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Horizon Scanning Technology Prioritising Summary

Opportunistic screening of asymptomatic individuals for Chlamydia

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PRIORITISING SUMMARY

REGISTER ID: **000297**

NAME OF TECHNOLOGY: **SCREENING FOR CHLAMYDIA IN PHARMACIES**

PURPOSE AND TARGET GROUP: **OPPORTUNISTIC SCREENING OF ASYMPTOMATIC, AT RISK INDIVIDUALS FOR GENITAL CHLAMYDIA TRACHOMATIS INFECTION**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- ☒ Yet to emerge
- ☐ Experimental
- ☐ Investigational
- ☐ Nearly established
- ☐ Established
- ☐ Established *but* changed indication or modification of technique
- ☐ Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- ☐ Yes — ARTG number
- ☐ No
- ☒ Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United Kingdom		✓	
Netherlands		✓	

IMPACT SUMMARY:

In 2005 the United Kingdom Department of Health initiated a project to provide *free-to-user* screening for the detection of genital *Chlamydia trachomatis* infection in 16-24 year olds though community pharmacies. The initial phase of this project made screening kits available from 31 branches of a popular, large chain of pharmacies within the greater London area (TNS Healthcare 2006).

BACKGROUND

Worldwide and in Australia, *Chlamydia trachomatis* is the most common sexually transmitted bacterial infection. In the majority of cases (80%) infection with chlamydia is asymptomatic, making detection difficult. If left undetected and untreated chlamydia infection can move into the upper genital tract, causing inflammation and scarring in both the male and female reproductive tracts. In women the most common complications of chlamydia infection include urethritis, cervicitis, pelvic inflammatory disease (PID), tubal

infertility, ectopic pregnancy (a principle cause of maternal death in the first trimester) and chronic pelvic pain. If left untreated, 10-40 per cent of chlamydia infections may lead to PID, and of these individuals, 20 per cent will become infertile. Chlamydia infection increases the risk of HIV transmission and can be transmitted to the neonate at birth, causing conjunctivitis and pneumonia (Hocking & Fairley 2003; Walleser et al 2006; Watson et al 2002).

The aim of a national screening programme would be to detect and subsequently treat a significant number of asymptomatic individuals, in order to reduce the incidence and prevalence of infection and to reduce the morbidity associated with infection (Ward et al 2006). *Universal* screening which would target all individuals within the target population (in this case sexually active 16-25 year olds) is considered to be cost-effective if the prevalence of the condition is above 3.1 per cent. The United States and Canada have advocated *opportunistic* screening of women only through sites such as general practitioners and STD clinics (Hocking & Fairley 2003).

The National Chlamydia Screening Programme was established in the United Kingdom in 2002. The programme offers opportunistic screening to men and women under 25 years of age in a range of settings outside genitourinary medicine (Fenton et al 2004). This initial scheme has been extended to include free testing at local pharmacies. Individuals can either approach pharmacy staff for a free testing kit, or to avoid embarrassment, they can obtain a voucher (available in store or as a printable download from the web) for a test kit. The test is a "first catch" urine test – preferably the first urination of the day. The sample must be returned to the pharmacy within six hours after collection, and are then sent on to an accredited diagnostic laboratory for testing. Test results are delivered to the individual either by phone, text or letter. Individuals testing positive receive a single dose of antibiotic treatment from the pharmacist and are advised to receive testing for any other sexually transmitted diseases. Sexual partners of positive individuals are offered free chlamydia testing regardless of age (DoH (UK) 2007; Younglivin.org.uk 2007).

CLINICAL NEED AND BURDEN OF DISEASE

A recent Australian prevalence survey of chlamydia among young women was conducted in Melbourne between March 2003 and June 2004. After an initial pilot study, it was estimated that at least 10,000 households would have to be contacted, assuming that only one in five households would include an eligible woman (aged 18-35 years) and that only 50 per cent of these women would provide a urine sample. Of the 11,001 households chosen at random, 979 women were eligible and interviewed. Of these, 657 provided a urine specimen (160 women aged 18-24 years and 497 women aged 25-35 years). A total of six cases of chlamydia were detected (five aged 18-24 years and one aged 25-35 years), with an overall prevalence of 0.9 per cent. The prevalence was 3.7% (95%CI [1.2, 8.4], n=135) in the 18-24 years group and 0.2% (95%CI [0.0, 1.1], n=489) in the 25-35 years group. Amongst 18-24 year old women, prevalence increased with the number of male sexual partners in the past 12-months ($p<0.01$): prevalence for one male partner = 1.1%

(95%CI [0.0, 5.7]) and prevalence for 3 or more male partners = 14.3% (95%CI [3.0, 36.3]). Those women reporting a new sexual partner in the last 3-months were 10 times more likely to test positive for chlamydia with a prevalence of 9.8% (95%CI [1.7, 54.4]). All women who tested positive were asymptomatic (Hocking et al 2006).

