

# **The Ballseye programme: a mixed-methods programme of research in traditional sexual health and alternative community settings to improve the sexual health of men in the UK**

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## Scientific summary

### The Ballseye programme

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# Scientific summary

## Background

Sexually transmitted infection (STI) diagnoses are increasing and efforts to reduce transmission have failed. There are major uncertainties in the evidence base surrounding the delivery of STI care for men. Coverage and uptake of chlamydia screening in men within England's National Chlamydia Screening Programme remains considerably lower than in women although the prevalence of chlamydia in men and women is similar. The annual NHS costs of untreated chlamydial infection are in excess of £100M.

The overall aims of this programme were to improve the sexual health of young men in the UK by resolving an evidence gap in strategies for STI diagnosis, using mathematical modelling and health economic analysis, to determine an optimal STI screening algorithm for asymptomatic men (workstream 1); implement new methods for the rapid treatment of male sex partners of people with STIs in primary care (workstream 2); and determine methods of engaging men in effective STI control activity including piloting a novel model for the promotion of STI testing by football captains (workstream 3).

## Workstream 1: impact of different clinical approaches to sexually transmitted infection testing in men

### Objectives

- To determine whether or not asymptomatic non-chlamydial non-gonococcal urethritis (NCNGU) is associated with significant clinical outcomes.
- To identify demographic, behavioural and clinical factors associated with NCNGU.
- To develop an evidence-based clinical algorithm for STI testing in asymptomatic men.
- To mathematically model the epidemiological and economic impact of removing microscopy from asymptomatic STI testing and to determine its cost-effectiveness.

### Methods

- Systematic literature review of the clinical consequences of asymptomatic NCNGU for men and their sexual partners. The following databases were searched from 1 January 1965 to 31 January 2010: MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and PsycINFO.
- Case-control study comparing factors associated with asymptomatic NCNGU with factors associated with symptomatic NCNGU and asymptomatic healthy men attending genitourinary medicine (GUM) clinics.
- Mathematical modelling and cost-effectiveness analysis exploring the potential public health consequences and costs of not screening asymptomatic men for NCNGU based on assumptions including the pathogenicity of *Mycoplasma genitalium*.

### Results

The systematic review found that NCNGU is not associated with significant clinical consequences for men or their sexual partners, but the quality of the literature on which the review was based was poor. In the case-control study, among heterosexual men, those with NCNGU (symptomatic or asymptomatic) and healthy men were very similar in their reported demographic, behavioural and clinical variables. Removal of urethral microscopy from routine screening of asymptomatic men is likely to lead to a small rise in pelvic inflammatory disease (PID) in women but could save > £5M over 20 years (mathematical modelling and health economic analysis).

## Conclusions

Our findings support the removal of urethral microscopy as part of a menu of tests offered to asymptomatic men requesting a STI screen. The similarities in risk variables associated with both symptomatic and asymptomatic NCNGU and also healthy men meant that we were unable to use these findings to conceptualise an evidence-based clinical algorithm for STI testing in asymptomatic men. The findings raise questions about the use of a uniquely symptom-based triage system to determine the tests offered to men attending GUM services. The sexual health of men may be better served by diverting the resources currently funding the remaining testing and treatment of men with asymptomatic NCNGU and their partners into increasing the coverage of screening for STIs with established adverse health consequences. However, our models and health economic analyses were reliant on parameters from the available literature and evidence on NCNGU is limited in breadth and quality and, inevitably, this questions the certainty of our assumptions. Even less work has been carried out on men who have sex with men (MSM) and our findings cannot be extrapolated to this group.

## Workstream 2: delivery of a modern, evidence-based approach to sexually transmitted infection partner notification for men in primary care – a pilot randomised controlled trial of accelerated partner therapy in general practice and community sexual health services

### Objectives

To determine the feasibility, acceptability and preliminary evidence of effectiveness of accelerated partner therapy (APT) in the non-specialist setting by conducting a pilot randomised controlled trial (RCT) of APT in contrasting primary care settings in England.

### Methods

We carried out a three-arm pilot RCT (UK Clinical Research Network Study Portfolio ID number 10123) of two APT interventions: APTHOTline [telephone assessment of partner(s)] and APTPharmacy [community pharmacist assessment of partner(s)] compared with routine care (patient referral). Index patients were women diagnosed with genital *Chlamydia trachomatis* infection in 10 general practices and two community contraception and sexual health services in London and the south coast of England. Participants were randomised between 1 September 2011 and 31 July 2013.

### Results

In total, 199 women described 339 male partners, of whom 313 were reported by the index as contactable. The proportion of contactable partners considered treated within  $\leq 6$  weeks of index diagnosis varied little by study arm [APTHOTline 39/111 (35%); APTPharmacy 46/100 (46%); routine care 46/102 (45%)]. The unadjusted and adjusted odds ratios (95% confidence intervals) for partner treatment in the hotline arm relative to routine care were 0.91 (0.48 to 1.73) and 0.64 (0.35 to 1.18), respectively, and for partner treatment in the pharmacy arm relative to routine care were 0.90 (0.65 to 1.27) and 1.06 (0.78 to 1.45), respectively. Among partners not considered treated, for the vast majority their treatment status was unknown. Among treated partners, only eight out of 39 (21%) in the hotline arm were treated via the hotline and only 14 out of 46 (30%) in the pharmacy arm were treated at a pharmacy. Only 38 index patients (19% of the total) were tested for reinfection/persistence and chlamydia positivity was 15% (2/13) in the routine care arm, 0% (0/15) in the hotline arm and 10% (1/10) in the pharmacy arm. Among partners none was known to have attended a clinic for a human immunodeficiency virus (HIV) or syphilis test. In the routine care arm no partners had a chlamydia or gonorrhoea test compared with 4% (4/111) in the hotline arm and 6% (6/100) in the pharmacy arm. Of those testing, one partner (in the hotline arm) tested positive for chlamydia. Community health-care professionals (HCPs) found the web tool easy to use and a useful adjunct to routine care. However, providing the explanations and choices necessary for informed consent to participate in a research study to people at what can be a difficult time emotionally was perceived to be difficult.

