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Abstract

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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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.

Aim: To improve the sexual health of young men in the UK by determining optimal strategies for STI testing and care

Objectives: To develop an evidence-based clinical algorithm for STI testing in asymptomatic men; model mathematically the epidemiological and economic impact of removing microscopy from routine STI testing in asymptomatic men; conduct a pilot randomised controlled trial (RCT) of accelerated partner therapy (APT; new models of partner notification to rapidly treat male sex partners of people with STIs) in primary

care; explore the acceptability of diverse venues for STI screening in men; and determine optimal models for the delivery of screening.

Design: Systematic review of the clinical consequences of asymptomatic non-chlamydial, non-gonococcal urethritis (NCNGU); case–control study of factors associated with NCNGU; mathematical modelling of the epidemiological and economic impact of removing microscopy from asymptomatic screening and cost-effectiveness analysis; pilot RCT of APT for male sex partners of women diagnosed with *Chlamydia trachomatis* infection in primary care; stratified random probability sample survey of UK young men; qualitative study of men's views on accessing STI testing; SPORTSMART pilot cluster RCT of two STI screening interventions in amateur football clubs; and anonymous questionnaire survey of STI risk and previous testing behaviour in men in football clubs.

Settings: General population, genitourinary medicine clinic attenders, general practice and community contraception and sexual health clinic attenders and amateur football clubs.

Participants: Men and women.

Interventions: Partner notification interventions: APTHotline [telephone assessment of partner(s)] and APTPharmacy [community pharmacist assessment of partner(s)]. SPORTSMART interventions: football captain-led and health adviser-led promotion of urine-based STI screening.

Main outcome measures: For the APT pilot RCT, the primary outcome, determined for each contactable partner, was whether or not they were considered to have been treated within 6 weeks of index diagnosis. For the SPORTSMART pilot RCT, the primary outcome was the proportion of eligible men accepting screening.

Results: Non-chlamydial, non-gonococcal urethritis is not associated with significant clinical consequences for men or their sexual partners but study quality is poor (systematic review). Men with symptomatic and asymptomatic NCNGU and healthy men share similar demographic, behavioural and clinical variables (case–control study). Removal of urethral microscopy from routine asymptomatic screening is likely to lead to a small rise in pelvic inflammatory disease (PID) but could save > £5M over 20 years (mathematical modelling and health economics analysis). In the APT pilot RCT the proportion of partners treated by the APTHotline [39/111 (35%)], APTPharmacy [46/100 (46%)] and standard patient referral [46/102 (45%)] did not meet national standards but exceeded previously reported outcomes in community settings. Men's reported willingness to access self-sampling kits for STIs and human immunodeficiency virus infection was high. Traditional health-care settings were preferred but sports venues were acceptable to half of men who played sport (random probability sample survey). Men appear to prefer a 'straightforward' approach to STI screening, accessible as part of their daily activities (qualitative study). Uptake of STI screening in the SPORTSMART RCT was high, irrespective of arm [captain led 28/56 (50%); health-care professional led 31/46 (67%); poster only 31/51 (61%)], and costs were similar. Men were at risk of STIs but previous testing was common.

Conclusions: Men find traditional health-care settings 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 literature is of poor quality. Similarities in characteristics of men with and without NCNGU precluded development of a meaningful clinical algorithm to guide STI testing in asymptomatic men. 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 it would be highly cost-effective. APT appears to improve outcomes of partner notification in community settings but outcomes still fail to meet national standards. Priorities for future work include improving understanding of men's collective behaviours and how these can be harnessed to improve health outcomes; exploring barriers to and facilitators of opportunistic STI screening for men attending general practice, with development of evidence-based interventions to increase the offer and uptake of screening; further development of APT for community settings; and studies to improve knowledge of factors specific to screening men who have sex with men (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.

Funding: The National Institute for Health Research Programme Grants for Applied Research programme.

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Glossary

Accelerated partner therapy Partner notification strategies that reduce the time for sexual partners to be treated and include a medical assessment of the sex partner by an appropriately qualified health-care professional.

Accelerated Partner Therapy Primary Care Trial A trial to see whether or not new accelerated partner therapy approaches are quicker and easier for partners of people who test positive for chlamydia at their general practice.

Accident and emergency Hospital department responsible for triaging and managing immediate problems of the acutely unwell and injured.

Adenovirus One of a group of DNA-containing viruses causing infections of the upper respiratory tract that produces symptoms resembling those of the common cold. Adenovirus can also cause urethral symptoms in men.

Adjusted (and unadjusted) odds ratio The odds of having the target condition or disease in the experimental group relative to the odds of having the disease or condition in the control group. An odds ratio of < 1 indicates an inverse or negative association.

Annuitise To convert the receipt of money (or similar) into a series of payments of income over a certain fixed period.

Antibiotic A substance that is used to treat infections caused by micro-organisms, including bacteria and fungi, by destroying or inhibiting their growth.

APTHotline A form of accelerated partner therapy in which the sexual partner undergoes a telephone consultation with a sexual health clinic health adviser and receives an invitation for future clinic-based human immunodeficiency virus and syphilis screening. The sexual partner or his/her representative collects treatment from the clinic reception.

APTPharmacy A form of accelerated partner therapy in which the sexual partner undergoes consultation and treatment with a sexual-health trained community pharmacist and receives an invitation for future clinic-based human immunodeficiency virus and syphilis screening.

(Trial/study/control) arm(s) A group of people whose outcome in a study is compared with that of another group or groups; commonly the arms of a trial are categorised as experimental and control groups.

Arthritis Inflammation of the joint(s).

Ascertainment bias Systematic failure to represent equally all classes of cases or people supposed to be represented in a sample. This bias may arise because of the nature of the sources from which people come (e.g. a specialised clinic) or from a diagnostic process influenced by culture, custom or idiosyncrasy.

Asymptomatic Not showing any symptoms of disease, whether or not disease is present.

Azithromycin Orally administered antibiotic used to treat respiratory, skin, soft tissue and other infections, including genital infections caused by *Chlamydia trachomatis*.

Balanitis Inflammation of the glans (head of) penis, usually associated with tightness of the foreskin (phimosis). An acute attack is associated with redness and swelling of the glans.

Balanoposthitis Inflammation of the foreskin and the surface of the underlying glans penis, associated with difficult and painful urination.

BD Viper™ System The BD Viper System is a machine that detects and helps diagnose chlamydia and/or gonorrhoea.

Beta distribution A family of continuous probability distributions defined on the interval [0, 1], parameterised by two positive shape parameters, denoted by α and β, that appear as exponents of the random variable and control the shape of the distribution.

(Recall) bias A systematic distortion of a statistical result due to a factor not allowed for in its derivation. Recall bias is the systematic error due to differences in completeness of recall to memory of past events or experiences.

Bivariate analysis A form of quantitative (statistical) analysis that involves the analysis of two variables (often denoted as X and Y), for the purpose of determining the empirical relationship between them.

Blind(ed) When subjects and/or investigators are unaware of the knowledge (i.e. intervention arm) that might introduce a bias.

British Association for Sexual Health and HIV A UK-based professional organisation dealing with all aspects of sexual health care.

British National Formulary A UK-published list of approved drugs and medications that lists their generic and proprietary names, pharmacological action, dosage, indications, contraindications, side effects and reported adverse reactions. This is produced and maintained up to date in collaboration between the British Medical Association and the Royal Pharmaceutical Society of Great Britain.

Case–control study Comparison of a group of people with a disease or condition and a control group of people free from that disease (e.g. people diagnosed with lung cancer and people without lung cancer). The groups are compared in terms of the frequency of variables in their backgrounds (e.g. cigarette smoking), allowing risk factors for the disease to be investigated.

Case series A collection of patients with common characteristics used to describe some clinical, pathophysiological or operational aspect of a disease, treatment or diagnostic procedure.

Cefoxitin A cephamycin antibiotic often grouped with the second-generation cephalosporins.

Ceftriaxone A third-generation cephalosporin effective against a wide range of micro-organisms and therefore used in a variety of infections.

Census A 10-yearly enumeration of the population based on the actual presence of individuals in a house or institution on a designated night.

Cervicitis Inflammation of the neck (cervix) of the uterus.

Chi-squared test A test, used in controlled trials and other studies, to determine whether or not the difference between two groups of observations is statistically significant. It measures the differences between theoretical and observed frequencies and identifies whether or not variables are dependent.

Chlamydia Screening Studies A NHS-funded project to find out how a screening programme for chlamydia could be designed and rolled out.

Chlamydia trachomatis A strain of *Chlamydia*, a bacterium that is a common cause of sexually transmitted infections, being responsible for non-specific urethritis in men and pelvic inflammatory disease in women.

Clinical governance The framework through which the NHS aims to deliver high-quality services within a safe system, with continuous efforts for service improvement. Introduced in 1998, clinical governance emphasises the concept of accountability in delivering care.

Clinical Research Network In 2006, the Department of Health set up the National Institute for Health Research to create a world-class health system within the NHS and the Clinical Research Network is part of this wider organisation.

Cluster randomised controlled trial A type of randomised controlled trial in which groups of subjects (as opposed to individual subjects) are randomised.

Condom A sheath made of latex rubber or plastic that is fitted over the penis during sexual intercourse. Use of a condom protects both partners against sexually transmitted diseases and, carefully used, it is a reasonably reliable contraceptive.

Confidence interval A range of values that contains the parameter of interest within a given probability. For example, with a 95% confidence interval the parameter value will lie in this interval 95 times out of every 100.

Conjunctivitis Inflammation of the conjunctiva (eye membrane), which becomes red and swollen and produces a discharge.

Consolidated Standards of Reporting Trials diagram A flow diagram of progress though phases of a research trial.

Contact tracing The method of epidemic investigation that is concerned with locating the source of an infection, such as a sexually transmitted infection.

Contraception and sexual health services Contraception, sexual health and reproductive health and gynaecology services.

Control (arm) See *Arm(s)*.

Convenience sampling A sample, usually of people, that has been collected by expedient means, such as because they happen to be available for study, not by using a random sampling method.

Core services General practice, contraceptive and sexual health services and pharmacies.

Cost–consequences analysis An analytical tool in which the components of incremental costs and consequences of alternative programs are computed and listed, without any attempt to aggregate these results.

Cost-effectiveness analysis An analytical tool in which the costs and effects of a programme and at least one alternative are calculated and presented as a ratio of incremental cost to incremental effect. Effects are health outcomes, such as cases of a disease prevented, years of life gained or quality-adjusted life-years, rather than monetary measures as in cost–benefit analysis.

Culture (test) A laboratory process to identify micro-organisms on or in a growth medium. Further testing can identify which antimicrobials have an effect on the found organism(s).

(Socio)demographic Of, relating to or involving a combination of social and demographic factors: age, ethnicity, sex, socioeconomic status, marital status and family size.

Denominator Number of patients included in an intervention/receiving treatment.

Department of Health A department of central government staffed by civil servants, including health-care professionals, that supports the Secretary of State for Health in meeting his or her obligations, which include the NHS, the promotion and protection of the health of the nation and social care, including the oversight of personal social services provided by local authorities.

Dermatosis Any disease of the skin, particularly one without inflammation.

Deterministic sensitivity analysis There is no randomness in this type of model calculation and, during each calculation, each model parameter uses its specified point value.

Diffusion of innovations A theory to explain the way that innovative ideas and concepts spread through society or portions of society, such as members of the medical profession.

Doctor of Philosophy An advanced research degree.

Doxycycline An orally administered tetracycline antibiotic used to treat infections caused by *Chlamydia*, rickettsiae, mycoplasmas and *Brucella*, as well as Lyme disease.

Dysuria Difficult or painful urination that is usually associated with urgency and frequency of urination if due to cystitis or urethritis. The pain is burning in nature and is relieved by curing the underlying cause.

Economic evaluation A broad term to describe various ways of assessing health interventions.

Ectopic pregnancy The implantation of a fertilised egg cell at a site outside the uterus. This may happen if the fertilised egg cell remains in the ovary or in the Fallopian tube or if it lodges in the free abdominal cavity.

Endometritis Inflammation of the endometrium (lining of the uterus) as a result of acute or chronic infection. It may be caused by foreign bodies, bacteria, viruses or parasites and in the acute phase may occur in the period immediately after childbirth.

Enzyme immunoassay An immunoassay (as an enzyme-linked immunosorbent assay) in which an enzyme bound to an antigen or antibody functions as a label.

Epidemiological treatment Antibiotics administered when a diagnosis is considered likely on clinical, laboratory or epidemiologic grounds, but before the results of confirmatory laboratory tests are known.

Epididymitis Inflammation of the epididymis, associated with pain, swelling and redness of the affected half of the scrotum. The usual cause is infection spreading down the vas deferens from the bladder or urethra.

EpiGeneSys A software development company based in Sheffield, UK.

Expedited partner therapy A form of partner notification in which the doctor provides the index patient with antibiotics or a prescription to give to their sexual partner.

Expert opinion Opinions of respected authorities based on clinical experience, descriptive studies, reports of expert committees, consensus conferences, etc.

Gamma distribution A continuous statistical distribution with two parameters, α and β. The probability density function is given by $f(x) = (x^{(\alpha-1)} e^{(-x/\beta)}) / (\beta^{\alpha} \Gamma(\alpha))$, where x, α, and β are all positive, and Γ is the gamma function.

General practitioner A doctor working in the community who provides family health services to a local area and usually acts as the first port of call for most patients with concerns about their health. General practitioners look after patients with wide-ranging medical conditions and can refer patients with more complex problems to specialists, such as hospital consultants.

Genitourinary medicine The medical specialty concerned with the study and treatment of sexually transmitted diseases.

Genitourinary Medicine Clinic Activity Dataset Coding database using national codes for the appropriate diagnoses and local codes to designate asymptomatic presentations.

Gram stain A method of staining bacterial cells, used as a primary means of identification. A film of bacteria spread onto a glass slide is dried and heat fixed, stained with a violet dye, treated with decolouriser (e.g. alcohol) and then counterstained with red dye.

Hawthorne affect A type of reactivity in which individuals modify or improve an aspect of their behaviour in response to their awareness of being observed.

(Sexual) health adviser A type of health-care professional working in sexual health clinics. The role of the sexual health adviser involves working with individuals and groups affected by issues related to sexual health in general and sexually transmitted infections (including human immunodeficiency virus infection) in particular. The role of the sexual health adviser will commonly embrace the following features: partner notification, sexual health promotion, teaching/training, counselling, research and audit.

Health-care assistant A support worker in a clinical area who works under the supervision of a registered practitioner who is accountable for the support worker's standards and activities.

Health-care professional An individual who provides preventative, curative, promotional or rehabilitative health-care services in a systematic way to people, families or communities.

Health Protection Agency A non-departmental public body set up as a special health authority in 2003 to protect the health of the UK population through advice and support given to the NHS, local authorities, the Department of Health, emergency services and others. The Health Protection Agency was involved in protecting people from communicable diseases and biological, chemical, poison and radiation hazards. The Health Protection Agency became part of Public Health England in 2013.

Health technology assessment The formal evaluation of technologies used in health care. It involves not only efficacy but also cost-effectiveness, cost–utility and all other aspects of technology that may be important for society. Health technology assessment supports evidence-based decision making in health-care policy and practice.

Hegemonic Normative.

Herpes simplex virus (infection) Inflammation of the skin or mucous membranes caused by herpesviruses and characterised by collections of small blisters. There are two types of herpes simplex virus: type I causes the common cold sore, usually present on or around the lips; type II is mainly associated with genital

herpes and is sexually transmitted. However, types I and II can both cause either genital herpes or cold sores, depending on the site of initial infection.

High-powered field The visible area when specimens are viewed under a high magnification using a microscope.

Human immunodeficiency virus A retrovirus responsible for acquired immunodeficiency syndrome. There are two varieties, HIV-1 and HIV-2; the latter is most common in Africa.

Incremental cost-effectiveness ratio The ratio of the difference in costs between two alternatives to the difference in effectiveness between the same two alternatives.

Index patient/diagnosis The first medically identified patient in a family or other group with a particular condition, often an infection, which triggers a line of investigation.

KC60 surveillance data The Department of Health requires information on services provided by genitourinary medicine clinics and this information is collected on the Department of Health central return form KC60.

Leucocyte esterase test Urine test for the presence of white blood cells and other abnormalities associated with infection.

Mathematical model – transmission dynamic, deterministic compartmental, compartmental transmission A mathematical model is a description of a system using mathematical concepts and language. A transmission dynamic model incorporates simultaneous interactions.

Medical Research Council A government-supported body that is an important source of funds for medical research.

Men who have sex with men This includes men who have only male sexual partners and men who have both male and female sexual partners.

Metronidazole An antibiotic used to treat infections of the urinary, genital and digestive systems.

Microbiota Micro-organisms that are normally associated with a particular tissue or organ.

Molluscum contagiosum A common disease of the skin, mainly affecting children. The disease is caused by a poxvirus and is spread by direct contact, including by sexual transmission in adults. Untreated, the papules generally disappear in 6–9 months.

Mucopurulent cervicitis Inflammation of the cervix usually caused by a sexually transmitted infection causing vaginal discharge.

Multisite sampling Obtaining samples for infection testing from several body sites.

Multivariable analysis/multivariable logistic regression A statistical technique that can be used to simultaneously explore whether or not multiple risk factors are related to a certain outcome.

Mycoplasma genitalium A bacterium causing inflammation of the male and female genital tracts.

National Centre for Social Research Britain's largest independent social research agency.

National Chlamydia Screening Programme A NHS sexual health programme that was set up by the Department of Health in England in 2003. The National Chlamydia Screening Programme aims to ensure that all sexually active young people aged < 25 years are aware of chlamydia and its effects and have access to free and confidential testing services.

National Health Service (In Britain) A comprehensive service offering therapeutic and preventative medical and surgical care, including the prescription and dispensing of medicines, spectacles and medical and dental appliances. Exchequer funds pay for the services of doctors, nurses and other professionals, as well as residential costs in NHS hospitals, and meet a substantial part of the cost of the medicines and appliances.

National Institute for Health and Care Excellence A special health authority covering England and Wales set up in April 1999 and originally called the National Institute for Clinical Excellence. It consists of policy makers, clinicians working in the NHS, academics and patients. The National Institute for Health and Care Excellence is responsible for examining the evidence for treatments and services and using that evidence to maximise cost-effectiveness.

National Institute for Health Research The National Institute for Health Research is funded through the Department of Health to improve the health and wealth of the nation through research.

National random probability sample survey A scientifically robust means of surveying people from different backgrounds, locations, ages, genders and ethnicities.

National Research Ethics Service The National Research Ethics Service (now part of the Health Research Authority) reviews research proposals to protect the rights and safety of research participants and enable ethical research that is of potential benefit to science and society.

(Britain's Third) National Survey of Sexual Attitudes and Lifestyles The British National Surveys of Sexual Attitudes and Lifestyles are among the largest and most detailed scientific studies of sexual behaviour in the world. Three National Surveys of Sexual Attitudes and Lifestyles have taken place: Natsal-1 in 1990–91, Natsal-2 in 1999–2001 and Natsal-3 in 2010–12.

Neisseria gonorrhoeae The bacterium responsible for gonorrhoea.

NIHR Evaluation, Trials and Studies Coordinating Centre Established in 2008, the NIHR Evaluation, Trials and Studies Coordinating Centre manages the identification, prioritisation, funding, delivery, publication and dissemination of high-quality research and leads other National Institute for Health Research initiatives to meet the needs of the public, patients and the NHS.

Non-chlamydial, non-gonococcal urethritis Inflammation of the urethra not attributable to gonorrhoea or *Chlamydia trachomatis*.

Non-gonococcal urethritis See *Non-specific urethritis*.

Non-specific urethritis Inflammation of the urethra not attributable to gonorrhoea. Often the cause is *Chlamydia trachomatis*.

Nucleic acid amplification tests Highly accurate laboratory tests based on deoxyribonucleic acid and ribonucleic acid amplification.

Observational study A research method in which the investigator records behaviour as far as possible without influencing it. Often used in certain areas of social psychology, developmental psychology and ethology.

Omnibus survey National Centre for Social Research quarterly social research survey.

Opportunistic screening Offering a check-up (for sexually transmitted infections) as and when a person interacts with medical services rather than by specific invitation for screening.

Partner notification The process by which a person exposed to a sexually transmitted infection is identified and informed of the need for testing and treatment.

Patient and public involvement The active involvement of NHS patients and members of the public in research.

Peer A person of the same standing or rank as the person(s) in question; a person or thing of the same effectiveness or ability as the one(s) in question; an equal.

Pelvic inflammatory disease An acute or chronic condition in which the uterus, Fallopian tubes and ovaries are infected. It is usually the result of infection ascending from the vagina; *Chlamydia trachomatis* and *Neisseria gonorrhoeae* have been identified as causative agents. Pelvic inflammatory disease may be associated with lower abdominal pain, irregular vaginal bleeding and vaginal discharge.

Personal identification number Unique number assigned to patients as a way to identify them in a medical setting.

Personal Social Services Research Unit The Personal Social Services Research Unit carries out policy analysis, research and consultancy in the UK and abroad. The unit's current research programme focuses on needs, resources and outcomes in social and health care, with particular emphasis on economic aspects of community care, residential and nursing home provision, social care markets and commissioning, long-term care finance and mental health policy.

Pilot study/pilot trial A small-scale trial or field test to evaluate methods and procedures that will be used in a larger-scale project if the methods work satisfactorily and without adverse consequences.

Polymerase chain reaction A technique of molecular genetics in which a particular sequence of DNA can be isolated and amplified sufficiently to enable genetic analysis. The technique may be utilised in the identification of viruses in tissue samples, for example human papillomavirus in cervical smears. See *Nucleic acid amplification tests*.

Polymorphonuclear leucocytes A type of white blood cell with a lobed nucleus.

Popular opinion leader A person from a social group who is able to influence other individuals' attitudes or overt behaviour informally in a desired way with relative frequency.

Posthitis Inflammation of the foreskin. This usually occurs in association with inflammation of the glans penis. Pain, redness and swelling of the foreskin occurs as a result of bacterial infection.

Power calculation A statistical test used to assess how many samples have to be analysed to maximise success in answering a hypothesis, while minimising the use of resources.

Primary care (professionals) Health care provided by general practitioners or other health professionals to whom patients seeking medical treatment have direct access and to whom they can usually self-refer.

Primary care trust Before the 2012 Health and Social Care Act there were 152 free-standing statutory bodies within the NHS, each known as a primary care trust. Their responsibility was the health-care needs of their local community and they aimed to improve the health of and address health inequalities in their communities. Their work has since been taken over by clinical commissioning groups.

Primary outcome The main factor of interest in a study.

Probabilistic sensitivity analysis Probabilistic sensitivity analysis uses Monte Carlo simulation, which refers to the use of random numbers in a model. Monte Carlo simulation recalculates a model multiple times. It can update any number of parameters between model recalculations, assigning values that are randomly sampled from probability distributions.

Process evaluation In the evaluation of health care, the process of assessing how services are used, by whom, under what circumstances and with what outcomes.

Psychometric testing The measurement of individual differences in psychological functions (such as intelligence and personality) by means of standardised tests.

Public Health England A non-departmental public body, set up as a special health authority in 2013 to protect the health of the UK population by providing advice and support to the NHS, local authorities, the Department of Health, emergency services and others.

Purposive sampling A method to help researchers choose the type of individuals to be included in a research study. This is based on a variety of criteria including specialist knowledge of the research issue or willingness to participate in the research.

***p*-value** The chances of obtaining a certain pattern of results if there really is no relationship between the variables and the result could therefore have been caused by chance. For example, a *p*-value of 0.01 ($p = 0.01$) means that there is a 1 in 100 chance that the result occurred by chance. If the *p*-value is < 0.05 ($p < 0.05$) then the result is not due to chance and is statistically significant. The lower the *p*-value the more rigorous the criteria for concluding significance.

Qualitative research A type of research that gathers information that might aim to understand the reasons why a behaviour occurs. Qualitative research uses methods such as observation, in-depth interviewing and focus groups.

Quality-adjusted life-year Measure of health outcome that assigns to each period of time a weight, ranging from 0 to 1, corresponding to health-related quality of life during that period, with a weight of 1 corresponding to optimal health and a weight of 0 corresponding to a health state judged to be equivalent to death; these are then aggregated across time periods.

Quality of life Broad construct reflecting subjective or objective judgement concerning all aspects of an individual's existence, including health, economic, political, cultural, environmental, aesthetic and spiritual aspects.

Randomised control trial (Intervention study) A comparison of the outcome between two or more groups of patients who are deliberately subjected to different regimes to test a hypothesis, usually about treatment (in a clinical trial). Whenever possible those entering the trial should be allocated to their respective groups by means of random numbers and one such group (control) should have no active treatment (randomised controlled trial).

Random permutation A random ordering of a set of objects, that is, a permutation-valued random variable.

Salpingitis Inflammation of one or both of the Fallopian tubes caused by bacterial infection spreading from the vagina or uterus or carried in the blood.

Sample size The number of observations in a sample.

Semistructured interview An interview technique that allows for deep and wide-ranging discussion within a predetermined structure.

(One-way) sensitivity analysis Mathematical calculations that isolate factors involved in a decision analysis or economic analysis to indicate the degree of influence that each factor has on the outcome of the entire analysis. Specifically measures the uncertainty of the probability distributions. One-way sensitivity analysis changes one factor at a time.

Sequela Any disorder or pathological condition that results from a preceding disease or accident.

Serology A laboratory examination of blood to measure the presence and levels of antibody or protein.

Sexually transmitted infection Any infection transmitted by sexual contact, be that vaginal, anal or oral.

Short Message Service Text message service component of telephone, web or mobile communication systems.

Snowball sampling A method of selecting for study the members of 'hidden' populations, for example injecting drug users. Those initially identified are asked to name acquaintances who are added to the sample; these, in turn, are asked to name further acquaintances and so on until enough people are accumulated to give adequate power to the proposed study.

Social desirability bias Reporting of behaviours that may be influenced by the perception of what the researchers want to hear or what is socially desirable.

SPORTSMART study A trial of sexually transmitted infection screening in a football club setting.

Standard deviation A measure of the scatter of observations about their arithmetic mean, which is calculated from the square root of the variance of the readings in the series. The arithmetic sum of the amounts by which each observation varies from the mean must be zero, but if these variations are squared before being summated a positive value is obtained. The mean of this value is the variance.

Standard error (Of a mean) The extent to which the means of several different samples would vary if they were taken repeatedly from the same population.

Stata A general-purpose statistical software package created in 1985 by StataCorp.

Statistical power In inferential statistics, the probability that a significance test will reject the null hypothesis when it is in fact false. Significance tests vary in power, but all tests increase in power with increasing sample sizes. The power of a test depends on the particular alternative hypothesis against which it is tested. See also *Type II error*.

Statistically significant/significance level Statistical significance is considered as $p < 0.05$.

Symptom-based triage/self-triage form A paper or computer form that patients are asked to fill in prior to seeing a health-care professional.

Syphilis A sexually transmitted disease caused by the bacterium *Treponema pallidum*, resulting in the formation of lesions throughout the body. Bacteria usually enter the body through the mucous membranes of the vagina or urethra, but they may be transmitted vertically or through wounds in the skin.

Systematic review A research literature review that is conducted to a rigorous, standardised method.

The Amateur Football Combination A European adult football league, with around 100 clubs and 350 sides playing on Saturday afternoons in and around London.

Transmission dynamic model A transmission dynamic model incorporates simultaneous interactions.

Trichomonas vaginalis The protozoan responsible for trichomoniasis (an infection of the vagina that causes inflammation of genital tissues with vaginal discharge). It can be transmitted to males in whom it causes urethral discharge.

Tubal factor infertility Difficulty conceiving because of problems within the Fallopian tubes.

Type II error (false negative) This occurs if the investigator fails to reject a null hypothesis that is actually false in the population.

Uptake (of screening) Percentage of people who, having been sent an invitation for screening, attend a screening unit in response to that invitation.

Urethra The tube that conducts urine from the bladder to the exterior.

Urethritis Inflammation of the urethra, often caused by gonorrhoea or infection with *Chlamydia trachomatis*. The symptoms are those of urethral discharge with painful or difficult urination.

Wellcome Trust A global charitable foundation dedicated to improving health by supporting those working in science, the humanities and the social sciences.

List of abbreviations

AFC	Amateur Football Combination
AOR	adjusted odds ratio
APT	accelerated partner therapy
CASH	contraception and sexual health
CI	confidence interval
ClaSS	Chlamydia Screening Studies
EIA	enzyme immunoassay
EPT	expedited partner therapy
GP	general practitioner
GUM	genitourinary medicine
HCP	health-care professional
HIV	human immunodeficiency virus
HPF	high-powered field
ICER	incremental cost-effectiveness ratio
MOA	major outcome averted
MRC	Medical Research Council
MSM	men who have sex with men
NAAT	nucleic acid amplification test
NatCen	National Centre for Social Research
Natsal	National Surveys of Sexual Attitudes and Lifestyles
Natsal-2	second National Survey of Sexual Attitudes and Lifestyles
Natsal-3	third National Survey of Sexual Attitudes and Lifestyles
NCNGU	non-chlamydial, non-gonococcal urethritis
NCSP	National Chlamydia Screening Programme
NETSCC	NIHR Evaluation, Trials and Studies Coordinating Centre
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NSU	non-specific urethritis
OR	odds ratio
PCT	primary care trust
PID	pelvic inflammatory disease
PIN	personal identification number
PMNL	polymorphonuclear leucocyte
PPI	patient and public involvement
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SD	standard deviation
STI	sexually transmitted infection
TDM	transmission dynamic model
TFI	tubal factor infertility

Plain English summary

The sexual health of people in the UK is poor. It is a particular problem for men, largely because men do not seem to take up the offer of check-ups, or be offered check-ups, for sexually transmitted infections (STIs) as frequently as women, with the reasons for this unclear. We also do not know the best selection of check-up STI tests that we should offer men with no symptoms and it is unclear how we should best arrange testing and treatment for men who have had sex with somebody with a STI (partner notification).

This research addressed these uncertainties in the delivery of care for men with STI concerns. We used different research methods including two trials, mathematical modelling, economic analyses, national surveys and interviews with men themselves.

We found that men prefer going to their general practitioner (GP) or sexual health clinic to get tested for STIs rather than non-medical settings. However, if access to local health services is poor, offering screening in local football clubs could be a good alternative. We also found that national recommendations for the tests that should be included in check-ups for men are good value for money for the NHS. Our new ways of getting treatment to men who had been exposed to a STI showed promise but were not particularly popular.

Future research needs to discover how to increase GP screening for STIs for men, consider the issues for men who have sex with men and further improve partner notification.

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 ≤ 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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Chapter 1 Impact of different clinical approaches to sexually transmitted infection testing in men: a systematic review, case–control study and modelling study with an economic evaluation

Abstract

Introduction: The optimal sexually transmitted infection (STI) screening strategy for asymptomatic men is unknown and whether or not we should screen asymptomatic men for non-chlamydial, non-gonococcal urethritis (NCNGU) is debated. *Mycoplasma genitalium* is an emerging cause of NCNGU.

Objectives: (1) To determine whether or not asymptomatic NCNGU is associated with significant clinical outcomes; (2) to identify demographic, behavioural and clinical factors associated with NCNGU; (3) to develop an evidence-based clinical algorithm for STI testing in asymptomatic men; and (4) to model mathematically the epidemiological and economic impact of removing microscopy from asymptomatic STI testing and to determine its cost-effectiveness.

Methods: (1) Systematic literature review; (2) case–control study comparing factors associated with asymptomatic NCNGU compared with factors associated with symptomatic NCNGU and asymptomatic healthy men; and (3) 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 *M. genitalium*.

Results: Available evidence on the clinical consequences of asymptomatic NCNGU is limited but does not suggest that asymptomatic NCNGU is associated with significant health consequences. Men with NCNGU (symptomatic or asymptomatic) and healthy men reported similar 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) but could save > £5M over 20 years.

Conclusions: The significance of asymptomatic NCNGU remains unclear. The similarities in clinical and sexual risk attributes between men with symptomatic NCNGU and men with asymptomatic NCNGU mean that it is not possible to develop an evidence-based clinical algorithm to guide the selection of STI tests to be included in the screening of asymptomatic men and this questions the rationale for the current symptom-based approach to testing. Resources supporting current levels of NCNGU screening in asymptomatic men could be better spent expanding testing and treatment for other STIs.

Background

Non-chlamydial, non-gonococcal urethritis is a common condition that is believed to be sexually transmitted. Approximately 70,000 men in the UK receive this diagnosis each year, accounting for half of all STI diagnoses in men.[1,2] It is characterised by microscopic findings of polymorphonuclear leucocytes (PMNLs) on urethral Gram stain in the presence (symptomatic NCNGU) or absence (asymptomatic NCNGU) of urethral discharge, dysuria, urethral itching and penile irritation in men in whom *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infection have been excluded.[3]

Obtaining a suitable urethral sample for Gram stain examination for microscopic urethritis involves a potentially uncomfortable procedure. A small plastic loop is inserted into the distal urethra and removed whilst applying pressure against the lateral urethra wall, thereby collecting cells for Gram staining.

Several pathogens, such as *Trichomonas vaginalis*, herpes simplex virus and adenovirus, have been linked with NCNGU.[3] However, recent interest has focused on *M. genitalium*, which accounts for between 10% and 46% of cases of NCNGU.[3,4] *M. genitalium* appears to be associated predominantly with symptomatic presentations[5–8] and, although associations have been reported with a number of adverse health consequences in women, including PID, tubal factor infertility (TFI) and ectopic pregnancy[9–21] and mucopurulent cervicitis[10,15] (around 20,000 cases reported annually, 70% of which are asymptomatically epidemiologically treated cases[22]), testing for and treatment of *M. genitalium* is not a current standard of care in the UK.[23]

Several studies have explored the role of *M. genitalium* in PID and found evidence for an association between exposure and outcome that is independent of *C. trachomatis*, an established cause of PID.[13,20] Specifically, the PID Evaluation and Clinical Health (PEACH) study[24] found *M. genitalium* by polymerase chain reaction in women with PID more frequently than in women without PID, independent of infection with *C. trachomatis*. Other studies have found evidence of a link between previous *M. genitalium* infection and TFI[18,21] and between *M. genitalium* infection and PID in the wake of a termination of pregnancy.[25] Finally, all-cause PID has long been linked to ectopic pregnancy and infertility.[12,14,19,25] *M. genitalium* has also been found to be associated with male sequelae of urethritis: balanitis, posthitis and balanoposthitis (independent of *C. trachomatis*).[26] There is evidence that *M. genitalium* responds to azithromycin, doxycycline and cefoxitin, although with treatment failure rates ranging from 12% to 40%.[27–30] Moxifloxacin has been documented to not be associated with treatment failure[31] but is not recommended as first-line treatment for NCNGU because of safety concerns.[32] Symptomatic cases of NCNGU caused by *M. genitalium* will be treated for *C. trachomatis* with azithromycin and some may recover.

The significance of NCNGU in men is the subject of debate,[33–37] largely because of the paucity of high-quality clinical studies. In particular, opinions are divided on whether or not to screen asymptomatic men for NCNGU. In the past, all men undergoing STI screening needed urethral swab sampling because the tests for *C. trachomatis* and *N. gonorrhoeae* at the time were reliant on urethral samples. All men with NCNGU, both symptomatic and asymptomatic, were treated with the aim of relieving symptoms as relevant, and somewhat speculatively, in a presumptive approach to treatment of a number of possible organisms of which *M. genitalium* was one. Sex partners were also contacted and treated as *M. genitalium* is associated with infertility and PID in women.

The introduction of urine-based nucleic acid amplification tests (NAATs) for the detection of *C. trachomatis* and *N. gonorrhoeae* means that it is no longer necessary to obtain urethral smear samples (an invasive procedure that men find unpleasant) to diagnose these infections. This is important in the current context of a wider roll-out of non-invasive STI screening in settings without access to microscopy. UK[23] and Australian[38] guidelines for STI testing no longer recommend urethral smear microscopy in asymptomatic men. Instead, there is a reliance on the presence of symptoms to indicate likely infection and the high sensitivities and specificities of non-invasive tests to detect asymptomatic infection with *C. trachomatis* and *N. gonorrhoeae*. Thus, men with symptoms undergo urethral smear microscopy in addition to urine testing for *C. trachomatis* and *N. gonorrhoeae* and men with no symptoms are offered only urine screening for *C. trachomatis* and *N. gonorrhoeae*. This assumes that asymptomatic NCNGU is of no clinical significance, as the absence of urethral smear microscopy means that the diagnosis cannot be made. However, the lack of a robust evidence base in the published literature has led many to question this assumption, with others proposing that diverting the resources associated with undertaking microscopy on asymptomatic men into widening access to urine-based testing is a more effective strategy for STI control. As a result, service provision now varies across the country, with some specialist clinics continuing to perform urethral smears on all men and thus diagnosing and treating asymptomatic NCNGU and other clinics and all non-specialist settings (in which microscopy facilities required for the diagnosis of asymptomatic NCNGU are unavailable)

adopting the new guideline.[39] We estimate that approximately 5% of asymptomatic men still receive microscopy.[39] It is accepted that such differing standards of clinical care are untenable. This has led to a reduction in the number of men diagnosed with, and treated for, asymptomatic NCNGU and is likely to limit research on this condition in the future. However, the public health consequences of untreated asymptomatic NCNGU for men and their sexual partners are unknown.

Screening all men (symptomatic and asymptomatic) for NCNGU using urethral smear microscopy, the only available test, creates a large financial burden on the NHS in the UK. The financial impact of withdrawing screening of asymptomatic men for NCNGU must be balanced against other indirect cost savings, for instance preventing the transmission of the STI could decrease the demand for adoptive services by preventing infertility and potential ectopic pregnancies caused by asymptomatic *M. genitalium*-positive NCNGU. Thus, if diagnosing and treating NCNGU prevents future infections as well as major adverse events and their associated costs, it is possible that this future benefit may compensate for the costs currently being incurred. Conversely, it may be that the resources associated with microscopy could be used in a more cost-effective manner through alternative strategies that ensure a better uptake of chlamydia and gonorrhoea screening.

To investigate these issues we conducted three research studies with the following aims and specific objectives.

Aims

- To evaluate the public health and economic impact of different clinical approaches to STI testing in men.
- To develop an evidence-based algorithm for STI testing of asymptomatic men.

Specific objectives

- To compare factors associated with asymptomatic and symptomatic NCNGU.
- To determine whether or not symptom-based triage correctly identifies men at risk of STIs.
- To develop an evidence-based algorithm for the STI testing of asymptomatic men.
- To mathematically model the epidemiological and economic impact of removing microscopy from routine STI testing in asymptomatic men across a range of assumptions about pathogenicity and cause.
- To determine whether or not the removal of microscopy from routine STI testing in asymptomatic men is an appropriate strategy on cost-effectiveness grounds and to ascertain whether or not the resources associated with microscopy could be more cost-effectively used in alternative strategies that ensure better uptake of chlamydia and gonorrhoea screening.

Phase 1: comparison of factors associated with asymptomatic and symptomatic non-chlamydial, non-gonococcal microscopic urethritis to develop a clinical algorithm for sexually transmitted infection testing in men

Phase 1a: systematic review of the clinical consequences of asymptomatic non-chlamydial, non-gonococcal urethritis for men and their partners

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Objectives

- To determine whether or not asymptomatic NCNGU is associated with significant clinical consequences for men and their sexual partners.
- To provide parameters for the modelling study.

Methods

Databases, search strategy and search terms

We searched four electronic databases [MEDLINE, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and PsycINFO] using terms including 'urethritis', 'non-specific', 'non-chlamydial', 'non gonococcal', 'NSU', 'NGU', 'NCNGU' and 'NGNCU' (see *Appendix 1* for search strategy) and included literature published between January 1965 (the year *C. trachomatis* was first recognised as a cause of urethritis[41]) and February 2010. Results were also restricted to English-language reports for practical reasons.

The first researcher screened titles and abstracts for potential relevance (based on accepted clinical knowledge of the subject[28]) and allocated them into two groups: 'for exclusion' or 'for further assessment to determine eligibility'. If relevance could not be assessed from the title and abstract, we obtained a full-text version. The second researcher, blinded to the first researcher's initial group allocation, reviewed a random sample of 10% of the study titles in each group to assess the reliability of the screening process. Any differences were resolved by discussion and a final group of relevant articles for assessment of eligibility was agreed. To capture articles potentially missed by the literature search, but with outcomes of relevance embedded in their text, full-text articles were also retrieved for relevant references quoted in review articles and editorials on NCNGU.

Types of study included

We included studies that reported clinical outcomes for men with asymptomatic NCNGU and/or their sexual partners. Trials and observational studies, including cohort and non-comparative case series, were eligible for inclusion but we excluded case reports.

Participants

Men with asymptomatic NCNGU and sexual partners (any gender) of men with asymptomatic NCNGU.

Inclusion and exclusion criteria

Studies had to meet the following accepted definition of asymptomatic NCNGU to be included:

1. Asymptomatic men with a Gram- or methylene blue-stained urethral smear containing five or more PMNLs per high-powered field (HPF) (×1000) averaged over five fields with the greatest concentration of PMNLs or a Gram stain of a pellet produced by centrifuge of first void urine containing $\geq$ 10 PMNLs per HPF averaged over five fields with the greatest concentration of PMNLs.[28] Studies not reporting diagnostic criteria based on microscopy were excluded. However, we did include studies using a higher threshold for detection than the five or more PMNLs per HPF, if explicitly stated. The asymptomatic status of the male index cases could be self-reported or clinician elicited.

And:

2. A negative urine or urethral swab NAAT or culture test for *C. trachomatis* and *N. gonorrhoeae*. Thus, studies that used enzyme immunoassay (EIA), serology or other non-NAAT, non-culture methods for the detection of *C. trachomatis* or studies that used a leucocyte esterase test to diagnose urethritis were excluded because of variable and low reported specificities and sensitivities.[42,43]

Validity
Because of the limited number of studies relating to asymptomatic NCNGU, we included all studies regardless of our assessment of validity.

Data extraction
Data were extracted by the authors independently and disagreements were settled by discussion.

Outcome measures
We included any recognised clinical outcome[44] in the index male patients and/or their sexual partners including, but not restricted to, epididymitis, conjunctivitis, arthritis, infertility, PID including salpingitis and endometritis, cervicitis, diagnosis with another STI, miscarriage, premature delivery and psychological diagnoses. We also included studies that investigated the relationship between asymptomatic NCNGU and human immunodeficiency virus (HIV) seminal plasma viral load as this has been linked with enhanced HIV transmission, which we considered a relevant potential clinical outcome.[45]

Results
We identified 1413 references from the search. There was an 85% agreement between reviewers for the initial screening process and we reached consensus by discussion for the remaining 15% of references. We retrieved full papers for 103 titles, 101 of which failed to meet the inclusion criteria, leaving two eligible studies (see *Appendix 1* for the flow diagram and table of excluded studies). No previous systematic review was found in The Cochrane Library databases and no ongoing UK-funded studies were identified from the National Institute for Health Research (NIHR) Clinical Research Network Portfolio Database. Three studies included asymptomatic and symptomatic men with NCNGU but did not report separate clinical outcomes for the asymptomatic group and were therefore excluded from further analysis.[5,22,46]

Association of asymptomatic non-chlamydial, non-gonococcal urethritis with adverse health outcomes in men
We did not find any eligible studies reporting adverse physical or psychological health outcomes for men with asymptomatic NCNGU.

Association of asymptomatic non-chlamydial, non-gonococcal urethritis with adverse health outcomes in sex partners of men with the condition
Two studies described relevant outcomes,[47,48] as summarised in *Table 1*. These studies investigated associations of asymptomatic NCNGU with concomitant STIs in sex partners. *C. trachomatis* was detected in 2.4%[48] and 8.3%[47] of female partners of men with asymptomatic NCNGU. One of the studies also detected pathogen-negative PID in 2.4% and cervicitis in 9.4% of female partners.[48]

Conclusions
We identified only two studies[47,48] that met the inclusion criteria for our review. The available research in this area, on which clinical guidelines are based, is insufficient in quality and breadth to enable us to draw robust conclusions on whether asymptomatic NCNGU is associated with significant health consequences for men or their sexual partners.

When literature exists, consequences for sexual partners focus on the diagnosis of concomitant STIs in female partners.[47,48] The prevalence of *C. trachomatis* in these women ranged from 2.4%[48] to 8.3%.[47] A single study also found PID in 2.4% and cervicitis in 9.4% of sexual partners who were negative for *C. trachomatis* and *N. gonorrhoeae*.[48] It is possible that these women had false-negative results or *M. genitalium*-associated disease. Although the identification of men with asymptomatic NCNGU may allow for contact tracing and discovery of STIs in sexual partners, the prevalence of *C. trachomatis* in female partners is no higher than would be reasonably expected in the general sexually active population.[49] It is difficult to know whether or not the prevalence of pathogen-negative PID and cervicitis detected is significantly different from the background prevalence.

It is unknown whether or not it is beneficial in public health and economic terms to redirect resources from screening asymptomatic men for NCNGU to specific STI screening programmes; no studies investigating these important issues were identified. We did not find any studies that investigated the effects of asymptomatic NCNGU on men with the condition. In particular, no studies addressing the psychosocial impact of asymptomatic NCNGU were found and no studies investigating the effect of asymptomatic NCNGU on HIV seminal plasma viral load were eligible for inclusion.

The studies included in this review have a number of important limitations. The total number of contactable sexual partners was reported only in the study by Blume *et al.*[48] and the prevalence of infection is presented as the number of infections found in the partners attending for testing. This gives an incomplete picture of partner pathology and it is not possible to calculate the true prevalence of infection in partners without testing all sexual contacts. Neither of the included studies reported whether or not a power calculation was performed to guide their sample size. Studies tend to include small numbers of index men and even smaller numbers of sexual partners, which, again, may give rise to a false estimate of the true burden of disease in both male index cases and their sexual partners. The included studies did not apply standardised time periods between the index man last passing urine and the urethral swabs being taken. This is known to influence the yield of PMNLs per HPF.[50] There is also significant intra- and inter-observer variability in reading urethral smear Gram stains.[51,52] The epidemiology of infections will vary between the geographical locations of the studies (Scotland[47] and south of England[48]) and when they were conducted (between 2002 and 2007), meaning that the findings are not directly transferable to current populations.

There are several limitations of the review itself. Although we included only studies that gave an explicit definition of microscopic urethritis (five or more PMNLs per HPF averaged over five fields), some studies used a higher PMNL threshold. This means that men with a lower 'grade' of urethritis may not be included, leading in turn to an over-representation of symptomatic men. The definition of 'asymptomatic' is difficult to standardise across the studies. Men who self-report as asymptomatic may have signs of infection when examined or have been symptomatic in the recent past. Studies not published in English were not included for practical reasons and there may be ongoing trials that are not in the NIHR database. It is possible that amongst the large number of studies on NCNGU we missed relevant results. However, we feel that it is unlikely that we have missed significant, well-conducted, appropriately powered studies investigating the clinical consequences of asymptomatic NCNGU.

