Evaluation of near patient testing for *Chlamydia trachomatis* in a pregnancy termination service

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**Abstract**

Aim. To identify and evaluate advantages and disadvantages of a near patient test (NPT) for *Chlamydia trachomatis*, using Clearview Chlamydia MF (Unipath Ltd) in a British Pregnancy Advisory Service (BPAS) clinic.

Method. The improved Clearview Chlamydia MF test was used to test endocervical swabs from 400 women attending BPAS clinic for termination of pregnancy. The results were compared with Ligase Chain Reaction (LCR), using Polymerase Chain Reaction (PCR) as the arbiter.

Results. Twenty-seven women tested positive by Clearview Chlamydia MF (24 confirmed by LCR) and 32 by LCR.

Comment. NPT has potential advantages in specific situations where a quick result is required for optimal management of those testing positive. However, the current technology available for detection of Chlamydia infection results in time constraints, which limited its benefits in this study, where there was a high throughput of clients.

A significant number of cases were missed by Clearview Chlamydia MF, though the sensitivity found is within the ranges reported for various enzyme immunoassays (EIA) – currently the most commonly used testing method.

The study confirmed the high positivity in those attending for termination, especially in under 25-year-olds.

**Key message points**

- A termination service provides an effective health care opportunity for finding chlamydial infection.
- This study confirms that the prevalence of *Chlamydia trachomatis* in over 25-year-olds is significantly less than in younger women.
- Twenty-six percent of women would have been especially likely to benefit from near patient testing.
- Clearview chlamydia MF results were available to be given before discharge from the clinic in 76% of cases.
- If a designated person can be used, the Clearview chlamydia technique can be incorporated effectively into a service, but there needs to be adequate time allocated to gain maximum benefit.

**Introduction**

Chlamydidal infection is the most common bacterial sexually transmitted infection (STI) and the most common cause of pelvic inflammatory disease (PID). Estimates of the incidence of PID after termination of pregnancy in infected women range from 25% to 63%. BPAS is a major national specialist provider of abortion services, offering diagnosis, information and counselling to women about being pregnant and, where requested and appropriate, treatment for termination of pregnancy. Founded after the Abortion Act of 1967, the charity now provides counselling and clinical assessment from a network of BPAS centres and conducts treatment in 12 Department of Health approved clinics. The interval between assessment and treatment may only be a few days for some clients.

Recognising the risk of ascending infection associated with instrumentation, it has always been the policy of BPAS to give prophylactic antibiotics, currently a course of doxycycline. This policy does not address the problem of partners, so for those with the infection re-infection is likely, and from the public health aspect, the prevalence of *C. trachomatis* is not likely to be effectively reduced in the community. There is a view, therefore, that testing for Chlamydial infection should be offered prior to termination so that appropriate advice can be offered when a test is positive. This is supported by the Chief Medical Officers report which recommends that screening should be offered to all women seeking termination of pregnancy and their partners. Screening is especially important for termination of pregnancy clients as the procedure increases the risk of pelvic inflammatory infection in women who are infected with *C. trachomatis*.

The performance of a test is often described in the terms of its sensitivity and specificity. These depend not only on the intrinsic qualities of the test, but also on the sample supplied, storage and transport conditions. The test must be acceptable and affordable and the results should be available so that appropriate and timely information and management can be given. In our previous study with 587 women using urine tested by Ligase Chain Reaction (LCR) at pregnancy counselling, together with endocervical swabs at the time of termination, we confirmed that after leaving the clinic, many were difficult to contact with their results. Women are referred and self-refer from a wide geographical area. They may not give their true address or want to be contacted after leaving the service.

Near patient testing (NPT) is any investigation carried out in a clinical setting or patient’s home for which the result is available without reference to a laboratory and perhaps rapidly enough to affect immediate patient management.

Quality control is as important in NPT as it is in a laboratory. Important issues to address include inter- and intra-observer variability and avoidance of cross contamination.
Clearview chlamydia MF is a rapid monoclonal antibody-based latex visual end point test, which works using immuno-chromatographic technology and is similar in appearance to the Clearview HCG II pregnancy test (Figure 1). The latter is fairly simple in that urine is a relatively uncontaminated sample and the test is for one relatively simple component, human chorionic gonadotrophin. Testing for C. trachomatis, however, is a technical challenge, as it is a complex organism from which lipopolysaccharide (LPS) antigen must be extracted by heating the sample. A further problem in non-amplification tests is that a swab sample is required which contains many contaminants. Once LPS has been extracted, the Clearview chlamydia MF test is then a one step process (some other manufacturers systems require additional reagents.)