## Conclusions

Similar proportions of partners were reported to have been treated across the three arms of the trial, which in each case was fewer than half. This does not meet national standards for partner notification for chlamydia but our outcomes were superior to previously reported partner notification rates in similar settings. Although overall outcomes for partner notification were similar between the three arms, only a minority of those in the hotline and pharmacy intervention arms actually used that modality and their availability did not appear to improve outcomes. The low uptake of follow-up STI testing or HIV testing was notable and suggests that these modes of partner notification, which do not require direct engagement with a clinical service that can provide comprehensive testing, may be unsuitable for higher-risk populations. The care pathways that we developed, all of which used a novel online patient and data management tool that we developed, provided a feasible and acceptable infrastructure for the onward referral of patients diagnosed with STIs in general practice and other community settings to receive support with partner notification.

## Workstream 3: development and evaluation of the disease control potential of a model for testing young men at high risk of sexually transmitted infections in a sports setting – how and where can we best reach men for effective sexually transmitted infection screening? The SPORTSMART study

### Objectives

- To explore the medical, sporting and social venues that young men find acceptable for accessing STI screening and to determine the optimal models of screening in those settings.
- To undertake a pilot RCT of two STI screening interventions in football settings.
- To explore the public health impact of screening in football settings.

### Methods

- Stratified random probability survey of 411 men aged 18–35 years in the UK.
- Qualitative study of men's preferences for STI screening.
- Pilot cluster RCT of two STI screening interventions in outer London football clubs with an integral health economic evaluation (SPORTSMART study).
- Anonymous questionnaire survey of STI risk and previous health service use among 212 men in football clubs (SPORTSMART survey).

### Results

Findings from the random probability sample survey showed that 75.3% of men had attended their general practice in the last year. Willingness to access self-sampling kits for STIs and HIV was high (85.1% and 86.9% respectively). Traditional health-care settings, such as general practice (79.9%), GUM clinics (66.8%) and pharmacies (65.4%), were preferred but sports venues were acceptable to half of men who played sport. In the RCT, uptake of screening was high irrespective of arm [captain led 28/56 (50%); HCP led 31/46 (67%); poster only 31/51 (61%)] and the costs of the interventions were similar. In the qualitative study, respondents valued easy, straightforward opportunities for STI screening, which fit in with their daily activities. In the football club survey, men in football clubs reported risk behaviours for STIs but previous testing was common (22.8% in the last year).

### Conclusions

Health-care settings were the most acceptable places for accessing STI and HIV self-testing kits. General practice offers considerable potential to screen large numbers of men. Screening men in football settings could be valuable in areas with limited access to other STI services but its impact requires further investigation.

## Overall conclusions

Young men find traditional health-care settings such as general practice or GUM clinics the most acceptable places to access STI screening. Self-sampling kits in football clubs could widen access to screening and offer a public health impact for men with limited local sexual health services. Available evidence does not support an association between asymptomatic NCNGU and significant adverse clinical outcomes for men or their sexual partners but the quality of the literature is poor. The mathematical modelling and cost-effectiveness analysis of removing all asymptomatic urethral microscopy screening suggests that this would result in a small rise in adverse outcomes such as PID but that this would be highly cost-effective.

The APT care pathways that we developed for partner notification, all of which used a novel online patient and data management tool, provide a feasible and acceptable infrastructure for the onward referral of patients diagnosed with STIs in general practice and other community settings to receive support with partner notification. APT appears to improve outcomes of partner notification in community settings but outcomes still fail to meet national standards.

This programme of work has focused on sexual health provision appropriate to the needs of heterosexual men. MSM experience a disproportionate burden of STIs and HIV infection and require more comprehensive suites of testing than those considered here, which are not generally available either in general practice or in enhanced sexual health services in the community. Further research is needed to optimise service provision for MSM.

## Future research priorities

1. Research to improve understanding of men's collective behaviours with respect to health interventions and how these could be harnessed to increase uptake. The field could benefit from ethnography and from queer theory, which has been a major current in the exploration of gender, sexuality and society in the humanities.
2. Exploration of barriers to and facilitators of opportunistic STI screening for men attending general practice, including increasing understanding of why men are not opportunistically offered tests at times when they engage with health care for other reasons. Gendered expectations could be explored and addressed through action research.
3. Development of evidence-based interventions to increase offers of opportunistic STI screening for men attending general practice/developing and evaluating different pathways of access to testing kits in general practice.
4. Partner notification trials: further work is required to optimise the uptake of APT both within and outside specialist services and to explore linkages between specialist services and community services, including the trade-off with other priorities.
5. Randomised controlled trial of football club-based screening in geographical areas with limited access to sexual health services.
6. Development of interventions that identify and reach higher-risk partners who may benefit from a more comprehensive range of sexual health services.
7. Better understanding of the issues specific to screening MSM and in particular how, with the different epidemiology of STIs in MSM and the current narrow focus on chlamydia, this could negatively impact MSM's sexual health.

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