions:**
To evaluate current practice for chlamydia infection in primary care, and determine whether self-swabbing test kits for *Chlamydia trachomatis* are generally available and used in GP practices in the UK.
To determine the optimal strategy for delivery of chlamydia infection screening in primary care.

**Suggested next step:**
1) Cross sectional study of the use of self-swabbing test kits for *Chlamydia* in primary care.
2) Randomized controlled trial of different methods of delivering chlamydia screening in primary care.

**Expected outcomes:**
Providing self-swabbing kits to patients in GP practices could be a simple, efficient method allowing patients to be tested for *Chlamydia* without the need to visit a GUM clinic in the first instance.

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**Comments:**

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