A recent systematic review on the prevalence of *C. trachomatis* in the United Kingdom found that the prevalence was higher in studies conducted in health care settings compared to population-based studies. In general practice surgeries, the prevalence in under 20 year olds was 8.1% (95%CI [6.5, 9.9]), 5.2% (95%CI [4.3, 6.3]) in 20-24 year olds, 2.6% (95%CI [2.0, 3.3]) in 25-29 year olds, decreasing to 1.4% (95%CI [1.0, 1.9]) in individuals aged over 30 years (Adams et al 2004).

Chlamydia is a notifiable disease and in Australia the number of notifications has risen steadily with 20,325 to 47,045 cases in 2001 and 2006, respectively. This translates to a rate of 282 cases per 100,000 head of population (Communicable Diseases Australia 2007). As most infections are asymptomatic, this figure may represent only a small fraction of the true incidence and prevalence. The increase may also be due to reporting artefacts such as the increased sensitivity of the available diagnostic tests (Chen & Donovan 2003).

DIFFUSION

Australia does not currently have a national chlamydia screening programme (Hocking et al 2006). National screening guidelines have been issued by the Victorian Government and the Royal Australasian College of Physicians and opportunistic screening of all women ≤ 25 years has been recommended (Walleser et al 2006). In Sweden, a national screening programme has been in place since the 1980s (Watson et al 2002).

COMPARATORS

Testing for chlamydia can be requested by patients at their general practitioner, dedicated sexual health clinics or family planning units.

EFFECTIVENESS AND SAFETY ISSUES

The first six months of the programme to provide free chlamydia testing via community pharmacies was evaluated. The kits were made available in 31 locations throughout London through a high-street chain of pharmacies. A total of 7,772 screens were undertaken between 14th November 2005 and 30th April 2006 an average of 324 per week. Based on this initial uptake, a total of 16,848 screens would be conducted in the first 12 months of the programme. This figure is well below the estimated 50,000 screens that were budgeted for. Although 7,772 screens were performed this figure represents only 41 per cent of the 16,163 kits that were requested by and given to individuals by pharmacies. Return rates were initially low (32%) but increased towards the end of the assessment period (51%), giving an overall average of 41 per cent. A total of 1,394 individuals were refused screening as they were out of the eligible age range (16-24 years). No record was kept as to whether or not these individuals were younger or older than the prescribed age.

Females predominantly used the service (79%), however the number of males screened (21%) far exceeded the number of males screened in the National Chlamydia Screening Programme (12.5%). The service tended to attract older males as 50 per cent of males screened were aged 23-24 years. Of the 7,060 successful screens, 25 and 13 per cent of users were aged 24 and 25 years, respectively (TNS Healthcare 2006) (level IV screening evidence).

Of those screened, a definitive result (either positive or negative) was obtained in 90.8 per cent of cases, with 712 tests returning an inconclusive result. Individuals tested in the correct age range (16-24) accounted for 5952/7060 (84%) of definitive results. Of these, 123/1227 (10%) of males and 284/4725 (6%) of females tested positive for chlamydia. The proportion of positive tests for each year of age is shown in Figure 1.