Finally, it is important to highlight that this review focused on whether asymptomatic NCNGU is associated with adverse health outcomes. Organisms such as *M. genitalium* are responsible for some cases of asymptomatic NCNGU and there is an increasing body of literature to support its role in genital tract pathology in women.[9,53] Therefore, a review looking at the clinical consequences of asymptomatic *M. genitalium*-positive NCNGU may have different findings. As current provision within UK sexual health services does not provide for *M. genitalium* testing, we feel that the clinical question of relevance is whether or not asymptomatic NCNGU has significant clinical consequences, not whether *M. genitalium*-positive NCNGU has significant clinical consequences. The development of more sensitive microassays may also find associations between NCNGU and other organisms not currently thought relevant. Again, the clinical consequences of this are currently unknown.

This review highlights the paucity of high-quality literature and the lack of knowledge about asymptomatic NCNGU. The two studies identified for inclusion report rates of infection in female partners of men with this condition that are no higher than those expected in the general population. However, it is important to consider the limitations of these studies when drawing conclusions about the significance of asymptomatic NCNGU and whether or not screening men is a useful clinical strategy. We conclude that current clinical guidelines are based on a very limited evidence base. We feel that it is unlikely that there will be any significant research into the implications of asymptomatic NCNGU in the future, although we would argue that well-designed prospective studies with good follow-up of men and their partners are needed to better inform clinical practice.

Phase 1b: factors associated with asymptomatic non-chlamydial, non-gonococcal urethritis in men – findings from a case–control study

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Objectives

- To compare factors associated with asymptomatic and symptomatic NCNGU.
- To determine whether or not symptom-based triage correctly identifies men at risk of STIs.
- To develop an evidence-based algorithm for the STI testing of asymptomatic men.

Methods

We used a retrospective case–control design to compare demographic, behavioural and clinical factors associated with a diagnosis of asymptomatic NCNGU (cases) with factors associated with two comparator groups: (1) symptomatic men with microscopic urethritis and negative tests for *C. trachomatis* and *N. gonorrhoeae* (symptomatic NCNGU) (positive control subjects); and (2) asymptomatic men without microscopic urethritis and negative tests for *C. trachomatis* and *N. gonorrhoeae* (negative control subjects).

Cases and comparators were sequential male attenders of two inner-city London sexual health clinics at Barts and The London NHS Trust between August 2009 and February 2010 who met the inclusion criteria. Men were identified retrospectively from the clinics' Genitourinary Medicine Clinic Activity Dataset (GUMCAD) coding database using national codes for the appropriate diagnoses and local codes to designate asymptomatic presentations. Men reported the presence or absence of symptoms at registration on a triage form. For men to be considered symptomatic they had to report at least one symptom consistent with urethritis (urethral discharge, penile irritation or itching, dysuria). Men were excluded from the study if they reported ever having a male sex partner and, to eliminate the possibility of including urethritis cases that were caused by recognisable genital conditions, if they had balanitis, balanoposthitis, penile dermatosis, genital warts, molluscum contagiosum or active herpes simplex virus infection.

Urethritis was diagnosed using accepted international criteria: a Gram-stained urethral smear containing five or more PMNLs per HPF averaged over five fields with the greatest concentration of PMNLs in the absence of Gram-negative intracellular diplococci.[28] First void urine was tested for *C. trachomatis* and *N. gonorrhoeae* using the BD Viper™ System (Becton, Dickinson and Company, Franklin Lakes, NJ, USA). All samples (urethral smears and first void urine) were analysed in the same laboratory service by trained staff who regularly undergo microscopy audit and quality control processes.

A number of variables were considered for the analysis based on the published literature and discussion with sexual health experts in the field, but this was limited to data that were routinely and consistently collected as part of the standard consultation.[1,6] Data for some variables were routinely recorded by clinicians, whereas others were supplied by the patients on a self-triage form.

Statistical methods

A sample of 115 heterosexual men with asymptomatic NCNGU, 129 men with symptomatic NCNGU (positive control subjects) and 309 asymptomatic men without urethritis or *C. trachomatis* or *N. gonorrhoeae* infection (negative control subjects) provided 80% power to detect as significant (at the 5% level) differences between groups of, for example, 17% compared with 33%. Data were manually extracted from the clinic notes, entered into a Microsoft Access® database (2003; Microsoft Corporation, Redmond, WA, USA) and analysed using Stata data analysis and statistical software version 12 (StataCorp LP, College Station, TX, USA). The data were cross-tabulated and compared using the chi-squared statistic. Variables that were statistically significant ($p < 0.05$) in bivariate analyses were then entered into a multivariate logistic regression model and backward stepwise selection was used to identify a parsimonious model of the key demographic, clinical and behavioural factors associated with (1) having asymptomatic NCNGU compared

with symptomatic NCNGU and (2) having asymptomatic NCNGU compared with asymptomatic men without urethritis and *C. trachomatis* or *N. gonorrhoeae* infection.

Results

Data for 115 cases (mean age 27 years; 50.9% white British or Irish), 129 positive control subjects (mean age 28 years; 29.7% white British or Irish) and 309 negative control subjects (mean age 29 years; 53.3% white British or Irish) were collected. The characteristics of each group are summarised in *Table 1*.

Factors associated with asymptomatic compared with symptomatic non-chlamydial, non-gonococcal urethritis

In bivariate analyses, eight factors were associated with asymptomatic compared with symptomatic NCNGU: reporting giving oral sex in the last 3 months, reporting receiving oral sex in the last 3 months, condom use in the last 3 months, new sexual partner(s) in the last 3 months, time since the last STI check, previous warts diagnosis, ethnicity and time since the last HIV test.

In the multivariate model, two factors remained associated with asymptomatic NCNGU among men with urethritis who had only had sex with women (*Table 2*): reporting receiving oral sex in the last 3 months and condom use in the last 3 months, specifically reporting condom use 'most of the time' [adjusted odds ratio (OR) 4.71, 95% confidence interval (CI) 1.76 to 12.6].

Factors associated with asymptomatic non-chlamydial, non-gonococcal urethritis compared with asymptomatic men without urethritis, chlamydia or gonorrhoea

Eight factors were associated with asymptomatic NCNGU compared with asymptomatic men without urethritis, chlamydia or gonorrhoea (see *Table 1*): a previous STI check (83.5% vs. 72.2%; $p = 0.016$); a previous non-specific urethritis (NSU) diagnosis (24.4% vs. 13.6%; $p = 0.008$); a previous syphilis diagnosis (1.7% vs. 0%; $p = 0.020$); any previous STI diagnosis (44.4% vs. 31.7%; $p = 0.015$); reporting vaginal sexual intercourse in the last 3 months (95.6% vs. 88.3%; $p = 0.026$); and previously testing for HIV (75.4% vs. 63.4%, $p = 0.020$), with differences in the reported condom use ($p = 0.007$) and HIV status profile ($p = 0.037$) between these two groups. In addition, vaginal intercourse was more commonly reported among men with asymptomatic NCNGU (95.6% vs. 88.3%; $p = 0.026$). In multivariate analysis only two factors remained statistically significant (see *Table 2*): condom use and reporting a previous STI check.

Conclusions

This study found that, among heterosexual men, some differences exist between those with NCNGU (symptomatic or asymptomatic) and those without symptoms, urethritis, chlamydia or gonorrhoea in terms of their reported demographic, behavioural and clinical variables. However, in multivariable analyses only two differences remained of statistical significance: men with asymptomatic NCNGU were more likely to report having given oral sex and to have used condoms 'most of the time' than men with symptomatic NCNGU and, among all asymptomatic men, those with NCNGU were more likely to report using condoms 'not at all' and to have had a previous STI check-up than men without urethritis.

There appears to be an association between the self-reported degree of condom use and the likelihood of having NCNGU and symptoms. The proportion of men who reported using condoms was greatest among those without pathology detected and least among those with symptomatic NCNGU. One possible explanation is that condoms provide partial protection for any aetiological cause of NCNGU whereby those men with the least condom use have the greatest exposure, which consequently leads to more noticeable pathology. Whether or not this is exposure to normal or pathological vaginal microbiota is not clear, but our findings may help to inform future studies using multiplex polymerase chain reaction to investigate causes of urethritis.

Men with asymptomatic NCNGU were more likely to have reported a previous STI check than those without urethritis; however, the effect observed was small. In the bivariate analysis, a self-reported

TABLE 1 Demographic, behavioural and clinical profiles of men with asymptomatic NCNGU, men with symptomatic NCNGU (comparator 1) and asymptomatic men without urethritis, chlamydia or gonorrhoea (comparator 2)

Factors	Asymptomatic NCNGU ($n = 115$) (%)	Comparator 1: Symptomatic NCNGU ($n = 129$) (%)	Comparator 2: Asymptomatic without urethritis, chlamydia or gonorrhoea ($n = 309$) (%)	*p*-value for comparison 1	*p*-value for comparison 2
Demographic factors					
Age (years)				0.676	0.420
< 25	26.1	29.5	21.0		
25–34	52.2	46.5	58.9		
35–44	21.7	24.0	20.1		
Median (lower, upper quartiles)	27 (24, 34)	28 (24, 34)	29 (25, 33)		
Ethnicity				0.011	0.291
White British/white Irish	50.9	29.7	53.3		
White, European/Eastern European	13.2	20.3	18.8		
Mixed/other ethnicities	3.5	8.6	3.9		
Asian	10.5	10.2	10.1		
Black	21.9	31.3	14.0		
Behavioural factors					
Sexual practices in the last 3 months					
Given oral sex	58.4	42.5	62.2	0.014	0.478
Received oral sex	70.8	52.0	76.6	0.003	0.227
Vaginal sex	95.6	98.4	88.3	0.187	0.026
Insertive anal sex	7.1	7.1	12.1	0.276	0.144
Time since last vaginal or anal sex				0.673	0.392
≤ 3 days	30.1	27.3	28.9		
> 3 but ≤ 7 days	24.8	21.9	21.9		
> 7 but ≤ 14 days	18.6	21.1	16.3		
> 14 but ≤ 28 days	7.1	13.3	8.3		
> 28 days but ≤ 3 months	14.2	12.5	12.0		
> 3 months	5.3	3.9	12.6		
Median (days) (lower, upper quartiles)	7 (2, 15.5)	8.5 (3, 18.75)	7 (3, 26)		
Condom use in the last 3 months				< 0.0001	0.007
Every time/no vaginal/anal sex	17.9	20.5	27.0		
Most of the time	27.7	6.3	32.6		
Sometimes/occasionally	20.5	41.7	21.8		
Not at all	33.9	31.5	18.6		

continued

TABLE 1 Demographic, behavioural and clinical profiles of men with asymptomatic NCNGU, men with symptomatic NCNGU (comparator 1) and asymptomatic men without urethritis, chlamydia or gonorrhoea (comparator 2) (*continued*)

Factors	Asymptomatic NCNGU ($n = 115$) (%)	Comparator 1: Symptomatic NCNGU ($n = 129$) (%)	Comparator 2: Asymptomatic without urethritis, chlamydia or gonorrhoea ($n = 309$) (%)	*p*-value for comparison 1	*p*-value for comparison 2
Number of sexual partners in the last 3 months				0.373	0.676
0/1	43.4	41.9	45.3		
2	32.7	25.6	27.0		
3–4	15.0	17.8	18.2		
5+	8.9	14.7	9.5		
Median (lower, upper quartiles)	2 (1, 2)	2 (1, 3)	2 (1, 3)		
Number of new sexual partners in the last 3 months				0.028	0.818
0	28.3	33.3	28.7		
1	38.9	23.3	35.8		
2+	32.7	43.4	35.5		
Median (lower, upper quartiles)	1 (0, 2)	1 (0, 2)	1 (0, 2)		
Clinical factors					
Had a previous STI check	83.5	83.7	72.2	0.959	0.016
Time since last STI screen (months)				0.045	0.160
≤ 3	6.4	20.0	9.3		
> 3 but ≤ 6	18.1	15.2	12.5		
> 6 but ≤ 12	27.7	18.1	21.8		
> 12 but ≤ 24	26.6	21.9	23.2		
> 24	21.3	24.8	33.3		
Median (lower, upper quartiles)	12 (6, 24)	12 (3, 26)	18 (7, 36)		
Previous STI diagnosis/es					
Chlamydia	20.0	25.6	15.2	0.301	0.238
Gonorrhoea	6.1	11.6	3.6	0.131	0.251
Non-specific urethritis	24.4	21.7	13.6	0.624	0.008
Genital warts	10.4	3.9	5.2	0.045	0.053
Genital herpes	5.2	1.6	2.9	0.108	0.253
Syphilis	1.7	0.0	0.0	0.133	0.020
Any of above STIs	44.4	51.2	31.7	0.287	0.015
Ever had a HIV test	75.4	71.1	63.4	0.447	0.020
Time since (last) HIV test (months)				0.030	0.101
≤ 3	5.9	15.7	10.0		
> 3 but ≤ 6	17.7	21.4	13.1		
> 6 but ≤ 12	30.6	18.0	24.6		
> 12 but ≤ 24	28.2	18.0	21.5		
> 24	17.7	27.0	30.9		

TABLE 1 Demographic, behavioural and clinical profiles of men with asymptomatic NCNGU, men with symptomatic NCNGU (comparator 1) and asymptomatic men without urethritis, chlamydia or gonorrhoea (comparator 2) (*continued*)

Factors	Asymptomatic NCNGU ($n = 115$) (%)	Comparator 1: Symptomatic NCNGU ($n = 129$) (%)	Comparator 2: Asymptomatic without urethritis, chlamydia or gonorrhoea ($n = 309$) (%)	*p*-value for comparison 1	*p*-value for comparison 2
Median (lower, upper quartiles)	12 (6, 24)	12 (4, 30)	13 (6, 36)		
HIV status				0.746	0.037
HIV negative	74.8	70.5	64.1		
HIV status unknown (as not tested)	25.2	29.5	35.9		
HIV positive	0.0	0.0	0.0		
Any medical conditions	16.7	16.3	12.0	0.935	0.206
Regular medication taken	11.4	12.5	10.1	0.793	0.689

TABLE 2 Key factors associated with having asymptomatic NCNGU by comparator

Comparator	Crude OR (95% CI)	Adjusted OR[a] (95% CI)
Comparator 1: symptomatic NCNGU (positive control subjects)		
Received oral sex	$p = 0.014$	$p = 0.015$
No (reference)	1.00	1.00
Yes	1.90 (1.14 to 3.17)	2.00 (1.14 to 3.48)
Condom use in the last 3 months	$p = 0.0001$	$p = 0.0001$
Every time/no vaginal/anal sex in last 3 months (reference)	1.00	1.00
Most of the time	5.04 (1.91 to 13.3)	4.71 (1.76 to 12.6)
Sometimes/occasionally	0.56 (0.26 to 1.21)	0.54 (0.25 to 1.19)
Not at all	1.24 (0.59 to 2.57)	1.18 (0.56 to 2.50)
Comparator 2: asymptomatic men without urethritis, chlamydia or gonorrhoea (negative control subjects)		
Condom use in the last 3 months	$p = 0.009$	$p = 0.007$
Every time/no vaginal/anal sex in last 3 months (reference)	1.00	1.00
Most of the time	1.29 (0.68 to 2.42)	1.15 (0.59 to 2.21)
Sometimes/occasionally	1.42 (0.72 to 2.81)	1.36 (0.67 to 2.73)
Not at all	2.77 (1.46 to 5.24)	2.70 (1.41 to 5.18)
Had a previous STI check	$p = 0.018$	$p = 0.028$
No (reference)	1.00	1.00
Yes	1.95 (1.12 to 3.38)	1.91 (1.07 to 3.40)

a OR adjusted for all other factors in *Table 2*.

previous diagnosis of NSU was associated with NCNGU among asymptomatic men and, although this fell out of the multivariate model, we suspect that it may play a role in why men with asymptomatic NCNGU are more likely to have been screened for STIs; men with a previous diagnosis of NSU may be more likely to have the condition, for whatever reason, and be more likely to return to a service where the condition can be diagnosed.

There are several possible explanations for an association between receiving oral sex and urethritis. Oral pathogens, both sexually transmitted and non-sexually transmitted, may explain some of these cases. It also seems plausible that salivary enzymes could induce mucosal inflammation in some men.

In contrast to many other studies of urethritis, we have used explicit and recognised criteria for the diagnosis of asymptomatic NCNGU. The study population, drawn from two inner-city London sexual health clinics, is likely to be generalisable to other specialist services but may not represent community settings. There are several limitations to this study. The retrospective design meant that we were limited to variables that were routinely and consistently recorded in the clinical notes, often using self-reported behavioural data. Furthermore, asymptomatic men are not routinely examined in our service and so we were unable to include examination findings. The cause of asymptomatic NCNGU is often unknown or unidentifiable and therefore potential confounders are difficult to predict. However, men with any identifiable potential cause of urethritis were excluded.

Our local guidelines require men to have held their urine for at least 2 hours prior to undertaking a urethral smear but this was inconsistently recorded. However, the consequence of men passing urine < 2 hours prior to testing would have weakened rather than strengthened the associations that we describe. Interobserver variation in urethral smear microscopy is well recognised[52] and, although we cannot exclude this, all of our microscopists adhere to regular audits and quality control processes. It is also possible that some of these men actually had chlamydial urethritis but a false-negative urine test, although the risk is small.

In an attempt to limit recall bias, sexual behaviours were recorded over a 3-month time period.[55] As far as possible, data have been used from the same method of collection (pen and paper or face-to-face) to reduce information bias between groups. Although there is some evidence to suggest that up to 10% of men misclassify themselves as asymptomatic when they actually have symptoms,[5,6,56] it may also be true that asymptomatic men report having symptoms when none are present.[57]

The homogeneous appearance of the men in our study suggests that symptom-based triage alone will not identify those at greatest risk of having NCNGU. Current clinical guidelines place significance only on symptomatic NCNGU and not asymptomatic NCNGU. Although antibiotic therapy to alleviate symptoms seems sensible, it is illogical to assign greater significance to symptomatic NCNGU when the importance of other STIs is not based on whether or not they cause symptoms. Although symptom-based triage may allow for the detection of men with a higher prevalence of infections, it misses men who are asymptomatic but who have significant sexual risk behaviours. It is important not to tacitly assume that asymptomatic is the same as low risk. This group of asymptomatic men could benefit from behavioural interventions to help prevent future infections, an opportunity for health promotion that may be missed when focusing purely on symptom-based triage.

Questions remain about the significance of asymptomatic NCNGU and whether or not its detection and treatment provides a cost-effective public health benefit. However, it is unlikely that there will be much future research in this area of sexual health given the current clinical guidelines, thus limiting our understanding of this condition. This study may help to inform and interpret future microbial studies looking at the causes of NCNGU.

The similarities in demographic and sexual risk between men in all study groups meant that we were unable to develop an evidence-based clinical algorithm to guide STI testing (specifically the use of urethral microscopy) in asymptomatic men based on these parameters. If we performed urethral microscopy in all men reporting

inconsistent condom use we would be likely to capture a significant proportion of men with asymptomatic NCNGU but without a meaningful reduction in the overall number of smears being performed (because many of the negative control subjects also report this behaviour). Similarly, performing smears in men who report receiving oral sex would not be sufficiently discriminatory. However, it is possible that adding a risk-based assessment to the current symptom-based approach to the menu of tests offered to men attending for screening would provide a more grounded strategy. However, this would require further investigation.

Phase 2: mathematical modelling and health economic analysis to explore the implications of abandoning microscopy of urethral smears in asymptomatic men for alternative strategies that ensure better uptake of chlamydia and gonorrhoea screening

Mathematical modelling

We constructed a transmission dynamic mathematical model to synthesise evidence on the natural history and epidemiology of *M. genitalium*, quantify the parameters contributing most uncertainty and examine the potential public health impact (primarily increases in serious sequelae in women) of changes in the use of microscopy in asymptomatic men in genitourinary medicine (GUM) clinics, both ending its use with the 5% of patients who currently receive it and increasing its use by making it routine practice. Additionally, we explored the potential impact of a licensed specific (e.g. nucleic acid amplification) test for *M. genitalium*.

Methods

Model description

To represent the transmission dynamics of *M. genitalium* in a heterosexual population, we developed a deterministic compartmental model. The model population was stratified into male and female, with each having groups with high and low rates of sexual partner change to represent heterogeneity in sexual behaviour. Susceptible individuals (S in *Figure 1*) who become infected enter a latent state (L) before

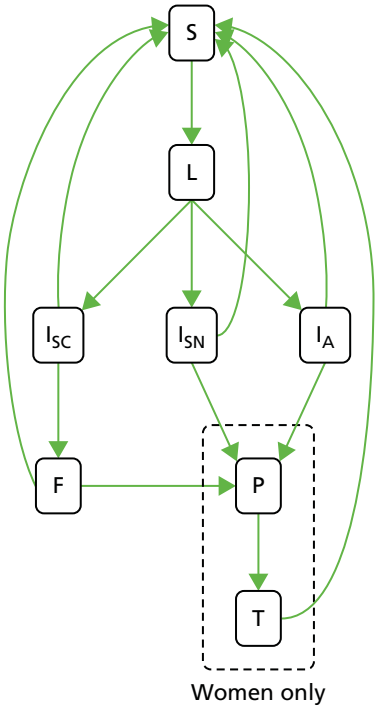

FIGURE 1 Model flow diagram. Members of the population move through states as described in the text. F, failed treatment; I_A, infectious and asymptomatic; I_{SC}, infectious and symptomatic and care seeking; I_{SN}, infectious and symptomatic but not care seeking; L, latent infection; P, PID; S, susceptible; T, treated for PID.

becoming infectious. Infectious individuals may be symptomatic and seek treatment prompted by their symptoms (I_{SC}), symptomatic without seeking treatment (I_{SN}) or asymptomatic (I_A). Others, both with and without symptoms, may seek care following partner notification. Successful treatment returns individuals to the uninfected susceptible state. Those unsuccessfully treated enter the treatment failure compartment (F) and will be retreated successfully or eventually recover naturally and return to the susceptible state or, in the case of women, may develop PID (P). In the absence of treatment, men eventually recover through natural immune processes and return to the susceptible state. Untreated women may also return to the susceptible state through natural recovery, but a proportion instead progress to PID, which may be symptomatic or asymptomatic. A proportion of women with symptomatic PID seek care because of symptoms and move into the treated PID state (T). All of those with PID may recover through natural processes and return to the susceptible state.

Model parameterisation

Prior expectations of ranges for parameter values were defined, based on the literature, data from our previous studies and Barts Health NHS Trust sexual health services and expert opinion (*Tables 3* and *4*).

The ranges were well defined for some parameters, as previous studies had acquired reliable data on their distributions. These parameters included lags associated with seeking care, receiving care and notifying partners; the proportion of patients abstaining from sexual activity when seeking care for symptoms; the proportion of partners traced; sexual partner change rates (from 2000); and treatment efficacy and failure rates. Other parameters such as the proportion of infections that are symptomatic, latent period and duration of infection, transmission probability and rate of progression to PID were less well defined either because of a lack of information about the parameter or a wide range of estimated values for it from different studies.

The model population consisted of 10,675,000 males and females aged 16–30 years (equal numbers of each sex, i.e. approximately 5 million each).

The model was fitted to KC60 surveillance data on annual diagnoses of NCNGU in men, collated by the Health Protection Agency (now Public Health England) from GUM clinics throughout the UK,[1] of which

TABLE 3 Model parameters 1[a]

Description	Gender	Symbol	Prior ranges	Mean	Posterior		Posterior mean	Source
					Min.	Max.		
Organism-related parameters								
Per-sex act transmission probability	F	β_f	0.0–0.3	0.155	0.07	0.3	0.18	Anagrius *et al.*,[7] Andersen *et al.*,[58] Quinn *et al.*,[59] Thurman *et al.*,[60] Keane *et al.*[61]
	M	β_m	0.01–0.3	0.155	0.08	0.3	0.23	Anagrius *et al.*,[7] Andersen *et al.*,[58] Quinn *et al.*,[59] Thurman *et al.*,[60] Keane *et al.*[61]
Natural recovery rate (per year)	F	γ_F	0.3–2.4	1.2	0.46	2.37	1.23	Jernberg *et al.*,[26] Cohen *et al.*,[62] Oakeshott *et al.*,[63] Smieszek and White[64]
	M	γ_M	0.3–1.0	0.65	0.3	0.955	0.6	Jernberg *et al.*,[26] Cohen *et al.*,[62] Oakeshott *et al.*[63]

TABLE 3 Model parameters 1[a] (*continued*)

Description	Gender	Symbol	Prior ranges	Mean	Posterior		Posterior mean	Source
					Min.	Max.		
Proportion of infected who are symptomatic	F	z_f	0.01–0.7	0.355	0.09	0.7	0.38	Falk *et al.*,[5] Anagrius *et al.*,[7] Lewis *et al.*[65]
	M	z_m	0.1–0.7	0.4	0.1	0.57	0.2	Falk *et al.*,[5] Anagrius *et al.*,[7] Lewis *et al.*[65]
Treatment failure proportion		ξ	0.05–0.6	0.351	0.05	0.596	0.28	Bradshaw *et al.*,[13] Jernberg *et al.*,[26] Björnelius *et al.*[66]
Behavioural parameters								
Proportion of contacts who are traced from GUM clinic		f_{gum}	0.01–0.7	0.55	0.03	0.6	0.28	Turner *et al.*[67]
Proportion of contacts who are traced from general practice		f_{gp}	0.01–0.5	0.255	0.01	0.5	0.19	Cassell *et al.*[68]
Proportion of patients who go straight to GUM clinic		$prop_{gum}$	0.3–0.7	0.5	0.303	0.7	0.47	Cassell *et al.*[69]
Proportion of patients who go to GUM clinic from general practice		$prop_{gpgum}$	0.1–0.4	0.25	0.103	0.4	0.24	Cassell *et al.*[31]
Proportion of infected seeking care who abstain from sex	F	α_f	0.2–0.6	0.4	0.2	0.6	0.40	Mercer *et al.*,[17] Irwin *et al.*,[70] Fortenberry[71]
	M	α_m	0.4–0.8	0.6	0.4	0.8	0.59	Mercer *et al.*,[17] Irwin *et al.*,[70] Fortenberry[71]
Proportion of symptomatic infected who go for treatment spontaneously	F	ρ_f	0.01–0.455	0.6	0.01	0.87	0.26	Expert opinion
	M	ρ_m	0.6–0.99	0.795	0.6	0.99	0.77	Expert opinion
Assortativity coefficient		ε	0.1–0.9	0.5	0.1	0.9	0.42	Expert opinion
Rate at which asymptomatic men go for screening spontaneously (per year)		σ_M	0.001–0.138	0.089	0.005	0.132	0.076	Saunders *et al.*[72]
Amount of time before seeking care (days)		*sk*	0–20	10	0.05	19.76	9.46	Mercer *et al.*,[17] Kretzschmar *et al.*[73]

F, female; m, male; max., maximum; min., minimum.
a The table summarises prior expectations and posterior distributions of parameters, and sources of estimates.

TABLE 4 Model parameters 2[a]

Description	Symbol	Value	Source
Rate of ageing in and out	μ	1/22 per year	The model considers a 22-year age range
Natural recovery rate – treatment failure	γ_{fail}	2 per year	Expert opinion
Natural recovery rate – PID	$\Upsilon\gamma_{Prec}$	0.25 per year	Expert opinion
Latent period	d_{lat}	14 days	Jensen[4]
PID treatment duration	d_{tp}	21 days	Expert opinion
Proportion of asymptomatic men screened with microscopy when at GUM clinic	η	5%	Carne *et al.*[39]
Specificity of microscopy	ν	97%	Smith *et al.*[52]
Sensitivity of microscopy	*sens*	80%	Smith *et al.*[52]
Delay before notifying partners	τ	10 days	Expert opinion
Proportion of population in low-risk activity class	*nch*	14%	White *et al.*,[2] Johnson *et al.*[74]
Proportion of population in medium-risk activity class	*ncm*	30%	White *et al.*,[2] Johnson *et al.*[74]
Proportion of population in high-risk activity class	*ncl*	56%	White *et al.*,[2] Johnson *et al.*[74]
Partner change rate in high-risk activity class	r_{high}	8.49	White *et al.*,[2] Johnson *et al.*[74]
Partner change rate in medium-risk activity class	r_{medium}	0.76	White *et al.*,[2] Johnson *et al.*[74]
Partner change rate in low-risk activity class	r_{low}	0.15	White *et al.*,[2] Johnson *et al.*[74]
Sex-act frequency per 4 weeks	q	7	Expert opinion

a The table summarises prior expectations and posterior distributions of parameters, and sources of estimates.

10–46% are estimated to be due to *M.* genitalium,[75] and the prevalence of infection in women estimated from the study by Oakeshott *et al.*[63]

Parameters that were varied in fitting were transmission probabilities (female-to-male and male-to-female), the proportion of incident infections that are symptomatic in females and males, the proportion of those with symptomatic infection who seek care, the rates of natural recovery from infection, the mixing coefficient (which varies how assortative sexual partner choice is) and the sensitivity of microscopy. These parameters were varied in combination across their prior ranges and the resulting model run compared with the target values for annual diagnoses in GUM clinics in men (10–46% of NCNGU diagnoses), and the prevalence in women derived from the study by Oakeshott *et al.*[63] Candidate parameter sets were accepted if both the criteria were met.

We examined the effect of stopping microscopy in the 5% of asymptomatic men in GUM clinics who still receive it, while continuing to use microscopy in symptomatic men in all GUM clinics. This means that asymptomatic NCNGU in men is not diagnosed and so not treated.

The incidence of TFI and ectopic pregnancy was estimated based on the incidence of PID in the model. Haggerty *et al.*[76] estimated that 18% of cases of symptomatic PID were followed by TFI; Westrom[20,21] estimated the frequency to be 12%; Hillis *et al.*[15] estimated that the incidence of ectopic pregnancy following TFI was 8%. It is unclear how frequently TFI and ectopic pregnancy occur following asymptomatic PID; it may be that the risk of these sequelae is lower because of infection being less severe, but asymptomatic PID is unlikely to be treated and therefore likely to be longer lasting, which may increase the risk of serious sequelae.

Results

The posterior ranges for the fitted parameters are shown in *Table 3*. There is much uncertainty in the proportion of NCNGU caused by *M. genitalium* and in the natural history of infection, which leads to uncertainty in the effects of reducing the use of microscopy in GUM clinics.

Stopping microscopy in asymptomatic men has the immediate effect of reducing the quantity of microscopy procedures performed. The consequent reduction in diagnosis and treatment of asymptomatic infection results in an increase in the average duration of asymptomatic infection in men (as all now recover as a result of natural immune processes rather than some through treatment). This causes an increase in transmission to women and consequently an increase in transmission to men. Thus, there is more disease in women and men because of an increased incidence of symptomatic infection (as well as asymptomatic infection), leading to an increase in general practitioner (GP) and GUM consultations and an increase in the incidence of PID and consequent serious sequelae (TFI and ectopic pregnancy) (*Figure 2* and *Table 5*). The most marked effect is in women, because symptomatic infection in men is still mostly diagnosed and treated effectively. Another reason for the increase in GP and GUM consultations – and reduction in partners managed as notified partners – is that asymptomatic infection in men is no longer being diagnosed and so their partners are no longer notified and women with symptoms who would previously have sought care as a notified partner will now seek care because of their symptoms and be treated as an index case instead. The reduction in treatment because of asymptomatic infections no longer being treated is partially offset over time by the increase in symptomatic infection that does get treated. Over both 10- and 20-year

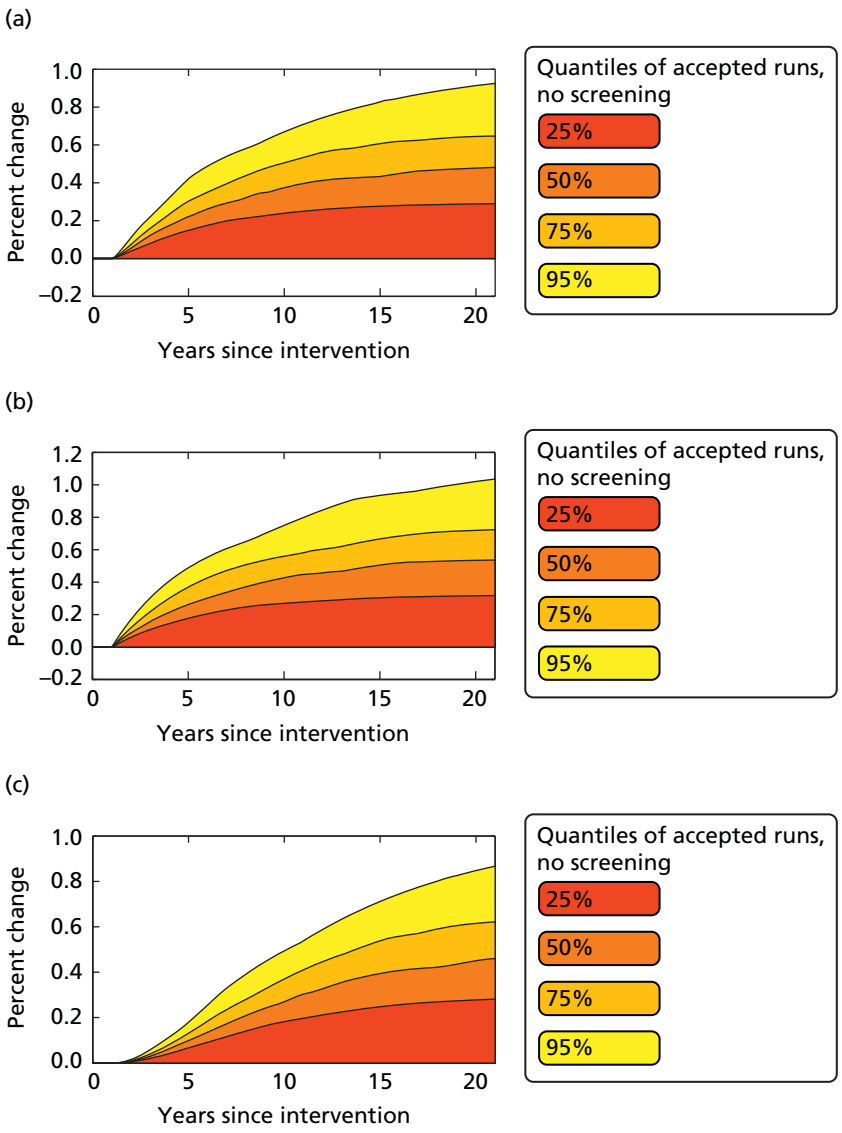

FIGURE 2 Impact of changing the use of microscopy in men in GUM clinics. (a) Total female infections; (b) total male infections; (c) PID cases.

TABLE 5 Impact of changing the use of microscopy in men in GUM clinics

Outcome	Total cases over 20 years	
	Likelihood-weighted cumulative incidence	Elimination of microscopy (excess cases occurring)
PID	2,374,364	2,379,943 (5578)
Ectopic pregnancy	189,949	190,395 (446)
TFI	284,924	285,593 (669)

time horizons there are net reductions in the amount of microscopy performed, treatment given and notified partners managed and net increases in infection (both symptomatic and asymptomatic) in both sexes, the incidence of PID and serious sequelae and GP and GUM consultations of index cases.

The graphs in *Figure 2* show the per cent change in the incidence of PID, TFI and ectopic pregnancy in women resulting from cessation of urethral smear microscopy in asymptomatic men in GUM clinics. In total, 25% of the simulations lie in the dark orange area; 50% lie in the mid-orange and dark orange areas; 75% lie in the light orange and mid-orange and dark orange areas; and 95% lie in the four shaded areas (orange areas and yellow area). The median of the simulations is represented by the line between the light-orange and mid-orange areas.

Discussion

We found that eliminating the remaining screening with microscopy for asymptomatic men in GUM clinics will lead to expected increases in rates of sequelae such as PID, ectopic pregnancy and TFI in women, although the effect is relatively modest because of the low current rates of screening. There is important uncertainty in the natural history of *M. genitalium* in males and females. Particularly important are the proportion of infections that are symptomatic in men and women, the duration of untreated infection and the incidence of PID, TFI and ectopic pregnancy attributable to *M. genitalium*.

We have determined that reductions in the use of microscopy could have important consequences for the incidence of serious sequelae in women through the effect on *M. genitalium* alone. This impact would likely be increased when other organisms that also cause asymptomatic NCNGU in men are considered. We have identified key questions about the prevalence and natural history of *M. genitalium* that need to be addressed by further empirical work to determine the health burden and treatment costs incurred as a result of sequelae and the cost-effectiveness of screening and treatment control policy options.

Economic analysis

Introduction

Screening all patients for NCNGU creates a large burden on the NHS in the UK as asymptomatic NCNGU is difficult to detect. Thus, maintaining microscopy screening for asymptomatically infected individuals could lead to an unnecessary financial burden on the NHS. However, its potential withdrawal must be balanced against other indirect cost savings, for instance preventing the transmission of the STI could decrease the demand for adoptive services by preventing infertility and potential ectopic pregnancies caused by asymptomatic *M. genitalium*-positive NCNGU. Thus, if diagnosing and treating NCNGU prevents future infections as well as major adverse events and their associated costs, it is possible this future benefit may compensate for the costs currently being incurred. Conversely, it may be that the resources associated with microscopy could be used in a more cost-effective manner through alternative strategies that ensure a better uptake of chlamydia and gonorrhoea screening.

Microscopy screening is not recommended for asymptomatic NCNGU by the British Association for Sexual Health and HIV.[23] Despite this, microscopy screening is offered in a small number of GUM clinics for asymptomatic men, whereas in others no microscopy testing occurs.

The objective of this economic evaluation was to determine whether the current practice of limited microscopy screening for asymptomatic men in England in GUM clinics is a cost-effective approach to diagnosing and treating NCNGU or if removing this practice is a viable option.

Methods

To appropriately estimate the impact of testing and treatment on the future transmission of NCNGU, it is necessary to use an appropriate modelling approach for infectious diseases that can describe the transmission of infection between individuals, a transmission dynamic model (TDM).[77,78] In this study, a TDM describing the transmission of NCNGU in a population of 16- to 30-year-olds in England was constructed to examine changes in the use of microscopy in asymptomatic men in GUM clinics. This economic evaluation relies exclusively on the outputs from this model, along with secondary data describing resource use, and takes the form of a cost-effectiveness analysis carried out from a health-care provider perspective.

Model structure

The output used in this economic analysis is taken from a TDM, which has been described in full (pp. 13–17). In brief, this is a compartmental transmission model which describes heterogeneous sexual behaviour that was parameterised by behaviour data from a number of key UK surveys and national surveillance data and with the natural history of NCNGU being informed from data in the literature. The model describes the incidence and prevalence of symptomatic and asymptomatic infection, PID, care-seeking behaviour as a result of symptoms, partner notification and the possibility of treatment failure. The uncertainty of the parameters in the model was also factored into the model parameterisation.

The time horizon for the economic analysis was 20 years, although this was subject to sensitivity analysis. It was felt that a time horizon that was longer than this would not be appropriate, as assumptions made in the transmission model regarding heterosexual behaviour amongst 16- to 30-year-olds are unlikely to be valid the further into the future the analysis is conducted. A discount rate of 3.5% was applied to the costs and outcomes in accordance with National Institute for Health and Care Excellence (NICE) guidelines.[79]

All settings where sexual health services are provided were initially considered for inclusion in this economic analysis, from general practices and GUM clinics to pharmacies and educational settings. However, guidelines detailing the specific pathways and resources used at different sexual health service settings were sparse, with the most reliable clinical data and cost data found in the literature being related to general practice and GUM settings. Therefore, in this study the methodological focus was narrowed to NCNGU in primary care and GUM clinics.

Testing pathways for economic analysis

Two different pathways were compared in terms of their resource use and costs, each representing alternative approaches to the testing and treatment of patients with asymptomatic NCNGU. These pathways represent current practice with respect to the implementation of microscopy screening in men and the impact of withdrawing the microscopy test for asymptomatic men in the GUM setting. The two pathways are referred to in this study as ‘current practice’ and ‘no screening’.

Initially, a patient can be either infected or non-infected with *M. genitalium* and either symptomatic or asymptomatic. The patient may attend either a general practice or a GUM clinic for screening. Symptomatic patients are index patients with symptoms resulting from their underlying infection, such as dysuria and urethral discharge.

In the general practice setting, regardless of the strategy, all patients (asymptomatic and symptomatic) receive the NAAT for chlamydia and gonorrhoea. A proportion of the patients are then referred from the

general practice setting to a GUM clinic for further diagnosis or treatment, for example those who are symptomatic or who have more complex sexual health needs.

In contrast, in the GUM setting the diagnostic approach varies depending on which strategy is being considered and whether a patient presents with symptoms or not. For the no screening strategy, microscopy screening is not offered to asymptomatic patients and these patients receive an NAAT only. All asymptomatic patients in all locations in the current practice scenario receive a NAAT, with one in 20 asymptomatic male patients receiving a microscopy test in a GUM setting (value derived from McClean *et al.*'s[16] national GUM clinic audit). During the course of the consultation all symptomatic patients in a GUM setting are also provided with partner notification leaflets and condoms, with the aim of attracting more contacts with infected patients to be tested and treated. The testing pathways considered in this study are summarised in *Tables 6* and *7*.

In this analysis, treatment can be deemed either a success or failure. Successful treatment indicates that a patient is no longer infected with *M. genitalium* and cannot transmit infection to their sexual partners. Treatment failure indicates that there has been a failure of the drug treatment to clear the STI infection. Female patients who fail treatment or who are not treated can develop PID, a proportion of which is treated. Female patients untreated for PID may go on to experience symptomatic PID, infertility or an ectopic pregnancy.

Assumptions and parameterisation

This cost-effectiveness analysis is parameterised through secondary sources, which are described below. It was necessary to make some pragmatic clarifying assumptions to carry out the analysis. All assumptions were confirmed and agreed with clinical experts within the team before the analysis was carried out.

The assumptions made were:

- Symptomatic patients are index patients with symptoms resulting from their underlying infection.
- HIV and syphilis blood tests are administered 5% of the time in a GP setting (expert opinion).

TABLE 6 'Current practice' testing scenario

		Testing strategy	
Group	Setting	Men	Women
Asymptomatic patients	General practice	NAAT only	NAAT only
	GUM clinic	NAAT; 5% of all asymptomatic patients receive microscopy[39]	NAAT only
Symptomatic patients	General practice	NAAT only	NAAT only

TABLE 7 'No screening' testing scenario

		Testing strategy	
Group	Setting	Men	Women
Asymptomatic patients	General practice	NAAT only	NAAT only
	GUM clinic	NAAT only	NAAT only
Symptomatic patients	General practice	NAAT only	NAAT only
	GUM clinic	Microscopy and NAAT	NAAT only

- All patients in all settings receive a NAAT test.
- A GP consultation takes 11.7 minutes, which is the average for a surgery consultation.[80]
- 50% of patients in a GUM setting are seen by a doctor and 50% by a band 7 nurse (expert opinion).
- Partner notification is conducted by a band 7 nurse with all index patients (symptomatic) in a GUM clinic setting who are positive and this takes 12 minutes.[49]
- No formal partner notification is conducted in a general practice setting, with just brief 'words of advice' being given, which are not considered in this economic analysis.
- Taking a case history takes 5 minutes for asymptomatic patients in a GUM setting (expert opinion – study team).
- Taking a case history takes 10 minutes for symptomatic patients in a GUM setting (expert opinion – study team).
- Examination of a female patient in a GUM setting takes 10 minutes (expert opinion – study team).
- Examination of a male patient in a GUM setting takes 5 minutes (expert opinion – study team).
- A single dose (1 g) of azithromycin is given as treatment for NCNGU.
- For all microscopy tests implemented it takes 10 minutes for a laboratory technician to obtain and report the results (expert opinion – study team).
- The treatment for PID considered in this study is 500 mg of ceftriaxone in a single dose followed by 100 mg twice daily of oral doxycycline plus 400 mg twice daily of metronidazole for 14 days.[81]
- All notified partners are assessed and presumptively treated in a GUM location and are asymptomatic (expert opinion – study team).

The non-cost parameters used in this cost-effectiveness analysis are shown in *Table 8*.

The costs used in this analysis were valued at 2011/12 UK prices. The cost of partner notification was adjusted to 2011/12 prices using the pay and price index for Hospital & Community Health Services.[80] Unit staff costs were obtained from *Unit Costs of Health and Social Care 2013*.[80]

The unit costs of the resources used in this economic evaluation are described in *Table 9* and the application of each of the unit costs to the output from the dynamic transmission model is shown in *Table 10*. The ranges for the costs were established by, first, describing the variation in the length of time of a procedure through the use of a gamma distribution, with the mean = the standard error and taking the values at the 5% and 95% points (with the minimum consultation time set to 2 minutes), and, second, when more than one member of staff is assumed to contribute to an examination, assuming that the cheapest and most

TABLE 8 Resource use and costs

Parameter	Value (range)	Source
Proportion of times a HIV test is delivered alongside a NAAT test in a GUM setting	83% (71–97%)	Irwin *et al.*[70]
Proportion of times a syphilis test is delivered alongside a NAAT test in a GUM setting	84% (72–97%)	Irwin *et al.*[70]
Proportion of PID cases that give rise to ectopic pregnancy	(99/1309) 7.6% (6.4–8.8%)	Donovan,[14] Iwuji *et al.*[82] Based on number trying to conceive after laparoscopy-diagnosed PID. Range calculated from a beta distribution taking values at 5% and 95% parameterised using the method of moments[83]
Proportion of PID cases that give rise to infertility	18% (15–21%)	Donovan,[14] Cohen *et al.*[62] Range calculated from a beta distribution taking values at 5% and 95% assuming that the standard error = mean/10[83]
Proportion of PID cases that are symptomatic	56% (30–89%)	Value from posterior mean of the infectious disease model
Delay from PID to manifestation of infertility/ ectopic pregnancy	5 years (1–15 years)	Expert opinion – study team

TABLE 9 Resource use and costs

Number	Resource	Unit cost (£)	Range (£)	Source
1	NAAT	9.15		£7.35 for a swab, 2005 prices = cost of hands-on time + equipment and consumables cost per test;[49] 2012/13 prices = £9.15
2	HIV test	8.36		Rapid test kit £5–11[84] (mid-point 2012/13 prices)
3	Syphilis test	2.00		EIA, assume £2
4	Microscopy test (including staff costs)	7.00		HRG DAPS07 Microscopy[85]
5	Laboratory technician (10 minutes of staff time) to obtain and report results of microscopy test	3.50	0.35–10.50	Clinical support worker nursing (community) (£21/hour)[80]
6	Staff time to give results of microscopy in GUM setting (5 minutes of staff time)	6.67	1.33–20.00	5 minutes with nurse advanced (£80/hour)[29]
7	Azithromycin – drug cost for treatment	2.17		250-mg tablets, four-tablet pack (£2.17)[86]
8	General practice visit (excluding testing costs)	44.85	3.83–134.17	Includes direct care staff costs (with qualification costs, £230/hour); assume 11.7-minute surgery consultation[29]
9	Cost of partner notification in GUM setting – administered to all symptomatic patients	16.00	1.33–48.00	12 minutes with nurse advanced (£80/hour)[29]
10	Partner notification leaflets plus condoms given out during partner notification	1.00		Assumed cost
11	Asymptomatic female at GUM clinic – case history plus examination (13 minutes of staff time), 50% with band 7 nurse and 50% with GP	31.50	2.67–129.00	Nurse advanced cost per hour in surgery excluding qualification costs (£80/hour) + GP cost excluding direct care staff costs (without qualification costs) (£172/hour of patient contact)[29]
12	Symptomatic female at GUM clinic – case history plus examination (18 minutes of staff time), 50% with band 7 nurse and 50% with GP	42.00	2.67–172.00	
13	Asymptomatic male at GUM clinic – case history plus examination (10 minutes of staff time), 50% with band 7 nurse and 50% with GP	21.00	2.67–86.00	
14	Symptomatic male at GUM – case history plus examination (15 minutes of staff time), 50% with band 7 nurse and 50% with GP	31.50	2.67–129.00	
15	Cost of treating PID	16.20		Ceftriaxone 500-mg single dose (1-g vial) (£9.58); doxycycline 100 mg twice daily for 14 days, 100-mg 8-capsule pack (£1.05 × 4); and metronidazole 400 mg twice daily for 14 days, 21-tablet pack (£1.21 × 2)[86]
16	Ectopic pregnancy	729.00		MA18C medical termination of pregnancy – < 14 weeks' gestation, elective inpatient[85]
17	Infertility	579.01		£428 in 2003.[87] Hospital & Community Health Services pay and price index[80] used to inflate to 2012 prices

BNF, *British National Formulary*; HRG, Healthcare Resource Group.