The test in the past has not been regarded as sufficiently sensitive. Sensitivity and specificity have previously been measured/calculated using culture as the comparator and FDA approval rests on this comparison.

There is a new extraction procedure which reduces the interference caused by soluble components in the sample, but which still produces a reactive form of the chlamydial LPS. The undoubted attraction of a rapid result led us to examine the performance of this improved technology and to compare it against LCR, which has greater sensitivity than culture in most clinical situations.

Results
In the time period, 400 women were tested, 399 by LCR and Clearview (one woman did not have an LCR swab taken) (Table 1).

Table 1 Results of Clearview Chlamydia MF and LCR tests

<table>
<thead>
<tr>
<th></th>
<th>Clearview Chlamydia MF</th>
<th>LCR</th>
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<tbody>
<tr>
<td></td>
<td>Negative</td>
<td>Positive</td>
</tr>
<tr>
<td>Negative</td>
<td>360</td>
<td>0</td>
</tr>
<tr>
<td>Positive</td>
<td>8*</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>368</td>
<td>16</td>
</tr>
</tbody>
</table>

* 7 confirmed by PCR
** PCR negative
*** PCR inhibitory

Three hundred and sixty tests were negative by both Clearview and LCR and 24 were positive by both (for eight of these Clearview was weakly positive).

Of the 11 reported as ‘weakly positive’ by Clearview, three were negative by LCR and PCR, so the women were possibly overcalled. Four tests were reported as ‘indeterminate’ by Clearview, these were negative by LCR and did not give a valid PCR result due to the presence of inhibitors, indicated by control tests carried out on each sample.

Of the eight tests that were Clearview negative/LCR positive, one was not confirmed by PCR. On re-testing by LCR this one was found to be at the cut-off for a positive reading.

Clearview missed eight of 32 (26%) LCR positive cases i.e. found 16 definitely and eight weakly.

There is a high prevalence of chlamydial infection in women presenting for termination of pregnancy, reflecting that they represent a group who have by definition recently been sexually active, but not necessarily that they are leading more risky lifestyles. More information would be necessary.
required for better interpretation of this common finding. This study confirms that the prevalence of chlamydial infection in over 25-year-olds is significantly less than in the younger women (Table 2).

In this study, 270 (68%) of the women tested asked for their result to be sent to their home address, and 23 (5.8%) to another address. The 104 (26%) of women who would have been harder to reach, and therefore especially likely to benefit from NPT, comprised 15 (3.8%) who gave a contact telephone number, 80 (20.2%) who wanted to phone the clinic, and nine (2.3%) who wanted to be contacted at various other places.

**Discussion**

A termination service provides an effective health care opportunity for finding Chlamydial infection, in addition to its special responsibility in minimising the effect of instrumentation of the uterus. So, as an adjunct to antibiotic prophylaxis, testing should be considered in order to identify women with the infection and to enable treatment to be given to their partners to avoid re-infection.

It is necessary in evaluating a test to examine all aspects of its performance. These include the resources and time to carry out the test, and the method of transmitting the results. If the results are available before discharge from the service, time is required to give them and to counsel the client appropriately. If the results are not available before discharge, then time is needed to trace clients and to discuss results with those who telephone, and there is the certainty that some will never access their results.

Clearview Chlamydia MF results were available to be given before discharge from the clinic in 76% of cases. In this study, the technique was incorporated effectively into the service by having a designated person to carry out the tests, but there does need to be adequate time allowed to gain maximum benefit. Clearview missed eight (26%) of 32 LCR positive cases i.e. found 16 plus eight weakly, though possibly by overcalling three, as three were negative by LCR and PCR. Only 1% gave indeterminate readings. Although cases were missed, its sensitivity lies within the ranges (55%–85%) reported for various enzyme immunoassays (EIA) – currently the most commonly used testing method.

The control of chlamydial infection would be revolutionised by a simple NPT so further improvements in technology will be welcomed.

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**References**