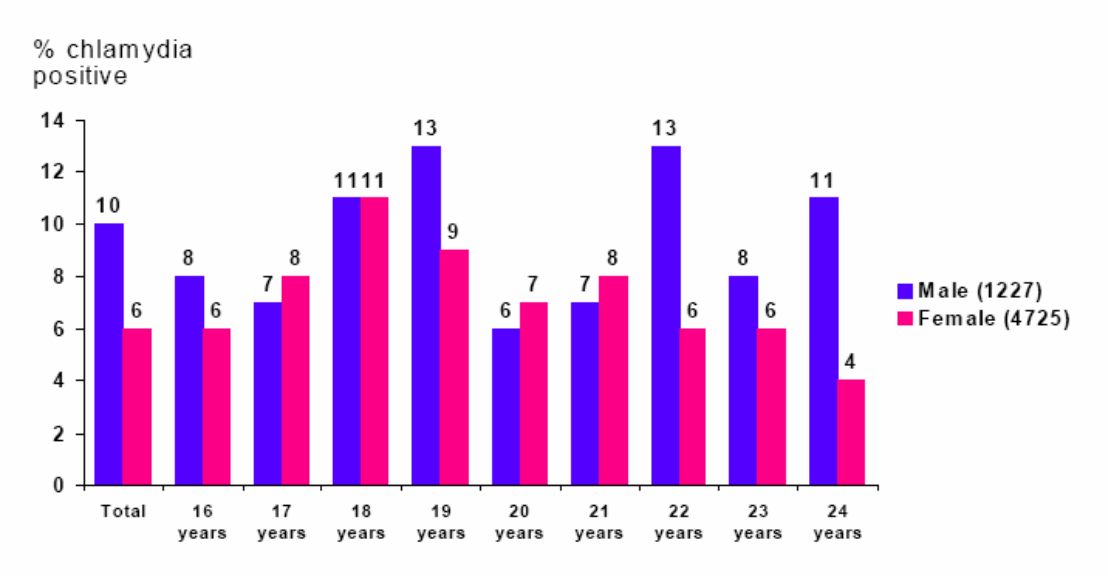

Figure 1 Proportion of positive tests by gender and age (TNS Healthcare 2006)

It was felt that uptake of the service may increase with increased external media advertising as 45% of service users knew about the service via in-store promotions with only 21 per cent via external means. The service tended to be provided only when requested by users rather than through the active promotion of the service by pharmacy staff. The low return rate of distributed kits is an issue that the programme is currently addressing (TNS Healthcare 2006).

A targeted screening study was conducted in Scotland where women attending a large family planning clinic for emergency contraception (EC) were offered *C. trachomatis* testing (level IV screening evidence). Of the 838 women (mean age 26 years, range 13-46 years) attending this clinic, 569 (68%) agreed to testing, and of these 7.6 per cent tested positive. This contrasted with a prevalence rate of 5.1 per cent for all women attending a family planning clinic who were tested. Rates for specific age groups were similar between the two groups (EC vs family planning users) except for the 25-29 years group. Women in this age bracket attending for EC were significantly more likely to test positive

than the family planning users of the same age (χ^2 = 9.06, p=0.003, 95%CI [7.71, 38.7] for odds ratio) (Kettle et al 2002).

Other screening strategies have been trialled. The UK set up a national screening programme in 2002, for the opportunistic testing of men and women aged under 25 years of age. Testing locations were not restricted to sexual health clinics but included family planning clinics, general practices, young person's services, antenatal services, and colposcopy, infertility and pregnancy termination units. In addition, outreach strategies were employed such as mobile testing units in universities. In the first full year of the screening programme, a total of 302 screening venues performed 16,413 chlamydia tests. The majority of service users were female (92.9 %) of whom 10.1 per cent tested positive for *C. trachomatis*. Of the small number of males who used the service (1,172) 13.3 per cent tested positive. These results were similar to those obtained in screening programmes offered in Sweden. The authors suggest that targeted screening of all 15-24 year old females and the treatment of the partners of positive women would dramatically reduce the prevalence of *C. trachomatis* in the population (LaMontagne et al 2004) (level IV screening evidence).

The national opportunistic screening programme in Sweden has been in place since the 1980s. The majority of individuals screened are women (75-80%). Rates of chlamydia and its associated complications (PID and ectopic pregnancy) did decline initially, however the rate of chlamydia infection has increased and by 2003 reached pre-screening levels. A cohort study followed the health records of 52,580 women aged 15-24 years from 1985 until 1999 (level III-2 screening evidence). During this study period 3,169 women developed PID, however of these only 360 (11.4%) returned a positive chlamydia test. The majority of complications occurred in women who had never been tested (31.8%) or who had only negative tests on their records (56.9%), therefore transmission of chlamydia persisted in the population. It is felt that opportunistic screening has not been effective and that a systematic, register-based screening programme similar to the cervical pap smear screening programme would be more effective in eliminating chlamydia (Low et al 2005).

COST IMPACT

A free pharmacy based testing programme in the Netherlands was assessed for its cost-effectiveness. Women aged 15-29 years of age collecting their contraceptive prescriptions were offered a free home urine chlamydia test by the pharmacist. Samples could be mailed to the laboratory and the general practitioner received the results. Uptake of the programme was low at only 29 per cent of eligible women and uptake decreased over the two-year life span of the programme. Net cost per PID event prevented ranged from cost-saving up to €3,872 in a low complication rate/high testing cost scenario. Overall the screening programme was not cost-effective (van Bergen et al 2004).

A cost-effectiveness analysis of a population-based screening programme for *C. trachomatis* was conducted in the Netherlands. Women aged 15-40 years were randomly

selected and invited to participate in a screening programme. Women were asked to provide a "first catch" urine test, which was then mailed back to the diagnostic laboratory for testing. Direct health care costs were considered as well as indirect costs including loss of productivity. The net cost of curing one woman of chlamydia infection was estimated to be US$1,210. To prevent one major complication such as an ectopic pregnancy, 479 women would have to be screened. The net cost of preventing one major complication was estimated to be $15,800. The authors concluded that screening for *C. trachomatis* is not cost-effective with costs exceeding benefits (van Valkengoed et al 2001).