TABLE 10 Application of resource usage to model states from the dynamic transmission model

Model state	Costs applied	Notes
GP consultation symptomatic females	1–3, 8	
GP consultation symptomatic males	1–3, 8	
GUM consultation asymptomatic females	1–3, 11	
GUM consultation symptomatic females	1–3, 9, 10, 12	
GUM consultation asymptomatic males	1–3, 9, 10, 13	
GUM consultation symptomatic males	1–3, 9, 10, 14	
PID treated	15	Only considers the actual treatment, with consultation/staff costs having been considered elsewhere
Microscopy	4–6	For asymptomatic and symptomatic men only
All treatment for NGNCU	7	Includes true positives and false positives treated in error
Partner-notified female partners of males	1–3, 11	
Partner-notified male partners of females	1–3, 13	
Ectopic pregnancy	16	Number based on total number with untreated PID and the delay from PID to manifestation
Infertility	17	

expensive members of staff conduct the examination for the lower and upper values of the range respectively. Some of the resources in *Table 9* do not have ranges as their unit costs are fixed and do not vary.

Outcomes

The main outcome measure for this evaluation was the cost per case of PID averted. The second outcome measure was the cost per major outcome averted (MOA), with a major outcome defined as a case of symptomatic PID, a case of ectopic pregnancy or a case of infertility. All major outcomes are reported for completeness.

Analysis

The base-case scenario uses the mean results of 215 parameter sets from the dynamic transmission model and applies the resource costs to obtain the baseline deterministic results. Results are presented in terms of incremental cost-effectiveness ratios (ICERs), which presents the additional cost per additional unit of outcome for one strategy compared with another, in this case current practice compared with no screening.

Sensitivity analysis

To examine the impact of uncertainties in the model parameters and the assumptions made on the model results, sensitivity analysis was conducted. Two scenarios were examined to assess the impact of increasing and decreasing the costs applied in the study:

- *Minimise costs*. All costs were set to a minimum by taking the lowest realistic length of time for each consultation (minimum 2 minutes). When two staff members undertake a consultation at baseline, only the lowest paid was assumed to carry out the consultation.
- *Maximise costs*. All costs were set to a maximum by taking the highest realistic length of time for each consultation. When two staff members undertake a consultation at baseline, the highest paid staff member was assumed to carry out the entire consultation.

In addition, three further outputs from the transmission model were also analysed to assess their impact on the model results. These were the median results from the 215 parameter sets of the TDM and the upper and lower results from the 95% range of values.

Further one-way sensitivity analysis of key parameters was also investigated, with particular attention paid to parameters that were estimated through expert opinion. In addition, the time horizon was also varied to show its impact on conclusions drawn from the model.

Mean output from the transmission model

The graphs in *Figure 3* provide a summary of the mean output from the transmission model that was utilised in this economic analysis at baseline for each of the two scenarios considered in this study.

It can be seen from *Figure 3* that increasing the coverage of microscopy leads to a reduction in the annual number of consultations in both general practice and GUM settings. Moreover, current practice also has a positive impact on reducing the number of cases of PID, the number of cases of infertility and the number of cases of ectopic pregnancy. It also lowers the number of true-positive patients with NGNCU being treated because of its impact on onward transmission.

Results

The base-case results for the two treatment strategies were calculated based on the outcomes of cost per case of PID averted and cost per MOA. All results presented here are shown for a time horizon of 20 years with discounting unless otherwise stated. In all cases the costs are presented to the nearest thousand and the outcomes to the nearest hundred. ICER values were calculated using the unrounded cost and outcome values, with these then being rounded to the nearest 100.

Outcomes

Table 11 shows that the current practice of limited microscopy testing among asymptomatic men in a GUM setting has a positive impact on the number of cases of PID, that is, the number of PID cases is lower for current practice than for no screening. Likewise, the current practice approach also has a positive impact on reducing the number of major outcomes.

Costs

When considering only costs, the cost of current practice is greater than the cost of no screening (*Table 12*). This indicates that any savings that might have been made as a result of a reduction in major outcomes are insufficient to make current practice cost saving.

Incremental results

For the outcome of case of PID averted the ICER value is shown in *Table 13*. Current practice is more effective than no screening and has an ICER of £15,800, meaning that an investment of £15,800 is required to avert one case of PID. For the outcome of MOA, current practice is more effective than no screening but in this case an investment of £50,200 is required to avert one major outcome (see *Table 12*).

Sensitivity analysis

Scenario analysis The two scenarios examined in this study considered the impact of reducing and increasing multiple cost parameters to see their cumulative impact on the results obtained from the model.

As shown in *Table 13*, by varying the costs applied in the model the ICER for case of PID averted ranged from £9600 to £34,300, whereas the ICER for MOA ranged from £30,500 to £109,400.

Variations in transmission model output The sensitivity analysis in the previous section considered only uncertainty in the parameters used in the economic evaluation and adopted only mean values from the infectious disease model. To examine how uncertainty in the output from the infectious disease model

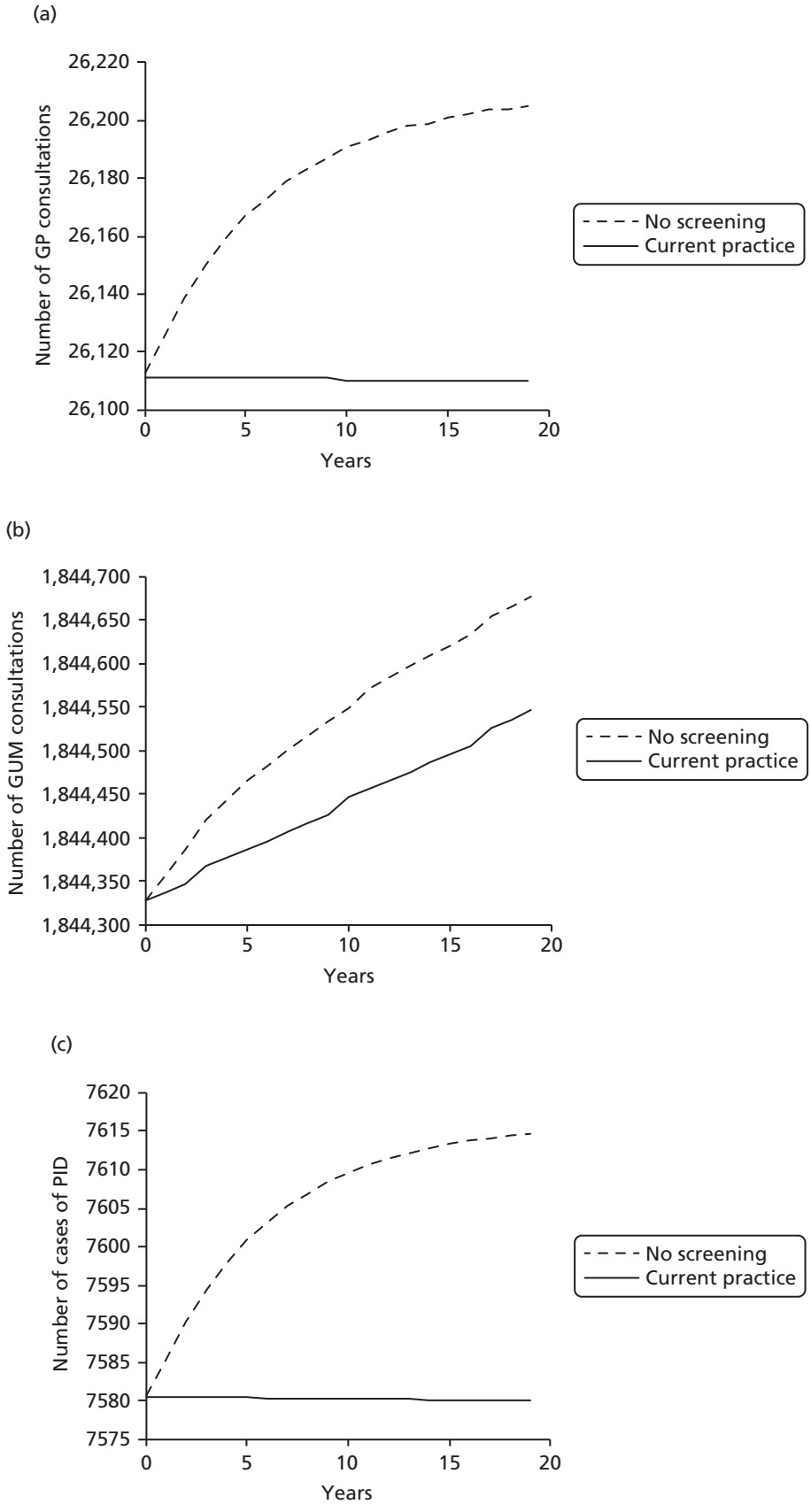

FIGURE 3 Output from the transmission model used in the baseline economic analysis with variation in the testing strategy. (a) GP consultations; (b) GUM consultations; (c) cases of PID; (d) true positive patients with NGNCU being treated; (e) cases of infertility; and (f) cases of ectopic pregnancy. (*continued*)

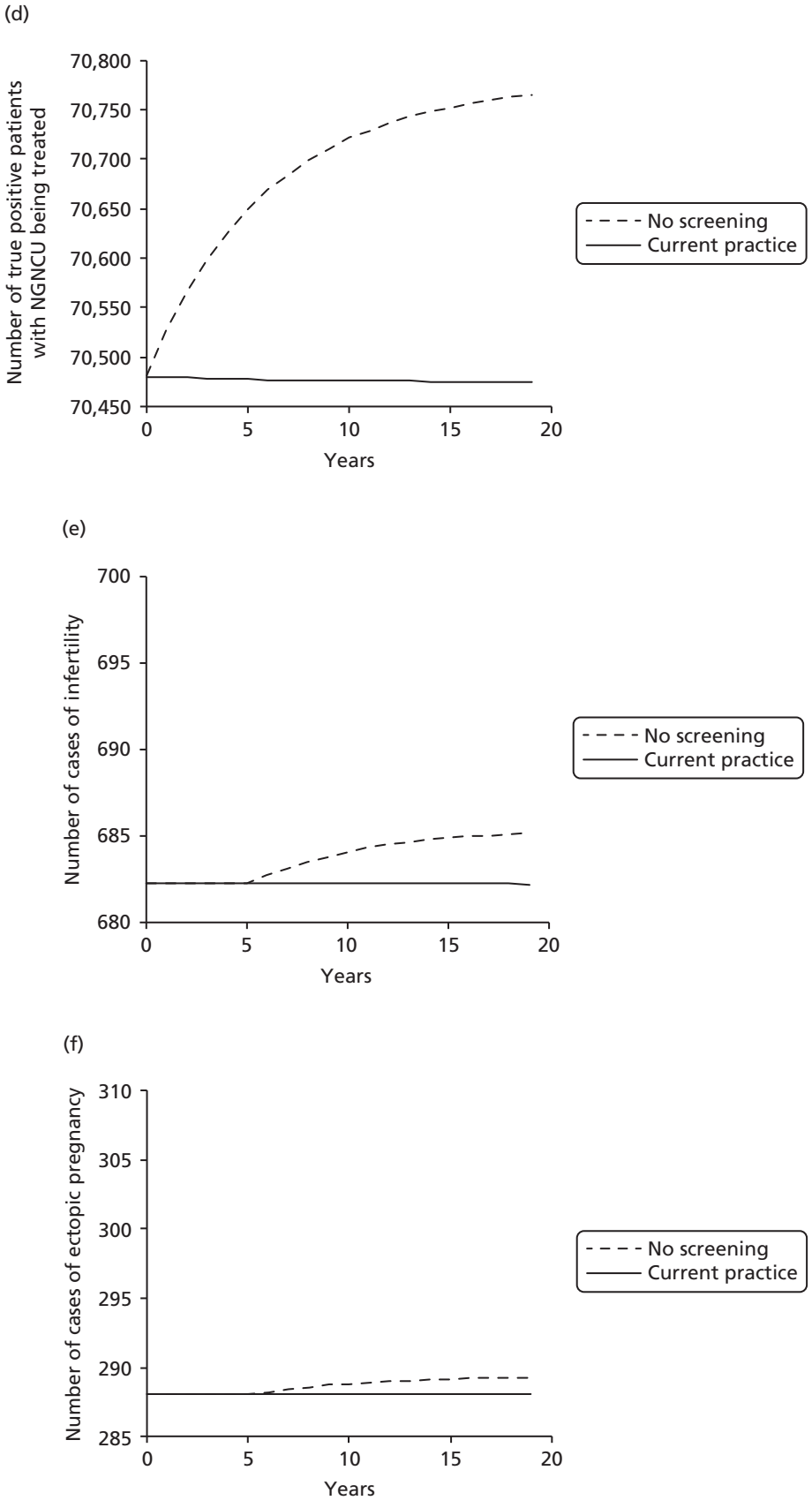

FIGURE 3 Output from the transmission model used in the baseline economic analysis with variation in the testing strategy. (a) GP consultations; (b) GUM consultations; (c) cases of PID; (d) true positive patients with NGNCU being treated; (e) cases of infertility; and (f) cases of ectopic pregnancy.

TABLE 11 Baseline results for the two strategies for cases of PID and all the major outcomes considered in this study

Strategy	Cost (£)	Cases of PID, *n*	Major outcomes, *n*[a]	Symptomatic PID, *n*	Infertility, *n*	Ectopic pregnancy, *n*
No screening	1,321,915,000	111,800	37,600	23,300	10,000	4200
Current practice	1,327,200,000	111,500	37,500	23,200	10,000	4200

a Symptomatic PID, infertility or ectopic pregnancy.

TABLE 12 Incremental cost per case of PID averted and per MOA

Strategy	Discounted cost (£)	Cases of PID, *n*	ICER (per case of PID averted) (£)	Major outcomes, *n*	ICER (per MOA)
No screening	1,321,915,000	111,800		37,600	
Current practice	1,327,200,000	111,500	15,800	37,500	£50,200

TABLE 13 Sensitivity analysis results for the alternative cost scenarios

Parameter	ICER (per case of PID averted) (£)	ICER (per MOA) (£)
Maximise costs	34,300	109,400
Minimise costs	9600	30,500

affects the conclusions drawn from the economic model, a further series of outputs from the infectious disease model were considered, these being the median results obtained from the 215 parameter sets along with the upper and lower limits informed by the 95% ranges.

Considering the various plausible outputs from the TDM resulted in the ICER values for current practice compared with no screening ranging from £10,500 to £39,400 for the outcome measure of case of PID averted and from £33,800 to £125,000 for MOA (*Table 14*).

Time horizon To investigate the impact of the time horizon on the model results, a range of alternatives was considered. *Table 15* shows the impact of varying the time horizon on the cost, the number of PID cases averted and MOA. It can be seen that in the short term no screening is least cost-effective but this strategy becomes more cost-effective the further the time horizon is extended into the future.

TABLE 14 Incremental cost-effectiveness ratios for the outcomes of case of PID averted and MOA with variation in the infectious disease model output

	ICER (current practice vs. no screening) (£)	
TDM output scenario	Per case of PID averted	Per MOA
Mean	15,800	50,200
Median	39,400	125,000
Upper	30,600	96,000
Lower	10,500	33,800

TABLE 15 Deterministic results for each of the outcomes considered with variation in the time horizon

Time horizon	Scenario	Cost (£)	Cases of PID (*n*)	ICER (per case of PID averted) (£)	Major outcomes	ICER (per MOA) (£)
5 years	No screening	419,901,000	35,500		11,900	
	Current practice	421,617,000	35,400	41,300	11,900	147,400
10 years	No screening	773,488,000	65,400		22,000	
	Current practice	776,616,000	65,300	22,700	21,900	77,300
15 years	No screening	1,071,221,000	90,600		30,500	
	Current practice	1,075,522,000	90,400	17,900	30,400	58,300
20 years	No screening	1,321,915,000	111,800		37,600	
	Current practice	1,327,200,000	111,500	15,800	37,500	50,200

One-way sensitivity analysis The proportion of PID cases that are symptomatic and the delay from PID to manifestation of infertility/ectopic pregnancy were informed by expert opinion in this study and as such it is necessary to examine their impact on the results from the model. Neither of these parameters had an impact on the main outcome measure used in this study, namely cases of PID averted (*Table 16*). In the case of MOA, as the estimated time to manifestation of infertility/ectopic pregnancy was increased, current practice became increasingly less cost-effective. For the proportion of PID cases that are symptomatic, increasing this value led to a decrease in the ICERs for MOA, thus making current practice more cost-effective.

Discussion

This economic evaluation utilised the output from a TDM to assess whether or not it is feasible to remove the use of microscopy to test asymptomatic men for NGNCU or whether or not the current practice of limited microscopy coverage for asymptomatic men is a relatively cost-effective option. The primary outcome measure used in this study was case of PID averted, with the secondary outcome being MOA (symptomatic PID, infertility or ectopic pregnancy).

TABLE 16 Results from one-way sensitivity analysis

Parameter	ICER (per case of PID averted) (£)	ICER (per MOA) (£)
Delay from PID to infertility/ectopic pregnancy (years)		
1	15,700	47,500
2	15,800	48,200
3	15,800	48,900
5 (baseline)	15,800	50,200
10	15,800	53,300
15	15,800	55,700
Proportion of PID cases that are symptomatic (%)		
20	15,800	97,500
40	15,800	64,000
56 (baseline)	15,800	50,200
60	15,800	47,700
80	15,800	38,000
100	15,800	31,500

The results of the base-case analysis indicate that the current practice of giving approximately 5% of asymptomatic men in the GUM setting a microscopy test has an incremental cost of £15,800 per case of PID averted, meaning that this strategy invests approximately £15,800 to generate one additional case of PID averted compared with a no screening strategy in which only symptomatic men are screened. In terms of MOA, current practice has an incremental cost of £50,200, meaning that this strategy invests approximately £50,200 to avert one major outcome.

Across all of the sensitivity analyses undertaken, current practice was never found to be cost saving but was always found to have a positive impact on reducing cases of PID and major adverse outcomes. Varying the outputs from the TDM provided a range of values for the outcomes in this study. For the case of PID averted, the ICER values ranged from £10,500 to £39,400, whereas for MOA the ICER values ranged from £33,800 to £125,000. By varying the time horizon of the analysis it was found that shorter time horizons made the intervention less cost-effective.

By implementing extreme scenarios in which the costs were minimised and maximised to the greatest extent, the ICER values for case of PID averted and MOA ranged from £9600 to £34,300 and from £30,500 to £109,400, respectively. However, these results must be approached with caution as it is very unlikely that these minimum and maximum costs across multiple parameters used in this analysis would be seen in practice.

This study has utilised the output from a well-parameterised dynamic model that describes the transmission of NGNCU in a population of males and females aged 16–30 years in England. Uncertainty in this model has been considered through the use of multiple parameter sets, whereas the results from this economic evaluation have been subject to extensive sensitivity analyses. Inevitably this has led to the range of plausible values obtained from the economic model being quite wide, although this does help to give confidence to the validity of the conclusions that might be drawn from this model.

A weakness of this study was the inability to conduct probabilistic sensitivity analysis for both the economic parameters and the parameters utilised in the TDM. Although it was possible to conduct probabilistic sensitivity analysis for just the economic parameters while maintaining the output from the TDM at constant values, the results describing the probability of a strategy being below a specific acceptable threshold would be meaningless.

To our knowledge this is the first economic analysis related to NGNCU in any setting and thus comparisons with the results from similar economic studies are impossible.

It is suggested that UK decision-makers are unlikely to fund an intervention if it has an ICER of > £30,000 per quality-adjusted life-year (QALY).[79] However, for the outcome measures used in this study, there are no accepted threshold values from which a conclusion can be drawn on whether an intervention should be accepted or not. It is therefore necessary to link the results here to the acceptance threshold values for the QALY to draw conclusions from this economic analysis.

Taking mean values from the transmission model, the ICER for the strategy of screening compared with no screening was £15,800 per case of PID averted and £50,200 per MOA. This means that it costs an additional £15,800 to avert each additional case of PID and an additional £50,200 to avert each major outcome as a result of screening compared with no screening. For case of PID averted, for this to be acceptable when using the maximum acceptance threshold of £30,000 per QALY from NICE, a case of PID averted would have to result in > 0.53 QALYs gained. This means that having PID would have to be equivalent to > 6 months in a state of death. Likewise, for MOA, this would have to result in > 1.67 QALYs, meaning that having a major outcome would have to be equivalent to > 18 months in a state of death for microscopy screening to be deemed cost-effective.

These observations can be extended by comparing them to previous estimates of the impact of PID sequelae on quality of life. Smith *et al.*[88] found that, using time trade-off amongst respondents with a

previous history of PID, the mean valuations for health states associated with PID were 0.79 [standard deviation (SD) 0.34] for ectopic pregnancy, 0.69 (SD 0.37) for pelvic pain and 0.76 (SD 0.34) for infertility. These values suggest that the mean QALY gain to avert a case of pelvic pain (the state with the reported greatest negative impact on quality of life) that lasted 1 year would be 0.31 QALYs. However, as noted above for the results described here, for current practice to be cost-effective a MOA must result in a gain of > 1 QALY, suggesting that current practice is far from being cost-effective.

Given the comparisons described above, and acknowledging the uncertainty in the results as described above, we tentatively suggest that the current practice of ad hoc testing of asymptomatic men in GUM locations is unlikely to be cost-effective. Considering the results at baseline in this study, if all microscopy testing for asymptomatic men in GUM locations was to be withdrawn then this would have the potential to save > £5M (discounted) over a 20-year period. This could then be better spent expanding testing and treatment regimes for different diseases in areas that are more cost-effective.

One of the major issues related to any testing and diagnostic strategy is the impact of the testing pathway on patients. Patients may suffer from anxiety while waiting for the results of a test or may incur societal costs as a result of having to take time off work to attend for testing. There are also issues specific to the context of STIs, with patients worried about the stigma of attending for testing and receiving a positive diagnosis. In the testing and diagnosis context, future work should focus on these issues to better quantify their impact on patients. The impact of these issues could then be included in economic studies such as this, to better describe the true impact of the complete testing pathway on patients.

One limitation of the analysis of this screening strategy and many analyses like it is that no account of the knock-on effects of testing are considered. As a result of patients coming into contact with health-care professionals (HCPs), there is the opportunity to provide them with health-care advice and also intervene in other diseases, which is outside the scope of this analysis. For example, in this study there is the possibility that patients may be identified as having syphilis or HIV infection, which may lead to quicker access to treatment and a reduction in onward transmission for these conditions. It would obviously be extremely difficult to incorporate more than one infectious disease into the same transmission model, but it would certainly be more realistic were this to be possible.

Chapter 2 The 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

This chapter contains information reproduced from Developing and testing accelerated partner therapy for partner notification for people with genital Chlamydia trachomatis diagnosed in primary care: a pilot randomised controlled trial, Estcourt CS, Sutcliffe LJ, Copas A, Mercer CH, Roberts TE, Jackson LJ, Symonds M, Tickle L, Muniina P, Rait G, Johnson AM, Aderogba K, Creighton S, Cassell JA, vol. 91, pp. 548–54, 2015,[89] with permission from BMJ Publishing Group Ltd.

Abstract

Background: Accelerated partner therapy (APT) is a promising partner notification intervention in specialist sexual health clinic attenders. To address its applicability in primary care, we undertook a pilot randomised controlled trial (RCT) of two APT models in community settings.

Methods: We carried out a three-arm pilot RCT of two APT interventions – APTHotline [telephone assessment of partner(s)] and APTPharmacy [community pharmacist assessment of partner] – 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 (CASH) 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 patient as contactable. The proportions of contactable partners considered treated within ≤ 6 weeks of index diagnosis were 39 out of 111 (35%) in the APTHotline arm, 46 out of 100 (46%) in the APTPharmacy arm and 46 out of 102 (45%) in the standard patient referral arm. Among partners not considered treated, treatment status was largely unknown. Among treated partners, eight out of 39 (21%) in the hotline arm were treated via the hotline and 14 out of 46 (30%) in the pharmacy arm were treated at a pharmacy.

Conclusions: We established a feasible system for primary care professionals to initiate and record partner notification using a web-based tool. The proportion of partners treated in either intervention arm was comparable to the proportion treated in the standard patient referral arm but greater than previously reported outcomes in similar settings. However, uptake of the APT interventions was low. Further work is required to optimise the uptake of APT outside specialist services as this has the potential to improve partner notification outcomes further.

Introduction

Background

Across England, reported diagnoses of genital *C. trachomatis* infection, the commonest STI, continue to rise.[90] The proportion of infections diagnosed in primary care settings has increased[90] and, in 2013, 58.2%[91]

of all cases of chlamydia in people aged < 25 years in England were diagnosed outside the specialist GUM setting, where partner notification services may not be routinely available.

Recent mixed-methods and mathematical-modelling studies suggest that improving the effectiveness of partner notification, the process of identifying exposed sex partners and offering them testing and treatment,[92] could have a more marked impact on population control of chlamydia than widening access to testing.[93] The aims of partner notification are twofold: to reduce the burden of infection by reducing reinfection from untreated sex partners and to reduce onward transmission. However, the optimal partner notification strategy for people with chlamydial infection is unknown. A recent systematic review of RCTs of partner notification[91] for STIs causing cervicitis and urethritis suggests that expedited partner therapy (EPT), in which the doctor provides the index patient with antibiotics or a prescription to give to their sex partner,[94] is more effective than simple patient referral [verbal advice that the partner(s) should attend] in preventing index reinfection and achieves treatment of a higher proportion of sex partners. However, EPT does not appear to be more effective than enhanced patient referral (simple patient referral supplemented by written advice, longer verbal explanation and/or internet resources) in preventing index reinfection and is not associated with higher numbers of partners treated.[93]

UK prescribing guidance does not support EPT in this form[95] as it does not include a medical assessment of the sex partner. We have previously developed a new form of EPT known as APT, which uses health adviser telephone-led and pharmacist-led partner notification interventions and includes medical assessment of the sex partner.[95] These meet UK prescribing guidance and have shown promise in the specialist setting.[95,96] Furthermore, modelling studies suggest that APT could play an important role in reducing index reinfection and the prevention of costly reproductive health consequences, especially in women,[93,94] by reducing the time to successful partner treatment.[95]

Successful control of chlamydia will need effective methods of partner notification, irrespective of the setting in which the infection is diagnosed. Partner notification is known to be problematic in primary care[68,97] but has been shown to be achievable in the context of a chlamydia screening trial.[98] Barriers to effective partner notification include lack of knowledge/skills, lack of time and organisational issues (e.g. partner is not patient of index practice).[99] Although GPs appear to be broadly supportive of APT methods of partner notification,[97] this type of intervention may not directly translate to primary care settings in which staff may have fewer specific sexual health skills and service users may be different from those attending specialist services.

Objectives

The objective of this study was to determine the feasibility, acceptability and preliminary evidence of effectiveness of APT for women diagnosed with chlamydia in the non-specialist setting by conducting a pilot RCT of APT in contrasting primary care settings in England.

Methods

Trial design

We carried out a three-arm pilot RCT of two APT interventions – APTHotline and APTPharmacy – compared with routine care (patient referral) with allocation in a 1 : 1 : 1 ratio.

Participants

Inclusion criteria were women aged at least 16 years, diagnosed with genital *C. trachomatis* infection (index patients) and at least one contactable male sex partner in the last 6 months. Exclusion criteria for index patients were known HIV-positive status, co-infection with other STIs as these would require tailored partner notification and/or different epidemiological treatment of partners and an inability to understand English. Exclusion criteria for male sex partners were symptoms of complicated infection, allergy or contraindications to azithromycin and an inability to understand English as we did not consider that it was

medically appropriate to conduct a telephone clinical assessment if someone was unable to fully comprehend the assessment.

Settings

The trial took place between 1 September 2011 and 31 July 2013 in two areas with diverse and contrasting patient populations: inner East London, which has a deprived young and ethnically mixed population [six general practices and two community (non-specialist) CASH services, supported by five pharmacies], and the south coast of England, which serves non-metropolitan populations, some of which are distant from GUM clinic provision and which therefore face contrasting challenges in access to services [six general practices and one community (non-specialist) CASH service, supported by nine pharmacies]. The pharmacies provided broad geographical coverage around each recruitment site.

Recruitment of health services

General practices and CASH services within the relevant geographical areas with the highest chlamydia screening and positivity rates were identified by the researchers and approached by e-mail from the chief investigator to the lead GP or lead clinician (CASH service) to introduce the study. A week later a researcher telephoned the lead GP/clinician to ascertain his/her level of interest in participating. A date was arranged to present the study to the whole general practice/CASH service and an agreement to take part in the study was obtained. Some general practices and one CASH service routinely devolved the provision of chlamydia test results and management for women aged < 25 years to the local National Chlamydia Screening Programme (NCSP) office. When this was the case, we worked with the relevant NCSP offices, as directed by the general practices/CASH service involved.

Independent or small-chain pharmacies (administratively easier than large-chain businesses) were initially chosen by the researchers for their proximity to good transport links (train, tube or bus) and their geographical coverage within the study area. A researcher then either telephoned or walked into each pharmacy to introduce the study to the lead pharmacist. Interested pharmacists were e-mailed further detailed information about the study and a researcher telephoned a week later to seek their agreement to take part. With some chain pharmacies, if the lead pharmacist was interested in participation the researchers also had to approach his or her business development manager to obtain permission for the pharmacy to participate.

Initially, six general practices, two CASH services and five pharmacies across Tower Hamlets Primary Care Trust (PCT) and City & Hackney PCT (London) and four general practices and five pharmacies across NHS East Sussex Downs & Weald PCT were recruited. However, during the trial there were extensive changes in NHS organisational structures[100] and research had a low priority within the general practice settings. We decided to recruit a third CASH/NCSP service outside London (Portsmouth Sexual Health Services CASH Clinic and NCSP) with high positivity rates and a further four pharmacies in the Portsmouth area.

Participant recruitment

Index patients

Practice nurses, GPs and community CASH service health advisers who had all been trained in the study procedures identified patients at the time of treatment and sought consent to participate. The HCP entered each participant's details and mobile phone number onto the APT web tool, which then randomised each participant to one of the three study arms and sent a text (SMS) message to the participant with her unique personal identification number (PIN) and information permitting her sex partner(s) to log on to the system, in addition to covering other routine elements of the partner notification interview. The participants were asked to forward this text message to their sex partner(s) when they told them of the need for treatment.

Male sexual partners

Male sexual partners allocated through their partner's randomisation to an offer of the APTHotline received an explanation of the study from the research health adviser on the hotline and provided informed consent prior to the consultation.

Male sexual partners allocated through their partner's randomisation to receive an offer of the APTPharmacy received an explanation of the study from the community pharmacist face-to-face and provided informed consent prior to the consultation.

All women and male sex partners who did not take up the offer of the trial were managed according to routine clinic protocols.

Development and features of the online patient and data management tool

We applied a user-centred approach to the design of a bespoke web-based tool to support the APT patient pathway in primary care, enabling rapid communication between the general practice, CASH service and the supporting hotline and pharmacy services. This was based on a similar tool used in a previous trial[101] and a tool used in a related study of the primary care management of STIs.[102] It relies on a secure website, compliant with NHS encryption and data transfer protocols.

We included a pre-design phase involving discussions with primary care health professionals and sexual health clinic health advisers to determine their needs, current activity and work habits, to ensure that the web-based tool could be successfully integrated into their daily work practice. The web tool was then developed according to our specification by EpiGeneSys, a software company affiliated with Sheffield Clinical Trials Unit.

We chose a web-based format so that it did not require software installation or downloads. Data were collected in real time and all partner notification and other study outcomes were recorded. In addition, the web tool removed patient-identifiable data, which enabled the trial manager to see inputted data from all study sites, allowing real-time monitoring of recruitment and follow-up.

Other potential advantages of the web tool included a full audit trail, which allowed monitoring of the input and modification of records and users' interactions with the system; access for health advisors to all index and sexual partner(s) reports to allow follow-up of partner notification; and the ability to download non-identifiable data by statisticians and health economists working on the study.

Interventions

All index patients were offered standard partner notification for all of their partners whereas those randomised to either of the APT options were offered APT *in addition* to standard partner notification for all of their partners. We define standard partner notification pragmatically as the routine method of partner notification offered by that service. In general practice this consisted of simple patient referral in which the GP or practice nurse advised the index patient of the need to inform her sex partners to undergo testing and obtain treatment.[81] Within the CASH services, enhanced patient referral was the standard partner notification offer. Enhanced patient referral consists of simple patient referral supplemented by written or online information about chlamydia and/or specific information on local health services at which the partner(s) could obtain appropriate care.[81] It is important to note that, as partner notification for these settings did not take place within the context of a GUM clinic but instead remotely, a direct and immediate offer of STI and HIV testing on first contact between the partner and the service did not take place. STI and HIV testing therefore depended on engagement either with self-sampling (urine sample kits for *C. trachomatis* and *N. gonorrhoeae* testing were included in the APT pack) or later attendance at a sexual health service for all three intervention arms.

Once the index patient gave consent the health professional began the partner notification consultation and filled in data using the web tool. Once the consultation was finished the health professional clicked a

tab on the web tool that randomised the index patient's sexual partners to receive routine partner notification, routine partner notification plus APTHotline or routine partner notification plus APTPharmacy. If either APTHotline or APTPharmacy was allocated, the web tool simultaneously and automatically sent a text message to the index patient with a unique PIN, which she was able to forward on to her sexual partners/contacts as her sexual contacts needed to quote this unique PIN to receive APTHotline or APTPharmacy treatment. If the index patient was allocated to routine care she did not receive a text message.

Details of the interventions are shown in *Figure 4*.

Outcome measures

The primary outcome, determined for each contactable partner, was whether they were considered to have been treated within 6 weeks of the index diagnosis. Accordingly, primary outcome partners for whom treatment information was unavailable were considered untreated and there was, by definition, no loss to follow-up.

Secondary outcome measures were determined for the index patient and for each partner and included whether the partner was notified that they were at risk of infection; partner uptake and acceptability of partner notification modalities, number of partners treated per index patient; number of contacts notified per index patient; time to partner treatment; and *C. trachomatis* reinfection/persistence rates in index patients 4–6 weeks after treatment.

We also collected resource data to inform our health economics evaluation, which are reported in full on pp. 45–48.

Ascertainment of outcomes

Health advisers staffing the APTHotline and pharmacists providing treatment entered clinical and partner notification data directly onto the web tool at the time of the patient interaction. Health advisers conducted follow-up telephone assessments with all index patients 4–6 weeks after treatment to elicit outcomes of partner notification for partners who did not access APT, to obtain routine clinical data and to explore the acceptability of the interventions. To determine reinfection/persistence, we sent index patients who could be reached for telephone follow-up and who agreed a urine collection kit for *C. trachomatis* NAAT testing, which they mailed to the study laboratory for testing.

Process evaluation

We carefully monitored the recruitment process by observing clinical staff at the different sites as they offered the trial to eligible patients, visiting pharmacies to observe practice and monitoring hotline consultations. We conducted informal interviews with a range of clinical staff involved with the study. We explored issues of acceptability and preference in more detail by undertaking limited qualitative telephone interviews with a sample of female index patients and with male sex partners. A preliminary thematic analysis was undertaken of the qualitative data.

Sample size

The study was designed as a pilot trial, in accordance with the Medical Research Council (MRC) framework for the development of complex interventions,[103] with randomisation of index patients on an individual basis, recognising that there would be clustering of partners by index patient. The unit of analysis was the individual male partner. We assumed that 25% of male partners would be reported (by index or health-care service) as treated via routine partner notification in primary care in comparison to 40% of male partners who would be reported as treated via either of the APT options. We chose 80% power and a 2% significance level (to take account of the need to make comparisons across three arms: routine care, APTHotline, APTPharmacy) and applied a 10% design effect (to take account of clustering of an average of 1.5 male partners per female index patient). We therefore sought to recruit 400 partners to participate across the 10 practices in the two PCTs.

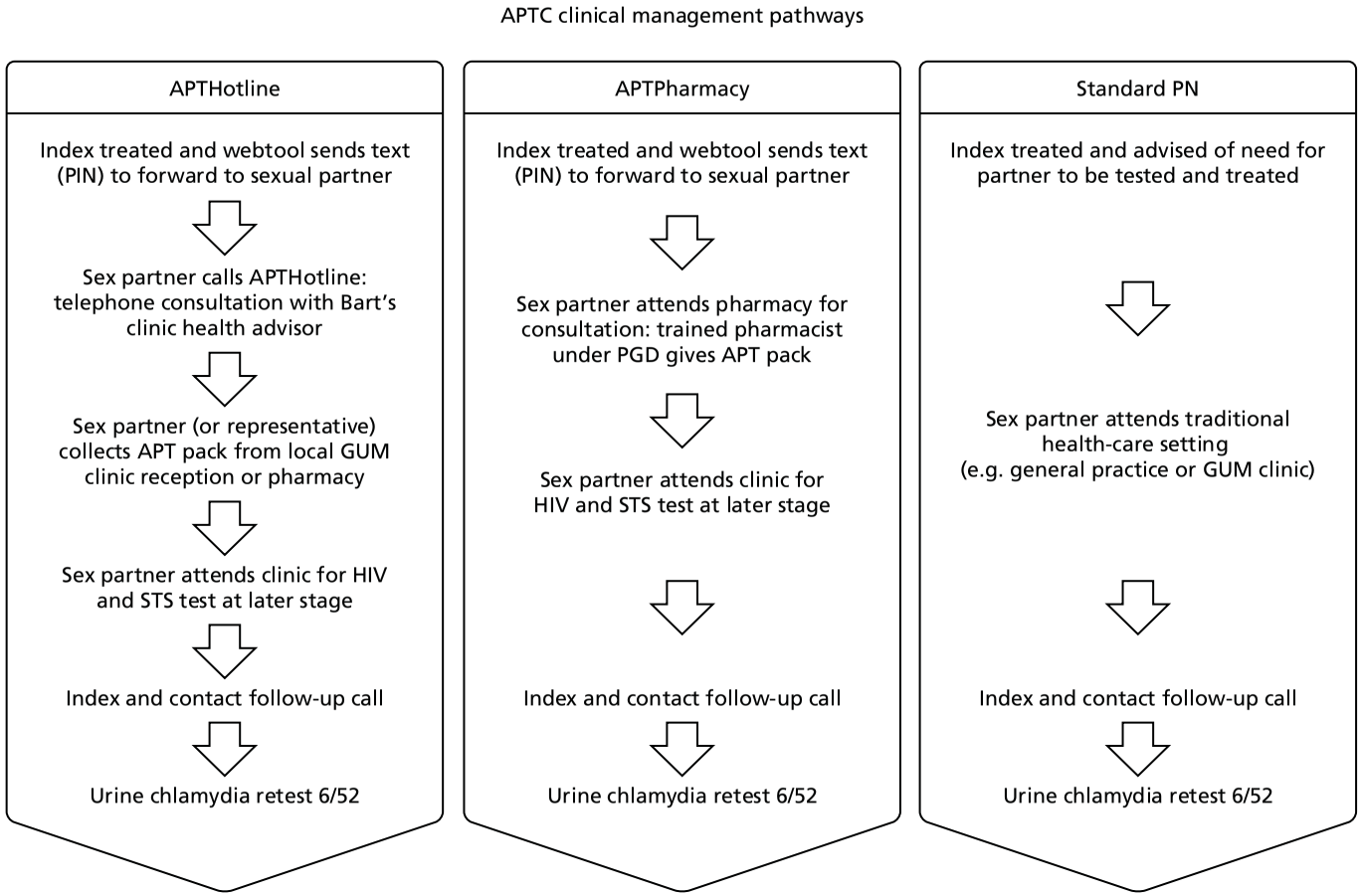

FIGURE 4 The APTPC trial interventions. *APT pack* – contained prepackaged azithromycin (1 g), condoms, chlamydia information leaflet, a urine sample collection kit for *C. trachomatis* NAAT with instructions to provide the sample before taking the antibiotics, a prepaid postal envelope and sample packaging for returning the sample to the study clinic and a patient information leaflet about the study. *APTHotline* – sex partner undergoes telephone consultation with a sexual health clinic health adviser to determine eligibility for APT and receives an invitation for future clinic-based HIV and syphilis screening. Sex partner or his representative collects the APT pack from the clinic reception. Sex partner posts back his completed *C. trachomatis* NAAT urine sample kit (contained in the APT pack). Results and future clinical care are managed by a specialist clinic. *APTPharmacy* – sex partner undergoes consultation with sexual health-trained community pharmacist to determine eligibility for APT and receives an invitation for future clinic-based HIV and syphilis screening. Pharmacist gives sex partner the APT pack at the time of consultation. Sex partner posts back his completed *C. trachomatis* NAAT urine sample kit (contained in the APT pack). Results and future clinical care are managed by a specialist clinic. *Standard partner notification (control)* – for the purposes of this study we define standard partner notification as the HCP advising the index patient to notify his/her sex partner of the need for treatment. In the CASH services this was supplemented by written information about chlamydia and the provision of details of local sexual health services to the index patient for her to give to her sex partner. APTPC, APT delivered in primary care settings; PGD, Patient Group Direction; PN, partner notification; STS, syphilis screening.

However, in light of recruitment rates being lower than anticipated, a pragmatic decision was made during the trial to seek to obtain outcome data, including index follow-up interviews, for at least 200 partners in total across study arms.

Randomisation

Index patients were randomised in a 1 : 1 : 1 ratio to one of the three study arms by simple computer-generated unrestricted randomisation within the web tool. The randomisation applied to all contactable partners identified by the index patient.

Blinding

It was not feasible for participants or researchers to be blind to the intervention type during implementation or evaluation. However, all statistical analyses were conducted blind.

Statistical analyses

Analysis of the primary outcome was by intention to treat with all partners not reported as treated assumed not to have been notified (therefore, by definition, there was no loss to follow-up). As a secondary outcome, we reported the proportion of contacts in each arm treated by each partner notification method (routine, APTHotline, APTPharmacy, other). Analysis was based on complete cases. However, as noted, the primary outcome relates to whether or not partners were considered treated and those for whom information was unavailable were analysed as if untreated. We also report the proportions of partners considered treated, considered untreated and with an unknown treatment status (by whether or not the index patient was followed up). Similarly, for the secondary outcome relating to partner notification, for ORs and statistical testing those partners for whom notification was unknown were considered not notified, but we also report the proportions notified, not notified and unknown (index followed up or not).

To calculate adjusted ORs logistic regression was used. Unadjusted and adjusted ORs are reported with 95% CIs and corresponding *p*-values. ORs were reported for comparisons between the hotline arm and routine partner notification and between the pharmacy arm and routine partner notification arm. Adjusted ORs were calculated adjusting for the age and ethnic group of the index patient. The analysis of outcomes determined for each partner, such as the primary outcome, was based on robust standard errors to acknowledge the clustering of partners by index patient. All analysis was conducted in Stata 13.

Registration

The trial was registered with a UK Clinical Research Network Study Portfolio ID number of 10123. Ethical approval for the trial was obtained from East London REC 1.

Results

Recruitment and follow-up

Of 357 chlamydia-positive women screened for eligibility, 49 were found not to be eligible, 67 declined to participate and 42 were not included for other reasons. In total, 199 women were randomised, who in total identified 313 contactable partners (*Figure 5*). A total of 199 index patients were randomised.

Baseline characteristics

By definition there was no loss to follow-up in the primary outcome. However, some secondary outcomes required further information from an index patient telephone follow-up, which did not occur for roughly one-quarter of index patients (53/199), affecting 28% of partners (87/313). This loss to follow-up was somewhat more common in the pharmacy partner notification arm.

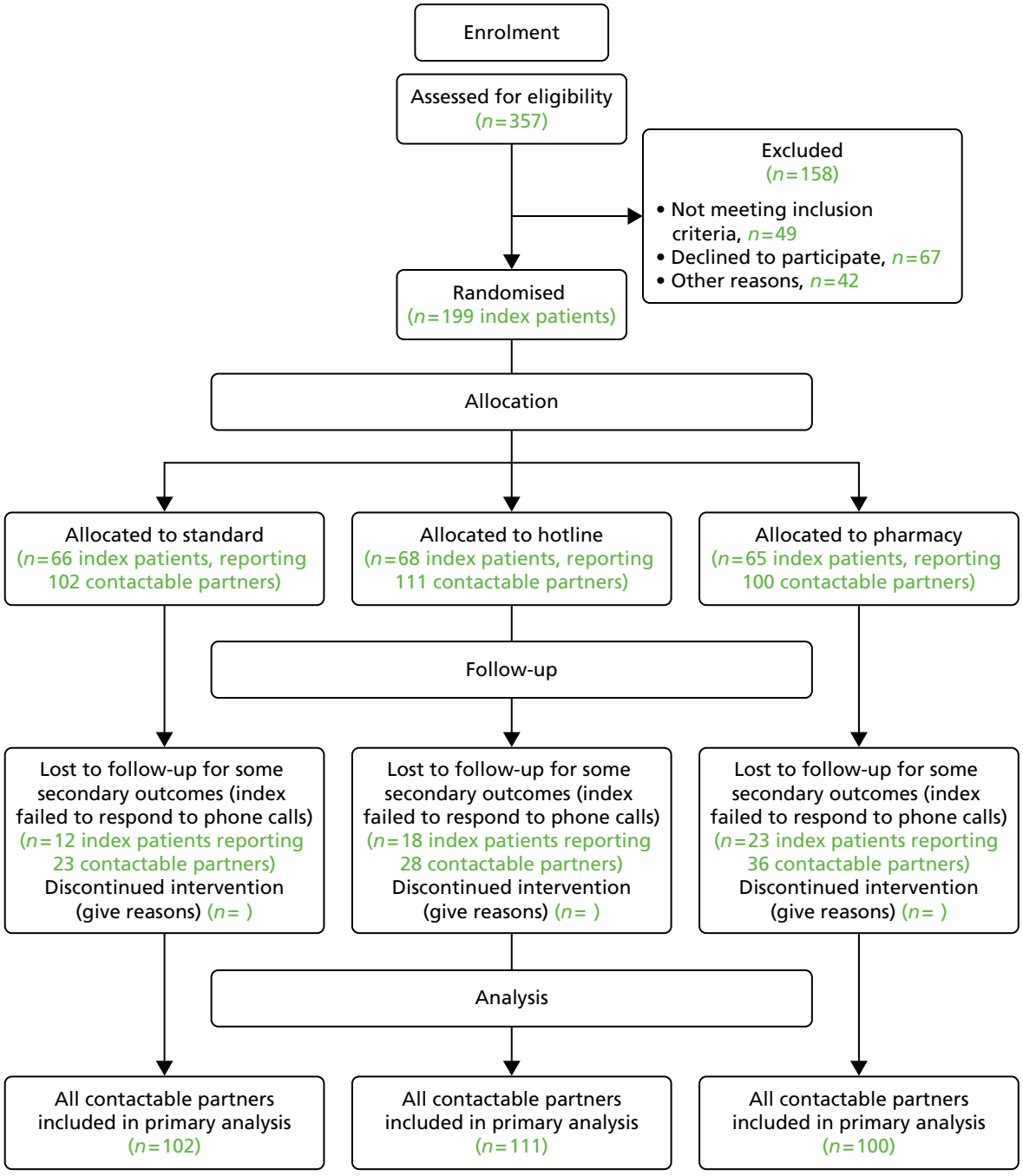

FIGURE 5 Consolidated Standards of Reporting Trials (CONSORT) diagram for the trial.

Table 17 shows the baseline characteristics of the index patients randomised and their contactable partners. These were similar across arms. Index patients were relatively young, with a median age of 21 years overall, the mean number of sexual partners over the last 6 months was 1.7 and the mean number of contactable partners was 1.6, indicating that the vast majority of partners were contactable.

Findings

For the primary outcome, *Table 18* shows that the proportion of partners known to have been treated varied little between study arms (from 39% to 46%) and the ORs in *Table 19* show that, with or without adjustment, there was little evidence of a difference between either APT method and standard patient referral. Specifically, the unadjusted and adjusted ORs (95% CIs) for partner treatment in the hotline arm relative to standard care were 0.91 (0.48 to 1.73) and 0.64 (0.35 to 1.18), respectively, and for partner

TABLE 17 Characteristics of index patients and contacts by randomisation arm

Characteristic	Standard	Hotline	Pharmacy	Total
Index patients				
N	66	68	65	199
Age (years), median (IQR)	20 (19–22)	21 (18–23)	21 (19–24)	21 (19–23)
Ethnicity, % (*n*)				
White British	59 (39)	53 (36)	57 (37)	56 (112)
White other	8 (5)	15 (10)	18 (12)	14 (27)
Mixed	2 (1)	6 (4)	8 (5)	5 (10)
Black/black British	3 (2)	3 (2)	2 (1)	3 (5)
Asian/Asian British	11 (7)	10 (7)	6 (4)	9 (18)
Other	8 (5)	3 (2)	3 (2)	5 (9)
Not answered	11 (7)	10 (7)	6 (4)	9 (18)
Number of sexual partners (last 6 months), % (*n*)				
1	64 (42)	56 (38)	60 (39)	60 (119)
2	23 (15)	22 (15)	23 (15)	23 (45)
3	8 (5)	15 (10)	9 (6)	11 (21)
4+	6 (4)	7 (5)	8 (5)	7 (14)
Mean (SD)	1.6 (1.18)	1.8 (1.10)	1.7 (1.12)	1.7 (1.13)
Number of contactable sexual partners, % (*n*)				
1	71 (47)	62 (42)	68 (44)	67 (133)
2	17 (11)	19 (13)	15 (10)	17 (34)
3	6 (4)	15 (10)	12 (8)	11 (22)
4+	6 (4)	4 (3)	5 (3)	5 (10)
Mean (SD)	1.5 (1.18)	1.6 (0.94)	1.5 (0.89)	1.6 (1.01)
Contactable partners				
N	102	111	100	313
Relationship to the index patient, % (*n*)				
Cohabiting/married/civil partnership	3 (3)	14 (15)	7 (7)	8 (25)
Steady but not cohabiting	48 (49)	38 (42)	44 (44)	43 (135)
Sex once	30 (31)	23 (26)	27 (27)	27 (84)
Have sex from time to time	3 (3)	12 (13)	12 (12)	9 (28)
Ex-partner	12 (12)	8 (9)	6 (6)	9 (27)
Just met for the first time	4 (4)	5 (6)	4 (4)	4 (14)

IQR, interquartile range.

TABLE 18 Treatment and notification of contactable partners by randomisation arm

Outcome	Standard	Hotline	Pharmacy	Total
All partners				
N	102	111	100	313
Notification, % (*n*)				
Notified	74 (75)	68 (75)	66 (66)	69 (216)
Not notified	4 (4)	11 (12)	3 (3)	6 (19)
Unknown (index followed up)	0 (0)	0 (0)	0 (0)	0 (0)
Unknown (index not followed up)	23 (23)	22 (24)	31 (31)	25 (78)
Treatment, % (*n*)				
Treated	45 (46)	35 (39)	46 (46)	42 (131)
Not treated	11 (11)	5 (5)	7 (7)	7 (23)
Unknown (index followed up)	22 (22)	37 (41)	15 (15)	25 (78)
Unknown (index not followed up)	23 (23)	23 (26)	32 (32)	26 (81)
Treated partners only				
N	46	39	46	131
Method of treatment, % (*n*)				
Hotline	0 (0)	21 (8)	0 (0)	6 (8)
Pharmacy	0 (0)	0 (0)	30 (14)	11 (14)
GP	28 (13)	21 (8)	7 (3)	18 (24)
GUM clinic	46 (21)	26 (10)	35 (16)	36 (47)
Other	11 (5)	8 (3)	9 (4)	9 (12)
Unknown (index followed up)	15 (7)	26 (10)	20 (9)	20 (26)

TABLE 19 Odds ratios for notification and treatment of contactable partners, comparing each APT arm with standard partner notification[a]

Outcome	OR hotline vs. standard (95% CI), *p*-value	Adjusted[b] OR hotline vs. standard (95% CI), *p*-value	OR pharmacy vs. standard (95% CI), *p*-value	Adjusted[b] OR pharmacy vs. standard (95% CI), *p*-value
Notified	0.75 (0.41 to 1.36), $p = 0.34$	0.91 (0.48 to 1.73), $p = 0.77$	0.70 (0.38 to 1.28), $p = 0.25$	0.90 (0.65 to 1.27), $p = 0.56$
Treated	0.66 (0.38 to 1.15), $p = 0.14$	0.64 (0.35 to 1.18), $p = 0.15$	1.02 (0.77 to 1.34), $p = 0.89$	1.06 (0.78 to 1.45), $p = 0.72$

a Partners for whom treatment or notification is unknown are treated as untreated and not notified, respectively.
b Adjusted for index age and ethnicity.

treatment in the pharmacy arm relative to standard care were 0.90 (0.65 to 1.27) and 1.06 (0.78 to 1.45), respectively.

Table 18 also shows that partners whom the index patient thought were untreated could be divided into two groups: those who were known to be untreated (7%) and those whom we assumed were untreated for the purposes of this analysis because the index had no information about them. When the number of partners known to have been treated was examined per index patient (*Table 20*), the mean was 0.7.

TABLE 20 Number of contacts treated per index patient by randomisation arm

Number of contacts	Standard (*N* = 66), % (*n*)	Hotline (*N* = 68), % (*n*)	Pharmacy (*N* = 65), % (*n*)	Total (*N* = 199), % (*n*)
0	36 (24)	53 (36)	42 (27)	44 (87)
1	58 (38)	41 (28)	51 (33)	50 (99)
2+	6 (4)	6 (4)	8 (5)	7 (13)
Mean number treated (SD)	0.7 (0.58)	0.6 (0.74)	0.7 (0.76)	0.7 (0.70)

Table 18 shows that around 70% of partners in each study arm were known to have been notified in each study arm and the ORs in *Table 19* confirm that there is no evidence of a difference between either APT arm and standard patient referral.

Table 18 also shows that among partners treated in the hotline arm only 21% were treated via the hotline and of those treated in the pharmacy arm only 30% were treated via a pharmacy.

Secondary outcomes

Reinfection/persistence

Only 38 out of 199 index patients (19% of the total) were tested for reinfection/persistence and chlamydia positivity was 15% (2/13) in the standard 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 HIV or syphilis test. In the standard arm, no partners had a chlamydia or a gonorrhoea test compared with 4% (4/111) in the hotline arm and 6% (6/100) in the pharmacy arm. Of those tested, one partner (in the hotline arm) tested positive for chlamydia.

Health economic evaluation

The health economic evaluation is presented on pp. 45–53.

Process evaluation

Recruitment

Community HCPs found the web tool easy to use and a useful adjunct to routine care, particularly as it provided a user-friendly interface on which to document the partner notification discussion, and they perceived that it provided 'added value' to patients. However, providing the explanations and choices necessary for informed consent to participate in a research study at what can be an emotionally difficult time for the index patient was perceived to be difficult.

Although all services were highly supportive of the research, they experienced difficulties with implementing the study. All CASH services underwent major organisational change during the recruitment period, with attrition of clinical and research liaison posts. One service moved premises and all of the general practices were affected by wide-ranging national changes in service commissioning and structures. Services reported that they were unable to prioritise the study during the upheaval and we took the decision to centralise recruitment by enabling the research health adviser to offer the study to eligible patients by telephone. This resulted in a rapid increase in recruitment rates when she was available.

Time to treat

Discussion with HCPs towards the end of the study revealed that, in an inadvertent attempt to boost recruitment, some were recruiting index patients whose sex partners had accompanied them to clinic on the day of index treatment. This meant that the intervention had been bypassed as the sex partner was already in the service and is likely to account for a large proportion of sex partners in the routine care arm treated on day 0 (*Table 21*).

TABLE 21 Time to partner treatment

Days	Standard ($n = 39$), % (n)	Hotline ($n = 23$), % (n)	Pharmacy ($n = 35$), % (n)	Total ($n = 97$), % (n)
0	82.1 (32)	78.3 (18)	60.0 (21)	73.2 (71)
1	2.6 (1)	13.0 (3)	2.9 (1)	5.2 (5)
2	10.3 (4)	0.0 (0)	5.7 (2)	6.2 (6)
3	2.6 (1)	0.0 (0)	5.7 (2)	3.1 (3)
4	0.0 (0)	4.3 (1)	2.9 (1)	2.1 (2)
5	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
6	0.0 (0)	0.0 (0)	0.0 (0)	0.0 (0)
7	0.0 (0)	4.3 (1)	5.7 (2)	3.1 (3)
8+	2.6 (1)	0.0 (0)	17.1 (6)	7.2 (7)
p-value for APT relative to standard care		0.783	0.015	

Acceptability to participants

Follow-up interviews with index patients and sex partners showed high levels of acceptability of the APT interventions.

Harms

There were no harmful clinical incidents reported during the trial. However, on two occasions a community pharmacist was unable to log in to the APT web tool because of user error and did not provide the APT pack to eligible sex partners. The sex partners were successfully managed in traditional services.

Conclusions

Main findings

Similar proportions of partners were reported to have been treated across the three arms of the trial, in each case fewer than half. Although overall outcomes for partner notification were similar between the three arms, only a minority of those in the APTHotline and APTPharmacy intervention arm actually used that modality and their availability did not appear to improve outcomes.

The online patient and data management tool was acceptable to clinical staff and feasible for the referral of patients for partner notification support, including in the intervention arms, and for outcome measurement. However, recruitment to the research study within the clinic setting was challenging. The need to seek individual informed consent from index patients at an often emotional time and often by telephone acted as a barrier to participation for both patients and HCPs, whereas rapid changes in health services created challenges to clinical services in terms of prioritising research. The numbers of sex partners reported by women were comparable to the numbers reported by women attending specialist sexual health services[104] and the majority of sex partners were contactable. However, fewer than half of the sexual partners were confirmed to have been treated across the trial and the addition of the APT interventions did not appear to improve outcomes. Uptake of the interventions was poor and most of the successful partner notification was achieved using standard methods rather than by APT.

No sex partners were known to have attended for HIV and syphilis testing although a small number of sex partners who took up the interventions returned a postal test kit for chlamydia and gonorrhoea. Despite good levels of index patient follow-up, including reminders about retesting, return of postal test kits for reinfection testing at 4–6 weeks post treatment was low.

Findings in the context of published literature

Effective partner notification in primary care is recognised as difficult to achieve[97,99] but the importance of improving the effectiveness of partner notification as a strategy for improving population control of *C. trachomatis* is well recognised. It is increasingly recognised that partner notification outcomes should be measured per partner, rather than per index patient,[105] as this reflects the true potential for the prevention of further transmission. However, current guidelines for partner notification, and newly available surveillance reports in England, continue to focus on outcomes per index patient.[106] Our choice to use partner-focused notification outcomes makes it hard to compare our data with audit data, which are typically reported as number of partners treated per index. Nevertheless, the suboptimal rates of partner notification described in this pilot trial are superior to those reported in similar settings.[68,104,105]

Beyond the availability of partner-focused outcome data, there are further conceptual and empirical challenges with regard to the comparison of our data with those from other settings. Primary care and other non-specialist settings have not historically had a routinely available partner notification infrastructure and partner notification outcomes have typically not been measured or recorded at all. The provision of a partner notification service is of itself likely to produce a substantial 'Hawthorne effect' by normalising the discussion of partner notification. This may on its own be sufficient to motivate and empower an index patient to attempt discussion of the need for testing and treatment with his/her partner(s). Ideally, we would compare our data, at least for general practice, with data from a completely undeveloped service, but this is not in fact possible. We can nevertheless compare our data with limited data from community services, including the NCSP.

Our previous study of APT in specialist sexual health/GUM settings did use partner-focused outcome measures and suggested that APT could provide an improvement in partner notification outcomes compared with standard patient referral.[101] However, there were important differences in the design, inclusion criteria and exact nature of the interventions, which make direct comparisons inappropriate. Our initial APT study allowed index patients to select the method of partner notification that they thought would best suit each sex partner, whereas this study randomised patients. In routine clinical practice, index patients choose from a range of partner notification options and we believe that removing the element of choice by randomising patients to one intervention may not be the optimal design for sensitive interventions such as partner notification.

Limitations

Implementation of a pilot trial of this size, which required a large number of recruitment sites, at a time of unanticipated and wide-ranging health service change was extremely difficult. We had to scale down our original sample size to provide more realistic recruitment requirements for each service and support recruitment centrally. Our primary outcome was largely index reported rather than sex partner verified, which introduces uncertainty around the robustness of outcome ascertainment. Although we included a biological outcome (index patient positivity 4–6 weeks post treatment), in practice it did not prove useful as postal retesting had a low uptake rate despite telephone reminders.

We do not know whether the partners of women who declined to take part, or who did not take part for other reasons, were more or less likely to be treated. Our sample could therefore be biased in either direction with respect to the target population of index patients and partners.

Although APT did not appear to reduce the time to partner treatment, some centres recruited sex partners who attended with the index patient (contrary to protocol), which would bias the measures of routine partner notification to make it appear much faster.

Implications for public health and clinical practice

The care pathways that we developed, 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.

Outside the research setting, where there are major barriers to recruitment and randomisation at an emotionally taxing time, our model interventions appear to be capable of providing acceptable approaches to partner notification support. These could usefully form part of the portfolio of partner notification choices aimed at improving outcomes for all kinds of partner. It is increasingly recognised that novel interventions should not be seen as standalone strategies, but rather in the context of a portfolio of partner notification modalities that collectively improve overall partner notification outcomes.

The low uptake of follow-up STI or HIV testing is 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. Although in the future this may be addressed through postal self-sampling as a means of delivering more comprehensive testing, they are not suitable either for individuals or for populations who have been identified as being of higher risk, such as men who have sex with men (MSM) and MSM partners of heterosexual women.[107,108]

Implications for research

Overall partner notification outcomes were superior to previously reported partner notification measures in similar settings and so further work is required to optimise the uptake of APT outside specialist services. An in-depth understanding of the reasons for poor uptake of the interventions, that is, whether it was the index patient failing to forward the text or partners not finding APT acceptable, will be important for future partner notification research, irrespective of setting. A cluster design in which whole services are randomised to the offer of an APT intervention is likely to facilitate uptake, improve staff familiarity, normalise the interventions and minimise the negative impact of health service changes on ongoing clinical staff-dependent research. However, this may be difficult to implement as large numbers of clinics may be required to accommodate the cluster design and this may prove excessively costly. In addition, given the difficulties in achieving individual consent, a non-consented trial could be considered, which, although controversial, has been undertaken in the field of chlamydia screening.[99,109]

Research should also be undertaken to explore how to identify and reach higher-risk partners who may benefit from a more comprehensive range of sexual health services.

Preliminary cost–consequence analysis of accelerated partner therapy in primary care

Introduction

The aim of the economic analysis was to compare the costs and outcomes for the three arms of the pilot RCT in terms of a preliminary cost–consequence analysis. As described in the first part of this chapter, the pilot trial compared two APT interventions (APTHotline and APTPharmacy) with routine partner notification (standard treatment) in a primary care setting. The success of any new trial or intervention must be balanced against the resources required to achieve the desired outcome; thus, any additional resources required must be evaluated in terms of any additional benefit that can be attributed to them.

Methods

The pilot RCT has been reported in the first part of this chapter. In brief, women diagnosed with chlamydia with at least one contactable male partner were randomised via a web tool to receive (1) APTHotline, which involved the telephone assessment of sex partners by a clinic-based qualified health advisor; (2) APTPharmacy, which involved partner assessment by a trained community pharmacist; or (3) standard partner notification, defined as the routine method of partner notification offered by the service. Those randomised to receive the APT treatment options were offered APT in addition to standard partner notification. The primary outcome for the pilot RCT was the proportion of contactable partners considered treated within 6 weeks of the diagnosis of the index patient.

For the economic analysis the costs and outcomes associated with the two APT treatment strategies were compared with the costs and outcomes associated with routine partner notification (standard treatment). This involved the collection of data on resource use and costs for each strategy, alongside their outcomes. The economic analysis was conducted alongside the pilot trial and the perspective adopted was that of the NHS and so only direct health service costs were included.

Data collection

All resource use and costs incurred as a result of the APT strategies were collected prospectively in the trial. For the index case consultations in primary care, staff recorded relevant data on the web tool, as well as the duration of the consultation. For the APT treatment arms, participating pharmacies and hotline staff recorded information on the web tool relating to the eligibility of partners, uptake of APT packs, etc. The duration of the partner consultation was also recorded on the web tool. For standard partner treatment we used information on resource use and cost data collected in a published primary study, the Chlamydia Screening Studies (ClaSS), which compared alternative chlamydia testing and partner notification strategies.[49] Costs from secondary sources were inflated to current prices using the Hospital & Community Health Services pay and price index.[80]

Resource use and cost definition

Some of the resources used in the trial were common to more than one strategy. The APT pack was common to both APT treatment strategies and we estimated costs for the pack based on data collected during the trial. The pack contained antibiotic treatment (azithromycin), condoms, a STI information leaflet and a chlamydia self-test kit (with postal return). A further common cost for the APT strategies was that associated with sending a text to index patients with details of treatment options for their partners and their unique PIN. Index patients needed to forward this text to their partners to enable their partners to access treatment. Text messaging service costs for a large London hospital trust were used as a proxy for the cost of text messaging in the trial. These cost data were used to estimate the costs associated with providing such as service at scale and because study costs for the text messaging service were combined with randomisation costs (and randomisation would not be required if the study were rolled out).

A web tool was developed for the trial to enable communication between clinicians in primary care and those providing APT treatment services. We excluded the costs associated with the development of the web tool from the base-case analysis as these are 'sunk' costs that would not need to be repeated if the intervention were rolled out.[18] Ongoing costs associated with the web tool can be divided into fixed costs and variable costs, with fixed costs being those that do not change according to the number of patients included.[110] For interventions that involve internet-based elements, a high proportion of the total costs are often fixed costs (e.g. maintenance of the server, storage of data, updating systems, etc.) that do not vary (overall) in terms of the number of patients involved. This means that the cost of delivering the intervention (per patient) will be determined primarily by the number of patients included (the denominator). Thus, reporting costs using the number of participants in a clinical trial will not provide an accurate reflection of the true cost per patient if the trial were rolled out to a wider patient group.[111] It is therefore recommended that the likely take-up rate for the intervention is taken into account to allow a more accurate estimate of the average costs per patient associated with ongoing costs for maintaining internet-based elements.[18] We therefore adjusted the ongoing costs associated with the web tool to give a more accurate estimate of these if the trial were rolled out. Taking into account possible take-up rates, we allowed £2.00 per randomised partner to cover the costs of the web-based tool, following methods adopted in a previous study.[111] We allowed a cost for each randomised partner rather than each partner treated, as the web tool was provided irrespective of whether or not the partner chose to accept the allocated method of treatment. We varied these costs extensively within the sensitivity analysis.

APTHotline

Using the information recorded on the web tool, we calculated the average duration of a hotline consultation with a partner and estimated the average cost of a consultation using the *Unit Costs of Health and Social Care 2013*.[80] In addition to the duration of the consultation, we included additional time for the health advisor to carry out administrative tasks such as registering patients (10 minutes) to reflect

trial practice and to ensure consistency with a previous study.[96] We also included costs associated with the purchase of a mobile phone and credit. We assumed that the phone unit could be reused for a period of 3 years and discounted costs accordingly (at an interest rate of 3%).

APTPharmacy

The average duration of a consultation with the community pharmacist was calculated using data recorded during the trial. The average cost of a consultation was estimated based on the *Unit Costs of Health and Social Care 2013*.[80] In addition to the duration of the consultation, we allowed an additional 10 minutes for the equivalent of a practice nurse to carry out administrative tasks such as registering patients, based on reported trial practice and to be consistent with the findings of a previous study.[96]

Standard partner notification

Analysis of resource use for standard partner notification was based on primary data recorded in the ClaSS project, which was carried out by a member of the research team (TR) and has also been used in subsequent studies.[49,96,102] As part of ClaSS, primary resource use and cost data associated with chlamydia testing and partner notification in a primary care and GUM setting were collected. We assumed that the process described in ClaSS was similar to standard partner treatment for the APT trial. The estimated cost of a consultation in ClaSS was £34.55 (in 2004/5 prices). Following the methods used to evaluate APT in a specialist care setting,[96] we subtracted the cost of treatment with azithromycin (£12.71) and the cost of a urine test (£4.47) from the ClaSS routine cost, resulting in a cost of £17.37 (in 2004/5 prices). We inflated this cost to 2012/13 prices giving a result of £21.62. We replaced the cost of the two items with the equivalent costs of the APT strategies (azithromycin and a testing kit) to ensure consistency between the trial arms. In addition, we included the cost of condoms and a STI leaflet as these are routinely given to patients in such consultations. In contrast to the previous APT study,[96,101] for routine partner notification we did not include costs relating to capturing details for research purposes, as such costs were not included for the other study arms.

Assumptions

To ensure a consistent approach to the comparative analysis of the intervention arms it was necessary to make a number of assumptions, which are summarised below:

- In the event of the trial being rolled out, a similar web tool to that developed in the trial would be used to enable communication between primary care and APT treatment services. We assumed that in the event of a roll-out a significant proportion of patients would be offered and take up APT and estimated costs for the web tool based on take-up at scale. Various assumptions about the costs associated with web tool maintenance and development were analysed within the sensitivity analysis.
- In the trial, primary care staff recorded index patient details and information about partners on the web tool as part of the consultation. We assumed that this process would not add significantly to the time required for the index consultation, based on information collected in the trial. Thus, additional time to record information on the web tool for the index consultation was not included in the base-case analysis but was explored within the sensitivity analysis.
- In cases in which index patients did not know the treatment method of partners we assumed that they had received 'standard partner treatment'. This was based on the fact that the partner had not been recorded as receiving treatment in either of the APT treatment arms.
- The mobile phone unit purchased for the APTHotline arm could be reused over a period of 3 years until it became outdated and costs were annuitised accordingly (at an interest rate of 3%).
- The staff needed to deliver the APTHotline would be able to undertake other tasks when not dealing with calls to the hotline. Hence, only the time taken to undertake consultations with partners was included in the analysis. This assumption was tested within the sensitivity analysis.
- For all treatment arms we assumed that, in addition to the time taken to undertake the consultation with partners, an additional 10 minutes would be spent on administrative tasks associated with registering the partner as a patient, etc. This was based on feedback from the trial and the findings of a similar trial in a specialist setting.[96] We assumed that such tasks would be undertaken by the equivalent of a practice nurse in all settings.

- For the standard treatment arm we assumed that costs and resource use would be similar to those previously reported in an empirical study concerned with chlamydia screening and partner notification (ClaSS).[49] We included the same treatment costs (for azithromycin) as recorded in the trial to enable comparison across trial arms.
- For partners in the APTHotline and APTPharmacy arms who did not receive treatment via the APT treatment strategies, we assumed that the costs of accessing treatment using alternative methods would be the same as those estimated for the standard treatment arm. As is shown elsewhere in the report, the highest proportion of partners treated in these arms received treatment at a GUM clinic.

Analysis

We compared costs and outcomes for all three trial arms separately in a cost–consequence analysis.[110] This form of analysis was deemed appropriate as the analysis was based on a pilot RCT. A cost–consequence analysis involves the assessment of costs and outcomes in a disaggregated manner to see if there is any strategy that shows clear dominance.[112] Dominance is said to occur when a strategy costs less but is more effective than another strategy in terms of the outcome achieved. A strategy is seen to be dominated when it costs more and is less effective than an alternative strategy. The methods of analysis followed those adopted in a previous study of APT in a specialist care (GUM clinic) setting,[96] with some adjustments to reflect differences in trial design. The primary cost–consequence analysis was based on the outcome of whether the index patient's partner(s) was considered to have been treated within 6 weeks of index diagnosis (intention to treat). In addition, the proportion of partners treated by each APT treatment option (APTHotline, APTPharmacy) within each study arm is presented.

A series of one-way deterministic sensitivity analyses were conducted. A probabilistic sensitivity analysis was not appropriate as this was a pilot trial and the results are illustrative and preliminary. We analysed uncertainties around all key cost and outcome parameters, specifying plausible ranges using information from the trial and from the literature. These analyses included (a) varying the costs associated with the web tool from £1 per player randomised to £20, to explore the potential impact of different take-up rates and web tool costs during roll-out; (b) including costs associated with recording information for index patients on the web tool, using information recorded in the trial; (c) increasing costs associated with the APTHotline consultations for a scenario in which hotline staff were less able to carry out other tasks between calls to the APTHotline service; (d) adjusting the cost of standard treatment; (e) including training costs for staff involved in inputting information on the web tool, using data recorded in the trial; and (f) varying the take-up of the APT strategies and standard partner notification. This included the application of estimates of take-up from a previous study in a specialist setting.[96] Further sensitivity analyses were carried out but are not reported.

In the reporting that follows, all cost data are presented in UK pounds in 2012/13 prices.

Results

The results of the trial have been reported in the first part of this chapter and are summarised in *Table 18*. *Table 22* shows that there was little difference in the proportion of partners considered treated within 6 weeks of index diagnosis between the standard treatment arm (46/102, 45%) and the APTHotline (39/111, 35%) and APTPharmacy (46/100, 46%) arms. The table also shows that, among partners considered treated in the

TABLE 22 Partner treatment outcomes for the study treatment arms

Study arm	Index patients, *n*	Contactable partners, *n*	Index patients followed up, *n* (%)	Partners treated, *n* (%)	Number of partners treated by APT treatment option, *n* (%)
APTHotline	68	111	50 (74)	39 (35)	8 (7)
APTPharmacy	65	100	42 (65)	46 (46)	14 (14)
Standard treatment	66	102	54 (82)	46 (45)	
Total	199	313	146	131	22

APTHotline arm, only 7% (8/111) received treatment via the hotline service and in the APTPharmacy arm only 14% (14/100) received treatment via a pharmacy. Other partners received treatment through standard partner notification routes such as GUM clinics or GP services.

The web tool and APT packs were common to both the APTPharmacy and APTHotline arms. The total cost of the APT pack was estimated to be £8.41 (*Table 23*). Full breakdowns of the health service costs associated with the APT treatment strategies are presented in *Tables 24* and *25*. Taking into account the likely uptake, the ongoing cost associated with the web tool was estimated to be £200–222 for the APT treatment arms. The cost associated with the text messaging service was £5.44 for the APTHotline arm

TABLE 23 Estimated cost of the APT pack

Item	Cost per item (£)	Number	Total cost (£)
Antibiotic pack[a]	5.90	1	5.90
Thermacor compact urine transporter (MedDXSolutions, Hereford, UK)	0.66	1	0.66
Urine container (30 ml)	0.15	1	0.15
Biohazard envelope	1.05	1	1.05
Information leaflet	0.03	1	0.03
Condoms	0.21	2	0.42
Outer envelope	0.20	1	0.20
Total			8.41

a Antibiotic costs were based on the prices recorded in the trial. The implications associated with adopting other prices (e.g. *British National Formulary*) were analysed within the sensitivity analysis.

TABLE 24 Health service costs for the APTHotline treatment arm

Resource use	Cost item	Unit cost (£)	*n*	Total cost (£)
Costs common to all randomised to APTHotline				
Web tool (ongoing costs)[a]	Per randomised partner	2.00	111	222.00
Consultation and treatment costs for those accessing APT treatment services				
Text message with APT treatment details	Per index	0.08	68	5.44
Mobile phone and credit				16.18
Consultation (non-eligible partners)[b]	Per non-eligible partner	2.93	2	5.86
Consultation (eligible partners)[c]	Per eligible partner	6.60	10	66.00
Administrative work (nurse)[d]	Per eligible partner	5.67	10	56.67
APT pack	Per partner treated	8.41	8	67.28
Consultation and treatment costs for those accessing standard partner notification				
Consultation and treatment	Per partner treated	30.10	31	933.10
Total cost for APTHotline treatment arm				1372.56
Average cost per partner treated			39	35.19

a Costs for the web tool were included for all randomised partners.
b Average non-eligible partner consultation duration was estimated to be 4 minutes as reported in the trial. The assumption was that the equivalent of a practice nurse would carry out the consultation (Personal Social Services Research Unit 2012/13 costs for patient time[80]).
c Average eligible partner consultation duration was estimated to be 9 minutes as reported in the trial. The assumption was that the equivalent of a practice nurse would carry out the consultation (Personal Social Services Research Unit 2012/13 costs for patient time[80]).
d An additional 10 minutes was assumed for administrative work (carried out by the equivalent of a practice nurse).

TABLE 25 Health service costs for the APTPharmacy treatment arm

Resource use	Cost item	Unit cost (£)	*n*	Total cost (£)
Costs common to all randomised to APTPharmacy				
Web tool (ongoing costs)[a]	Per randomised partner	2.00	100	200.00
Consultation and treatment costs for those accessing APT treatment services				
Text message with APT treatment details	Per index patient	0.08	65	5.20
Consultation (non-eligible partners)[b]	Per non-eligible partner	2.13	4	8.52
Consultation (eligible partners)[c]	Per eligible partner	8.53	14	119.42
Administrative work (nurse)[d]	Per eligible partner	5.67	14	79.38
APT pack	Per eligible partner	8.41	14	117.74
Consultation and treatment costs for those accessing standard partner notification				
Consultation and treatment	Per partner treated	30.10	32	963.20
Total cost for APTPharmacy treatment arm				1493.46
Average cost per partner treated			46	32.47

a Costs for the web tool were included for all randomised partners.
b Average non-eligible partner consultation duration was estimated to be 3 minutes as reported in the trial. The assumption was that the pharmacist would carry out the consultation (Personal Social Services Research Unit 2012/13 costs for patient time[80]).
c Average eligible partner consultation duration was estimated to be 8 minutes as reported in the trial. The assumption was that the pharmacist would carry out the consultation (Personal Social Services Research Unit 2012/13 costs for patient-related activities[80]).
d An additional 10 minutes was assumed for administrative work (carried out by the equivalent of a practice nurse).

and £5.20 for APTPharmacy (see *Tables 24* and *25*). The average cost per partner treated for the APTHotline arm was estimated to be £35.19 and that for the APTPharmacy arm was £32.47.

The breakdown of costs for standard partner treatment is shown in *Table 26*. The average cost per partner treated for the standard treatment arm was £30.10. The standard treatment arm had the lowest average cost per partner treated of the three trial arms.

Table 27 presents a summary of the total costs and outcomes for the APT treatment arms compared with the standard treatment arm. The number of partners considered to be treated is shown as well as information about the number of partners treated by the two APT treatment options.

TABLE 26 Cost of routine sexual health check-up in the clinic: standard treatment arm

Resource use	Cost item	Unit cost (£)	*n*	Total cost (£)
Standard treatment minus drug minus test[a]	Per partner	21.62	1	21.62
Antibiotics	Per partner	5.90	1	5.90
Testing kit	Per partner	0.81	1	1.86
Information leaflet	Per partner	0.10	1	0.10
Condoms	Per partner	0.21	2	0.42
Outer envelope	Per partner	0.20	1	0.20
Total cost of standard treatment				30.10

a Cost for routine sexual health check-up inflated to 2012/13 prices.

TABLE 27 Summary of the total costs and outcomes for the APT treatment arms compared with the standard treatment arm

Study arm	Total cost (£)	Average cost per partner treated (£)	Number of partners considered treated, *n* (%)	Number of partners treated by APT treatment option, *n* (%)
APTHotline	1372.56	35.19	46 (46)	8 (7)
APTPharmacy	1493.46	32.47	39 (35)	14 (14)
Standard treatment	1384.60	30.10	46 (45)	

The cost–consequence analysis examined the costs of all three arms and compared their outcomes in terms of the number of partners considered treated. The results in *Table 27* show that there was little difference in the proportion of partners considered treated between the standard treatment arm and the APT treatment arms. The APTHotline and APTPharmacy arms had a higher average cost per partner treated than the standard treatment arm, primarily because of the additional costs associated with the web tool and text messaging, which were not required for partners receiving standard treatment. The total cost associated with the APTPharmacy arm was higher than the total cost associated with the APTHotline arm because of the higher costs associated with the pharmacist carrying out partner consultations. However, the cost per partner treated in the APTPharmacy arm was lower than that for the APTHotline arm because of the higher number of patients receiving treatment (the denominator). Both the APTHotline arm and the APTPharmacy arm had a low proportion of partners treated by APT treatment services (7% and 14%, respectively), with the majority of partners receiving treatment from other services.

These preliminary results do not suggest that the additional costs associated with the APT strategies can be balanced against increased effectiveness in achieving partner notification, as the proportion of partners considered treated in the standard treatment arm was similar to the proportions considered treated in the APT treatment arms and the cost was lower. It is also evident that a high proportion of partners considered treated in the APTHotline and APTPharmacy arms received treatment using standard partner notification methods (e.g. general practice or specialist sexual health services).

Sensitivity analysis

As demonstrated in *Table 28*, the results of the sensitivity analysis were as follows: (a) increasing the costs associated with the web tool increased overall costs for the APT treatment strategies, with the cost per partner treated increasing to a maximum of £86.42 for APTHotline and £71.60 for APTPharmacy; (b) including costs associated with recording information for index patients on the web tool increased overall costs for both APT strategies; (c) increasing the staffing costs associated with the APTHotline service made this arm more expensive; however, as feedback from the trial revealed that hotline staff were able to carry out other tasks when not speaking to partners, we would not expect the additional impact of staffing the hotline to be substantial; (d) increasing the cost of standard partner notification naturally meant that the APT strategies were less costly in comparison; hence, it is important to estimate such costs accurately; (e) including training costs for staff involved in inputting information on the web tool increased the costs associated with the APT treatment strategies; however, these are one-off costs that would become negligible if the trial were rolled out at scale; and (f) increasing the estimated take-up of the APT strategies (e.g. using take-up estimates from a previous study) made these strategies more cost-effective as the increased costs associated with the strategies were balanced out by increased effectiveness in achieving partner treatment.

Discussion

The results of this preliminary cost–consequence analysis suggest that, although APTHotline and APTPharmacy have been demonstrated to be cost-effective alternative strategies to routine partner notification in specialist settings,[96] further evidence is needed about their potential within a primary care

TABLE 28 Sensitivity analysis: selected results

Sensitivity analysis	Original value	Revised value	APTHotline total cost (average cost per partner treated)	APTPharmacy total cost (average cost per partner treated)	Standard treatment total cost (average cost per partner treated)
Base case			£1372.56 (£35.19)	£1493.46 (£32.47)	£1384.60 (£30.10)
Varying the costs associated with the web tool for APT arms	£2 per randomised partner	£1–20 per randomised partner	£1261.56–3370.56 (£32.35–86.42)	£1393.46–3293.46 (£30.29–71.60)	
Including costs associated with recording index information on the web tool for APT arms		£6.60 per index patient	£1821.36 (£46.70)	£1942.26 (£42.22)	
Increasing staffing costs for APTHotline	£6.60 per eligible partner (9 minutes) and £2.93 per ineligible partner (4 minutes)	£14.67 per eligible partner (20 minutes) and £7.33 per ineligible partner (10 minutes)	£1462.03 (£37.49)		
Adjusting the cost of standard treatment	£30.10 per partner treated	£36.67 per partner treated	£1576.23 (£40.42)	£1703.7 (£37.04)	£1686.82 (£36.67)
Including training costs for the web tool		£939.17 for primary care staff training, £612 for pharmacy staff training and £11.33 for hotline staff training	£1853.48 (£47.53)	£2575.04 (£55.98)	
Varying the take-up of APT strategies	APTHotline 46%, APTPharmacy 35%, standard treatment 45%	APTHotline 59%, APTPharmacy 66%, standard treatment 36%	£1917.4 (£29.15)	£1933.72 (£29.34)	£1102.12 (£30.10)

Note
Costs are in UK pounds (2012/13).

setting. The proportion of partners treated was lower than was demonstrated by a previous trial of APT in specialist services, which meant that the higher fixed costs associated with the APT treatment strategies were not offset by a higher proportion of partners treated (as was found in the trial in the specialist setting). The reasons why partners did not elect to access APT treatment strategies in the APT treatment arms requires further investigation. However, overall partner notification outcomes were superior to those reported in previous studies in similar settings, suggesting that further work is needed to explore strategies to optimise partner notification outside specialist settings.

This is the first study to collect and analyse costs and outcomes for APT in a primary care setting in the UK, as previous studies have been concerned with APT within a specialist care setting. Its main strength is that costs and resource use were collected prospectively within a pilot RCT. There are several limitations associated with the study. The ability to follow up index patients varied by study arm, which had an impact on the denominators used to calculate the proportion of partners treated. In addition, the primary outcome relied on index-reported results, rather than being sex partner verified, which potentially reduces the robustness of outcome measurement. To ensure consistency between study arms a number of assumptions were made within the economic analysis. Although these assumptions were tested within the sensitivity analysis, further exploration of such factors would be required before the interventions were rolled out.

The poorer uptake of APT treatment strategies in the primary care setting compared with previous findings in a GUM setting may reflect the fact that for the current study index patients were randomised to a treatment arm and were not able to choose a partner notification approach. Further analysis is planned that will examine the likely impact of allowing index patients to choose a treatment strategy for their partners in a primary care setting. This will use data previously collected on partner type and treatment strategy selection to assess the likely impact of such factors on cost-effectiveness.

Chapter 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

Abstract

Introduction: The optimal strategies for increasing men's uptake of STI testing and the acceptability and public health impact of screening in different settings are poorly understood.

Objectives: (1) To explore the medical, sporting and social venues that young men find acceptable for accessing STI screening and determine the optimal models of screening therein; (2) to undertake a pilot RCT of two screening interventions in football settings; and (3) to explore the public health impact of screening in football settings.

Methods: (1) Stratified random probability survey of men aged 18–35 years; (2) qualitative study of men's preferences for STI screening; (3) pilot cluster RCT of two STI screening interventions in football clubs with an integral health economic evaluation; and (4) anonymous questionnaire survey of men's STI risk and prior health service use.

Results: Willingness to access self-sampling kits for STIs and HIV infection was high. Traditional health-care settings, such as general practice and GUM services, were preferred but sports venues were acceptable to half of men who played sport. Uptake of screening in the RCT was high irrespective of arm and costs of the interventions were similar. Men were at risk of STIs but previous testing was common.

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.

Background

Over the last decade, there has been a sustained rise in the number of reported STIs in men and women[90] and the number of reported chlamydial infections in men is similar to that in women.[90] However, men's uptake of chlamydia screening within the English NCSP has been substantially lower than that reported for women.[90] Although the proportion of men being tested is rising, in 2013 the NCSP tested twice as many women as men.[116]

Over the last decade, highly sensitive and specific tests have been developed for the diagnosis of chlamydia and other infections such as *N. gonorrhoeae* and HIV, which can be performed on non-invasive, self-collected samples.[23,117] As a result, testing for STIs and HIV can now be conducted in a variety of non-health-care settings without the need for access to microscopy or interaction with HCPs. These technological advances have underpinned the development of the NCSP in England.

More than half of the NCSP tests carried out on women are carried out in 'core services' (general practice, CASH services and pharmacies).[118] In contrast, around one-quarter of tests on men are carried out in 'core services', with testing more commonly occurring in 'outreach' and non-health-care settings.[118] Positivity rates of men tested by the NCSP in non-health-care settings are generally lower than those from men tested in core services.[119] This suggests that screening men in non-health-care settings may have a limited impact on public health, as it is not only the coverage of screening that is important but also ensuring that populations with the highest prevalence of infection are tested.[67] The difference in approach to screening for men as opposed to women has probably developed as a result of widely held perceptions that young men are infrequent attenders at general practice whereas women are believed to attend more frequently and have multiple opportunities for screening as part of 'routine' visits for related health needs such as contraception. Data do not support this view[16] and the vast majority of men have attended their GP within the last year.[59] In spite of this, there appears to be a mismatch between GP's perceptions of men's low attendance rates and reality.[102]

Evidence suggests that, although women of reproductive age bear the majority of adverse health consequences of chlamydial infection,[120] the inclusion of men in screening efforts can be effective in reducing the population burden of infection.[23,121] However, this may be less cost-effective than other strategies such as improving the effectiveness of partner notification.[117,122,123] It is also possible that the inequity in screening uptake may inadvertently fuel the perception that chlamydia is a woman's infection, which could lead to a situation in which 'men have been effectively silenced on these issues . . . if both responsibility and accountability are defined as exclusively female, men have neither the social means nor the personal motivation to take a more active interest' (p. 932).[124] Mindful of these factors, it is generally accepted that efforts should be made to engage more men with STI screening and the Department of Health has commissioned research to look specifically at this issue.[125]

Men's lower uptake of screening could be explained by differences in men's and women's health-seeking behaviours, underpinned by different beliefs about health and illness.[116,126,127] However, growing evidence suggests that men are beginning to appreciate the rationale for STI screening and have clear preferences for how and where they would like to access it.[72,128–133] To date there has been limited success in implementing effective male STI screening in primary care in England, suggesting that offering men screening in other settings remains important.

Sports settings offer the potential for STI screening activities for men who engage in sport and STI screening in some sports settings has been undertaken in the UK and overseas in a variety of ways and with varying degrees of success. The aim of such initiatives has been to encourage more men to test for STIs and to engage in

general health care.[134–136] In a recent English survey, 40% of men (aged > 16 years) reported participating in sport at least once a week.[137] Football is the most popular team sport in England, with over 16% of those aged 14–25 years playing at least once a week.[137] Many teams operate within a national league structure, which could facilitate widespread implementation of new interventions. Although this suggests that football venues could provide feasible settings in which to provide large numbers of men with access to STI and HIV testing, the acceptability of this approach is poorly understood.

The optimal approach to offering screening in other settings is also unknown. Involving people who are not medically trained to impart information about sexual health, testing and treatment offers potential and seems to be well accepted by targeted populations.[138–140] Two broad types of 'promoter' have been used: peers and opinion leaders. A peer is 'a person of the same standing or rank as the person(s) in question; a person or thing of the same effectiveness or ability as the one(s) in question; an equal' (p. 795),[141] although this definition is rarely strictly adhered to in studies. A popular opinion leader is a more complex concept to define but involves 'the degree to which an individual is able to influence other individuals' attitudes or overt behaviour informally in a desired way with relative frequency' (p. 27).[142] Although several theories potentially help to explain the use of popular opinion leaders to encourage men to screen for STIs and HIV,[143] no one theory explains all of the processes involved and often no underlying theory is stated in published studies of peer-led and popular opinion leader-led interventions. These approaches have not been evaluated as a means of promoting sexual health in sports settings in the UK.

To investigate these issues we conducted three research studies with the following overarching aims and specific objectives.

Aims

- To explore the medical, sporting and social venues that young men find acceptable and feasible for accessing STI screening and to determine the models of screening that young men consider acceptable and feasible in those contexts (phase 1).
- To undertake a pilot RCT of two screening interventions in sports settings (phase 2).

Specific objectives

- To determine young men's usage of medical, sporting and leisure venues.
- To determine which venues young men would find acceptable and feasible for accessing STI screening.
- To develop through qualitative research and consumer and stakeholder consultation two feasible and replicable interventions for delivering STI screening in football club venues.
- To determine the acceptability to young men and feasibility of football trainer-led STI and HIV screening.
- To undertake a pilot RCT of football captain-led STI screening in two contrasting football clubs in different geographical areas.
- To determine the uptake of STI screening by young men in football club settings.
- To obtain cost data for the football captain-led STI screening strategies to use in a preliminary economic evaluation.

Phase 1: random probability survey of men's sexual health-care usage and preferences and leisure and sporting activities

Objectives

- To determine young men's usage of medical, sporting and leisure venues.
- To determine which venues young men would find acceptable and feasible for accessing STI screening.