In 2006, Walleser et al modelled the cost-effectiveness of a hypothetical *Chlamydia trachomatis* screening programme of all women aged 25 years or younger, based on annual opportunistic testing by general practitioners. Costs for the Australian health care system included the costs of screening and treatment for chlamydia, PID, long-term complications of chlamydia infection, ectopic pregnancy, infertility and chronic pelvic pain. The model determined the ICER[1] of screening compared to no screening over a 25 year period. Over 25 years, the expected discount cost to the health system was $257 and $217 for each woman in the screening and no-screening arms, respectively. Therefore the ICER of screening was $2,968 per QALY[2]. A sensitivity analysis gave a wide range of values for cost-effectiveness ranging from screening being effective and cost-saving, to an ICER of $67,715 per QALY. The authors considered that opportunistic screening may have merit but uncertainties concerning the natural history of chlamydia may undermine an effective screening programme (Walleser et al 2006).

However, another Australian study also conducted in 2006 modelled the impact of opportunistic screening and found that such a programme is likely to be cost-saving to the Australian public health care system. This model included only direct health care costs and not indirect costs. The estimated prevalence of *C. trachomatis* was the most significant variable affecting the model. A prevalence of 2.5 per cent yields health care costs of $17 and $37 per woman, comparing no screening to a one-off test, respectively. At a prevalence of 5.7 per cent the two strategies have the same health care costs of $39. With increasing prevalence rates the public healthcare cost savings increase to $11 for 7.5 per cent prevalence, $26 for 10 per cent and $56 for 15 per cent prevalence. The authors support the introduction of opportunistic screening for *C. trachomatis* in populations with a prevalence rate greater than 5.7 per cent (Ward et al 2006).

From May 1st 2007, the MBS item number for *C. trachomatis* testing will be 69316 and it will attract a fee of $28.85 (personal communication Institute of Medical & Veterinary Science).

[1] ICER = incremental cost-effectiveness ratio
[2] QALY = quality adjusted life year

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

It is likely that some younger individuals would feel uncomfortable consulting their general practitioner, especially a family GP or attending a sexual health clinic and therefore may feel happier collecting a test kit from a pharmacy. Concerns have been raised, however, as to whether or not pharmacists are fully equipped to explain the testing process or the results of the test, be they positive or negative. Individuals who test positive should be given advice about informing their sexual partners of their results and be supplied with information regarding testing for other possible sexually transmitted diseases (Editorial 2005).

In addition, with the advent of urine tests it is now feasible to easily screen men for chlamydia, perceived to be the hidden reservoir. From the results of the UK study, it appears men may be more likely to be tested in a pharmacy-based programme than a conventional GP or sexual health clinic setting.

OTHER ISSUES

Further reports on the United Kingdom screening programme are due to be published in July 2007 (TNS Healthcare 2006).

CONCLUSION:

There appears to be conflicting evidence on the effectiveness and cost-effectiveness of screening programmes for chlamydia. Opportunistic screening programmes may not reach enough individuals to impact on the transmission of infection, especially as these programmes appear to be more effective at reaching females, with testing rates in males continuing to be low, thus maintaining infection in the population.

HEALTHPACT ACTION:

HealthPACT has recommended that further assessment of this technology is no longer warranted and that this information be forwarded to the National Screening Committee.

SOURCES OF FURTHER INFORMATION:

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van Valkengoed, I. G., Postma, M. J. et al (2001). 'Cost effectiveness analysis of a population based screening programme for asymptomatic Chlamydia trachomatis infections in women by means of home obtained urine specimens', *Sex Transm Infect,* 77 (4), 276-282

Walleser, S., Salkeld, G. & Donovan, B. (2006). 'The cost effectiveness of screening for genital Chlamydia trachomatis infection in Australia', *Sex Health,* 3 (4), 225-234

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Watson, E. J., Templeton, A. et al (2002). 'The accuracy and efficacy of screening tests for Chlamydia trachomatis: a systematic review', *J Med Microbiol,* 51 (12), 1021-1031

Younglivin.org.uk (2007). *Chlamydia voucher* [Internet]. Available from: http://www.younglivin.org.uk/advice/sexual_health/chlamydia_voucher.htm [Accessed 19th March 2007].

LIST OF STUDIES INCLUDED

Total number of studies	
Level IV screening evidence	3
Level III-2 screening evidence	1

SEARCH CRITERIA TO BE USED:

Chlamydia Infections/*diagnosis/epidemiology
Chlamydia trachomatis
Humans
Mass Screening
Pharmacies
Community Pharmacy Services
Sexually Transmitted Diseases/prevention & control