Here, we report findings from a stratified random probability survey that explored the medical, social and sporting venues in which men aged 18–35 years and resident in the UK find it acceptable to access self-collected testing kits for STIs and HIV infection. We also aimed to determine whether or not those men who play football would find their football venues acceptable as pick-up points for self-testing kits in an attempt to further understand the acceptability and feasibility of using football settings to engage men in STI testing.

Methods

Our study formed part of the National Centre for Social Research (NatCen) quarterly social research survey (Omnibus).[144] This is a stratified random probability survey of adults aged > 16 years in the UK. A multistage sampling design technique is used for the Omnibus survey. First, postcode sectors are ordered according to government office regions and the national statistics socioeconomic classification before selecting 153 sectors. Twenty addresses are then selected from the postcode address file for each of the 153 postcode sectors. This gives a total sample size of 3060 addresses. Finally, a single participant aged > 16 years is selected at random from these addresses (although questions relating to our study were delivered only to men aged between 18 and 35 years). Appropriate selection and calibration weights are applied to correct for the unequal probability of selection in households of different numbers of occupants and to ensure that the weighted distributions match population totals. The Omnibus survey is conducted in accordance with the Social Research Association ethical guidelines.[145]

We developed 10 questions exploring the use of general and sexual health care; key sexual risk behaviours; participation in sporting activities; and the acceptability of self-collected STI and HIV testing in a variety of medical, social and recreational settings. When applicable we used questions validated for the National Surveys of Sexual Attitudes and Lifestyles (Natsal).[146] Surveys were delivered using a combination of computer-assisted personal interviewing and self-interviewing techniques. Questions were piloted with researchers at NatCen prior to inclusion in the survey and the survey programme was tested for correct routing; internal range and consistency error warnings were also created.

Data were collected in three waves between January and October 2010. Selected participants were sent an invitation letter prior to the interview together with an unconditional £5 voucher. Interviewers called at each address on at least six, and a maximum of nine, separate occasions at different times of the day and week, including evenings and weekends, before an address was recorded as a non-response. The first three calls were conducted after 6 p.m. on Monday to Thursday or at a weekend. In an attempt to increase participation and the accuracy of the data recorded, more sensitive questions were completed by participants without the interviewers seeing their responses and data were immediately and confidentially stored on the laptop computers. Interviews lasted between 25 and 30 minutes.

Coding of the data was performed by researchers at NatCen. Free-text responses to questions were back-coded when possible into existing codes for that question. New code frames were created for open questions from responses given in initial interviews.

Statistical methods

A sample size of 225 men aged 18–35 years was calculated to provide adequate statistical power (80%) to detect clinically important differences in key predictors at the 5% level. However, over the course of three Omnibus waves, data were collected from 411 men, enabling more precise estimates to be obtained.

The chi-squared statistic was used to detect statistically significant differences in proportions between men aged 18–24 years, men aged 25–29 years and men aged 30–35 years. Data were analysed using the statistical package Stata (version 12) to account for the complex survey design of the Omnibus survey. Statistical significance is considered as $p < 0.05$ for all analyses.

Results

The three waves of the survey had an overall response rate of 53%. The median age of men was 28 years, with 130 men (38.9%) aged 18–24 years, 124 men (28.2%) aged 25–29 years and 157 men (32.9%) aged 30–35 years.

Health-care use and previous sexually transmitted infection/human immunodeficiency virus testing

Almost all men (93.5%) were registered with a general practice and 75.3% had seen their GP within the last year (*Table 29*), with no difference by age group. In total, 28.7% and 19.8% of men had previously tested for STIs and HIV infection respectively. Among those who had tested for STIs, 68.2% (95% CI 52.2% to 80.7%) of men aged < 25 years had done so in the last year compared with 30.4% (95% CI 17.1% to 48.1%) of men aged 25–29 years and 9.1% (95% CI 2.3% to 29.8%) of men aged 30–35 years ($p < 0.001$). Of the men who had previously tested for HIV, those aged < 25 years were more likely to have tested in the last year than older men [25–29 years: 69.9% (95% CI 45.7% to 86.5%); 30–35 years: 20.0% (95% CI 10.4% to 35.0%); $p = 0.0004$]. The majority of STI and HIV tests had been performed in a clinical setting with over half of men reporting testing in sexual health (GUM) clinics and approximately one in six reporting testing in general practice. Relatively few men reported testing for STIs in non-clinical settings.

Behavioural factors

In total, 86.2% of all men reported at least one sexual partner in the last year, with 73.4% reporting at least one sexual partner over the last 3 months (*Table 30*). Younger men reported greater numbers of sexual partners over the last year and the last 3 months than men in the older age groups ($p < 0.001$ and $p = 0.003$ respectively). Condom use was greatest in men aged < 25 years, with 34.7% reporting using condoms every time they had sex in the last 3 months in comparison to less than one-quarter of men aged ≥ 25 years ($p < 0.001$). Among men who had had sex, 3.8% reported that the gender of their last sexual partner was male and this did not vary by age group.

Willingness to use self-collected testing kits for sexually transmitted infections (urine) and human immunodeficiency virus (oral fluid) and acceptability of different settings

The majority of men were willing to provide a self-collected sample for STI/HIV testing (*Table 31*). Specifically, 85.1% of all men reported that they were willing to provide a urine sample for STI testing, with no variation by age group, whereas 86.9% of all men reported their willingness to provide an oral fluid sample for HIV testing, although this did vary by age group, from 79.7% of men aged 25–29 years to 95.0% of men aged 18–24 years ($p = 0.001$). General practices (79.7%), sexual health clinics (66.8%) and pharmacies (65.4%) were the most acceptable test kit pick-up points, with no variation by age. Further education settings were more popular than school settings as pick-up points (41.6% vs. 28.1%), whereas the workplace was acceptable to 22.4% of all men. Gyms and sports centres were considered acceptable pick-up points by 18.5% and 13.4% of all men, respectively, with no variation by age.

Participation in sport

In total, 69.4% (95% CI 63.9% to 74.5%) of all men had participated in a sporting activity at least once within the 4 weeks prior to interview, with this proportion greatest among men aged > 30 years [78.3% (95% CI 69.7% to 84.9%) vs. 65.9% (95% CI 59.0% to 72.2%) among men aged 18–29 years; $p = 0.0189$] (*Table 32*). Among all men aged 18–35 years, the five most popular activities to participate in were football (soccer) [52.9% (95% CI 46.2% to 59.5%)], jogging [45.4% (95% CI 38.7% to 52.2%)], gym [36.8% (95% CI 30.3% to 43.8%)], cycling [31.9% (95% CI 26.0% to 38.6%] and swimming [29.6% (95% CI 23.9% to 35.9%)]. Men aged < 30 years were more likely to have participated in football than men aged at least 30 years [57.5% (95% CI 49.2% to 65.4%) vs. 43.3% (95% CI 33.1% to 54.0%); $p = 0.033$], with 74.4% (95% CI 65.2% to 81.8%) of men who played football reporting that they played at least once a week (no variation by age group).

TABLE 29 Factors related to health service use among men aged 18–35 years

Factor	All men		18–24 years		25–29 years		30–35 years		*p*-value for difference between age groups
	%	95% CI	%	95% CI	%	95% CI	%	95% CI	
Denominator (unweighted, weighted)[a]	411, 632		130, 246		124, 178		157, 208		
Factors related to health service use									
Registered with a general practice	93.5	90.2 to 95.7	92.5	86.6 to 96.0	93.5	84.8 to 97.5	94.8	90.0 to 97.3	0.778
Been to a GP in the last 12 months	75.3	70.2 to 79.8	73.9	65.1 to 81.1	78.4	69.3 to 85.3	74.1	65.2 to 81.4	0.694
Ever been tested for STIs	28.7	23.9 to 34.1	27.1	19.4 to 36.6	34.8	26.4 to 44.2	24.8	17.3 to 34.1	0.275
Time since last STI test (if ever tested for STIs)									< 0.001
< 1 month	4.4	1.6 to 11.8	9.3	2.8 to 26.4	2.3	0.3 to 15.1	0	NA	
> 1 month but < 6 months	10.0	5.4 to 17.9	15.1	6.2 to 32.4	11.5	5.0 to 24.5	0	NA	
> 6 months but < 1 year	25.2	17.1 to 35.6	43.8	28.2 to 60.7	16.6	6.2 to 37.4	9.1	2.3 to 29.8	
> 1 year but < 5 years	37.0	28.7 to 46.1	30.2	17.9 to 46.0	44.5	30.0 to 60.0	36.7	22.2 to 54.0	
> 5 years	23.4	16.3 to 32.3	1.7	0.2 to 11.5	25.1	13.5 to 41.9	54.3	34.9 to 72.5	
Where last tested for STIs									0.272
GUM clinic	53.4	43.5 to 63.1	44.7	28.2 to 62.5	55.1	38.6 to 70.5	64.4	46.6 to 78.9	
GP surgery	17.1	10.9 to 25.8	24.7	13.1 to 41.7	12.2	5.8 to 24.0	12.6	4.2 to 32.6	
NHS walk-in centre	8.3	3.3 to 19.0	12.1	4.0 to 31.5	9.9	2.3 to 34.4	0.0	NA	
Family planning clinic	6.6	2.9 to 14.5	3.5	0.5 to 21.6	9.6	3.8 to 22.1	7.2	1.6 to 27.2	
University/college health centre	4.4	1.5 to 12.2	10.4	3.3 to 28.7	1.2	0.2 to 8.5	0.0	NA	
Private medical clinic	1.7	0.5 to 5.5	1.6	0.2 to 11.0	1.1	0.2 to 8.0	2.8	0.4 to 17.3	
Pharmacy	0.9	0.1 to 6.6	0.0	NA	0.0	NA	3.7	0.5 to 22.8	
Internet test	1.1	0.2 to 7.9	3.0	0.4 to 18.9	0.0	NA	0.0	NA	
A&E department	1.3	0.3 to 5.4	0.0	NA	2.3	0.3 to 15.1	1.9	0.3 to 12.7	
Somewhere else	5.0	2.0 to 12.0	0.0	NA	8.6	2.6 to 25.1	7.5	1.8 to 26.3	

Factor	All men		18–24 years		25–29 years		30–35 years		*p*-value for difference between age groups
	%	95% CI	%	95% CI	%	95% CI	%	95% CI	
Ever had a blood test for HIV	19.8	15.7 to 24.6	15.7	9.7 to 24.2	25.9	18.3 to 35.2	19.3	12.9 to 27.8	0.172
Time since last HIV test (if ever tested for HIV)									0.012
< 1 month	10.4	4.3 to 23.2	19.6	5.9 to 48.4	7.4	1.4 to 30.7	4.2	0.6 to 25.5	
> 1 month but < 6 months	11.1	5.0 to 22.8	24.5	9.1 to 51.3	5.8	1.3 to 22.6	3.2	0.4 to 20.8	
> 6 months but < 1 year	14.7	7.1 to 27.9	25.9	9.5 to 53.8	8.7	2.6 to 25.0	10.1	2.3 to 34.6	
> 1 year but < 5 years	37.7	26.3 to 50.7	30.1	13.5 to 54.4	38.3	22.3 to 57.4	45.6	25.1 to 67.6	
> 5 years	26.1	17.0 to 37.9	0.0	NA	39.9	23.4 to 59.2	36.9	19.3 to 59.0	
Where last tested for HIV									0.198
GUM clinic	50.8	38.2 to 63.4	45.9	23.8 to 69.8	59.2	40.1 to 75.9	45.1	25.1 to 66.7	
GP surgery	16.0	8.1 to 29.3	27.1	10.1 to 55.2	9.1	2.1 to 31.8	12.9	3.9 to 34.9	
Family planning clinic	6.7	2.8 to 15.2	10.7	2.9 to 32.7	6.3	1.5 to 23.0	2.7	0.4 to 17.9	
Private medical clinic	5.7	1.8 to 16.6	0.0	NA	5.0	1.1 to 20.2	13.3	2.9 to 43.9	
NHS walk-in centre	4.4	1.0 to 17.6	13.6	3.1 to 43.4	0.0	NA	0.0	NA	
University/college health centre	4.1	1.2 to 12.8	0.0	NA	5.8	1.3 to 22.8	6.5	0.9 to 35.2	
A&E department	1.2	0.2 to 8.2	0.0	NA	3.0	0.4 to 19.2	0.0	NA	
Somewhere else	11.0	5.4 to 21.0	2.6	0.3 to 17.6	11.7	3.5 to 32.5	19.6	7.8 to 41.5	

A&E, accident and emergency; NA, not applicable.
a Percentages presented for weighted sample.

TABLE 30 Key sexual risk behaviours among men aged 18–35 years

Behaviour	All men		18–24 years		25–29 years		30–35 years		*p*-value for difference between age-groups
	%	95% CI	%	95% CI	%	95% CI	%	95% CI	
Denominator (unweighted, weighted)[a]	411, 632		130, 246		124, 178		157, 208		
Number of partners in the last year									< 0.001
0	13.8	10.1 to 18.7	17.8	11.1 to 27.4	13.8	7.8 to 23.2	8.2	4.5 to 14.6	
1	61.4	55.8 to 66.6	43.5	34.6 to 52.9	66.2	56.2 to 74.9	81.8	73.7 to 87.8	
2	8.9	6.2 to 12.5	14.0	8.8 to 21.5	6.0	2.8 to 12.6	4.5	2.3 to 8.6	
3–4	8.0	5.3 to 11.9	10.3	5.6 to 18.4	9.3	4.7 to 17.8	3.3	1.4 to 7.6	
5+	8.0	5.3 to 11.9	14.3	8.7 to 22.7	4.8	2.4 to 9.2	2.2	0.5 to 9.4	
Median number of partners (lower, upper quartiles)	1 (1, 2)		1 (1, 2)		1 (1, 1)		1 (1, 1)		
Number of partners in the last 3 months									0.003
0	26.6	21.4 to 32.6	34.4	25.3 to 44.9	26.7	18.1 to 37.4	15.4	10.1 to 23.0	
1	65.4	59.3 to 70.9	52.7	42.5 to 62.6	66.9	55.8 to 76.4	81.7	73.6 to 87.7	
2+	8.1	5.4 to 11.9	12.9	7.6 to 21.1	6.4	3.1 to 12.9	2.9	0.9 to 9.0	
Condom use in last 3 months									< 0.001
Every time	26.9	21.3 to 33.4	34.7	24.5 to 46.6	22.6	14.7 to 33.0	22.0	14.4 to 32.1	
Sometimes	24.7	19.4 to 31.0	36.9	26.4 to 48.9	19.5	12.0 to 30.1	15.8	9.5 to 25.3	
Not at all	48.4	41.8 to 55.0	28.4	18.7 to 40.5	58.0	46.7 to 68.4	62.2	51.6 to 71.7	
Last sexual partner was male (if had sex)	3.8	2.2 to 6.4	4.5	1.9 to 10.5	4.9	2.1 to 11.2	1.6	0.5 to 5.4	0.345

a Percentages presented for weighted sample.

TABLE 31 Willingness to use self-collected STI and HIV testing kits and acceptable pick-up points for tests among men aged 18–35 years

Factors	All men (95% CI) (%)	18–24 years (95% CI) (%)	25–29 years (95% CI) (%)	30–35 years (95% CI) (%)	*p*-value	Footballers (95% CI) (%)	Non-footballers (95% CI) (%)	*p*-value
Willingness to use novel methods for testing								
Willing to provide urine sample for STI testing	85.1 (80.1 to 88.8)	88.7 (81.0 to 93.5)	82.1 (71.2 to 89.5)	83.1 (75.2 to 88.9)	0.3687	88.6 (80.8–93.4)	83.1 (76.9 to 87.9)	0.2244
Willing to provide mouth swab for HIV testing	86.9 (82.4 to 90.4)	95.0 (89.7 to 97.6)	79.7 (69.9 to 87.0)	82.7 (74.2 to 88.9)	0.001	90.2 (82.2 to 94.8)	85.1 (79.1 to 89.5)	0.2320
Acceptable pick-up points for testing kits								
General practice	79.7 (74.5 to 84.2)	79.3 (70.0 to 86.3)	76.4 (66.1 to 84.3)	83.7 (74.7 to 90.0)	0.5195	78.2 (69.1 to 85.2)	80.6 (74.2 to 85.8)	0.6167
GUM clinic	66.8 (60.8 to 72.3)	68.2 (58.4 to 76.6)	62.8 (52.3 to 72.3)	68.7 (58.5 to 77.3)	0.6563	65.6 (55.7 to 74.3)	67.5 (60.0 to 74.2)	0.7518
Pharmacy	65.4 (59.4 to 71.0)	64.4 (54.3 to 73.4)	57.9 (46.9 to 68.2)	74.4 (64.2 to 82.5)	0.0947	63.5 (53.4 to 72.5)	66.6 (59.0 to 73.4)	0.6108
Sent in the post	52.2 (46.4 to 58.0)	53.5 (43.4 to 63.3)	51.4 (40.9 to 61.9)	51.1 (41.5 to 60.6)	0.9271	55.9 (46.2 to 65.1)	50.1 (42.5 to 57.7)	0.3699
College/university campus	41.6 (35.9 to 47.6)	47.4 (38.1 to 56.9)	34.2 (24.7 to 45.1)	40.3 (31.2 to 50.1)	0.1540	54.1 (43.9 to 63.9)	34.4 (27.7 to 41.7)	0.0024
School	28.1 (23.0 to 33.8)	25.8 (18.0 to 35.4)	29.2 (20.2 to 40.3)	30.5 (22.1 to 40.4)	0.7435	34.4 (25.6 to 44.5)	24.4 (18.6 to 31.3)	0.0834
Workplace	22.4 (17.8 to 27.8)	16.2 (10.0 to 25.2)	24.0 (16.3 to 33.9)	30.1 (21.6 to 40.2)	0.0636	26.0 (18.0 to 36.0)	20.2 (15.1 to 26.6)	0.2693
Youth club	20.8 (16.3 to 26.2)	23.4 (16.1 to 32.7)	15.9 (9.6 to 25.1)	21.9 (14.6 to 31.4)	0.4056	31.3 (22.7 to 41.4)	14.7 (10.2 to 20.7)	0.0013
Gym	18.5 (14.5 to 23.4)	13.9 (8.2 to 22.6)	20.0 (13.1 to 29.3)	24.1 (16.9 to 33.0)	0.1673	23.2 (15.8 to 32.7)	15.9 (11.4 to 21.7)	0.1368
Bar/pub/nightclub	17.3 (13.3 to 22.3)	16.1 (10.0 to 24.9)	14.9 (9.1 to 23.5)	21.5 (14.3 to 30.9)	0.4711	18.8 (12.2 to 27.8)	16.5 (11.7 to 22.7)	0.6263
Recreational/leisure/sport centre/swimming pool	13.4 (9.9 to 17.9)	9.1 (4.8 to 16.5)	15.5 (9.4 to 24.4)	17.9 (11.4 to 27.0)	0.1485	16.3 (10.4 to 24.7)	11.7 (7.9 to 17.0)	0.2436
Sports club	11.7 (8.4 to 16.1)	8.0 (3.9 to 15.7)	13.4 (8.0 to 21.7)	15.5 (9.3 to 24.2)	0.2186	11.9 (6.7 to 20.3)	11.5 (7.7 to 16.9)	0.9298
Coffee shop/café	6.9 (4.6 to 10.3)	2.6 (0.9 to 7.4)	9.8 (5.2 to 17.7)	10.6 (5.8 to 18.7)	0.0309	7.4 (3.8 to 14.0)	6.6 (3.9 to 10.9)	0.7778
Other	0.4 (0.0 to 3.0)	1.0 (0.1 to 6.7)	0.0	0.0%	0.4700	0.0	0.7 (0.0 to 4.6)	0.4438

TABLE 32 Participation in sport among men aged 18–35 years

Factors	All men (95% CI) (%)	18–24 years (95% CI) (%)	25–29 years (95% CI) (%)	30–35 years (95% CI) (%)	*p*-value
Taken part in sport/physical activity in last 4 weeks	69.4 (63.9 to 74.5)	68.3 (58.7 to 76.6)	62.5 (52.1 to 71.8)	78.3 (69.7 to 84.9)	0.0637
Activities taken part in					
Football	52.9 (46.2 to 59.5)	59.2 (47.6 to 69.9)	55.0 (43.5 to 66.0)	43.3 (33.1 to 54.0)	0.1052
Jogging	45.4 (38.7 to 52.2)	43.6 (32.4 to 55.5)	42.0 (30.8 to 54.0)	50.4 (39.8 to 60.9)	0.5599
Gym/health club	36.8 (30.3 to 43.8)	37.4 (26.5 to 49.7)	43.7 (31.6 to 56.5)	30.2 (21.2 to 41.0)	0.2964
Cycling	31.9 (26.0 to 38.6)	35.3 (25.1 to 47.0)	20.8 (13.0 to 31.6)	37.1 (27.2 to 48.2)	0.0878
Swimming	29.6 (23.9 to 35.9)	30.8 (21.0 to 42.8)	34.6 (23.5 to 47.7)	23.9 (16.3 to 33.5)	0.4029
Martial arts	7.7 (4.5 to 12.7)	13.2 (6.8 to 24.1)	2.8 (0.7 to 10.6)	5.0 (4.5 to 12.7)	0.0386
Athletics	6.6 (3.9 to 11.1)	9.8 (4.7 to 19.3)	5.3 (2.0 to 13.8)	3.8 (1.5 to 9.2)	0.2070
Badminton	6.0 (3.5 to 10.3)	8.6 (3.8 to 18.4)	5.6 (2.1 to 13.8)	3.3 (1.2 to 8.8)	0.3110
Cricket	5.9 (3.1 to 11.2)	11.2 (5.5 to 21.6)	5.2 (1.1 to 21.1)	0	0.0572
Boxing	5.5 (3.2 to 9.3)	5.4 (2.0 to 13.8)	7.8 (3.5 to 16.7)	3.7 (12.7 to 10.1)	0.5539
Tennis	5.3 (2.7 to 10.1)	4.7 (1.5 to 13.3)	6.9 (2.0 to 21.1)	4.7 (1.6 to 13.5)	0.8488
Basketball	3.2 (1.5 to 6.5)	6.2 (2.6 to 13.8)	0	2.1 (0.5 to 8.1)	0.0701
Rowing	2.5 (1.0 to 5.9)	3.0 (0.6 to 12.9)	2.6 (0.8 to 8.4)	1.7 (0.4 to 7.2)	0.8304
Rugby union	1.7 (0.7 to 4.1)	0.9 (0.1 to 6.5)	1.9 (0.4 to 7.9)	2.5 (0.6 to 9.4)	0.6912
Rugby league	1.8 (0.7 to 4.6)	3.5 (1.1 to 10.3)	1.3 (0.2 to 8.5)	0	0.1916
Hockey (field)	1.6 (0.4 to 5.7)	3.5 (0.8 to 13.6)	0.6 (0.0 to 4.5)	0	0.1793
Other	12.6 (8.7 to 17.7)	13.5 (7.3 to 23.5)	12.4 (6.3 to 22.9)	11.6 (6.6 to 19.7)	0.9327
Frequency of that activity in the last 4 weeks					
Football					0.3408
Every day	4.5 (1.8 to 10.6)	8.1 (2.9 to 20.5)	0	3.1 (0.4 to 19.6)	
Not every day but more than once a week	31.1 (22.8 to 40.7)	32.4 (20.3 to 47.5)	40.1 (24.4 to 58.2)	19.3 (9.3 to 35.8)	
Once a week	38.9 (29.9 to 48.6)	34.9 (21.7 to 50.8)	41.0 (26.0 to 57.8)	43.4 (28.2 to 59.9)	
Less than once a week but more than once a month	14.3 (8.8 to 22.4)	16.4 (7.6 to 31.8)	6.2 (1.9 to 18.4)	19.3 (9.3 to 35.7)	
Once a month	11.3 (6.5 to 18.9)	8.3 (3.3 to 19.7)	12.7 (5.0 to 28.6)	14.9 (6.5 to 30.7)	
Jogging					0.0285
Every day	8.5 (4.1 to 16.9)	13.7 (4.9 to 33.0)	5.6 (1.4 to 20.5)	5.1 (1.5 to 15.7)	
Not every day but more than once a week	46.8 (37.2 to 56.7)	34.5 (20.4 to 52.0)	47.6 (31.1 to 64.7)	59.6 (44.5 to 73.1)	
Once a week	18.7 (11.9 to 28.2)	14.5 (5.7 to 32.4)	30.8 (16.3 to 50.4)	14.9 (6.9 to 29.3)	

TABLE 32 Participation in sport among men aged 18–35 years (*continued*)

Factors	All men (95% CI) (%)	18–24 years (95% CI) (%)	25–29 years (95% CI) (%)	30–35 years (95% CI) (%)	*p*-value
Less than once a week but more than once a month	17.6 (10.7 to 27.4)	32.0 (17.4 to 51.1)	3.9 (0.5 to 23.7)	11.6 (5.2 to 23.6)	
Once a month	8.3 (4.5 to 14.9)	5.4 (1.3 to 19.8)	12.1 (4.6 to 28.4)	8.9 (4.5 to 14.9)	
Gym/health club					0.2757
Every day	13.5 (7.7 to 22.8)	18.6 (7.9 to 37.7)	15.2 (6.7 to 31.0)	3.8 (0.5 to 23.6)	
Not every day but more than once a week	60.7 (49.3 to 71.1)	47.3 (28.0 to 67.6)	74.4 (56.5 to 86.7)	64.9 (44.5 to 81.0)	
Once a week	10.4 (5.3 to 19.3)	10.3 (3.4 to 26.9)	5.5 (1.2 to 21.6)	16.4 (5.7 to 38.7)	
Less than once a week but more than once a month	10.5 (5.1 to 20.4)	15.8 (5.5 to 37.5)	3.3 (0.5 to 19.1)	11.0 (3.8 to 27.7)	
Once a month	4.9 (1.7 to 13.3)	8.1 (1.9 to 28.1)	1.6 (0.2 to 11.1)	3.9 (0.5 to 24.0)	
Cycling					0.8358
Every day	20.4 (12.2 to 32.1)	21.7 (9.3 to 42.9)	12.6 (3.1 to 39.6)	22.5 (10.6 to 41.6)	
Not every day but more than once a week	29.9 (20.2 to 41.9)	30.3 (15.1 to 51.6)	25.3 (10.2 to 50.3)	31.5 (17.7 to 49.7)	
Once a week	13.9 (7.8 to 23.5)	6.5 (1.5 to 24.5)	23.0 (8.3 to 49.6)	18.4 (8.6 to 35.2)	
Less than once a week but more than once a month	23.1 (13.8 to 35.9)	27.1 (11.6 to 51.5)	28.2 (11.2 to 55.0)	15.9 (7.3 to 31.0)	
Once a month	12.7 (6.2 to 24.5)	14.4 (4.5 to 37.3)	10.9 (2.3 to 38.4)	11.7 (3.8 to 30.6)	
Swimming					0.2397
Every day	2.4 (0.6 to 9.6)	3.0 (0.4 to 19.6)	3.7 (0.5 to 23.1)	0	
Not every day but more than once a week	13.4 (7.3 to 23.4)	7.0(1.7 to 25.1)	12.8 (4.8 to 30.0)	24.5 (10.1 to 48.5)	
Once a week	23.5 (13.9 to 36.8)	19.7 (7.5 to 42.5)	22.8 (9.6 to 45.3)	30.4 (14.2 to 53.7)	
Less than once a week but more than once a month	36.2 (24.9 to 49.3)	30.6 (14.8 to 52.9)	47.3 (28.1 to 67.4)	31.7 (14.7 to 55.5)	
Once a month	24.5 (15.1 to 37.2)	39.8 (21.3 to 61.7)	13.4 (5.7 to 28.3)	13.4 (4.2 to 35.4)	
Acceptable to pick up urine test at place of activity	48.3 (42.4 to 54.1)	48.3 (38.6 to 58.2)	40.2 (31.1 to 50.1)	56.4 (46.8 to 65.6)	0.0884
Acceptable to pick up mouth swab from that place	46.9 (41.3 to 52.6)	47.3 (38.0 to 56.7)	43.1 (33.8 to 53.0)	50.3 (40.8 to 59.9)	0.6079

As reported earlier, there was generally low acceptability of sports settings as pick-up points for STI and HIV testing kits, but, among those who reported participation in a sporting activity within the last 4 weeks, 53.9% (95% CI 46.9% to 60.8%) and 51.6% (95% CI 44.8% to 58.4%) said that they would be willing to pick up STI and HIV testing kits from the place of activity, respectively, with no significant variation by age group. Among the 129 men who reported playing football in the last 4 weeks, these figures were 47.3% (95% CI 37.2% to 57.6%) and 43.5% (95% CI 34.1% to 53.3%) respectively (*Table 33*). There was no difference in health-care use between men who had and men who had not played football in the previous 4 weeks, with equal proportions being registered with a GP, having seen a GP in the last year and having undergone previous testing for STIs and HIV. Men who played football reported similar numbers of sex partners and were as likely to report their last sex partner as being male as men who did not play football (see *Table 33*).

Discussion

Overall, men appeared well engaged with health care, with almost all being registered with a GP and three-quarters having seen their GP in the last year. Awareness of sexual health appeared high, as almost one-third of men had been screened for STIs and one-fifth had been tested for HIV. The most acceptable venues for young men to pick up self-collected STI and HIV test kits were health-care settings (general practice, sexual health clinics, pharmacies), whereas sports, social and recreational venues were acceptable to a smaller proportion of men. Football (soccer) was the most popular sport played and around half of men who played football would find their football venue an acceptable place to access STI and HIV testing kits.

To our knowledge this is the first stratified random probability survey of young men in the UK to determine the acceptability of various settings for accessing self-collected STI and HIV test kits. The findings directly informed the settings and intervention for the subsequent pilot cluster RCT. The study provides generalisable data that should be beneficial to those involved in researching, developing and delivering STI services for men in health-care and non-health-care settings within the UK, particularly in the context of low uptake of testing in men reported by the NCSP. However, we do not know the reasons for refusal to take part in the survey or how those who declined differed from participants. Although the questions that we developed did not undergo formal psychometric testing, when possible we used questions that had been validated for use in the highly regarded Natsal surveys.[146]

Although many studies have shown that using non-traditional and sports settings to screen for STIs is feasible,[134,147] few have focused on the acceptability of different settings for men. Lorimer *et al.*'s[148] study of willingness to participate in a non-medical approach to chlamydia screening found that men in particular valued the possibility of screening in these settings. Furthermore, the uptake of screening varied by setting,[136] supporting our finding that the acceptability of sports settings was greater in those who had actually engaged in sporting activities over the last month. Anonymity appeared to be a key factor in determining the acceptability of screening in a qualitative study of young men's experiences and perceptions of chlamydia screening commissioned by the NCSP.[149] Men in that study rejected many of the proposed sports and social venues for fear of the stigma of being seen to take a test. Men also appeared to perceive a degree of incongruity between attending these locations for recreation and the health message of screening.[149]

Our finding that most men had seen their GP in the last year is in keeping with the findings from other studies.[150] Taken together with the high acceptability of general practices for accessing STI and HIV testing kits, this highlights the importance of, and potential for, chlamydia and HIV screening in general practice, especially among younger men.[119] However, current rates of STI and HIV screening in general practice are low, which could suggest a reluctance on the part of the health-care provider to offer testing.[140]

A substantial proportion of men in our study had previously tested for STIs (28.7%) and HIV (19.8%), mostly within specialist sexual health settings. Among those aged 18–24 years, over one-quarter reported that they had previously been tested for STIs; however, NCSP data suggest a coverage of around 12% for those aged 16–24 years in England and Wales.[151] This probably reflects testing in GUM services among

TABLE 33 Health-care use, sexual behaviour and participation in sport among those who did and did not play football over the last 4 weeks

Factors	All men (95% CI), % (*n*)	Footballers (95% CI), % (*n*)	Non-footballers (95% CI), % (*n*)	*p*-value
Demographic factors				
Age (years), median (lower, upper quartiles)				
18–24	38.9 (246)			
25–29	28.2 (178)			
30–35	32.9 (208)			
Health service use				
Registered with a general practice	93.5 (90.2 to 95.7)	91.7 (84.0 to 95.9)	94.5 (91.1 to 96.7)	0.3468
Been to GP in the last 12 months	75.5 (70.5 to 80.0)	71.8 (62.4 to 79.6)	77.7 (71.8 to 82.7)	0.2413
Ever been tested for a STI	28.8 (24.0 to 34.2)	30.9 (23.4 to 39.6)	27.6 (21.9 to 34.2)	0.5009
Time since last STI test				0.5700
< 1 month	4.4 (1.6 to 11.8)	4.6 (1.1 to 17.2)	4.3 (1.0 to 16.7)	
> 1 month but < 6 months	10.0 (5.4 to 17.9)	15.3 (6.7 to 31.2)	6.6 (2.6 to 15.9)	
> 6 months but < 1 year	25.2 (17.1 to 35.6)	24.5 (12.5 to 42.6)	25.7 (15.2 to 40.0)	
> 1 year but < 5 years	37.0 (28.7 to 46.1)	38.9 (25.3 to 54.6)	35.7 (25.0 to 48.0)	
> 5 years	23.4 (16.3 to 32.3)	16.6 (8.4 to 30.2)	27.8 (17.9 to 40.3)	
Where last tested for STIs				0.4537
GUM clinic	53.4 (43.5 to 63.1)	49.8 (34.4 to 65.2)	55.8 (42.4 to 68.4)	
GP surgery	17.0 (9.1 to 29.5)	17.3 (8.6 to 32.0)	17.0 (9.1 to 29.5)	
NHS walk-in centre	8.3 (3.3 to 19.0)	8.5 (2.1 to 28.9)	8.1 (2.4 to 24.0)	
Family planning clinic	6.6 (2.9 to 14.5)	10.5 (4.1 to 24.7)	4.1 (0.8 to 17.9)	
University/college health centre	4.4 (1.5 to 12.2)	0.0	7.4 (2.5 to 19.5)	
Private medical clinic	1.7 (0.5 to 5.5)	1.6 (0.2 to 10.6)	1.9 (0.4 to 7.6)	
Pharmacy	0.9 (0.1 to 6.6)	2.4 (0.3 to 15.4)	0.0	
Internet test	1.1 (0.2 to 7.9)	2.9 (0.4 to 18.3)	0.0	
A&E department	1.3 (0.3 to 5.4)	3.3 (0.8 to 13.2)	0.0	
Somewhere else	5.0 (2.0 to 12.0)	3.8 (0.5 to 23.1)	5.8 (2.2 to 14.6)	
Ever had a blood test for HIV	19.8 (15.8 to 24.6)	22.7 (15.6 to 31.9)	18.1 (13.5 to 23.9)	0.3430
Time since last HIV test				0.1543
< 1 month	10.4 (4.3 to 23.2)	18.7 (6.5 to 43.3)	4.4 (1.1 to 16.5)	
> 1 month but < 6 months	11.1 (5.0 to 22.8)	17.9 (6.6 to 40.4)	6.1 (1.7 to 19.5)	
> 6 months but < 1 year	14.7 (7.1 to 27.9)	10.9 (2.5 to 36.5)	17.4 (7.5 to 35.6)	
> 1 year but < 5 years	37.7 (26.3 to 50.7)	24.8 (11.4 to 45.8)	47.2 (31.7 to 63.3)	
> 5 years	26.1 (17.0 to 37.9)	27.8 (13.9 to 48.0)	24.9 (13.7 to 40.7)	
Where last tested for HIV				0.6670
GUM clinic	50.8 (38.2 to 63.4)	53.6 (32.7 to 73.4)	48.8 (33.1 to 64.7)	
GP surgery	16.0 (8.1 to 29.3)	19.6 (6.9 to 43.7)	13.8 (5.5 to 29.9)	

continued

TABLE 33 Health-care use, sexual behaviour and participation in sport among those who did and did not play football over the last 4 weeks (*continued*)

Factors	All men (95% CI), % (*n*)	Footballers (95% CI), % (*n*)	Non-footballers (95% CI), % (*n*)	*p*-value
Family planning clinic	6.7 (2.8 to 15.2)	8.2 (2.0 to 28.6)	5.2 (1.5 to 15.9)	
Private medical clinic	5.7 (1.8 to 16.6)	6.6 (0.9 to 35.4)	5.1 (1.5 to 15.9)	
NHS walk-in centre	4.4 (1.0 to 17.6)	7.1 (1.0 to 37.3)	2.5 (0.3 to 16.0)	
University/college health centre	4.1 (1.2 to 12.8)	0.0	7.1 (2.2 to 21.1)	
A&E department	1.2 (0.2 to 8.2)	0.0	2.0 (0.3 to 13.6)	
Somewhere else	11.0 (5.4 to 21.0)	5.2 (0.7 to 30.0)	15.3 (7.4 to 28.8)	
Behavioural factors				
Number of partners in the last year				0.0814
0	13.8 (10.1 to 18.7)	10.1 (5.3 to 18.4)	16.0 (11.1 to 22.5)	
1	61.4 (55.8 to 66.6)	59.1 (49.7 to 67.8)	62.7 (55.5 to 69.3)	
2	8.9 (6.2 to 12.5)	8.5 (4.5 to 15.4)	9.1 (5.9 to 13.8)	
3–4	8.0 (5.3 to 11.9)	13.5 (7.9 to 22.4)	4.8 (2.6 to 8.8)	
5+	8.0 (5.3 to 11.9)	8.8 (4.6 to 16.1)	7.5 (4.4 to 12.4)	
Number of partners in the last 3 months				0.9899
0	26.6 (21.4 to 32.6)	25.7 (17.4 to 36.2)	27.1 (20.9 to 34.5)	
1	65.4 (59.3 to 70.9)	66.2 (55.7 to 75.3)	64.9 (57.7 to 71.4)	
2	2.9 (1.6 to 5.3)	2.8 (1.0 to 8.0)	3.0 (1.4 to 6.1)	
3–4	3.4 (1.8 to 6.3)	3.1 (1.1 to 8.3)	3.5 (1.6 to 7.7)	
5+	1.8 (0.7 to 4.5)	2.2 (0.5 to 8.4)	1.5 (0.4 to 5.4)	
Gender of last sexual partner				0.350
Male	3.5 (2.0 to 6.1)	1.3 (0.3 to 6.3)	4.8 (2.7 to 8.6)	
Female	90.5 (86.1 to 93.6)	92.7 (84.3 to 96.8)	89.4 (83.4 to 93.1)	
Never had sex	6.0 (3.5 to 10.1)	6.0 (2.4 to 14.5)	6.0 (3.1 to 11.3)	
Condom use in last 3 months				0.8757
Every time	26.9 (21.3 to 33.4)	27.7 (18.9 to 38.7)	26.4 (19.6 to 34.5)	
Sometimes	24.7 (19.4 to 31.0)	26.1 (17.6 to 36.8)	23.9 (17.7 to 31.6)	
Not at all	48.4 (41.8 to 55.0)	46.2 (35.1 to 57.6)	49.7 (41.8 to 57.6)	
Willingness to use novel methods for testing				
Willing to provide urine sample for STI testing	85.1 (80.5 to 88.8)	88.6 (80.8 to 93.4)	83.1 (76.9 to 87.9)	0.2244
Willing to provide mouth swab for HIV testing	86.9 (82.4 to 90.4)	90.2 (82.2 to 94.8)	85.1 (79.1 to 89.5)	0.2320
Acceptable to pick up urine test at place of activity	48.3 (42.4 to 54.1)	47.3 (37.2 to 57.5)	48.8 (41.8 to 55.9)	0.8014
Acceptable to pick up mouth swab at place of activity	46.9 (41.3 to 52.6)	43.5 (34.2 to 53.2)	48.9 (41.8 to 56.1)	0.3827
Acceptable pick-up points for testing kits				
General practice	79.7 (74.5 to 84.2)	78.2 (69.1 to 85.2)	80.6 (74.2 to 85.8)	0.6167
GUM clinic	66.8 (60.8 to 72.3)	65.6 (55.7 to 74.3)	67.5 (60.0 to 74.2)	0.7518

TABLE 33 Health-care use, sexual behaviour and participation in sport among those who did and did not play football over the last 4 weeks (*continued*)

Factors	All men (95% CI), % (*n*)	Footballers (95% CI), % (*n*)	Non-footballers (95% CI), % (*n*)	*p*-value
Pharmacy	65.4 (59.4 to 71.0)	63.5 (53.4 to 72.5)	66.6 (59.0 to 73.4)	0.6108
Sent in the post	52.2 (46.4 to 58.0)	55.9 (46.2 to 65.1)	50.1 (42.5 to 57.7)	0.3699
College/university campus	41.6 (35.9 to 47.6)	54.1 (43.9 to 63.9)	34.4 (27.7 to 41.7)	0.0024
School	28.1 (23.0 to 33.8)	34.4 (25.6 to 44.5)	24.4 (18.6 to 31.3)	0.0834
Workplace	22.4 (17.8 to 27.8)	26.0 (18.0 to 36.0)	20.2 (15.1 to 26.6)	0.2693
Youth club	20.8 (16.3 to 26.2)	31.3 (22.7 to 41.4)	14.7 (10.2 to 20.7)	0.0013
Gym	18.5 (14.5 to 23.4)	23.2 (15.8 to 32.7)	15.9 (11.4 to 21.7)	0.1368
Bar/pub/nightclub	17.3 (13.3 to 22.3)	18.8 (12.2 to 27.8)	16.5 (11.7 to 22.7)	0.6263
Recreational/leisure/sport centre/ swimming pool	13.4 (9.9 to 17.9)	16.3 (10.4 to 24.7)	11.7 (7.9 to 17.0)	0.2436
Sports club	11.7 (8.4 to 16.1)	11.9 (6.7 to 20.3)	11.5 (97.7 to 16.9)	0.9298
Coffee shop/café	6.9 (4.6 to 10.3)	7.4 (3.8 to 14.0)	6.6 (3.9 to 10.9)	0.7778
Other	0.4 (0.0 to 3.0)	0.0	0.7 (0.0 to 4.6)	0.4438
Participation in sport				
Taken part in sport/physical activity in last 4 weeks	69.4 (63.9 to 74.5)	100	51.7 (44.7 to 58.7)	< 0.0001
Activities taken part in				
Football	52.9 (46.2 to 59.5)	100	0	< 0.0001
Jogging	45.4 (38.7 to 52.2)	46.8 (37.0 to 56.8)	43.8 (34.4 to 53.6)	0.6816
Gym/health club	36.8 (30.3 to 43.8)	32.0 (23.4 to 42.0)	42.1 (32.9 to 51.9)	0.1355
Cycling	31.9 (26.0 to 38.6)	34.6 (26.5 to 43.8)	28.9 (21.0 to 38.3)	0.3560
Swimming	29.6 (23.9 to 35.9)	24.1 (17.1 to 32.8)	35.8 (27.5 to 45.0)	0.0519
Martial arts	7.7 (4.5 to 12.7)	4.4 (1.6 to 11.7)	11.3 (6.1 to 20.1)	0.0999
Athletics	6.6 (3.9 to 11.1)	7.8 (4.2 to 14.3)	5.3 (2.1 to 12.8)	0.4770
Badminton	6.0 (3.5 to 10.3)	7.4 (3.6 to 14.7)	4.5 (1.9 to 10.2)	0.3640
Cricket	5.9 (3.1 to 11.2)	6.6 (2.7 to 15.4)	5.2 (1.9 to 13.2)	0.7112
Boxing	5.5 (3.2 to 9.3)	6.4 (3.1 to 12.6)	4.5 (1.9 to 10.3)	0.5484
Tennis	5.3 (2.7 to 10.1)	8.5 (4.0 to 17.1)	1.7 (0.5 to 5.8)	0.0154
Basketball	3.2 (1.5 to 6.5)	4.9 (2.2 to 10.9)	1.2 (0.3 to 4.9)	0.0685
Rowing	2.5 (1.0 to 5.9)	2.9 (0.8 to 10.0)	2.0 (0.7 to 5.5)	0.6224
Rugby union	1.7 (0.7 to 4.1)	2.9 (1.1 to 7.6)	0.4 (0.0 to 2.6)	0.0311
Rugby league	1.8 (0.7 to 4.6)	1.5 (0.4 to 6.1)	2.0 (0.5 to 7.8)	0.7974
Hockey (field)	1.6 (0.4 to 5.7)	2.7 (0.6 to 10.5)	0.4 (0.0 to 2.6)	0.0615
Other	12.6 (8.8 to 17.7)	5.4 (2.3 to 12.5)	20.6 (14.1 to 29.0)	0.0019
Frequency of that activity in the last 4 weeks				
Football				
Every day		4.5 (1.8 to 10.6)		

continued

TABLE 33 Health-care use, sexual behaviour and participation in sport among those who did and did not play football over the last 4 weeks (*continued*)

Factors	All men (95% CI), % (*n*)	Footballers (95% CI), % (*n*)	Non-footballers (95% CI), % (*n*)	*p*-value
Not every day but more than once a week		31.1 (22.8 to 40.7)		
Once a week		38.9 (29.9 to 48.6)		
Less than once a week but more than once a month		14.3 (8.8 to 22.4)		
Once a month		11.3 (6.5 to 18.9)		
Jogging				0.1119
Every day	8.5 (4.1 to 16.9)	9.5 (3.9 to 21.1)	7.4 (2.1 to 23.5)	
Not every day but more than once a week	46.8 (37.2 to 56.7)	34.5 (23.6 to 47.2)	61.7 (46.6 to 74.8)	
Once a week	18.7 (11.9 to 28.2)	23.9 (13.5 to 38.8)	12.5 (6.0 to 24.0)	
Less than once a week but more than once a month	17.6 (10.7 to 27.4)	22.0 (11.9 to 37.1)	12.2 (5.6 to 24.9)	
Once a month	8.3 (4.5 to 14.9)	10.1 (4.6 to 20.7)	6.2 (2.3 to 15.9)	
Gym/health club				0.9450
Every day	13.5 (7.7 to 22.8)	13.2 (5.1 to 29.9)	13.9 (6.8 to 26.3)	
Not every day but more than once a week	60.7 (49.3 to 71.1)	56.9 (38.6 to 73.6)	64.0 (48.8 to 76.8)	
Once a week	10.4 (5.3 to 19.3)	10.8 (4.0 to 7.4)	1.0 (4.0 to 23.0)	
Less than once a week but more than once a month	10.5 (5.1 to 20.4)	12.6 (4.3 to 31.6)	8.7 (3.2 to 21.3)	
Once a month	4.9 (1.7 to 13.3)	6.5 (1.9 to 19.8)	3.5 (0.5 to 21.7)	
Cycling				0.5208
Every day	20.4 (12.2 to 32.1)	25.4 (13.8 to 42.1)	13.6 (4.8 to 32.9)	
Not every day but more than once a week	29.9 (20.2 to 41.9)	23.4 (12.3 to 39.9)	38.7 (23.1 to 57.0)	
Once a week	13.9 (7.8 to 23.5)	11.1 (4.8 to 23.7)	17.7 (7.6 to 35.8)	
Less than once a week but more than once a month	23.1 (13.8 to 35.9)	25.6 (12.7 to 44.9)	19.7 (9.1 to 37.4)	
Once a month	12.7 (6.1 to 24.5	14.5 (5.6 to 32.5)	10.4 (3.4 to 27.6)	
Swimming				0.4525
Every day	2.4 (0.6 to 9.6)	0.0	4.3 (1.0 to 16.2)	
Not every day but more than once a week	13.4 (7.3 to 23.4)	7.6 (2.2 to 23.0)	17.8 (8.8 to 32.8)	
Once a week	23.5 (13.9 to 36.8)	23.2 (11.4 to 41.6)	23.7 (11.9 to 41.8)	
Less than once a week but more than once a month	36.2 (24.9 to 49.3)	38.0 (21.4 to 58.0)	34.8 (51.4 to 21.2)	
Once a month	24.5 (15.1 to 37.2)	31.1 (15.7 to 52.2)	19.5 (9.4 to 35.9)	

A&E, accident and emergency.

participants in our survey. Our data reveal a testing rate for HIV that is higher than equivalent data from the most recent Natsal, which found that 6.63% (95% CI 5.14% to 8.52%) of men aged 16–24 years and 14.8% (95% CI 13.0% to 16.7%) of men aged 25–34 years reported having had a blood test for HIV.[139] Both our data and the second National Survey of Sexual Attitudes and Lifestyles (Natsal-2) data[139] excluded blood donation as a reason for a HIV test, although the Natsal data are now more than a decade old.

It is important that venues in which STI screening and testing kits are offered are acceptable to target populations. Although it is now possible to deliver testing in non-clinical settings, this research highlights that, among men aged 18–35 years, in Great Britain at least, it is the traditional health-care settings that are most acceptable as pick-up points for self-testing kits. Young men frequently access primary care and we feel that there is considerable potential to engage more men in STI and HIV testing through general practice.[138] NCSP data show that only 25% of tests in men are carried out in 'core' health settings.[151] In contrast, our research shows that these are the preferred access points for as many as 80% of men. Based on our findings, there is clearly a mismatch between where services are currently provided and the settings in which men prefer to access STI and HIV screening. However, non-traditional settings are acceptable to a minority of men and may be important in reaching men who would otherwise not seek STI screening and for men who perceive their local sexual health services to be inaccessible, The importance of appropriate analysis of the cost-effectiveness and public health impact of the later pilot cluster RCT cannot be underestimated, to enable resources to be used most appropriately. This is especially important when considering the potentially low rates of chlamydia detected among the men screened in non-health-care settings.[119]

Phase 2: development and evaluation of the disease control potential of a model for testing young men at high risk of sexually transmitted infection in a sports setting – the SPORTSMART intervention

Phase 2a: Qualitative survey of men's preferences for sexually transmitted infection screening

Objectives

- To develop, through qualitative research and consumer and stakeholder consultation, two feasible and replicable interventions for delivering STI screening in football club venues.
- To determine the acceptability to young men and the feasibility of football trainer-led STI and HIV screening.

Methods

Study design

Theoretical framework The underpinning methodology for this study was one of pragmatism, recognising that a mixture of quantitative and qualitative methodologies can be combined to gain a holistic understanding of issues relating to health service research. This qualitative component works together with the pilot RCT to deliver a deeper context for the results, as well as to help inform the design of the pilot.

We used a framework approach to interpretation of the data[111] as we felt that it best suited the practical and applied nature of the research to answer questions about health service development. Although this approach is based in the original accounts and observations of the participants, and therefore 'grounded' and inductive, it uses a priori categories to analyse the data. It also allows multiple researchers to analyse

transcripts simultaneously to reduce bias and reach consensus. The process consists of five main components:

1. *Familiarisation*. After conducting the interviews, one researcher (JS) listened to the taped recordings and read the transcripts many times to become familiar with the raw data. JS also made notes in the margins of transcripts and in a notebook of recurring themes, ideas and thoughts about the data.
2. *Identifying a thematic framework and developing a coding framework*. Through this process of rereading the transcripts two researchers (JS and LS) identified and provisionally organised key and emergent themes based on the a priori research questions. We also developed codes based on key phrases and responses in the interviews. This process was carried out on an initial sample of four transcripts to code the transcripts line by line according to the ideas being expressed by the participant. In this way a long list of codes was created. The next step was to group together closely related codes under broader headings. These new codes were then used in the next 'indexing' stage.
3. *Indexing*. Two researchers (JS and LS) systematically applied these codes to the initial interviews independently of each other before comparing the coding. Discrepancies in how the codes had been applied were discussed, a consensus was agreed and alterations were made to the coding tree. These codes were then systematically applied to the remaining interviews.
4. *Charting*. We used Microsoft Excel® 2010 (Microsoft Corporation, Redmond, WA, USA) to chart and manage the data of specific qualitative data management software because of familiarity with the software. We developed major themes and subthemes and defined and placed key excerpts from the interviews into the charts to ensure that the findings were grounded in what the participants said, as well as to facilitate comparison of experiences and responses within and between cases.
5. *Mapping and interpretation*. During this stage we developed ideas and meanings behind the data through discussion, writing descriptive accounts of the findings, looking for relationships between themes and testing the findings back against the initial research questions and transcripts.

Participant selection The Amateur Football Combination [AFC; see www.amateurfootballcombination.com (accessed 16 June 2016)] is 'one of the biggest adult football leagues in Europe, with around 100 clubs and 350 sides playing Saturday afternoons in and around London'. Because of its location, size and level within the league pyramid, we used it as the sampling frame for both the qualitative and the pilot trial stages of the SPORTSMART study. We viewed club websites, if available, before contacting clubs to obtain a preliminary view of clubs' suitability for the different elements of the SPORTSMART workstream. This was primarily based on whether or not a club had its own clubhouse and grounds and the number of teams it had.

We then e-mailed club secretaries introducing our research team and the study and to request a telephone or face-to-face meeting to discuss the study in more detail. These meetings gave us an opportunity to learn more about the clubs (how many teams, demographics of the club, club infrastructure) and also to see whether or not they might be interested in taking part in the research. If they were interested, we went on to discuss which stage of the study might be more suitable (interviews vs. pilot trial). Club secretaries then discussed it with the club committees before making a decision on participation.

Participating clubs disseminated study information to their members using e-mail and club newsletters. Men were asked to contact the research team directly if they were interested in taking part. This process took many months as initial calls for interest did not result in any men coming forward to be interviewed. Therefore, several follow-up calls were made to the club secretaries reinviting them to disseminate information to members.

Inclusion criteria were men aged between 18 and 35 years currently playing football in an amateur club. Participants were given £20 for their time. Clubs received £10 for each participant from their club who took part as recompense for the time that it took to disseminate information to club members.

A mixture of convenience and snowball sampling was used to recruit participants. Participants were selected based on whether or not they contacted us to take part in the study (convenience sampling).

After the interviews, we encouraged participants to promote taking part in the research amongst their teammates and this produced further participation (snowball sampling). As saturation was reached we still had interested men coming forward who had to be turned down.

Nineteen interviews were conducted with participants from five different clubs. Two of these were conducted as pilot interviews. One of these pilots has been included in the analysis as the participant met the inclusion criteria. The other is not included as the man was aged > 35 years.

As potential participants were not approached directly by the researcher to take part, it is not possible to report a refusal rate. Around 25 of the 100 clubs in the AFC were contacted by e-mail to participate in the study. Only six clubs responded and men from five clubs took part in the interviews. However, many of the details on the clubs' websites, particularly contact details, were found to be inaccurate.

Ethical approval was granted for the study by the Queen Mary University of London Ethics Committee. Verbal and written information was provided to all participants. Written consent was taken from participants before the interviews were conducted. Participants were free to withdraw consent at any point up until analysis of the anonymised data; however, no participants withdrew consent.

Setting All of the interviews were conducted within Greater London between October and December 2011 in a number of settings and at different times of the day depending on participant preference. Most commonly interviews were carried out at participants' place of residence in the early evening (after work) but other settings included the research offices at St Bartholomew's Hospital, their place of work and the training grounds. No one else was present during the interviews.

Data collection An interview topic guide (see *Appendix 2*) was developed by the research team. A single researcher conducted all interviews. Interviews started with general questions about the participant and his involvement with the football club. This was to allow the rest of the interview to be seen in the context of the participant's age, background and reasons for playing team football. These initial questions were also considered fairly unthreatening and helped to create a rapport between the researcher and the participants before moving onto potentially more sensitive questions about attitudes to sexual health and testing for chlamydia. Participants were then asked about attitudes to general health promotion within the football club setting as an opportunity to draw out general thoughts and ideas about health promotion in football clubs before asking specifically about sexual health promotion. It gave an overview of how health was viewed by men and challenged apparent contradictions in attitudes to sexual health compared with general health.

The topic guide then became more structured and asked about attitudes to the proposed models of chlamydia testing (coach led, health professional led, poster led). To enable them to have a preference about a new way of testing, it was important for men to have an understanding about what traditional options for testing looked like. This would allow men to compare and contrast the proposed models with standard testing in traditional settings. Without this it would be difficult for men who had a low baseline knowledge of STI testing to appropriately assess the potential advantages and disadvantages of testing in football clubs. Therefore, a traditional testing pathway involving visiting a clinic for urine testing was described to participants before they were asked about novel models of delivering testing opportunities. Subsequent pathways then showed coach-led, health professional-led and poster-led promotion in football clubs.

The topic guide was piloted on two men who either were currently involved in playing football for a team or had been in the past. These pilots enabled the researchers to become more comfortable with the flow of the questions, develop language to use when asking questions and ensure that the questions were ordered appropriately. Following these pilots, extra questions were added to make sure that the relationship status of the participants was known, as this was felt to have a potential impact on attitudes to testing.

Participants were interviewed only once over a period of between 40 and 70 minutes. Interviews were digitally recorded to ensure accurate documentation of what was said and to allow the researcher to concentrate on participant responses. Recordings were transcribed verbatim with participant-identifying information removed. Some brief field notes were made following the interviews to help contextualise the interviews. Questions were open-ended with further, more directive questioning used to explore the reasons behind attitudes and statements.

New participants were accepted for interview until saturation was reached.

Relationship with participants Specific details about the selection and recruitment of participants are provided in *Participant selection*. The only contact that the researchers had with participants before the interviews came in the form of brief telephone and e-mail exchanges. In order to consent to participate in the interviews, participants were told the purpose of the research, with reference to the larger programme of research, and that the findings would also be used as part of a PhD thesis. Participants were aware that the interviewer was a sexual health physician. Although there was some concern among the research team that participants may alter their responses because they knew this or use the interviews as an opportunity to ask questions relating to their sexual or general health, in reality we do not think this had a major impact on the process and may have helped participants to feel at ease discussing issues relating to sexual health. Any questions asked during the interview about personal situations were dealt with once the interviews had finished.

Results

The characteristics of the interview participants are provided in *Table 34*.

Offering chlamydia testing in football settings is, under certain situations, acceptable. Factors that influenced men's attitudes towards this way of testing fell into three main themes:

- theme 1: characteristics of the provider of the sexual health message (coach/HCP/poster)
- theme 2: characteristics of the testing pathway itself (how, where and when to use the tests)
- theme 3: characteristics of the men.

TABLE 34 Interview participant characteristics

Characteristics	Number of participants
Ethnicity	
White British	15
White European	2
British Asian	1
Chinese	1
Age range (years)	
18–24	4
25–29	10
30–35	4
> 35	1 (pilot – excluded from analysis)
Team position	
Captain/committee/coach	6
Player	13

In the background, differences in demographic factors will also play a role as do broader themes about how the men feel they are viewed by others, avoiding stigma, ideals of masculinity and reasons for being within a homosocial environment. These factors are summarised in *Table 35*.

Theme 1: Characteristics of the provider of the sexual health message

Three models of sexual health promotion were explored with the participants: coach- or captain-led promotion, HCP-led promotion and poster-led promotion.

TABLE 35 Factors that influence men's attitudes towards testing for STIs in football clubs

Theme	Factors
1. Characteristics of the provider of the sexual health message	1. Coach/popular opinion leader: (a) familiarity may act as promoter or barrier (b) may be more likely to test if the person is respected within the club 2. HCP: (a) effect of age and gender of HCP is mixed (b) respect for the HCP's knowledge, professionalism and time 3. Posters: (a) positive influence related to discreet nature of posters (b) discreet nature also means that they are easily overlooked (c) best used in combination with methods above
2. Characteristics of the testing pathway	1. Cost: (a) time: brief messages, minimal impact on football (b) value: professional-looking testing kits 2. Convenience: (a) fit in around normal, scheduled activities (b) options to perform test in a variety of settings 3. Discreet settings: (a) opportunities to test in settings that maintain anonymity and reduce stigma
3. Characteristics of the men	Stigma: (a) desire to be distanced from association with STIs Emotional response to sexual health/STIs/testing (a) fear of STIs (linked to stigma and knowledge) (b) embarrassment (linked to perceived maturity and stigma) (c) amusement (linked to ideas of gender performance) (d) boredom and apathy (linked to knowledge and gender) Knowledge: (a) can act to create fear of STIs and testing (b) uncertain where and how to access traditional services Gender role performance (a) reluctance to seek health advice unless sexual function impaired (b) perception of individual by others and maintaining status
Demographic factors	Effect of age, ethnicity, cultural background, social class, education and sexual attitudes

Familiarity with the promoter had a mixed effect on acceptability among men. Because of the sensitive subject, some men preferred to talk about sex with people they knew, for example the coach or captain, whereas for others this may act as a barrier. Respect for the person within the club who was delivering the promotion was important to ensure that the message was taken seriously and that he or she was not seen as hypocritical or lacking in knowledge:

> *as a team, as a club, you probably put your trust in them, so maybe you can be comfortable to speak with them about this. Yeah, you only need to give the chance to talk about it.*
>
> *Participant 011*

> *I think with a manager you'd be kind of like, unless he was reading it, you're kind of like, has he made that bit up?*
>
> *Participant 012*

Men generally felt that HCPs were knowledgeable and authoritative. As a result, many felt that they would be taken more seriously than an internal health promoter, although there were mixed opinions about what effect their age and gender would have on the process:

> *I think for a start you would think, this person has given up their time on a Saturday to come and talk to me. The least I can do – they've come down to wherever it is I play football. They probably work Monday to Friday. The least I can do is at least show them some respect and listen to them.*
>
> *Participant 015*

A perception that younger, male HCPs would have similar life experiences meant that some men would be more willing to listen to them than female or older professionals:

> *if you had a nurse or a doctor I'd get someone of your age to come in rather than a 50-year-old. Because if you've got a doctor that's coming in it's immediately, 'Oh he's a doctor. How am I going to relate to a doctor?' If he's a 50-year-old doctor you're not. If he's someone closer to their age then you are much more likely to, I would think.*
>
> *Participant 004*

Because of the desire to keep the impact of receiving the health promotion on time to play football to a minimum, participants felt that having a male HCP would allow for men to continue changing and showering in the changing rooms with little interference:

> *you'd be taking up the players' time, 'cos that's why I keep mentioning 10 or 15 minutes, you'd have to make it concise. It couldn't be more than that I don't think. Especially if it's after training people wanna get home. So it'd just be like a quick session.*
>
> *Participant 016*

The most positive perceived characteristic of posters related to their discreet nature. However, for some participants, this was also considered a negative as they could be easily overlooked and therefore lack any impact whatsoever. Although posters were felt to be relatively ineffectual as a sole method of health promotion, it was suggested that they could increase the impact of other promotional methods if used together:

> *I think that would be kind of a decent option because it's kind of not forcing it on anyone. It's kind of there if you want it. It's not saying that, 'You need to sit down and listen to me about what I say', it's kind of just there if you're interested. Which I think is possibly a better way to approach it.*
>
> *Participant 010*

Theme 2: Characteristics of the testing pathway

Key factors relating to the testing process were those of cost, in terms of time and value, convenience and testing in a way that minimised felt stigma. To these ends, men valued processes that were quick, did not interfere with their main reasons for being at the club (to play football and socialise), fitted in around their daily activities and routines and gave them opportunities to test in a variety of settings to maintain anonymity. It was also important that test kits looked discreet but also inherently valuable, so as to appear medicalised but not frightening:

> *you'd be taking up the players' time, 'cos that's why I keep mentioning 10 or 15 minutes, you'd have to make it concise. It couldn't be more than that I don't think. Especially if it's after training people wanna get home. So it'd just be like a quick session.*
>
> *Participant 016*

Overall, the perceived complexity of the testing process should be kept to a minimum. This starts with when, where and for how long the promotion message should be given. Despite a concern in previous studies that men lack knowledge about STIs, and that this may influence their decision to test, participants in this study were not concerned with receiving detailed information about infections. Instead, most favoured brief messages that highlight the ease of testing and simple curative treatment. These served to minimise the anxiety and fear that men can feel towards STIs and the treating process. A balance between giving enough knowledge to keep men informed and being able to make a free choice while not creating fear because of too much or too little information must be found:

> *So if you don't know, if someone says do this test you might have this, but you don't know what this is then the unknown's always scary to people. So, you know if you explained, you know, 'Do this test, you may have chlamydia. You may not show any symptoms but if you've got it these can be the long-term effects, you know. It's quite easily spreadable so this is it and also what we'll do is give you a couple of tablets. You'll take them there and then and you're done.' All of a sudden, well that's not scary, it's just like having a cold or something I think, when you break down the walls like that it's a better way to do it.*
>
> *Participant 013*

Although few men had tested for STIs in the past, this did not seem to be because of an active desire not to test. Although the stigma and fear of STIs explains part of this behaviour, because men wanted to limit the amount of time that they spent engaging with a stigmatised behaviour, the time and effort to access testing was also a major barrier. The opportunity to access testing kits at the football clubs meant that men could continue with normal, scheduled and enjoyable activities and also come into contact with opportunities to test. Central to the acceptability of the proposed interventions was that it should be short and simple, thereby minimising the impact on their time. To introduce a complex and timely intervention in the football club would potentially be worse than doing nothing, as it would not only perpetuate current barriers to testing but also intrude on men's time for recreation and socialising:

> *with men there's a great deal of apathy about anything that's not a big heap of fun to do outside their general busy lives . . . It's just quite low down on most blokes' radars. I think most guys, beyond a misguided few, will admit that they should do it. It's just you need to give them a much, much easier opportunity to do it.*
>
> *Participant 003*

Although handing test kits out to all team members removed a degree of free will in whether or not men got a test kit, it was the preferred option. It took away the idea of being singled out, meaning that all the men would now be in the same position, helping to normalise and destigmatise the situation as well as maintaining the 'sameness' of men within their homosocial group:

> *if you have these kits that people have to go over and pick up, thinking, OK, I need one of these, whereas if they're kind of literally handed out, 'Here's your thing, here's your thing, here's your thing',*

> *I feel like once you put that in someone's hand, again that's the kind of situation where there will probably be some people who will take it and think like, 'I'm only taking this because you're giving it to me', but who actually are probably thinking, 'I'm quite happy this has been given to me because I would quite like to do this', and they may not have had the confidence to go over and pick one up. Because again it is just that whole thing that as soon as you actively step towards doing this that is, in some people's case, an admission that you have a reason to do it. So having something handed to you does get over that hurdle.*
>
> *Participant 014*

Although using the test in the club setting may initiate a 'domino effect' and encourage others to also test, a more discreet option was to use the testing kit at home and return it by post. By giving multiple options for how and when to use the testing kit, men would be able to reduce the stigma attached to testing and maintain a degree of autonomy. Again, this is important in how others see them within the club: being told what to do and when to do it is at odds with ideals of masculinity and exercising free will. This idea of making the process as discreet as possible is balanced with making the process as easy as possible. Therefore, some men preferred to test there and then, handing the sample back to the promoter or placing it into a collection bin. This was the least complex option, but it came with a cost of being seen to perform a test:

> *I'd probably go, 'I tell you what, I'll do it now'. And then you'd probably have another couple of lads go, 'Yeah, no sod it, let's do it then'. Then I think if the lads in the changing room saw a couple of lads doing it there and then, they'd be like, oh might as well do it, or whatever.*
>
> *Participant 012*

Theme 3: Men's characteristics

Influencing factors were not only external but also included features of the men themselves. STIs and being associated with them, either through being seen to test for them or having one, are recognised by participants as stigmatised behaviours. These feelings of stigma meant that men preferred testing options that kept any possibility of this to a minimum. Closely related to this was how men viewed and performed gender. Features of hegemonic masculinity prevented men from accessing screening for asymptomatic infections. To seek help and health care is at odds with how society expects men to perform. It also meant that anything that may tarnish their status amongst others should be avoided. For the purpose of the testing pathways, no one should be singled out for testing and men need to be able to test without others knowing that they have done so:

> *from a personal point of view I wouldn't really want to get tested unless I was ill almost. And I know that's wrong but it's kind of the way it is and kind of like, you know, to sweep something under the carpet almost.*
>
> *Participant 009*

Interestingly, throughout the interviews, men identified numerous barriers to testing but would often distance themselves from these. Participants felt that these barriers were problems for other men but not for them personally. The reasons for this were obscure, but seemed to relate to participants feeling that they were more mature than other men and therefore able to deal with sexual health issues in a different way. Therefore, although being seen to be associated with STIs is stigmatising, for some men it was more important to be seen as an adult and display maturity about these issues, in itself perhaps a more valued display of masculinity. In this way, participants clearly demonstrated their knowledge of how to perform a normative and hegemonic gender role but at times in the interviews also distanced their own behaviours from these expectations, opting instead to align themselves with a masculinity that engaged with health-seeking behaviours. By bringing screening to men, not only could more convenient opportunities to screen be created, but also this requirement to actively seek out and ask for testing could be abolished:

> *I'd say, yeah, 'cos you've got a lot of lads who would go out on a Saturday night and, do you know what I mean, pull a lady. So it makes sense for it to be there, do you know what I mean? . . . So it*

> *makes textbook sense for that to be brought to the attention at the one place where every lad is on a Saturday before going out.*
>
> *Participant 012*

Participants had a range of pre-existing knowledge about STIs and felt that information given during testing pathways should be kept to a minimum. Not only did this lessen the impact on their time, but also they felt that too much knowledge could make STIs more frightening (see *Theme 2*). Emotional responses to sexual health, STIs and testing were frequently voiced during the interviews. Fear of STIs seemed to be related to the stigma and variable knowledge about infections. The testing process was potentially embarrassing for some men but linked to their perceived level of maturity. Amusement and joking about sex and sexual health seems to be an expression of normative gender roles, and ensuring that these normative gender roles are displayed appropriately within the homosocial, all-male sports environment. Some men expressed boredom and apathy towards sexual health, which, once again, may be linked with ideals of gender performance: the body is a machine and real men should not seem interested in their health:

> *'cos it's in a lads' environment, it's all like, oh he's got a testing kit, he must be getting some action. That kind of thing. So I think 'cos it's in that environment I don't really think people would be embarrassed about it. They'll probably go, yeah, you know, I had this girl last week and a girl the week before and you just get a bit, a lot of egos flying about and it will create a lot of banter I think.*
>
> *Participant 007*

Discussion

This qualitative study found that it is acceptable to young men to be offered testing for chlamydia in football club settings. As outlined in the previous sections, many factors influence this acceptability. Factors relating to how the message to test is provided and who it is provided to, as well as factors specifically relating to the testing process, are important. Underlying these factors are influences of masculinity, gender performance, stigma and emotional responses to STIs.

The ideas of complexity also feed back into how others see them. The amount of information given needs to be non-patronising, thereby maintaining ideas of masculinity and being knowledgeable about sex, but also ensure that STIs are not portrayed as frightening and stigmatising, thereby discouraging men from testing.

It could be argued that by making the testing process as basic and simple as possible, as small a number of options as possible need to be given to men for testing. This may be simple but may also reduce autonomy and once again impact on masculinity: men do not want to feel that they are being told what to do. Similarities with HIV testing exist with a move away from lengthy pretest counselling towards opt-out testing and brief 'pretest discussions'.

Findings in relation to existing literature

We are not aware of any qualitative work exploring the acceptability of this strategy. However, sports settings have been used in a small number of studies to promote testing for STIs, with variable uptake and diagnosis rates of infections.[134] The use of sports settings may be particularly useful in rural settings where access to sexual health-care services is limited.

Popular opinion leader theory, based on Roger's[142] theory of diffusion of innovations, suggests that individuals are more likely to act on advice, or to adopt a new innovation (in this case testing for chlamydia), if this is promoted to them by a member of their community at the centre of communication networks. Although this holds true for some of the participants in this study, not all men favoured hearing about sexual health from another member of the club, even if they were well respected within the team. However, when considering HCPs, it seems important that they have some similarities to the men within the team in terms of gender and age. The importance of this goes beyond practical issues of being in the all-male environment of the changing rooms and includes the assumption that there will be a common understanding when it comes to sex and sexuality. Therefore, even though HCPs are not directly from these men's football communities, and occupy a

position in society that may be removed from these men, they were not dismissed as acceptable providers of sexual health promotion in this setting. In fact, there is a balance between the delicate and stigmatised nature of sexual health and the comfort of discussing these issues with someone you know personally, and see as no different from yourself, and a HCP who is unknown but an expert.

Although, in women at least, there is concern that screening in non-traditional settings may also be accompanied by a greater visibility of screening, thereby turning a 'discreditable' setting into a 'discredited' one and increasing felt stigma,[102] the men in this study felt that testing within the all-male, homosocial group of the football team, although visible to others, could help to facilitate testing in a number of ways. First, it allowed men to test within the context of their daily lives, thereby removing the need to seek out health care and find the time to perform testing. Second, it allowed men to test in a setting in which they felt at home, surrounded by other men whom they saw as similar to themselves and avoiding this feeling of 'otherness' that sets people apart and fuels stigma. Finally, for some men, observing peers performing the test acted as an incentive to testing themselves – the 'domino effect'.

Recommendations for further work

The findings from these interviews were used to inform and design the SPORTSMART pilot RCT of testing in football clubs (see *Phase 2b*). However, taken together with the findings from the stratified random probability sample survey, it would appear that health-care settings, especially general practice, offer the greatest potential for upscaling testing for STIs. These settings are frequently accessed by men and highly acceptable as venues for testing. They also fulfil the requirements of settings to be discrete (testing would not be observed by others), fit in with daily activities (men are already going to these settings for general health concerns) and offer access to trusted HCPs as promoters of testing.

Therefore, it would seem to be most practical to focus further research efforts on how to increase testing in general practice rather than pursue testing in football clubs. Although recent studies have shown initial promise in using the theory of planned behaviour to increase testing rates in general practice for chlamydia,[112] it could be useful to explore other models of testing using the framework set out above as a basis (characteristic of the provider, characteristic of the testing pathway, characteristics of men). In particular, the time taken to promote testing may be a perceived barrier to GPs offering testing, although men do not want, or necessarily need, lots of information in order to test. Furthermore, just testing seems to have a positive impact on risk and future testing behaviour.[152]

Strengths and weaknesses

A true purposive sampling technique was not possible as many of the clubs were not themselves aware of the precise characteristics of their players. Therefore, the sample characteristics of the participants are not as diverse as would have been seen if using a purposive sample. However, it is thought to be broadly reflective of the demographic in the football clubs that were used and some key and important differences exist between participants (age, relationship status, sexual orientation, educational status, previous testing history and previous STI diagnoses). This helps to add diversity to the findings.

Phase 2b: the SPORTSMART study – a pilot randomised controlled trial of sexually transmitted infection screening interventions targeting men in football club settings with a preliminary cost–consequence analysis and behavioural survey

Objectives

- To undertake a pilot RCT of football captain-led STI screening in two contrasting football clubs in different geographical areas.
- To determine the uptake of STI screening by young men in football club settings.
- To obtain cost data for the football captain-led STI screening strategies to use in a preliminary economic evaluation.

SPORTSMART pilot randomised controlled trial

We developed two interventions to explore the acceptability and feasibility of football clubs as settings for STI screening (specifically *C. trachomatis* and *N. gonorrhoeae*) and the potential role of team captains in increasing the uptake of screening in young men. We tested these interventions in the SPORTSMART pilot cluster RCT to determine preliminary evidence of effectiveness.

Methods

Trial design

We used a cluster RCT design. We allocated two clubs to each of our three trial arms: team captain led and poster STI screening promotion (arm one), sexual health advisor led and poster STI screening promotion (arm two) or poster-only STI screening promotion (control/comparator arm three).

Outcomes

The primary outcome was the proportion of eligible men accepting the offer of screening (intervention uptake). Secondary outcomes were the proportion of screened men who tested positive for chlamydia and/or gonorrhoea and health service costs (reported later and in Jackson *et al.*[114]).

Statistical analysis

We reported the primary outcome with a 95% CI based on a robust standard error that acknowledges the clustering of participants by club.

Club recruitment

We identified all potentially eligible amateur clubs in appropriate geographical areas from the AFC listings available on the internet.[153]

Randomisation

Prior to randomisation we divided clubs into three pairs. Pairing was based on a description of the club memberships' ethnicity, age, education status and size, as described by early qualitative work[132] and club representatives' reports, and was performed to achieve approximate balance across pairs in these characteristics. The pairs of clubs were then allocated to one of the three study arms by the lead study statistician by random permutation. Clubs (and thus participants) were unblinded directly following study arm allocation. It was not feasible that clubs or investigators be blind to the intervention type during implementation or evaluation.

Team captain and health adviser recruitment

During the recruitment phase the trial co-ordinator explained to the club contacts that two of the participating clubs would be randomly allocated to a captain-promoted screening intervention and so all participating clubs needed to have at least one captain willing to promote the screening intervention among two teams in each club.

Health advisor selection

Based on our preclinical qualitative work,[132] we recruited a male health advisor to deliver our STI screening promotion. The health advisor was also in the same age group as the football players involved in the intervention and so the distinguishing difference between the self-selected team captain and the health advisor was that the health advisor was a medical professional from outside the club.

Delivery of the interventions

The trial co-ordinator e-mailed the club contacts prior to the football matches with brief details of the screening event. On the day, the trial co-ordinator put up posters in all participating clubs and set up the test kit collection boxes in the club changing rooms just prior to the players' arrival. The interventions were

delivered according to randomisation during the usual pre- or post-match team briefing. Interventions were as follows:

1. *Captain and poster screening promotion*. The team captain delivered a standardised brief screening promotion talk of < 5 minutes' duration (*Table 36*) and then handed each player a test kit (*Figure 6*) and answered any questions from participants.
2. *Health adviser and poster screening promotion*. A sexual health adviser from the study clinic delivered the standardised brief screening promotion talk of < 5 minutes' duration and then handed each player a test kit and answered any questions from participants.
3. *Poster-only screening promotion (comparator arm)*. Posters were displayed that the men were free to read, with kits readily available, but no verbal information was given.

Men who wished to participate completed a sample kit according to the instructions provided and placed the completed kit back into the secure collection box. Alternatively, men could take the kit away with

TABLE 36 Screening promotion content

Topic	Message
Health promotion message	Chlamydia and gonorrhoea are common and often present without any sign that anything is wrong (asymptomatic)
Screening information	Confidential; right to refuse; how contacted with results
Test kit instructions	Step-by-step instructions
Further research participation	Invitation to follow-up qualitative interview

FIGURE 6 SPORTSMART self-sampling kit.

them for later completion and post it back to the clinic in a discreet postage-paid package. All clinical follow-up, including provision of test results via text message, was carried out by clinic staff according to routine standards of care.

Process evaluation and additional data collection

Captains and the sexual health advisor completed a 'report-back' form directly after each intervention. Information gathered included the number of men in the changing room and exposed to the intervention and their views of implementing the intervention. In addition, the trial co-ordinator took field notes to describe the circumstances of each intervention (including weather, match outcome, timing of intervention) to assess the fidelity of the interventions in practice.

Resource use data were collected prospectively for use in the health economics analyses, which we report on pp. 90–92.

Participants (players) were invited to take part in a telephone semistructured interview to explore their views of the interventions within a month of participating in the initial screening event.

At the time of the SPORTSMART survey distribution (see below), captains of the participating football teams were prompted by the trial co-ordinator to ask players who took part in the intervention if they would like to participate in a one-to-one telephone interview with a researcher to explore their experiences of receiving STI screening promotion as part of the trial. A list of players and captains who agreed to participate was provided to the researcher, who then telephoned, and explained the purpose of the qualitative interviews, gained informed consent and organised a date and time for the telephone interview.

Data collection Individual semistructured telephone interviews were conducted with the players who had consented. The interviews varied slightly according to whether the participant was a player or a captain of a football team; however, all interviews explored the players' basic demographic characteristics, their views and experiences of the process of the intervention they had received (or gave if the participant was a captain) at their club, their thoughts of having STI testing sample collection kits available at the football club, their views of the contents and use of the kits, whether or not they had previously tested for a STI, their experiences of testing for an STI elsewhere and their preferences for future STI testing. All interviews were audio recorded, lasted approximately 30 minutes and were conducted 4–6 weeks after the SPORTSMART intervention by a female researcher. Participants were given a £30 online store voucher for their participation.

Data analysis Interviews were transcribed verbatim and analysed using the framework approach.[154] Transcripts were read and reread by four researchers and coded into broad themes based on the research objective and interview content to create an initial coding framework. This framework was further discussed and modified within the research group. Two members of the research group then systematically applied these codes to the transcripts. Reliability was enhanced by double coding and comparing a subset of transcripts. Few discrepancies emerged and, when they did, consensus was negotiated.

Two weeks after the intervention was completed, all (playing and non-playing) club members aged at least 18 years were invited to take part in a brief, self-administered, anonymous pen-and-paper survey questionnaire (the SPORTSMART survey) to assess club members' sexual risk behaviour and previous STI testing history to inform estimates of the public health impact of offering screening in these settings. We report these findings on pp. 98–101.

Sample size

We aimed to recruit 200 men to estimate the overall acceptance of screening rate with acceptable precision, considering a wide range of possible rates because of the lack of directly relevant evidence from previous studies. Specifically, this sample size would allow us to estimate the rate within 7% if the rate was 50% (i.e. a 95% CI of 43% to 57%) or within 5% if it was either higher or lower (85% or 15%), assuming minimal variability between clubs.

Consent

Club managers gave consent for clubs' involvement in the study. Signed informed consent was obtained from captains before the intervention. Football team members opted in to screening by completing the kit offered, but could opt out of the intervention at any time.

Ethical approval for this study, (including the SPORTSMART survey) was given by the National Research Ethics Service (reference number 13/SC/0029).

Results

Recruitment

Recruitment of football clubs was conducted between October and December 2012. Clubs were contacted by the trial co-ordinator by e-mail and/or telephone to assess interest and eligibility. Five of the 18 clubs initially identified had invalid contact details. Of the remaining 13 clubs, five did not respond and eight (62%) indicated that they were willing to participate. Six were chosen based on the willingness of a club representative to meet with the study co-ordinator and fully discuss the study objectives; the remaining two clubs were placed on a reserve list (*Figure 7*).

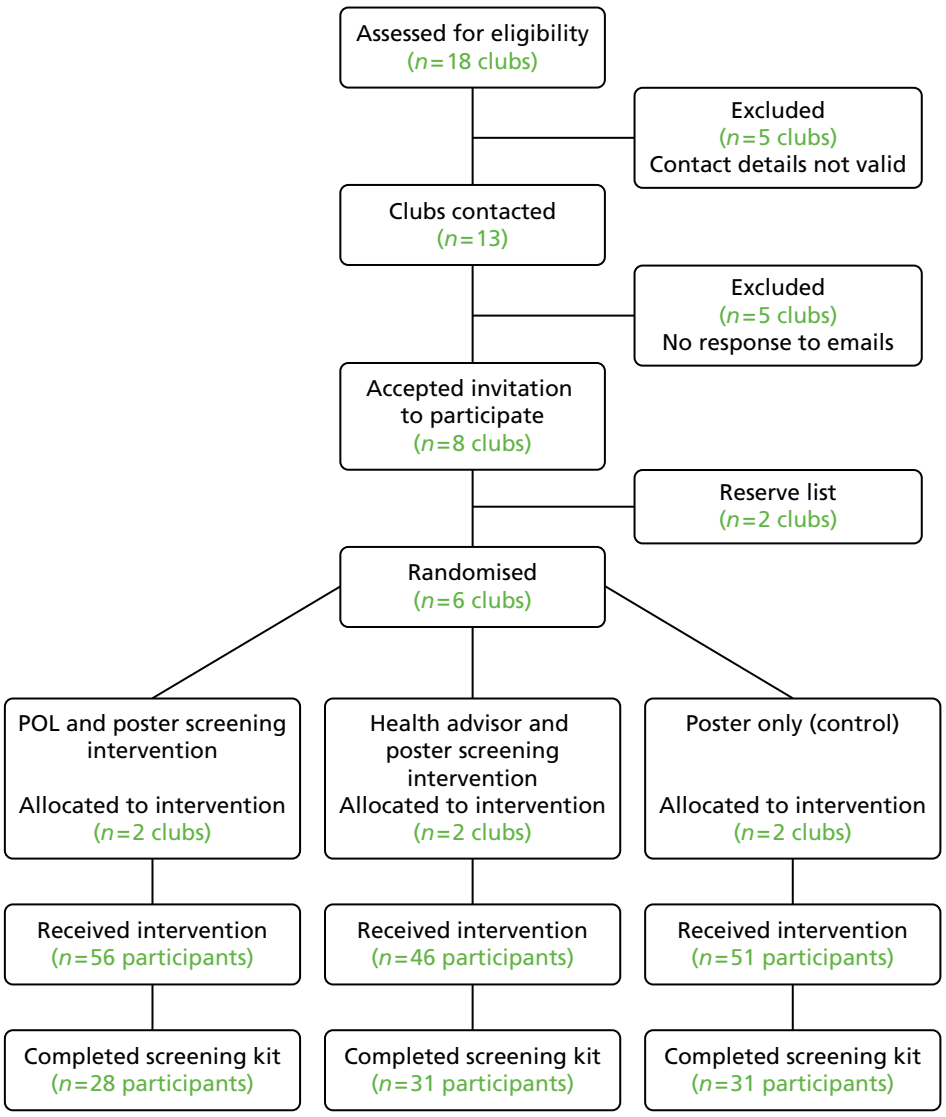

FIGURE 7 Participant flow in the SPORTSMART trial. POL, popular opinion leader.

Acceptability of screening and sexually transmitted infection positivity

The interventions were implemented between February and April 2013. Across the three arms 153 men in six clubs participated in the trial and 90 (59%, 95% CI 35% to 79%) accepted the offer of screening (*Table 37*). Acceptance rates varied considerably by club (see *Table 37*), but the aggregate rates were broadly comparable across the arms: captain led: 28 out of 56 (50%); health professional led: 31 out of 46 (67%); control: 31 out of 51 (61%). The variability within arms was greater than the variability between arms. The majority of test kits were completed within the clubs and only one was returned by mail. There were no positive tests for chlamydia or gonorrhoea from any of the study arms.

Process evaluation

The AFC club listings were a useful initial resource to identify clubs, but contact details for individual clubs were often incorrect and some club websites contained out-of-date contact information. We do not know whether the reason why five clubs did not respond was because of a lack of interest in the study or our failure to establish an appropriate means of communication.

A number of cancelled and rescheduled matches meant that we were unable to deliver the interventions to as many players as planned. Evaluation of field notes and report-back forms from captains and the sexual health adviser confirmed that the interventions were delivered in a standardised way across all study arms and captains felt comfortable delivering the short intervention. However, the poster comparator arm was unintentionally 'enhanced' by some captains, who actively publicised the availability of STI screening at the club prior to the day by including details of the research in their weekly team information e-mail and encouraging players to participate. There were no adverse effects from this research.

Men's views on the acceptability of the SPORTSMART intervention Thirteen men (10 players and three captains) agreed to participate in the follow-up interviews. Two captains and six players from two different football clubs received the poster intervention, four players from two different teams received the poster and HCP intervention and one captain from one team gave the poster and the captain-led intervention.

Men were aged between 21 and 31 years and all had previously tested for a STI. Seven had tested at a specialist GUM clinic, three at university, four at their GP surgery and one at school. Eight men (one married) described themselves as in a monogamous relationship of $\geq$ 12 months; three men described themselves as single with no new sexual partners in the past 3 months; one man reported 'four to five' new sexual partners; and one man reported one new sexual partner during the last 3 months.

The following themes emerged from the analysis.

Delivery and content of the intervention Some men who had experienced the poster and HCP-led intervention felt that the HCP brought some legitimacy to STI testing at football clubs, as they perceived

TABLE 37 Screening kit uptake among participating clubs

Study arm	Club	Players in changing room	Completed kits returned	% return
Health professional led	1a	24	10	42
Health professional led	1b	22	21	95
Captain led	2a	26	10	38
Captain led	2b	30	18	60
Control	3a	24	20	83
Control	3b	27	11	41
Total	All	153	90	59

the HCP to be more knowledgeable and better able to give advice and reassurance before and after testing for a STI:

> *if someone just said, 'oh there's a few things there or there's a few checks there', you feel a bit, mmm, you know, you're a bit wary. But when someone's there to explain to you the ins and outs, know what I mean, it makes it a bit comfortable.*

When the health professional delivered the screening intervention message the men seemed to better appreciate the importance of testing for a STI:

> *I thought it was a good in terms of importance, I remember he told us like statistically someone in here will have it and some people thought that was a bit strong. It's true I guess.*

> *He obviously sold it as the idea that these things can be very serious and definitely worth getting checked for. That's pretty much it. It was sort of quite a strong message. It's the sort of thing that you should be doing and it's definitely worthwhile getting checked.*

They also thought the length of the screening intervention message was about right and liked the tone in which it was delivered:

> *What I did like was the fact that – I can't remember the gentleman's name – he was very matter of fact, just came in, 'right this is what you need to do'. It wasn't a lecture or anything like that. It was very concise.*

Poster-promoted screening All of the men from the clubs that had been assigned the poster-only intervention had been made aware that there would be STI testing kits available at the football club, despite guidance from the trial co-ordinator that testing kits should just be made accessible to the men should they want to test after reading the poster, rather than being 'promoted' in any way. Some men said that they had been told the week before by e-mail as part of the regular team newsletter whereas others said that they had been encouraged to test by the team manager or captain; thus, without consciously doing so these managers and captains were acting like our captain-led intervention based on the popular opinion leader theory. However, the players seemed happy with this approach:

> *I quickly, briefly read over the poster and then just explained it to the team, and just sort of said, 'OK guys, it's obvious there's a couple of posters in the changing room'. There was a drop-in bin, and a box full of the kits. Everyone was kind of wondering what it was all for, although I had warned them before. I just explained, you know, 'All you need to do, piss in a pot, fill out the form, and it will be sent off and you'll get your results back'.*
>
> *Captain*

> *He told us on the day [the manager] that it was on, then he came up with a couple of forms with more detail more information about it and I then had to pass it on to the team. He just told me exactly what was going on, 'the bins are in there, get everyone who wants to to take part'. From my point of view, I thought it was kind of . . . well the important thing is I think the club wanted to do it so it was important thing for us. So I kind of took it on to introduce it to everyone. I think that probably made sure that everyone was involved because it was almost like no one wanted to be left out.*
>
> *Captain*

> *Yeah we walked in and then the manager gave a small speech on how we need to do some testing and read some leaflets. And we did, we all went in the toilet separately and we did a test.*

> *the e-mail said boys, this weekend we gonna have STD [sexually transmitted disease] tests in the changing room, part of this survey and it's a pilot scheme for testing lots of young men in one place*

at a time. And that the football team will be compensated for taking part so please boys, if you can, if you don't mind, please do the test.

Poster and captain-promoted screening We were unable to obtain the opinions of players who received this intervention, but we did interview one captain who gave the message to the players. He was very enthusiastic about STI testing being made available at the football clubs as he had previously tested for a STI at a GUM clinic and found it embarrassing and time-consuming:

Well I thought it was a good idea to be honest. Personally for me, and a couple of other boys were sort of saying as well, going down to the clinic is, well once you're in the clinic it could take up to 2, 3 hours depending how busy the clinic is. And also sort of, it's quite embarrassing to be seen there. It's not a good thing to be seen in a clinic, so sometimes, you know, I've needed to go but I'd probably avoid going in case I bumped into somebody I knew. But having it at the football if a couple of boys that did the test at football then the other boys seem to and it sort of, it's not really embarrassing really at football because you're with the boys.

After going through the message to convey with the researcher, the captain said that he felt comfortable giving the message and subsequently felt that it was well received. However, he thought that a few of the less mature men who usually hang round in a gang felt it embarrassing, whereas the older men found it easy. This seemed to be because the captain himself felt more comfortable giving the message to men whom he had perceived as having the same values as himself:

well I got there a bit early, and [the researcher] made me aware of what was happening and went through it with me so when the boys came in I just sort of spoke to them about what was happening, and then when they were all sitting down and ready I just sort of repeated myself again and just said to complete one of the bottles and I think the majority did, we only got a few where some of them were a bit sort of were against it. I don't know why. I think a few of them were saying it was intrusive, but I don't think it was the way it was presented. I think it was just what the test was for and stuff.

When prompted by the interviewer to explain why he thought some men found it intrusive, the captain gave this explanation:

Well to me it was the boys that were, the younger boys that were, it was like not involved in gangs but sort of . . . the sort of I don't know how to explain it. I wouldn't say they were involved in gangs but the young, street boys. But I think the older players found it easier. I think the younger lads found it a bit more embarrassing.

Captain

It is important to note that, even though the captain refers to some participants as 'boys', all men were aged ≥ 18 years.

Reasons for testing Several of the men mentioned the inconvenience of testing at other services, including making appointments and the time required to attend those appointments. They explained that they had done the test in the trial because it was simple and easy to do, with easy to understand instructions. One of the men who had identified himself at risk said that he would not go to his GP or GUM clinic as he found it embarrassing and had done it once before and found it 'horrible', whereas testing at the club he found easy and felt comfortable 'around his mates':

This is quite easy 'cos you're at football, everyone's doing it and you just do it. It's a lot less worrying. Whereas if you were to book an appointment to go and do it, you'd probably, I don't know, I'd personally get a bit nervous.

Interestingly, few men tested because they thought that they were at risk of having a STI, saying that they just did it because everyone else was doing it. The following dialogue is with a player who reported four to five sexual partners in the last 3 months:

> Participant: *Well I suppose I had no reason for doing it, but everyone else was doing it, there was that, and certainly it was that because I had a test not so long ago, so it wasn't that I was looking to do it relatively soon, but I think it was a sensible thing to do. It was a case of it was there, the opportunity was there, everybody else was doing it, so that was it really the thinking behind it.*
>
> Interviewer: *So do you think you would have been at risk of chlamydia since your last test in January until now?*
>
> Participant: *No. Well I can't tell you 100% but I don't think so no.*
>
> Interviewer: *OK, so have you had any new sexual partners since January?*
>
> Participant: *Mm yes.*
>
> Interviewer: *And that was protected or unprotected sex?*
>
> Participant: *That was unprotected.*
>
> Interviewer: *OK, I was just wondering why you thought you weren't at risk?*
>
> Participant: *Actually when you put it like that . . . actually, I suppose you always assume it's not going to happen to you don't you, when you put it like that I suppose I am at risk.*

Feelings about testing When men were asked how they felt about STI testing at the football club, the majority of them said that they were very comfortable testing with their football colleagues in an all-male sports environment. They did not feel embarrassed to be testing and despite doing a test with all of the other team members they perceived the whole process to be more private and confidential than going to a GUM clinic or their GP:

> *No, I think maybe if it had been just 11 guys at work and stuff, it would be a bit weird but we're all quite good friends and football teams are quite confident with each other anyway, like a shower, we all to do on a Saturday, so like putting a pee in a pot isn't too much of an issue really.*
>
> *I would say no one was embarrassed. I guess probably the nature of the culture, so you know, it's a football club and we're all close mates. We chat about this sort of stuff all the time. Well, not about this sort of stuff, but we chat about sex and women all the time. We're fairly open. We shower together. So actually it's probably as good an environment as you're gonna get, if that makes sense?*
>
> *I think it's a good thing in that it's, well it seems like it's a, you know, it's a targeted, it's a group that, sort of men between the ages of 18 and 30 so this, I found it accessible as well. And at first I had my sort of, I wasn't sure how confidential it would be but then when I saw that there was just a drop box, sort of no one, yeah, I thought it was good because it was confidential.*

Preferences for future testing Overall, the men interviewed would prefer to be tested at a football club in future, because of the 'all lads together' relaxed environment. They also preferred the ease and simplicity of the tests and the convenience – not having to travel to a doctor or a clinic and the fact that

the tests were available in the changing rooms next to the toilets so they could use them when they were changing:

> Participant: *I'd probably, being a boy, I'd prefer it how I have just done it with the football team. I don't know, I suppose it's more confidential if you know what I am saying.*
>
> Interviewer: *In what way?*
>
> Participant: *Don't know, I suppose if you go to your doctor you're doing it face-face sort of thing. I suppose if you're doing it like how your team done it, then I suppose it makes people feel a bit more relaxed and stuff. It certainly made me a bit more relaxed than going to the doctor's or something.*
>
> *I thought it was very good actually, because I think a lot of people, probably myself included, should get tested a lot more often than we do. But actually we all lead very busy lives and we're probably a little bit lazy. But having it there, it's very easy to do, and it was a good thing. It was well received.*

Discussion

To our knowledge this is the first UK trial of STI screening that targets young men in the football clubs in which they play. The design enabled us to report accurate measures of uptake as, unlike many published community and non-health-care-based screening evaluations, we measured the number of men to whom the interventions was offered. Urine-based STI screening was acceptable irrespective of how it was offered. The additional support of team captains and sexual health advisers in the form of a short verbal explanation of the rationale and process for STI screening, followed by handing a kit directly to each man, did not result in greater uptake than simply making the tests kits available on the day, supported by an explanatory poster.

Although implementation of the interventions was straightforward, the poster-only arm was unintentionally promoted by some team captains, who encouraged men to participate in the research through their regular team information e-mails. We were dependent on club fixtures and subject to last-minute match cancellations, which meant that we were unable to deliver the interventions to as many players as planned and thus did not achieve our intended sample size. The interventions began late in the match season and, although we were confident that extending the recruitment phase would have enabled us to reach our intended sample size, this was unfeasible as no further matches were scheduled until after the 4-month match break. We found a greater than anticipated variability between clubs in the acceptability of screening, which limited our ability to estimate acceptability under any single intervention and reduced the precision in our estimate of overall acceptability.

Although many different forms of 'outreach' screening have been described, very few focus exclusively on men, despite research indicating that male patterns of sexual health-care access differ from those of women.[130,133,155] A recent systematic review that included 25 chlamydia screening outreach strategies for men and women found a median participation rate of 53%, with close to 80% of participants tested.[155] The highest uptake of testing (85%), which was considerably higher than in our study, was reported in one of the two studies offering chlamydia screening in Australian Football League clubs,[134,156,157] However, the Australian studies were set in rural areas with few alternative opportunities for STI screening, unlike our London urban areas, which all had multiple different STI screening venues within easy reach. Only one of the included studies (young people attending a leisure centre) was conducted in the UK and uptake in this study was just under 50%.[155] Other studies of chlamydia screening promotion have found varying uptake of screening within similar venues, but unlike our trial this was attributed to differences in the way that researchers invited potential participants to engage in the study.[130]

More young men play football at least once a week than any other sport[158] and so amateur football clubs could be promising settings for STI screening initiatives. A recent random probability sample survey of young UK men suggests that men who do and do not play football are at similar risk of STIs.[72] The same survey also reported that just over half of men who play football at least once a month would find the venue in which they play an acceptable setting to access self-testing kits,[72] reflected in the uptake of testing within this pilot study.

The qualitative data from this study suggested that the football location, the traditionally male environment therein and the approach used to encourage STI testing in all of the SPORTSMART intervention arms enabled men to test in circumstances that felt 'right' rather than threatening to their masculinity. On the whole, men in our study appeared to appreciate testing with others 'like them' and were encouraged to test through shared experiences and the light-hearted atmosphere ('banter') in those settings, as much as by the particular content of the SPORTSMART interventions. These findings concur with a growing literature surrounding the potential of sporting organisations to deliver health initiatives to men.[159,160] This type of approach, which facilitates health promotion activities in a way that is consistent with, rather than challenging to, common ideals of masculinity, appears to be highly acceptable to some men but we recognise that the nature of recruitment and the low numbers of men available to interview are likely to have introduced ascertainment bias.

Our approach appears to be broadly acceptable to, and feasible for, young football players, team captains and football clubs. However, several clubs were uncontactable and others did not respond. Although the poster-only arm was unintentionally enhanced because of the enthusiasm of the captains in this arm, their strategy for enhancement required minimal effort at no additional cost. Should this type of screening be implemented more widely, we would expect captains to forewarn their players of the screening activity even if they had no further role in promotion of screening.

We did not detect any new *C. trachomatis* or *N. gonorrhoeae* infections but this was not unexpected given the estimated population prevalence.[161] Adopting a male-focused approach to screening may have been an important factor in the high uptake, and factors related to the role of setting and collective screening within groups of men who know each other deserve further study. Although we have developed a simple, feasible and acceptable approach to male STI screening and operationalised it within football clubs, given men's reported preference for traditional health-care settings,[72,132] a clearer view of the public health benefits of this approach is needed before we can be certain of its wider impact.

Preliminary cost–consequence analysis of the SPORTSMART pilot randomised controlled trial

The objectives of this economic analysis were to obtain cost and outcome data for the alternative screening interventions developed by the SPORTSMART pilot trial and to use these data in a preliminary economic evaluation. The success of any new intervention in increasing screening uptake needs to be balanced against the resources required to achieve the desired outcome and any additional costs must be evaluated in terms of additional benefits that can be attributed to them.

Methods

Data collection

For all study arms, resource use and cost data were collected prospectively in the trial. This included the time needed to recruit and brief the clubs, transport costs and the costs and resource use associated with delivering the interventions and testing the samples. For all arms, data were collected on direct health service costs and some of the private costs incurred by the players and captains.

Resource use and cost definition

There were several elements that were common to all of the intervention arms. These related to the recruitment and briefing of the clubs, the materials used within the interventions and the collection and processing of completed samples. The time taken to recruit, brief and prepare the clubs for the screening intervention was recorded and staffing costs were estimated using the *Unit Costs of Health and Social Care 2013*.[80] Costs associated with travel to the clubs to prepare for the interventions were also included.

Specially designed posters were used at all locations to promote screening and provide information. Testing kit packs were common to all promotions and contained the equipment necessary to complete a urine sample along with a patient registration form, information leaflet and football-themed condoms. The outer box for the testing kit pack was specially designed and included football photographs and logos. Special, secure collection containers, with football-themed wrapping, were made available for players to deposit their samples into at the club. The aim of all of the football-themed design elements was to encourage players to participate. We assumed that all of these elements were an essential part of the intervention and included their costs in our estimates. We assumed that designs and logos could be reused over a period of 3 years until they became outdated and thus annuitised all design and editing costs for 3 years at an interest rate of 3%.[96] Transport costs associated with returning the samples to the clinic were also included. Although players were given the option to return their samples by post, only one sample was returned using this method and, for the base case, we assumed that the secure collection box would be the only method of specimen return provided.

Additional facilities were required to store the samples before they were sent to the laboratory for processing. We assumed that such additional storage would be needed if the intervention was rolled out; these facilities could be reused over a period of 3 years and we included annuitised costs accordingly. Costs associated with processing samples were estimated using the cross charge between the processing laboratory and the study clinic. This represents the actual cost to the clinic of processing samples. Staff time at the clinic associated with patient administration was recorded and costs estimated.

Captain and poster-promoted screening

The estimated cost of the captain-led screening intervention included costs for a member of staff (a health-care assistant) from the clinic to undertake the sample processing and be on site before and after the intervention to deliver and prepare all of the materials and facilitate the safe return of the completed samples to the clinic. We included this cost to reflect recorded practice within the pilot trial and to meet clinical governance requirements. For the base case it was assumed that the time taken by the team captain to prepare for and deliver the intervention was forgone leisure time and would not impact on health service costs. However, the effect of including these costs or some kind of financial incentive for the captain was analysed as part of the sensitivity analysis.

Sexual health advisor and poster-promoted screening

The estimated costs for the health advisor-promoted intervention included the costs for a sexual health advisor to lead the screening promotion. We assumed that the health advisor would also take the materials to the club, prepare the promotion and ensure the safe return of completed specimen samples to the clinic, in accordance with trial processes and clinical governance requirements, and hence included time and travel costs in our estimates.

Poster-promoted screening only (control)

As for the captain-led arm, we assumed that a member of staff (a health-care assistant) from the clinic undertaking the testing and notification would need to be on site before and after the promotion and included costs accordingly. These costs were included to reflect recorded practice within the pilot trial and to meet clinical governance requirements.

Assumptions

It was necessary to make a number of assumptions to ensure a consistent approach to the comparative analysis of the intervention arms:

- In the event of a roll-out of the interventions, a similar process of club recruitment as recorded in the pilot trial would be required.
- The football-themed designs used on the test kit boxes, pens, posters and specimen collection boxes were an integral part of the trial. We also assumed that such elements could be reused for a period of 3 years until they became outdated and annuitised costs accordingly.
- Additional storage facilities would be required to accommodate the return of completed samples to the clinic and we assumed that these facilities could be reused for a period of 3 years.
- The completed samples would be deposited by players within a specimen collection box.
- A member of clinic staff would need to be on site before and after the promotion to set up the materials and ensure the safe return of specimens to the clinic. This member of staff would be the sexual health advisor in the health advisor-led screening arm or a health-care assistant or equivalent.
- The time taken by the team captain to deliver the intervention would be foregone leisure time and would not impact on health service costs.

Analysis

We conducted a cost–consequence analysis that involved comparing the costs and outcomes associated with all three interventions separately.[110] This kind of analysis is more appropriate than a full economic evaluation because the current study is a pilot only and a full RCT from the NHS perspective has not been carried out. The main analysis was conducted from the perspective of the NHS.

We assessed costs and outcomes in a disaggregated manner for each intervention arm to establish whether or not any showed clear dominance. Dominance is judged to have occurred when one intervention costs less but is more effective, in terms of the outcome achieved, than a different intervention. Conversely, an intervention is dominated if it costs more but is less effective than the comparator. We examined costs and consequences for all three arms. The main analysis is based on the outcome of whether or not the player accepted the offer of screening. All cost data reported are presented in UK pounds at 2012/13 prices.

A series of one-way deterministic sensitivity analyses were carried out to examine uncertainties around all key cost and outcome parameters. Plausible ranges were specified using information from the trial and from the literature. These analyses included (a) reducing club recruitment time substantially from 11 hours to 4 hours per club by developing a higher-level agreement with the Football Association; (b) including an incentive of £1000 for each club to help maximise participation (to reflect practice within the study); (c) expanding from the NHS perspective (in which only health service costs are included) to incorporate broader societal costs associated with captain and player participation in screening, with the assumption that the time taken to participate in the intervention was forgone leisure time, valued at 40% of the median hourly wage;[162,163] and (d) adjusting the cost of the test kit boxes to account for the logo and design costs associated with unused boxes. Further sensitivity analyses were carried out but are not reported.

Results

The outcomes by trial arm are reported in *Table 37* and are summarised below. It is evident that, although there was considerable variation in the uptake rates between individual clubs, the results were broadly comparable across study arms.

The cost of the SPORTSMART testing kit was common to all study arms. The kit included equipment for testing and registering as a patient. The overall cost of the kit was £5.66, which included the cost of several specially designed elements to make the pack as attractive as possible to the players (*Table 38*).

Specimen collection boxes were used in all locations and had a football-themed design to encourage players to deposit their samples. The costs associated with the boxes are shown in the *Table 39*.

TABLE 38 Cost of the SPORTSMART testing kit

Component	Unit cost[a] (£)[b]	*n*	Cost per pack (£)[b]
Biohazard envelope	1.05	1	1.05
Testing kit outer box[c]	2.23	1	2.23
Thermacor compact urine transporter (MedDXSolutions, Hereford, UK)	0.66	1	0.66
Urine container (30 ml)	0.15	1	0.15
Test request form	0.03	1	0.03
Pen[c]	0.85	1	0.85
Condoms	0.22	3	0.66
Information sheet	0.03	1	0.03
Total cost of one testing pack			5.66

a Including value-added tax (VAT) and shipping costs.
b Costs are in UK pounds, 2013.
c Includes costs for the first year of the design elements of the test kit box and pens, annuitised at 3% for 3 years.

TABLE 39 Cost of the SPORTSMART specimen collection box

Item	Total cost (£)
Storage box (for transport)	19.96
Specimen collection box (×2)	21.09
Design and production of themed coverage for collection boxes[a]	290.30
Protective sheeting	2.40
Total cost	333.75
Per club	55.62

a The costs associated with the design elements of the collection box have been annuitised at 3% for 3 years. The costs given are for the first year. Costs include valued-added tax (VAT) when applicable.

Full costs for each of the intervention arms are shown in *Tables 40–42*. The results of the pilot trial suggested that total costs were similar across all of the intervention arms, with the total costs of the captain-promoted screening intervention estimated to be £2489.37 compared with £2735.61 for the health advisor-led arm and £2535.61 for the poster-only arm. Overall costs were similar because the highest proportion of costs related to fixed costs, such as staff time for recruiting and briefing the clubs and the equipment required for delivering the promotion.

The aim of the cost–consequences analysis was to examine the costs for all three intervention arms and compare these with the main outcome of screening uptake (*Table 43*). The average cost per player tested was comparable across the trial arms using the base-case results, with the average cost per player tested for the captain-led promotion estimated to be £88.91, compared with £88.25 for the sexual health advisor-led screening promotion and £81.79 for the poster-only (control) arm. Because overall costs are similar, the average cost per player screened will naturally be affected by the relative effectiveness of any particular intervention model. For example, if a particular intervention arm results in more players accepting screening than an alternative strategy at the same cost, the cost per player screened will be lower relative to the alternative as more players have been screened. However, as uptake rates varied considerably at the club level, our ability to estimate uptake definitively for any single intervention arm is limited.

TABLE 40 Health service costs for the captain-promoted screening intervention arm (two clubs)

Resources used	Cost item	Unit cost (£)[a]	*n*	Total cost (£)[a]
Recruitment of club	Per club	516.88	2	1033.75
Poster pack[b]	Per pack	53.92	2	107.85
Test kit[b]	Per player	5.66	46	260.36
Promotion	Per club	125.00	2	250.00
Specimen collection box[b]	Per club	55.62	2	111.25
Transport of specimen collection box	Per club	135.64	2	271.28
Additional storage facilities[c]	Per club	11.63	2	23.26
Sample processing	Per player tested	10.79	28	302.12
Patient administration	Per player tested	4.63	28	129.50
Total cost				2489.37
Number of players tested			28	
Average cost per player tested				88.91

a Costs are in UK pounds, 2013.
b Includes costs for the first year for the design elements of the posters, test kit box, pens and specimen collection boxes, annuitised at 3% for 3 years.
c Includes costs for the first year for the storage facilities, annuitised at 3% for 3 years.

TABLE 41 Health service costs for the sexual health advisor-promoted screening intervention arm (two clubs)

Resources used	Cost item	Unit cost (£)[a]	*n*	Total cost (£)[a]
Recruitment of club	Per club	516.88	2	1033.75
Poster pack[b]	Per pack	53.92	2	107.85
Test kit[b]	Per player	5.66	46	260.36
Promotion	Per club	225.00	2	450.00
Specimen collection box[b]	Per club	55.62	2	111.25
Transport of specimen collection box	Per club	135.64	2	271.28
Additional storage facilities[c]	Per club	11.63	2	23.26
Sample processing	Per player tested	10.79	31	334.49
Patient administration	Per player tested	4.63	31	143.38
Total cost				2735.61
Number of players tested			31	
Average cost per player tested				88.25

a Costs are in UK pounds, 2013.
b Includes costs for the first year for the design elements of the posters, test kit box, pens and specimen collection boxes, annuitised at 3% for 3 years.
c Includes costs for the first year for the storage facilities, annuitised at 3% for 3 years.

TABLE 42 Health service costs for the poster-promoted screening intervention (control arm) (two clubs)

Resources used	Cost item	Unit cost (£)[a]	*n*	Total cost (£)[a]
Recruitment of club	Per club	516.88	2	1033.75
Poster pack[b]	Per pack	53.92	2	107.85
Test kit[b]	Per player	5.66	46	260.36
Promotion	Per club	125.00	2	250.00
Specimen collection box[b]	Per club	55.62	2	111.25
Transport of specimen collection box	Per club	135.64	2	271.28
Additional storage facilities[c]	Per club	11.63	2	23.26
Sample processing	Per player tested	10.79	31	334.49
Patient administration	Per player tested	4.63	31	143.38
Total cost				2535.61
Number of players tested			31	
Average cost per player tested				81.79

a Costs are in UK pounds, 2013.
b Includes costs for the first year for the design elements of the posters, test kit box, pens and specimen collection boxes, annuitised at 3% for 3 years.
c Includes costs for the first year of the storage facilities, annuitised at 3% for 3 years.

TABLE 43 Comparison of costs and outcomes for the intervention arms

Intervention arm[a]	Total cost (£)[b]	Number of players tested	% accepting screening offer	Average cost per player screened (£)[b]
Captain led	2489.37	28	50	88.91
Health advisor led	2735.61	31	67	88.25
Poster only (control)	2535.61	31	61	81.79

a Includes costs and outcomes for both clubs in each trial arm.
b Costs are in UK pounds, 2012/13.

Sensitivity analysis

The results of the one-way deterministic sensitivity analysis are shown in *Table 44*. First, the results associated with decreasing the time needed for club recruitment are presented. Such a scenario might be expected if a higher-level agreement was secured with the Football Association. As expected, this reduced overall costs, with the cost per player screened ranging from £60.06 to £66.51. Second, including an incentive for clubs to participate increased the overall costs for all trial arms. The results for the third scenario show that including costs for team captains to deliver the promotion made the captain-led arm slightly more expensive. However, as the process evaluation revealed that team captains had also informally promoted the screening intervention in the other trial arms, including these costs for the captain-led arm alone may not be justified. In the final scenario, increasing the costs associated with the test kit boxes (to adjust for costs associated with unused boxes) increased the total costs for all intervention arms, with estimates per player screened ranging from £84.18 to £91.55. If the trial were rolled out at scale, the costs associated with the logo and design elements would become negligible and the costs associated with any unused boxes would not be important.

TABLE 44 Sensitivity analysis: selected results

Sensitivity analysis	Original cost (£)[a]	Revised cost (£)[a]	Captain-led arm: total cost (average cost per player screened) (£)[a]	Health advisor-led arm: total cost (average cost per player screened) (£)[a]	Poster-only arm: total cost (average cost per player screened) (£)[a]
Base case	–	–	2489.37 (88.91)	2735.61 (88.25)	2535.61 (81.79)
Reducing club recruitment time to 4 hours per club	516.88[b]	180[b]	1815.62 (64.84)	2061.86 (66.51)	1861.86 (60.06)
Including £1000 incentives for each club	–	1000[b]	4489.37 (152.76)	4735.61 (160.33)	4535.61 (146.31)
Including costs for team captains to deliver promotion	–	2.68[b]	2494.63 (89.09)	–	–
Increasing costs for testing boxes	5.66[c]	7.27[c]	2563.43 (91.55)	2809.67 (90.63)	2609.67 (84.18)

a Costs are in UK pounds, 2012/13.
b Per club.
c Per item.

Discussion

This was an exploratory economic evaluation comparing the costs and outcomes of alternative models for promoting screening amongst young men. The results as a whole suggest that all of these methods of screening promotion are acceptable to players within amateur football clubs, with 153 men receiving the intervention and 90 accepting the offer of screening (59%, 95% CI 35% to 79%). The overall costs associated with the intervention arms were similar. The outcome of average cost per player screened was comparable across all arms, with the average cost per player tested for the captain-led promotion estimated to be £88.91, compared with £88.25 for the sexual health advisor-led screening promotion and £81.79 for the poster-only (control) arm. This outcome is obviously affected by the estimate of the number of players accepting screening and, as our ability to estimate uptake for any single intervention arm is limited, drawing conclusions about the relative costs and consequences of the interventions is not justified. No intervention model can be judged to be dominant and the average cost per player tested can be seen as comparable across all of the study arms.

It might have been expected that the poster-only control and captain-led arms would have significantly lower costs than the health advisor arm as no member of staff was required to deliver verbal information to the players. However, costs were actually found to be similar because of the need for a member of clinic staff to deliver the materials to the study location and ensure the safe return of testing samples to the clinic, to meet clinical guidelines. In the event of a roll-out of the trial, a satisfactory alternative to the presence of a clinic member of staff might be found, which would make the costs associated with these arms slightly lower.

This study has highlighted several limitations, as is typical of exploratory research. It was difficult to draw firm conclusions about the relative cost-effectiveness of the interventions in the trial as screening uptake could not be estimated with precision for any single intervention arm because acceptance rates varied considerably at the club level and the overall target sample size was not achieved. This was because of difficulties in recruitment linked to poor weather and the need to reschedule a number of matches. Within the economic analysis some assumptions were made about how the interventions would operate

if they were rolled out and, although these were examined within a sensitivity analysis, they would need to be tested on a larger scale. A one-way deterministic sensitivity analysis was carried out as this is a preliminary economic analysis alongside a pilot trial and a full probabilistic sensitivity analysis would not be appropriate because of the small sample size and the heterogeneity of uptake rates at club level. Further uncertainties around cost and outcome parameters would need to be analysed if a full RCT were conducted. Finally, it was intended that players in the control arm would be uninfluenced by team captains. However, the process evaluation revealed that team captains in this arm had informally encouraged players to participate in screening, because they were so enthusiastic about the study. This is likely to have affected the results for the poster-only arm.

The strength of this study is that detailed data on costs and resource use were collected, which can inform similar interventions in this area and enable comparisons with other research findings. In addition, data were collected on the numbers of players who attended the screening promotion events and thus it is possible to estimate the level of uptake of screening. Often with such health promotion interventions, the number of people exposed to a particular intervention is unknown, which limits the type of economic analysis possible.

Very little information exists about the cost-effectiveness of screening programmes in non-clinical settings. A recent systematic review of studies concerned with chlamydia and gonorrhoea screening outreach programmes identified only three studies that included information on costs.[155] Buhrer-Skinner *et al.*[164] calculated a cost per test carried out for outreach clinics in Australia but did not include staff time, transport and set up costs. Morris *et al.*[165] calculated the costs associated with two Californian youth programmes but did not include additional time associated with volunteer input. Detailed costings were also provided by a study evaluating the cost-effectiveness of a multifaceted community intervention to increase screening in Stockholm.[166] However, because of the nature of the intervention, which involved a large-scale publicity campaign and expanded access to testing facilities, it is difficult to compare these results with those of the SPORTSMART study. The findings of a costing study of chlamydia screening within primary care suggest that the costs per case screened for the SPORTSMART study are higher than would usually be expected in a UK primary care setting.[102]

However, the additional public health benefits associated with outreach activities would also need to be taken into account. In addition, achieving adequate coverage of screening in primary care, especially in men, is challenging.

Conclusions

This preliminary economic evaluation has shown that similar costs and outcomes were demonstrated across all three study arms. This suggests that further evidence is needed about the most cost-effective way to encourage screening in a football setting. The results may suggest that simply displaying posters and providing testing equipment offers the best value for money compared with providing formal verbal information to promote screening. However, the fact that the control arm was unintentionally 'enhanced' by enthusiastic team captains needs further investigation. It may suggest that team captains can have an important influence on screening uptake, irrespective of whether or not they take on a formal role in promoting the intervention. This has implications for economic analyses, as the potential costs associated with their informal and formal input need to be carefully considered. Additional evidence is needed about the public health benefits associated with screening interventions in non-clinical settings so that their cost-effectiveness can be fully evaluated. The potentially higher costs associated with 'outreach' activities need to be weighed against their wider health benefits so that policy makers can be fully informed about which approaches offer the best value for money. This may involve consideration of a broader range of outcomes that can capture both the health and non-health benefits potentially associated with public health interventions.

An anonymous survey of sexual risk and sexual health screening behaviours of men in amateur football clubs: the SPORTSMART survey

Objective

- To examine the potential public health benefit of the SPORTSMART intervention by comparing the sociodemographic and behavioural profile of men who completed the SPORTSMART survey with that of similarly aged men in the general population.

Methods

Two weeks after the STI intervention was completed, all club members aged at least 18 years were invited to take part in a brief, self-administered, anonymous pen-and-paper survey questionnaire to assess their sexual risk behaviour and STI testing history, as well as collect standard sociodemographic data. Club managers, secretaries and team captains offered the survey to all male members aged at least 18 years and completed surveys were returned to a locked box on display in the club premises. The 20-item questionnaire is provided in *Appendix 2*. As far as possible, questions used the same wording as in the third National Survey of Sexual Attitudes and Lifestyles (Natsal-3),[146,167] permitting comparisons with this general population survey.

The third National Survey of Sexual Attitudes and Lifestyles survey

Full details of the methods for Natsal-3 have been reported elsewhere.[146,167] Briefly, Natsal-3 is a stratified probability sample survey of 15,162 women and men aged 16–74 years in Britain who were interviewed between September 2010 and August 2012. Participants were interviewed with a combination of computer-assisted face-to-face and self-completion questionnaires, which included questions about participants' sexual lifestyle and attitudes. To ensure the greatest comparability with the SPORTSMART sample, only men in the Natsal-3 sample aged 18–44 years and resident in London are included in these analyses.

Statistical analysis

Data from the two surveys were compared using the survey analysis functions of the statistical software Stata 13, enabling us to account for the weighting, clustering and stratification of the Natsal-3 data. Survey weights were applied to the Natsal-3 data to adjust for the unequal probability of selection and non-response, ensuring that these data were broadly representative of the British general population, according to the 2011 census,[168,169] in terms of gender, age group and region.[146,167]

Percentages are presented for each sample for key sociodemographic characteristics, reported sexual behaviours and sexual health outcomes for which data are available in the two surveys. In addition, 95% CIs are presented for the Natsal-3 estimates.

The chi-squared test was used to examine significant differences in reporting between the men in the two samples. As the SPORTSMART sample was significantly younger than the Natsal-3 sample, and a larger proportion reported having at least a degree, reflecting that one of the football clubs was a university 'old boys' team, multivariable logistic regression was used to calculate adjusted OR to account for the confounding effect of differences in age and educational attainment when comparing the characteristics and behaviours of men in the SPORTSMART sample with men in the Natsal-3 sample. Similarly, multivariable logistic regression was also used to calculate adjusted ORs to take account of differences between the two samples in terms of the number of sexual partners reported (in addition to age and educational attainment) when comparing the data on non-use of condoms, STI/HIV risk perception and sexual health outcomes. Statistical significance is considered as $p < 0.05$ for all analyses.

Data are also reported for the type of setting in which SPORTSMART men who had tested for any STI in the past year had done so, excluding as part of the SPORTSMART intervention. The corresponding data for Natsal-3 refer specifically to testing for chlamydia in the past year. Formal statistical comparisons were not made because of the small numbers.

Ethical approval for the SPORTSMART study was given by the National Research Ethics Service (reference number 13/SC/0029). The Natsal-3 study obtained ethics approval from Oxfordshire Research Ethics Committee A (reference number 09/H0604/27).

Results

In total, 212 men completed the SPORTSMART survey, of whom 192 were aged 18–44 years. This corresponds to an estimated response rate of 61.9% of the total number of questionnaires left with the football clubs. In the Natsal-3 sample, 409 men were in this age group and resident in London. The estimated overall response rate for Natsal-3 was 57.7% and the co-operation rate was 65.8% (of all eligible addresses contacted).[146,167]

Sociodemographic characteristics

Men who completed the SPORTSMART survey were younger than London-resident men in the Natsal-3 sample, with 32.8% aged < 25 years in the SPORTSMART survey compared with 21.7% in the Natsal-3 sample. Men who completed the SPORTSMART survey were more likely to report a university education (61.5% vs. 50.0%), a difference that remained significant after adjusting for age [adjusted odds ratio (AOR) 1.83, 95% CI 1.26 to 2.65]. Although a smaller proportion of SPORTSMART men than men in Natsal-3 reported living with a partner (32.2% vs. 50.5%; AOR 0.64, 95% CI 0.40 to 1.01), a larger proportion of SPORTSMART men reported currently having regular sexual partner(s) (AOR 1.92, 95% CI 1.25 to 2.97).

Sexual partners

Almost all men in the SPORTSMART sample (96.5%) reported at least one sexual partner in the past year, in contrast to 87.6% of men in the Natsal-3 sample (AOR 4.51, 95% CI 1.84 to 11.1). Nearly half (48.2%) of the SPORTSMART sample reported two or more partners in the past year, which was significantly higher than the rate in the general population (20.6%; AOR 3.25, 95% CI 2.15 to 4.92). Men in the SPORTSMART sample were also more likely to report having had concurrent sexual partners in the past year (22.9% vs. 7.7%, AOR 2.05, 95% CI 1.39 to 3.02) but, among those reporting two or more partners, the SPORTSMART men were less likely to report concurrency (AOR 0.39, 95% CI 0.21 to 0.75).

There was no difference in the proportion of men in the two samples reporting same-sex partner(s) in the past year, at around 4%. A similar proportion reported paying for sex in the past year but this proportion was greater than in the general population sample (4.6% vs. 1.4%), a difference that remained significant after adjusting for age and education (AOR 3.33, 95% CI 1.04 to 10.7) but not after additionally adjusting for the number of sexual partners reported in the past year.

Non-use of condoms

Men in the SPORTSMART sample were more likely to report not using condoms for vaginal or anal sex on at least one occasion in the past year (AOR 2.17, 95% CI 1.39 to 3.41). After additionally adjusting for partner numbers, SPORTSMART men had a higher odds of reporting this measure of unprotected sex, although this was of borderline statistical significance (AOR 1.57, 95% CI 0.93 to 2.64). A similar pattern was observed for the study's measure of experiencing unsafe sex, defined as reporting at least two partners and no condom use, both in the past year.

Sexually transmitted infection/human immunodeficiency virus risk perception

Relative to men in the general population, a larger proportion of men in the SPORTSMART sample considered themselves to be 'greatly' or 'quite a lot' at risk of STIs (but not HIV), although this was not statistically significant in multivariable analyses.

Sexual health outcomes

A larger proportion of men in the SPORTSMART sample than men in the general population reported having tested for STIs in the past year (22.8% vs. 15.4%), but no difference was observed in multivariable analysis. The proportion reporting ever having had a STI diagnosis/es was the same in the two samples (around 14%).

Venue of sexually transmitted infection testing in the past year

Among the 37 SPORTSMART men who reported STI testing in the past year (not including testing as part of the SPORTSMART study) and who reported the venue of their most recent test (if more than one), 22 (59.5%) reported that this was at a sexual health clinic. Seven (18.9%) reported the venue as general practice and a further three (8.1%) reported another type of clinic, such that the majority (86.5%) had tested in a health-care setting. The remaining five men reported 'a test you sent for from the internet' ($n = 2$, 5.4%) or 'other' ($n = 3$, 8.1%). A similar distribution was observed for the 68 men in the Natsal-3 survey who reported testing specifically for chlamydia in the past year: the most commonly cited setting was a sexual health clinic (44.1%), followed by general practice (17.7%), with 79.4% overall citing testing in a health-care setting.

Discussion

Men attending amateur football clubs who completed the SPORTSMART survey were more likely to report some sexual risk behaviours, and they seemed aware of their increased STI risk, relative to men in the general population. These differences may explain the larger proportion of SPORTSMART men reporting STI testing in the past year. This suggests that the SPORTSMART initiative is unlikely to reach men who would not otherwise use sexual health services. However, the data also suggest that men who participate in amateur football may benefit from the opportunity to test for STIs and to receive health promotion messaging in non-traditional venues such as football clubs. Guidelines recommend STI testing on change of sexual partner,[29,31] yet, although almost half of the men in the SPORTSMART sample reported two or more partners in the past year (and thus had experienced partner change), only around one in five reported STI testing during this time. As football is the highest participation team sport in England,[137] there are potential health benefits for both the population and the individual from providing novel opportunities for STI testing. Furthermore, the football clubs that participated in the SPORTSMART study were all situated in London, which as a large city in the UK has a number of opportunities to access free sexual health care. It is highly likely that initiatives such as SPORTSMART may therefore yield an even greater public health benefit in more geographically remote settings with limited access to sexual health care.[156]

It is important to consider whether or not methodological differences between SPORTSMART and Natsal-3 may account for some of the findings observed. For example, the SPORTSMART sample data may be subject to greater reporting bias as, although they were collected using an anonymous self-completion survey, the men completed the surveys alongside their peers. The direction of this bias is unclear as over- and under-reporting of behaviours are both plausible. It is also necessary to question the impact that participation in the SPORTSMART intervention may have had on participants' responses in the subsequent survey. STI screening promotion featured in all three arms of the SPORTSMART intervention and so social desirability bias is probable. Because of the anonymous nature of the survey it is not possible to know which men who completed the survey also participated in the SPORTSMART intervention and so it is not possible to determine whether the uptake of testing through the SPORTSMART study varied according to risk behaviour and/or STI testing history.

The SPORTSMART survey used identically worded questions to those used in Natsal-3 for almost all of the characteristics and behaviours compared to allow valid comparisons. One notable exception is the question regarding STI testing. The SPORTSMART survey asked about testing for any STI whereas Natsal-3 asked about testing for particular STIs, including chlamydia.[115] Although this may therefore explain some of the difference observed, this is perhaps a reasonable comparison as a chlamydia test is the minimum test to be offered when testing for STIs, regardless of setting[170,171]

To ensure valid comparisons in terms of the men being compared it was necessary to limit the Natsal-3 denominator to men resident in London. Thus, although Natsal-3 has a large sample size overall, the number of participants eligible for this study may have limited the detection of statistically significant differences, especially in multivariable analysis. However, it was necessary to use this statistical technique to take account of the confounding effects of demographic and behavioural differences between the two samples. Furthermore, although the Natsal-3 survey is broadly representative of the British general

population,[28] with a response rate in line with that of other major social surveys completed in Britain around the same time,[17,172] it is worth noting that the response rate was slightly lower among young men resident in London, the population group of interest for this paper.[30]

In conclusion, men who completed the SPORTSMART survey were more likely to report some sexual risk behaviours and they seemed aware of their increased STI/HIV risk. This may explain the greater proportion reporting to have tested for STIs in the past year relative to men in the general population. Offering STI testing in amateur football clubs – regardless of mode of delivery[124] – is therefore unlikely to reach men who would not otherwise test for STIs unless access to sexual health services is poor.[156] However, it does provide men who seem to be at a greater risk of STI transmission an alternative venue to test and receive health promotion advice. As well as increasing access, this approach may also help to normalise sexual health care for men, yielding a public health benefit. With the recent changes in sexual health service delivery and commissioning in England,[13,75] including in terms of recognising STI prevention as just one component of sexual health and well-being[173] and, in turn, sexual health as just one component of public health, this survey provides empirical evidence to inform the planning and delivery of services and health promotion interventions to maximise public health benefit across the piece.

Conclusions, recommendations for future research and implications for clinical practice The Invisible Man

Our research focused particularly on sexual health needs and provision among young heterosexual men. Throughout the programme we identified wider gender issues that create structural inequalities in sexual health provision and access. Gendered expectations of men's health-seeking behaviour, along with the offer and provision of services in line with stereotypes of male behaviour and need that are out of line with evidence, often limit men's ability to seek and use health care. Although there is growing understanding of gender in health,[174] this largely focuses on the vulnerabilities of women. As the Chief Medical Officer report states, women need to be able to address their health needs in the workplace and across civil society.[174] Throughout our programme of research, which unusually focuses on the needs of younger heterosexual men, it grew increasingly clear that the health of men and women alike requires radical development in our understanding of the relationship between gender and health.

We identify and challenge an overarching myth that heterosexual men are both incompetent and unwilling to engage with health services. Our data comprehensively demonstrate that young heterosexual men are far more engaged with services than clinicians believe, or than media stereotypes suggest.

Myth and reality: young men's relationship to conventional and novel sexual health services

Our findings from the national random probability sample survey (see *Chapter 3*) confirmed that men use, and prefer to use, conventional services, including general practice and GUM clinics, for their sexual health needs, with around three-quarters of young men surveyed having attended their GP in the past year. These findings are supported by the narratives of men who participated in the qualitative interviews (see *Chapter 3*). These men also placed value on accessing screening in a discrete, time-efficient way that fitted in with their normal routines and day-to-day life. The preference for conventional services may reflect cultural expectations with regard to access to and supply of health care along with a degree of perceived congruency between health-care settings and medical testing. Taken together with the high acceptability of general practice for accessing STI and HIV testing kits, this highlights the importance of, and potential for, chlamydia and HIV screening in general practice, especially among younger men,[72] and aligns with the latest NCSP strategy. However, this approach has many inherent challenges, which we discuss below.

The finding that most men had seen their GP in the last year is in keeping with the findings of other studies.[107,108,150,159,175] However, young men's high reported rates of attendance in general practice are not in line with the perceptions of general practice staff, who tend to substantially underestimate the frequency with which men attend general practice.[102] Current rates of STI and HIV screening in general

practice are low, which could suggest reluctance on the part of the health-care provider to offer testing[140] or a failure to recognise the attendance of young men as a common opportunity for health promotion.

The many barriers both to opportunistic chlamydia screening and HIV testing in general practice are well recognised.[102,160,176–178] As a result of strongly held beliefs that men are difficult to reach primarily because of non-attendance at traditional health-care venues, attempts to increase chlamydia screening uptake in men have to date focused on trying to create innovative and customised approaches rather than exploiting the potential of mainstream health services.[179] The NCSP data show that only 25% of tests in men are carried out in 'core' (general practice, GUM clinic, CASH service) health settings.[151] However, given our findings, and the considerable potential to engage more men in STI and HIV testing through general practice,[138] it is likely that basic sexual health services could be more efficiently placed within existing frameworks, irrespective of how 'non-innovative' they may seem.

Although many studies have shown that using non-traditional and sports settings to screen for STIs is feasible,[134,147] few have focused on the acceptability of different settings for men. Lorimer *et al.*'s[136] study of willingness to participate in a non-medical approach to chlamydia screening found that men in particular valued the possibility of screening in these settings. Furthermore, the uptake of screening varied by setting, supporting our finding that the acceptability of sports settings was greater in those who had actually engaged in sporting activities over the last month.[136] Our findings contrast with those of others which suggest that anonymity is a key factor determining the acceptability of screening. In a qualitative study of young men's experiences and perceptions of chlamydia screening commissioned by the NCSP,[125] men rejected many of the proposed sports and social venues for fear of the stigma of being seen to take a test. Men also appeared to perceive a degree of incongruity between attending these locations for recreation and the health message of screening.[125] The high uptake of screening within our trial and the narratives of the men who participated (see *Chapter 3*) suggest that, for some men, undertaking screening within the football team environment felt safe and private, facilitating uptake of the interventions.

The potential of new testing technologies

New technologies are available and widen the range of opportunities to test both within and beyond conventional sexual health services. These technologies are changing the face of established services, yet their evaluation has to date focused largely on issues affecting women. The roll-out of chlamydia testing through the NCSP and other initiatives has raised awareness of STI risk among men, as evidenced in our programme through both the qualitative and the survey work.

Men reported a willingness to use self-collected testing kits for HIV and STIs in the national survey and the high uptake of screening within the SPORTSMART pilot RCT adds support to this finding. The speed and convenience of self-collected samples, together with their ability to afford privacy (they can be collected in private and sent back to laboratories by post), aligns well with men's views on the acceptability of screening models from the qualitative study and trial process evaluation (see *Chapter 3*).

Self-sampling kits can be used in a variety of settings, including general practice. However, the use of self-collected urine testing kits is appropriate only for asymptomatic men and would also miss infections at non-genital sites. This is particularly important for MSM, who are recommended to undergo multisite sampling, dependent on reported sexual risk. Opportunities for more comprehensive self-sampling do exist but are currently rather cumbersome: self-collected rectal and pharyngeal swabs appear to perform as well as provider-taken swabs and seem to be acceptable[180–182] but to our knowledge have not been evaluated in general practice. Self-collecting specimens for syphilis testing is feasible using dried blood from a finger prick and appeared to be acceptable in one study among MSM recruited from non-clinical settings.[183]

Faced by the challenges of implementing wider STI screening in general practice, other settings must continue to be considered. Offering STI screening using self-sampling kits in football clubs may have the potential to widen access to screening and offer a public health impact for men with limited local traditional services. However, men in our outer-London trial and survey (see *Chapter 3*) appeared to be

aware of their STI risk to some degree and reported high levels of previous screening. Simply providing the opportunity to test in these settings appears to result in a similar uptake to interventions that rely on direct promotion by a HCP or club captain (popular opinion leader) and the costs of these approaches within our trial were similar.

Self-testing compared with point-of-care testing: is non-chlamydial, non-gonococcal urethritis a tipping point?

A range of novel testing technologies has recently emerged and is likely to continue to offer new opportunities both for self-testing (e.g. posting of samples) and point-of-care testing (results immediately available to patients). We should not, however, lose sight of the history of point-of-care testing and the implications of novel technologies. STI clinics have long offered a range of point-of-care testing, which has paradoxically declined as the availability of NAAT tests has grown. It is now less common for syphilis or gonorrhoea to be diagnosed through microscopy, although HIV rapid tests now provide quick initial results. We explored NCNGU both as a specific example of biomedical uncertainty as to its pathogenic consequences and as a potential example of outdated fetishism about the 'point of care', which may no longer be relevant to STI services. Depending who is asked, NCNGU may be seen as an example of overmedicalisation or as a potentially missed opportunity to prevent the onward transmission of infection.

Currently, men accessing health services are recommended to undergo urethral smear microscopy only if they have symptoms of urethritis[63] (although some clinics continue the practice). This means that asymptomatic NCNGU ceases to be a diagnosable and treated condition. Our systematic review (see *Chapter 1*) shows that available evidence, albeit poor in quality, does not support an association between asymptomatic NCNGU and significant adverse clinical outcomes for men or their sexual partners. The mathematical modelling and cost-effectiveness analysis of removing all asymptomatic urethral microscopy screening suggests that, despite a small rise in adverse outcomes, it would be highly cost-effective to stop all urethral microscopy in asymptomatic men. (see *Chapter 1*).

These findings fill an evidence gap in the literature and support national clinical guidance in this respect but published studies on which this work is based are few and mostly of poor quality. However, emerging knowledge of the complexity of the urethral biome, together with likely routinely available tests for *M. genitalium*, should resolve some of the uncertainty around this multifactorial condition. Currently, the sexual health of men may be better served by diverting the resources funding remaining testing and treatment of men with asymptomatic NCNGU and their partners into increasing coverage of screening for STIs with established adverse health consequences.

Novel technologies that can be accessed online or otherwise beyond the settings that people attend because of symptoms or a perceived risk will themselves profoundly influence debates about what health services should be or should offer. Such technologies break down conventional distinctions between a motivated STI clinic visit and an opportunistic invitation to test in the context of some other health-care encounter. Register-based screening, so well suited to cancers with a well-characterised natural history, is not well suited to the disparate clustering of behavioural and lifestyle risks that make STI epidemiology so very uneven. The SPORTSMART study, in particular, raises complex issues about what counts as a health service in the age of online risk calculators and self-sampling.

Partner notification interventions in primary care and community settings

Our partner notification studies demonstrated that, in the age of novel communication technologies, there are trade-offs between partner notification and other prevention technologies. For example, the trade-off for novel partner notification models may be low rates of HIV/STI testing among partners, which may need to be addressed contextually with an eye to relative benefits in different populations.

We developed and evaluated through a pilot RCT two novel interventions for partner notification (APTPharmacy and APTHotline), offered in addition to a 'routine' control arm, to which patients were referred through a web tool (see *Chapter 2*). In all arms of the trial, reported partner notification outcomes

were better than previously reported outcomes in similar settings but did not reach national standards for partner notification. Uptake of the specific interventions was low and addition of either type of APT did not appear to improve outcomes. The cost-effectiveness of APTPharmacy and APTHotline over routine partner notification was not demonstrated.

The care pathways that we developed, 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. Outside the research setting, where there are major barriers to recruitment and randomisation at an emotionally taxing time, our model interventions appear to be capable of providing acceptable approaches to partner notification support. These could usefully form part of the portfolio of partner notification choices aimed at improving outcomes for all kinds of partner. It is increasingly recognised that novel interventions should not be seen as stand alone but rather in the context of a portfolio of partner notification modalities that collectively improve overall partner notification outcomes.

The low uptake of follow-up STI testing or HIV testing is 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. Although in the future this may be addressed through postal self-sampling as a means of delivering more comprehensive testing, these modes of partner notification are not suitable either for individuals or for populations who have been identified as being at higher risk, such as MSM partners of heterosexual women.[184]

If STI screening for men in primary care is prioritised, the need for effective partner notification becomes even more important. The challenges in achieving this should not be underestimated, as shown by the considerable difficulties experienced in this and previous large trials.[102]

'Queering' sexual health services: a way forward?[185]

The myths that we encountered about heterosexual males' health care-seeking behaviour, which have already been disproved in numerous studies, raise interesting issues about how health-care services and policy makers can avoid 'othering' men from the beginning of their independent engagement with health services in adolescence. Just as contraception services are a gateway to adolescent women using health services independently, sexual health needs are highly prevalent among young men, yet the health service response to their need if much more limited, and may indeed amount to denial.

By contrast, MSM are recommended to have regular HIV check-ups,[117] which might be seen as a feminine and health-protecting behaviour, yet experience very poor outcomes in sexual and other domains of health, as documented in a recent Public Health England report.[186]

Interestingly, the health service attitude to MSM and female use of services contrasts with how services tend to marginalise both the health, and the health-seeking behaviours, of heterosexual men. This paradox may provide some insights into ways forward that could address provider perceptions and structural inequalities that may make sexual health care less available and accessible to heterosexual men, even though study after study suggests that they are attending services unnoticed and without receiving health promotion.

It is important to note that 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 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.[187] Our work does not address their needs and further research is needed to optimise both provision of and signposting to specialist services for young MSM who may of course also be sexually active with women.

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.[185]
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 and development and evaluation of 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 of specialist services and to explore the linkage 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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Contributions of authors

Claudia Estcourt (Professor of Sexual Health and HIV) was Principal Investigator. She conceived the original idea for the programme, collaboratively designed the studies, working with the other co-applicants, led the implementation of all of the workstreams, data analysis and authorship of the report and was primary supervisor for John Saunders' doctoral work.

Lorna Sutcliffe (Ballseye Programme Manager and Senior Researcher) managed the whole programme of research, co-ordinated the APT Primary Care Trial, including design of the web tool, led the qualitative elements of the programme and contributed to data analysis and authorship of the report.

Catherine H Mercer (Reader in Sexual Health and HIV) contributed extensively to the study design, data analysis and interpretation across the programme, led the analysis of the national random probability sample survey and SPORTSMART survey and contributed to authorship of the report.

Andrew Copas (Reader in Statistics) was statistical lead for the programme, advising on trial design, analysis and interpretation, and contributed to authorship of the report.

John Saunders (PhD Student and Honorary Clinical Research Fellow) conducted the systematic review and the NCNGU case–control study, co-ordinated the national random probability sample survey work and qualitative work in the pretrial phase of the SPORTSMART study and contributed to the design of the SPORTSMART interventions and authorship of the report.

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Sebastian S Fuller (Trial Co-ordinator for the SPORTSMART pilot RCT) contributed extensively to the analysis and interpretation of the trial data and the SPORTSMART survey and contributed to authorship of the report.

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Greta Rait (Senior Clinical Scientist) contributed extensively to the design of the APT trial and data interpretation and contributed to authorship of the report.

Anne Johnson (Professor of Infectious Disease Epidemiology) contributed extensively to design and data interpretation across the programme and contributed to authorship of the report.

Graham Hart (Dean of UCL Faculty of Population Health Sciences) to John Saunders' doctoral work) contributed extensively to design and data interpretation for the SPORTSMART trial and qualitative work across the programme, contributed to authorship of the report and was the secondary supervisor for John Saunders' doctoral work.

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Jackie Cassell (Professor of Primary Care and Epidemiology) was extensively involved in designing the programme, assisting with implementation planning and planning data analyses and data interpretation across the programme and contributed significantly to authorship of the report.

Data sharing statement

All data may be obtained from the corresponding author.

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Appendix 1 Additional materials supporting the studies in *Chapter 1*

Search strategy

MEDLINE search (18 August 2009)

1. urethritis.ti	1976
2. URETHRITIS/	4015 (MeSH term)
3. urethritis.ti,ab	3649
4. 2 OR 3	5224
5. "non specific".ti,ab	33,130
6. "non chlamydial".ti,ab	57
7. "non gonococcal".ti,ab	656
8. "NSU".ti,ab	93
9. "NGU".ti,ab	273
10. "NCNGU".ti,ab	5
11. "NGNCU".ti,ab	2
12. 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11	33,975
13. 4 AND 12	918
14. 1 NOT 13	1385
15. 13 [Limit to: English language]	715
16. 14 [Limit to: English language]	789
17. 15 AND 14	1504
18. 17 [Duplicates removed]	1481

Cumulative Index to Nursing and Allied Health Literature search (18 August 2009)

1. urethritis.ti	41
2. URETHRITIS/	96 (MeSH term)
3. urethritis.ti,ab	86
4. 2 OR 3	130
5. "non specific".ti,ab	824
6. "non chlamydial".ti,ab	0
7. "non gonococcal".ti,ab	8
8. "NSU".ti,ab	16
9. "NGU".ti,ab	4
10. "NCNGU".ti,ab	0
11. "NGNCU".ti,ab	0

12. 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11	850
13. 4 AND 12	12
14. 1 NOT 13	36
15. 13 [Limit to: English language]	0
16. 14 [Limit to: English language]	0
17. 13 AND 14	48
18. 17 [Duplicates removed]	26

EMBASE search (18 August 2009)

1. urethritis.ti	1081
2. URETHRITIS/	2296 (MeSH term)
3. urethritis.ti,ab	2411
4. 2 OR 3	3474
5. "non specific".ti,ab	25,330
6. "non chlamydial".ti,ab	49
7. "non gonococcal".ti,ab	441
8. "NSU".ti,ab	57
9. "NGU".ti,ab	220
10. "NCNGU".ti,ab	6
11. "NGNCU".ti,ab	2
12. 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11	25,908
13. 4 AND 12	563
14. 1 NOT 13	758
15. 13 [Limit to: English language]	449
16. 14 [Limit to: English language]	462
17. 15 AND 14	911
18. 17 [Duplicates removed]	432

PsycINFO search (18 August 2009)

1. urethritis.ti	5
2. URETHRITIS/	0 (MeSH term)
3. urethritis.ti,ab	26
4. 2 OR 3	26
5. "non specific".ti,ab	1434
6. "non chlamydial".ti,ab	0
7. "non gonococcal".ti,ab	2
8. "NSU".ti,ab	10
9. "NGU".ti,ab	2

10. "NCNGU".ti,ab	0
11. "NGNCU".ti,ab	0
12. 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11	1448
13. 4 AND 12	5
14. 1 NOT 13	5
15. 13 [Limit to: English language]	5
16. 14 [Limit to: English language]	3
17. 13 AND 14	8
18. 17 [Duplicates removed]	6

Flow diagram of study selection process

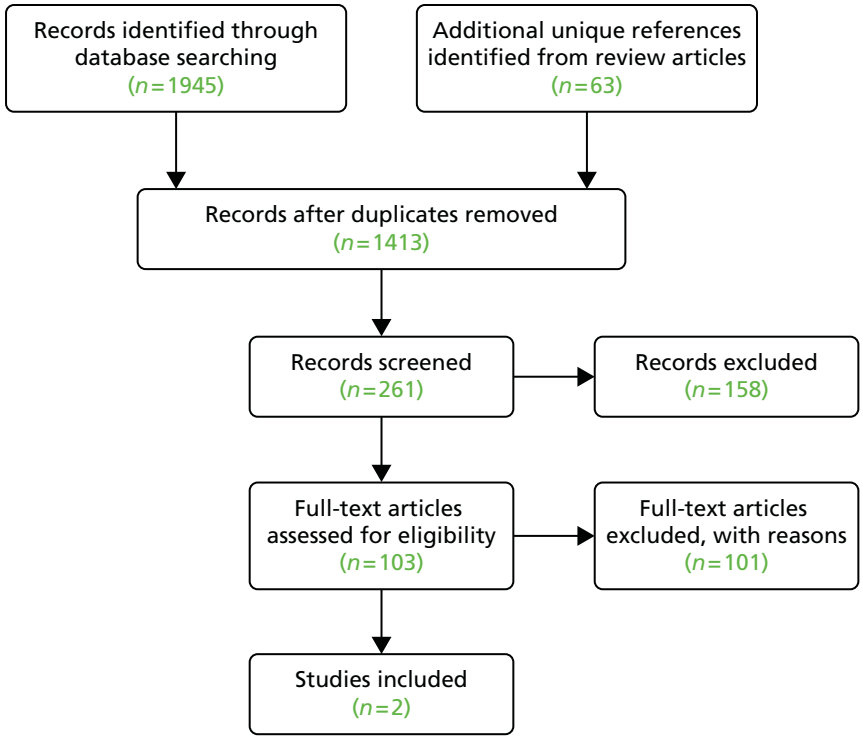

FIGURE 8 Flow diagram of study selection process.

List of excluded studies

Study	Reason for exclusion
Anagrius C, Lore B, Jensen JS. Mycoplasma genitalium: prevalence, clinical significance, an transmission. *Sex Transm Infect* 2005;**81**:458–62	Did not specifically report outcomes for men with asymptomatic NCNGU and, despite attempts to contact the authors for further information and data, we were unable to get a response
Arumainayagam JT, de Silva Y, Shahmanesh M. Anaerobic vaginosis: study of male sexual partners. *Int J STD AIDS* 1991;**2**:102–4	No reported outcome of relevance

Study	Reason for exclusion
Atkins MC, Carlin EM, Emery VC, Griffiths PD, Boag F. Fluctuations of HIV load in semen of HIV positive patients with newly acquired sexually transmitted diseases. *BMJ* 1996;**313**:341–2	*C. trachomatis* infection not excluded as cause of NCNGU
Azariah S, Reid M. Adenovirus and non-gonococcal urethritis. *Int J STD AIDS* 2000;**11**:548–50	No explicit microscopic definition for urethritis; *C. trachomatis* not detected using culture or NAAT
Belsey EM. Epidemiological treatment gonorrhoea and non-specific genital infection in female sexual contacts. Current practices in STD clinics in England and Wales. *Br J Vener Dis* 1982;**58**:113–16	Criteria for diagnosis of urethritis not met; *C. trachomatis* infection not excluded as cause of NCNGU
Bhaduri S, De Silva Y. Chlamydial infection in female partners of male patients diagnosed with asymptomatic non-gonococcal urethritis. *Int J STD AIDS* 2006;**17**:498	No statement of diagnostic criteria for *N. gonorrhoeae*
Bradbeer C, Welch J, Thin RN. Treatment for sexual partners of men with non-specific urethritis. *Lancet* 1986;**1**:1442	Opinion article
Bradshaw CS, Tabrizi SN, Read TR, Garland SM, Hopkins CA, Moss LM, Fairley CK. Etiologies of nongonococcal urethritis: bacteria, viruses, and the association with orogenital exposure. *J Infect Dis* 2006;**193**:336–45	No reported outcome of relevance
Burns DC, Darougar S, Thin RN, Lothian L, Nicol CS. Isolation of Chlamydia from women attending a clinic for sexually transmitted disease. *Br J Vener Dis* 1975;**51**:314–18	Criteria for diagnosis of urethritis not met
Burstein GR, Zenilman JM. Nongonococcal urethritis – a new paradigm. *Clin Infect Dis* 1999;**28**(Suppl. 1):S66–73	Review article
Chalker VJ, Jordan K, Ali T, Ison C. Real-time PCR detection of the mg219 gene of unknown function of Mycoplasma genitalium in men with and without non-gonococcal urethritis and their female partners in England. *J Med Microbiol* 2009;**58**:895–9	No reported outcome of relevance
Chen MY, Ryder N, Donovan B. Completeness and timeliness of treatment for chlamydia within a sexual health service. *Int J STD AIDS* 2004;**15**:762–4	No reported outcome of relevance
Clad A, Prillwitz J, Hintz KC, Mendel R, Flecken U, Schulte-Monting J, Petersen EE. Discordant prevalence of chlamydia trachomatis in asymptomatic couples screened using urine ligase chain reaction. *Eur J Clin Microbiol Infect Dis* 2001;**20**:324–8	No reported outcome of relevance
Clarke GN. Sperm antibodies in normal men: association with a history of nongonococcal urethritis (NGU). *Am J Reprod Immunol Microbiol* 1986;**12**:31–2	Unable to obtain full-text copy
Cohen MS, Hoffman IF, Royce RA, Kazembe P, Dyer JR, Daly CC, *et al.* Reduction of concentration of HIV-1 in semen after treatment of urethritis: implications for prevention of sexual transmission of HIV-1. AIDSCAP Malawi Research Group. *Lancet* 1997;**349**:1868–73	No NCNGU group reported, only non-gonococcal urethritis
Dean GL. Near-patient testing will not improve the control of sexually transmitted infections. *Sex Transm Infect* 2006;**82**:509–12	Opinion article
Donovan B. Asymptomatic non-chlamydial, non-gonococcal urethritis – an iatrogenic disease? *Sex Health* 2004;**1**:65–7	Editorial
Donovan B. With tradition travels inertia: time to bury the routine urethral smear. *Int J STD AIDS* 2004;**15**:849	Opinion article
Falk L, Fredlund H, Jensen JS. Tetracycline treatment does not eradicate Mycoplasma genitalium. *Sex Transm Infect* 2003;**79**:318–19	No reported outcome of relevance
Falk L, Fredlund H, Jensen JS. Symptomatic urethritis is more prevalent in men infected with Mycoplasma genitalium than with Chlamydia trachomatis. *Sex Transm Infect* 2004;**80**:289–93	Outcomes not reported separately for asymptomatic NCNGU
Fish AN, Fairweather DV, Oriel JD, Ridgway GL. Isolation of Chlamydia trachomatis from endometriums of women with and without symptoms. *Genitourin Med* 1988;**64**:75–7	Criteria for diagnosis of urethritis not met; *C. trachomatis* infection not excluded as cause of NCNGU

Study	Reason for exclusion
Fitzgerald MR. Effect of epidemiological treatment of contacts in preventing recurrences of non-gonococcal urethritis. *Br J Vener Dis* 1984;**60**:312–15	*C. trachomatis* infection not excluded as cause of non-gonococcal urethritis
Fortenberry JD, Brizendine EJ, Katz BP, Orr DP. The role of self-efficacy and relationship quality in partner notification by adolescents with sexually transmitted infections. *Arch Pediatr Adolesc Med* 2002;**156**:1133–7	No definition of urethritis
Furuya R, Takahashi S, Furuya S, Saitoh N, Ogura H, Kurimura Y, Tsukamoto T. Is urethritis accompanied by seminal vesiculitis? *Int J Urol* 2009;**16**:628–31	Criteria for diagnosis of urethritis not met
Geisler WM, Yu S, Hook EW III. Chlamydial and gonococcal infection in men without polymorphonuclear leukocytes on gram stain: implications for diagnostic approach and management. *Sex Transm Dis* 2005;**32**:630–4	No reported outcome of relevance
Giard R. Male gonococcal urethritis and its psycho-emotional effects. *Postgrad Med J* 1972;**48**(Suppl. 1):47–53	Abstract from conference
Gilroy SA. Bacterial vaginosis and non-gonococcal urethritis: does an association exist? *Clinical Microbiology Newsletter* 2001;**23**:86–8	Review article
Goh BT, Morgan-Capner P, Lim KS. Chlamydial screening of pregnant women in a sexually transmitted diseases clinic. *Br J Vener Dis* 1982;**58**:327–9	Criteria for diagnosis of urethritis not met; *C. trachomatis* infection not excluded as cause of NCNGU
Haddow LJ, Bunn A, Copas AJ, Gilson R, Prince M, Ridgway GL, Sadiq ST. Polymorph count for predicting non-gonococcal urethral infection: a model using Chlamydia trachomatis diagnosed by ligase chain reaction. *Sex Transm Infect* 2004;**80**:198–200	No reported outcome of relevance
Hawkins DA, Fontaine EA, Thomas BJ, Boustouller YL, Taylor-Robinson D. The enigma of non-gonococcal urethritis: role for Bacteroides ureolyticus. *Genitourin Med* 1988;**64**:10–13	No reported outcome of relevance
Horner P. Asymptomatic men: should they be tested for urethritis? *Sex Transm Infect* 2007;**83**:81–4	Editorial
Horner P, Thomas B, Gilroy CB, Egger M, Taylor-Robinson D. Role of Mycoplasma genitalium and Ureaplasma urealyticum in acute and chronic nongonococcal urethritis. *Clin Infect Dis* 2001;**32**:995–1003	No reported outcome of relevance
Horner P, Thomas B, Gilroy C, Egger M, McClure M, Taylor-Robinson D. Antibodies to Chlamydia trachomatis heat-shock protein 60 kDa and detection of Mycoplasma genitalium and Ureaplasma urealyticum are associated independently with chronic nongonococcal urethritis. *Sex Transm Dis* 2003;**30**:129–33	Opinion article
Horner PJ. Should we still be testing for asymptomatic non-specific urethritis in departments of genitourinary medicine? *Int J STD AIDS* 2005;**16**:273–7	Review article
Horner PJ, Gilroy CB, Thomas BJ, Naidoo RO, Taylor-Robinson D. Association of Mycoplasma genitalium with acute non-gonococcal urethritis. *Lancet* 1993;**342**:582–5	No reported outcome of relevance
Horner PJ, Cain D, McClure M, Thomas BJ, Gilroy C, Ali M, *et al.* Association of antibodies to Chlamydia trachomatis heat-shock protein 60 kD with chronic nongonococcal urethritis. *Clin Infect Dis* 1997;**24**:653–60	No reported outcome of relevance
Horner PJ, Thomas B, Gilroy CB, Egger M, Taylor-Robinson D. Do all men attending departments of genitourinary medicine need to be screened for non-gonococcal urethritis? *Int J STD AIDS* 2002;**13**:667–73	*C. trachomatis* not detected using culture or NAAT
Hunter JM, Smith IW, Peutherer JF, MacAulay AJ. Chlamydia trachomatis infection of the cervix: the need for a diagnostic service. *Scott Med J* 1982;**27**:147–51	Criteria for diagnosis of urethritis not met; *C. trachomatis* infection not excluded as cause of NCNGU
Iser P, Read TH, Tabrizi S, Bradshaw C, Lee D, Horvarth L, *et al.* Symptoms of non-gonococcal urethritis in heterosexual men: a case control study. *Sex Transm Infect* 2005;**81**:163–5	No reported outcome of relevance

Study	Reason for exclusion
Janier M, Lassau F, Casin I, Grillot P, Scieux C, Zavaro A, *et al.* Male urethritis with and without discharge: a clinical and microbiological study. *Sex Transm Dis* 1995;**22**:244–52	No reported outcome of relevance
Jensen JS, Bjornelius E, Dohn B, Lidbrink P. Use of TaqMan 5' nuclease real-time PCR for quantitative detection of Mycoplasma genitalium DNA in males with and without urethritis who were attendees at a sexually transmitted disease clinic. *J Clin Microbiol* 2004;**42**:683–92	No reported outcome of relevance
Judson FN, Tavelli BG. Comparison of clinical and epidemiological characteristics of pelvic inflammatory disease classified by endocervical cultures of Neisseria gonorrhoeae and Chlamydia trachomatis. *Genitourin Med* 1986;**62**:230–4	Criteria for diagnosis of urethritis not met; *C. trachomatis* infection not excluded as cause of NCNGU
Kamwendo F, Johansson E, Moi H, Forslin L, Danielsson D. Gonorrhea, genital chlamydial infection, and nonspecific urethritis in male partners of women hospitalized and treated for acute pelvic inflammatory disease. *Sex Transm Dis* 1993;**20**:143–6	No reported outcome of relevance
Keane FE, Thomas BJ, Whitaker L, Renton A, Taylor-Robinson D. An association between non-gonococcal urethritis and bacterial vaginosis and the implications for patients and their sexual partners. *Genitourin Med* 1997;**73**:373–7	*C. trachomatis* not detected using culture or NAAT
Keane FE, Thomas BJ, Gilroy CB, Renton A, Taylor-Robinson D. The association of Chlamydia trachomatis and Mycoplasma genitalium with non-gonococcal urethritis: observations on heterosexual men and their female partners. *Int J STD AIDS* 2000;**11**:435	*C. trachomatis* not detected using culture or NAAT
Khadra A, Fletcher P, Luzzi G, Shattock R, Hay P. Interleukin-8 levels in seminal plasma in chronic prostatitis/chronic pelvic pain syndrome and nonspecific urethritis. *BJU Int* 2006;**97**:1043–6	No NCNGU group reported, only NSU
Kinghorn GR, Duerden BI, Hafiz S. Clinical and microbiological investigation of women with acute salpingitis and their consorts. *Br J Obstet Gynaecol* 1986;**93**:869–80	*C. trachomatis* infection not excluded as cause of NCNGU
Kissinger P, Mohammed H, Richardson-Alston G, Leichliter JS, Taylor SN, Martin DH, Farley TA. Patient-delivered partner treatment for male urethritis: a randomized, controlled trial. *Clin Infect Dis* 2005;**41**:623–9	No reported outcome of relevance
Lee CT, Lim KB, Thirumoorthy T, Nadarajah M. Bacampicillin to treat non-gonococcal urethritis in men: pilot study. *Genitourin Med* 1989;**65**:32–4	No reported outcome of relevance
Lee PM, Ho KM. Risk factors associated with human immunodeficiency virus (HIV) infection among attendees of public sexually transmitted infection clinics in Hong Kong: implications for HIV prevention. *Hong Kong Med J* 2008;**14**:259–66	*C. trachomatis* infection not excluded as cause of NCNGU
Lesseps A, Kenney A. Simultaneous treatment for sexual partners of men with non-specific urethritis. *Lancet* 1986;**1**:1216	Opinion article
Leung A, Taylor S, Smith A, Spencer R, Horner P. Urinary tract infection in patients with acute non-gonococcal urethritis. *Int J STD AIDS* 2002;**13**:801–4	No reported outcome of relevance
Leung A, Eastick K, Haddon LE, Horn CK, Ahuja D, Horner PJ. Mycoplasma genitalium is associated with symptomatic urethritis. *Int J STD AIDS* 2006;**17**:285–8	No reported outcome of relevance
Lim KB, Thirumoorthy T, Lee CT, Sng EH, Tan T. Endocervical chlamydial infection in female contacts of patients with nongonococcal urethritis. *Singapore Med J* 1989;**30**:164–6	Criteria for diagnosis of urethritis not met; *C. trachomatis* infection not excluded as cause of NCNGU
Manavi K, McMillan A, Young H. Non-chlamydial non-gonococcal urethritis or undiagnosed chlamydial urethritis? *Int J STD AIDS* 2006;**17**:296–8	No reported outcome of relevance
Maw RD, Robinson A. Asymptomatic urethritis; the case for a considered view! *Int J STD AIDS* 2004;**15**:849–50	Opinion article

Study	Reason for exclusion
McCathie RP, Carlin EM. Does partner notification of men with asymptomatic non-gonococcal non-chlamydial urethritis identify chlamydia-positive women? *Int J STD AIDS* 2007;**18**:606–9	Criteria for diagnosis of urethritis not met
McMillan A, Pakianathan M, Mao JH, Macintyre CC. Urethral stricture and urethritis in men in Scotland. *Genitourin Med* 1994;**70**:403–5	Criteria for diagnosis of urethritis not met; no statement of diagnostic criteria for *C. trachomatis* and *N. gonorrhoeae*
Mena L, Wang X, Mroczkowski TF, Martin DH. Mycoplasma genitalium infections in asymptomatic men and men with urethritis attending a sexually transmitted diseases clinic in New Orleans. *Clin Infect Dis* 2002;**35**:1167–73	No reported outcome of relevance
Mohanty KC. Sexually transmitted diseases among patients seeking HIV antibody test for AIDS. *Int J STD AIDS* 1990;**1**:207–8	Criteria for diagnosis of urethritis not met
Monteiro EF, Bradbury JA, O'Donnell M, Rennie IG, Kinghorn GR. Occult chlamydial ophthalmia in men with non-gonococcal urethritis. *Br Med J (Clin Res Ed)* 1987;**294**:349	Criteria for diagnosis of urethritis not met; no statement of diagnostic criteria for *N. gonorrhoeae*
Nayyar KC, O'Neill JJ, Hambling MH, Waugh MA. Isolation of Chlamydia trachomatis from women attending a clinic for sexually transmitted diseases. *Br J Vener Dis* 1976;**52**:396–8	Criteria for diagnosis of urethritis not met; *C. trachomatis* infection not excluded as cause of NCNGU
Ness RB, Markovic N, Carlson CL, Coughlin MT. Do men become infertile after having sexually transmitted urethritis? An epidemiologic examination. *Fertil Steril* 1997;**68**:205–13	Review article
O'Mahony C. Asymptomatic Chlamydia trachomatis-negative non-gonococcal urethritis. *Int J STD AIDS* 2005;**16**:330–1	Opinion article
O'Mahony C. Adenoviral non-gonococcal urethritis. *Int J STD AIDS* 2006;**17**:203–4	Case report
Ozgul A, Dede I, Taskaynatan MA, Aydogan H, Kalyon TA. Clinical presentations of chlamydial and non-chlamydial reactive arthritis. *Rheumatol Int* 2006;**26**:879–85	*C. trachomatis* not detected using culture or NAAT
Paavonen J, Kousa M, Saikku P, Vesterinen E, Jansson E, Lassus A. Examination of men with nongonococcal urethritis and their sexual partners for Chlamydia trachomatis and Ureaplasma urealyticum. *Sex Transm Dis* 1978;**5**:93–6	Only symptomatic cases included
Paavonen J. Chlamydia trachomatis-induced urethritis in female partners of men with nongonococcal urethritis. *Sex Transm Dis* 1979;**6**:69–71	Criteria for diagnosis of urethritis not met
Pattman RS. The significance of finding curved rods in the vaginal secretions of patients attending a genito-urinary medical clinic. *Scand J Urol Nephrol Suppl* 1984;**86**:143–6	Criteria for diagnosis of urethritis not met
Potterat JJ. Active detection of men with asymptomatic chlamydial or gonorrhoeal urethritis. *Int J STD AIDS* 2005;**16**:458	Opinion article
Quinn TC, Gaydos C, Shepherd M, Bobo L, Hook EW III, Viscidi R, Rompalo A. Epidemiologic and microbiologic correlates of Chlamydia trachomatis infection in sexual partnerships. *JAMA* 1996;**276**:1737–42	No definition of urethritis
Riemersma WA, van der Schee CJ, van der Meijden WI, Verbrugh HA, van Belkum A. Microbial population diversity in the urethras of healthy males and males suffering from nonchlamydial, nongonococcal urethritis. *J Clin Microbiol* 2003;**41**:1977–86	No reported outcome of relevance
Ross J. Pelvic inflammatory disease. *Clin Evid* 2006;**15**:2176–82	Review article
Sadiq ST, Taylor S, Kaye S, Bennett J, Johnstone R, Byrne P, *et al.* The effects of antiretroviral therapy on HIV-1 RNA loads in seminal plasma in HIV-positive patients with and without urethritis. *AIDS* 2002;**16**:219–25	Criteria for diagnosis of urethritis not met
Sadiq ST, Taylor S, Copas AJ, Bennett J, Kaye S, Drake SM, *et al.* The effects of urethritis on seminal plasma HIV-1 RNA loads in homosexual men not receiving antiretroviral therapy. *Sex Transm Infect* 2005;**81**:120–3	Outcomes not reported separately for asymptomatic NCNGU

Study	Reason for exclusion
Say PJ, Hookham AB, Willmott FE. Unsuspected Chlamydia trachomatis in females attending a sexually transmitted diseases clinic. *N Z Med J* 1983;**96**:716–18	Criteria for diagnosis of urethritis not met; *C. trachomatis* infection not excluded as cause of NCNGU
Schmid GP, Fontanarosa PB. Evolving strategies for management of the nongonococcal urethritis syndrome. *JAMA* 1995;**274**:577–9	No reported outcome of relevance
Schwebke JR, Hook EW III. High rates of Trichomonas vaginalis among men attending a sexually transmitted diseases clinic: implications for screening and urethritis management. *J Infect Dis* 2003;**188**:465–8	No reported outcome of relevance
Scott GR, Thompson C, Smith IW, Young H. Infection with Chlamydia trachomatis and Neisseria gonorrhoeae in women with lower abdominal pain admitted to a gynaecology unit. *Br J Obstet Gynaecol* 1989;**96**:473–7	No reported outcome of relevance
Shahmanesh M. Problems with non-gonococcal urethritis. *Int J STD AIDS* 1994;**5**:390–9	Opinion article
Shahmanesh M, Stedronska J, Hendry WF. Antispermatozoal antibodies in men with urethritis. *Fertil Steril* 1986;**46**:308–11	Unable to obtain full-text copy
Sizemore JM Jr, Sanders WM, Lackey PC, Ennis DM, Hook EW III. Risk-taking and health-seeking behavior in men with a history of urethritis: is there a learning curve? *Sex Transm Dis* 2004;**31**:225–8	Criteria for diagnosis of urethritis not met; *C. trachomatis* infection not excluded as cause of NCNGU
Smith R, Copas AJ, Prince M, George B, Walker AS, Sadiq ST. Poor sensitivity and consistency of microscopy in the diagnosis of low grade non-gonococcal urethritis. *Sex Transm Infect* 2003;**79**:487–90	No reported outcome of relevance
Swartz SL, Kraus SJ. Persistent urethral leukocytosis and asymptomatic chlamydial urethritis. *J Infect Dis* 1979;**140**:614–17	No reported outcome of relevance
Tait IA, Hart CA. Chlamydia trachomatis in non-gonococcal urethritis patients and their heterosexual partners: routine testing by polymerase chain reaction. *Sex Transm Infect* 2002;**78**:286–8	No statement of diagnostic criteria for *N. gonorrhoeae*
Tait IA, Rees E, Hobson D, Byng RE, Tweedie MC. Chlamydial infection of the cervix in contacts of men with nongonococcal urethritis. *Br J Vener Dis* 1980;**56**:37–45	*C. trachomatis* infection not excluded as cause of NCNGU
Taylor-Robinson D, Jensen JS, Fehler G, Radebe F, Ballard RC. Observations on the microbiology of urethritis in black South African men. *Int J STD AIDS* 2002;**13**:323–5	Editorial
Terho P. Chlamydia trachomatis in non-specific urethritis. *Br J Vener Dis* 1978;**54**:251–6	Outcomes not reported separately for asymptomatic NCNGU
Thin RN. Prostatitis after urethritis in Singapore. *Br J Vener Dis* 1974;**50**:370–2	*C. trachomatis* infection not excluded as cause of NCNGU
Totten PA, Schwartz MA, Sjostrom KE, Kenny GE, Handsfield HH, Weiss JB, Whittington WL. Association of Mycoplasma genitalium with nongonococcal urethritis in heterosexual men. *J Infect Dis* 2001;**183**:269–76	No reported outcome of relevance
Watson P. Measuring the value of the microscopy of urethral material. *Int J STD AIDS* 2004;**15**:846	Opinion article
Watson P. Asymptomatic urethritis needs to be defined and the value of its diagnosis measured. *Int J STD AIDS* 2005;**16**:769	Opinion article
Watson P. Routine screening of asymptomatic men for Chlamydia trachomatis-negative urethritis. *Int J STD AIDS* 2005;**16**:769	Opinion article
Watson PG. Identifying men with non-gonococcal urethritis who should have a mid-stream specimen of urine sent for culture. *Int J STD AIDS* 2003;**14**:503	Opinion article
Wiggins RC, Holmes CH, Andersson M, Ibrahim F, Low N, Horner PJ. Quantifying leukocytes in first catch urine provides new insights into our understanding of symptomatic and asymptomatic urethritis. *Int J STD AIDS* 2006;**17**:289–95	No reported outcome of relevance

Study	Reason for exclusion
Willcox JR, Adler MW, Belsey EM. Observer variation in the interpretation of Gram-stained urethral smears: implications for the diagnosis of non-specific urethritis. *Br J Vener Dis* 1981;**57**:134–6	No reported outcome of relevance
Willmott FE. Mucopurulent cervicitis: a clinical entity? *Genitourin Med* 1988;**64**:169–71	*C. trachomatis* infection not excluded as cause of NCNGU
Winter AJ, Taylor S, Workman J, White D, Ross JD, Swan AV, Pillay D. Asymptomatic urethritis and detection of HIV-1 RNA in seminal plasma. *Sex Transm Infect* 1999;**75**:261–3	Outcomes not reported separately for asymptomatic NCNGU
Wood PL, Hobson D, Rees E. Genital infections with Chlamydia trachomatis in women attending an antenatal clinic. *Br J Obstet Gynaecol* 1984;**91**:1171–6	Criteria for diagnosis of urethritis not met; *C. trachomatis* infection not excluded as cause of NCNGU
Woolley PD. Anaerobic bacteria and non-gonococcal urethritis. *Int J STD AIDS* 2000;**11**:347–8	No reported outcome of relevance
Woolley PD, Wilson JD, Kinghorn GR. Epidemiological treatment of sexual contacts prevents recurrence of non-gonococcal urethritis. *Genitourin Med* 1987;**63**:384–5	Did not meet eligibility criteria

Appendix 2 Additional materials supporting the SPORTSMART study

Topic guide for the SPORTSMART study

Aims and objectives

The overall aim of this study is to explore the acceptability of using football coaches as popular opinion leaders to promote sexually transmitted infection screening of young men in sport settings.

Introduction

Aim: To introduce the research and set the context for the proceeding discussion.

- Introduce self.
- Introduce the study: who it is for; what it is about.
- Talk through key points:
    - purpose of the interview
    - length of the interview
    - thank you payment
    - reasons for recording the interview
    - confidentiality and reporting of findings.
- Any questions participant may have.

1. Background and personal circumstances – brief

Aim: To introduce the participant and to highlight any key background issues that might influence how acceptable they find the proposed screening model.

- Age; household circumstances (whether they live alone or with others):
    - relationship with
    - their age
    - activity.
- Main daytime activity (whether in work or not; details of work).
- Other interests/activities (spare time).

2. Football club

Aim: To understand why the participant is involved in the club and what they gain from their involvement.

- Involvement in football club:
    - how they became involved
    - length of time with the club
    - purpose of involvement with the club:
        - recreation
        - health
        - community
        - socialising, etc.
    - position played on team.

- Relationships within the club:
  - with other players
  - with 'officials':
    - coach
    - committee
  - types of interactions:
    - just sport
    - talking (about what?)
    - socialising (outside of the club setting).
- Thoughts on using the club to deliver health promotion:
  - Is this an acceptable setting to deliver health messages? (general health/diet/exercise/obesity/smoking, etc.)
  - What about sexual health messages?
- Thoughts on using coaches to deliver health promotion:
  - Is this an acceptable way to deliver health promotion?
  - Is it appropriate to discuss health with coaches?
  - What about sexual health?
- Thoughts on having health specialist enter the club to deliver health promotion:
  - Is this an acceptable way to deliver health promotion?
  - Doctor versus nurse
  - Is it appropriate to discuss health with HCPs in the club?
  - What about sexual health?
- Thoughts on having leaflets and posters in the club setting to promote health:
  - Is this an acceptable way to deliver health promotion?
  - What about sexual health?
- When to deliver messages – and how to deliver them (formal/informal).

3. Acceptability of different sexual health promotion models

Aim: To explore the acceptability of delivering sexual health screening in different ways (use picture flow charts to aid discussion).

Describe model 1 (traditional/clinic/general practice)

What are your initial thoughts about testing for STIs in this way?

- Why do you think that?
- Probe/expand.

Go through each step of that model:

- Attending the clinic:
  - What are the advantages?
    - See a HCP
    - Quality of service/advice
    - Anonymous – unlikely to see someone you know
    - Professional
    - Full screens (including HIV/syphilis)
  - What are the disadvantages?
    - Waiting times
    - Clinic times/away from work
    - Embarrassment
    - Fear
  - What are the barriers to this screening method?
    - Waiting times
    - Clinic times/away from work
    - Embarrassment
    - Fear
  - What would motivate you to attend a clinic?
    - Symptoms
    - Partner request
    - Particularly concerned about sexual encounter
- Self-collected urine test (vs. swab test – put urine into context and only for *C. trachomatis* infection):
  - What are the advantages?
    - Self-collected
    - No need for examination
    - No invasive test (umbrella)
    - Easy
    - Quick
  - What are the disadvantages?
    - Accuracy
    - Only *C. trachomatis*/*N. gonorrhoeae* test
- Text message result (*only for C. trachomatis infection*):
  - What are the advantages?
    - Always get your results
    - Personal/confidential
    - Result to show partners

- What are the disadvantages?
    - Might be seen by someone
    - Intrusive

Describe model 2 (coach-led, club-based promotion)

What are your initial thoughts about testing for STIs in this way?

- Why do you think that?
- Probe/expand

Go through each step of that model:

- Receiving promotion message from coach:
    - What are the advantages?
        - Someone you know
        - Less embarrassing
        - No need to go to a clinic
    - How much information do you think you would need to have about the benefits of testing to encourage you to test?
        - None – just get coach to tell us to test
        - A little
        - A lot
        - Etc./why why why?
    - What are the disadvantages?
        - Someone you know
        - More embarrassing
        - Intrusive
    - What are the problems with this method?
        - As above
        - At the club to play football not have lecture
    - What would encourage you to test in this way?
        - Peers
    - What would discourage you to test in this way?
- How does this compare to going to the clinic/GP?
    - Better or worse? Why?

- Self-collected urine test kits left at club:
  - What are the advantages?
    - Self-collected
    - No need for examination
    - No invasive test (umbrella)
    - Easy
    - Quick
  - What are the disadvantages?
    - Where would you leave them?
    - Someone might see you
  - How should they be distributed?
    - Handed out
    - Left for collection
    - Etc.
    - Why?
  - Where should they be left (if this is a viable option)?
    - Changing room
    - Toilets
    - Bar
    - Handed out
  - What should they look like?
    - Bland/brown bags
    - Club colours
    - Premier League branding
  - When should the test be done?
    - Pre training
    - Post training
    - Somewhere other than the training site (home, etc.)
    - Why?
  - Suggestions/comments about the labelling process
    - Is this likely to be a problem?
    - Why?
- Posting kits to hospital:
  - What are the advantages?
  - What are the disadvantages/problems?
    - Fear of leaking
    - Lost in post
    - Time to get to hospital/knock-on effect on results

- Text message result (as before):
    - What are the advantages/disadvantages?

Describe model 3 (health care professional-led, club-based promotion)

What are your initial thoughts about testing for STIs in this way?

- Why do you think that?
- Probe/expand

Go through each step of that model:

- Receiving promotion message from HCP:
    - What are the advantages?
        - Professional
        - Knowledge
        - Anonymous
    - What are the disadvantages?
        - Intrusive
        - Embarrassment
    - What are the problems with this method?
        - As above
        - At the club to play football not have lecture
    - What would encourage you to test in this way?
        - Peers
    - What would discourage you to test in this way?
- How does this compare to going to the clinic/GP/coach led?
    - Better/worse/why?

Describe model 4 (poster-led, club-based promotion)

What are your initial thoughts about testing for STIs in this way?

- Why do you think that?
- Probe/expand

Go through each step of that model:

- Receiving promotion message from poster:
    - What are the advantages?
    - What are the disadvantages?
    - What would encourage you to test in this way?
    - What would discourage you to test in this way?

- How does this compare to models 1–3?
    - Better/worse/why?

What do you think are the advantages of accessing screening in the football club?

- Easy
- Accessible
- No appointment/quicker
- Non-invasive
- No examination/no need to see HCP
- Free
- Less stigma vs. more stigma?
- Others?

What do you think are the disadvantages of accessing screening in the football club?

- Coach not an expert
- No discussion with HCP
- Concern about test accuracy
- Observed taking test/test seen by others at home/in the club, etc.
- Others?

Can you put these into the order in which you would prefer to test for STIs? (Participant puts picture sheets in order of preference) (Read out the order and ask why they have done this order)

4. Observability

What impact does the possibility of seeing someone take a test or being seen to take a test have on the likelihood of testing?

Would you be more or less likely to take a test if you saw a team member take one?

Would you discuss the test with team members?

5. Identifying an opinion leader

Which members of the club do others go to for:

- general advice?
- health advice?
- personal advice?
- sex advice?

Why?

Which member of the club would be best to talk about why to test?

14. Was a condom used on any occasion whilst having sex in the last 12 months?

- ☐ Every time
- ☐ Sometimes
- ☐ Not at all in the last 12 months
- ☐ Not applicable as no sex in the last 12 months (go to question 19)
- ☐ Prefer not to answer

15. Do you currently have a regular sexual partner(s)? (This may be someone you have sex with regularly, or consider to be your girlfriend/boyfriend, or if you are married, your wife/husband).

- ☐ Yes, I currently have a regular female partner(s)
- ☐ Yes, I currently have a regular male partner(s)
- ☐ No regular partner (go to question 17)
- ☐ Prefer not to answer

16. Do you use condoms when you are having sex with your current regular sexual partner(s)?

- ☐ Always use condoms
- ☐ Sometimes use condoms
- ☐ Never use condoms
- ☐ Not applicable as no vaginal or anal sex
- ☐ Prefer not to answer

17. Thinking about all of the people you have had sex with in the last 12 months, did any of them overlap in time? In other words did you have sex with someone (person A), then have sex with someone else (person B), and then have sex with the first person (person A) again.

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Prefer not to answer

18. Have you paid money for sex in the last 12 months?

- ☐ Yes
- ☐ No
- ☐ Prefer not to answer

19. There are different opinions about how many people are at risk of becoming infected with HIV, the virus that causes AIDS, but we would like to know what you think about the risks to you, personally, with your present sexual lifestyle? Do you think you are...

- ☐ Greatly at risk
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all at risk
- ☐ Don't know
- ☐ Prefer not to answer

20. People are also at risk of getting other STIs like chlamydia and gonorrhoea. What do you think about the risks to you, personally, with your present lifestyle of getting a sexually transmitted infection that is not HIV? Do you think you are...

- ☐ Greatly at risk
- ☐ Quite a lot
- ☐ Not very much
- ☐ Not at all at risk
- ☐ Don't know
- ☐ Prefer not to answer

Thank you for your participation!

If you would like to discuss this study please contact:

Sebastian S Fuller
SPORTSMART trial coordinator
Tel. [redacted]
Email: [redacted]

If you have any sexual health issues you want to discuss, you can get confidential specialist advice and support:

Merle Symonds
Head of Health Advisory Services
at Barts Health NHS Trust
Tel. [redacted]
www.bartssexualhealth.nhs.uk

FC code _____

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DOI: 10.3310/pgfar04200

ABOUT YOU

1. What is the first half of your home postcode (e.g., EC1)?

_____

2. What is your ethnicity? Tick one

- ☐ White British
- ☐ White, Other Background
- ☐ Asian/Asian British
- ☐ Black British
- ☐ Black, other background
- ☐ Mixed ethnic group
- ☐ Other ethnic group
- ☐ Prefer not to answer

3. What was your age at your last birthday?

_____

4. At present are you...

- ☐ married/registered same-sex civil partnership and living with wife/husband
- ☐ cohabiting but not married/registered same-sex, civil partnership
- ☐ separated, divorced, or, widowed
- ☐ single (that is never married or never registered in a same-sex civil partnership)
- ☐ prefer not to answer

5. What is the highest qualification you have completed?

- ☐ GCSE or equivalent level
- ☐ A Level or equivalent
- ☐ BA, BSc, or other undergraduate degree
- ☐ Postgraduate degree / qualification (MA, MSc, PhD, MD, etc.)
- ☐ Other (please say what qualification) _____

ABOUT YOUR SEXUAL HEALTH

6. In the last month your football club has been involved in the SPORTSMART research study. Some people were given sexually transmitted infection (STI) testing kits as part of this research study. Did you test for an STI with the SPORTSMART study at your football club?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Prefer not to answer

7. Have you ever been tested for an STI? (Do not include testing with SPORTSMART at your football club.)

- ☐ Yes
- ☐ No (go to question 11)
- ☐ Don't know
- ☐ Prefer not to answer

8. Have you ever been told that you had tested positive for an STI (meaning that you had an infection)?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Prefer not to answer

9. When was the last time you were tested for an STI? (Do not include testing with SPORTSMART at your football club.)

- ☐ Less than one month ago
- ☐ More than one month ago but less than 6 months ago
- ☐ More than 6 months but less than 1 year ago
- ☐ More than 1 year but less than 5 years ago
- ☐ More than 5 years ago
- ☐ Don't know
- ☐ Prefer not to answer

10. Where were you last tested for an STI? (Do not include testing with SPORTSMART at your football club.)

- ☐ General practice (GP) surgery
- ☐ Sexual health clinic (GUM clinic) / Brook
- ☐ NHS Family planning clinics / contraceptive clinic reproductive health clinic
- ☐ Private (non-NHS) clinics or doctor
- ☐ University or college health centre / campus
- ☐ A test you collected from Pharmacy / chemist
- ☐ A test you sent for from internet
- ☐ Youth centre

options continue on next column...

- ☐ Other (please say where) _____
- ☐ Don't know
- ☐ Prefer not to answer

11. If all options were available to you, where would you most prefer to test for STIs? Tick only one

- ☐ A test you collect from Pharmacy/chemist
- ☐ A test you send for from Internet
- ☐ A test you collect from your local football club
- ☐ General practice (GP) surgery
- ☐ NHS Family planning clinics/ contraceptive clinic/ reproductive health clinic
- ☐ NHS walk-in centre
- ☐ Sexual health clinic (GUM clinic) / Brook
- ☐ University or college health centre / campus
- ☐ Youth centre
- ☐ Other (please say where) _____
- ☐ Don't know
- ☐ Prefer not to answer

ABOUT YOUR SEX LIFE

Note: When we ask about having "sex" we mean when a man puts his penis into a vagina (vaginal intercourse), or anus (anal intercourse). "Sexual partner" is defined here as someone whom you have had or are having oral, vaginal or anal sex with.

12. In the last 12 months, how many female sexual partners have you had? Please use your best guess if you cannot remember exactly how many.

- ☐ _____
- ☐ None
- ☐ Prefer not to answer

13. In the last 12 months, how many male sexual partners have you had? Please use your best guess if you cannot remember exactly how many.

- ☐ _____
- ☐ None
- ☐ Prefer not to answer

Appendix 3 Coding tree

1. Demographics

- Age.
- Employment/occupation.
- Relationship.
- Football history (length played/team/position/reason for playing).
- Ranking of options.
- Previous STI test/diagnosis.

2. Health promotion

A. Sexual health promotion.

B. Non-sexual health promotion.

2.1 General attitudes and feelings.

2.2 Alignment of message and reason for playing football.

2.3 Time until behaviour impacts on health.

2.4 Who is the message appropriate for?

2.5 Other.

3. Delivery of the message

A. Coach.

B. HCP.

C. Poster.

D. Other.

3.1 When to deliver the message.

3.2 Characteristics of the deliverer.

3.3 How to deliver the message.

3.4 Content of the message.

3.5 General attitudes and feelings about the delivery method.

3.6 Other.

4. The sexually transmitted infection testing kit

4.1 Appearance of testing kit.

4.2 Distribution of testing kits (before kit is in the hands of the user).

4.3 Use of testing kits (after kit is in the hands of the user).

4.4 Return of testing kits.

4.5 General attitudes and feelings about STI testing.

4.6 Comments about text messages.

4.7 Other.

Appendix 4 Patient and public involvement

We have engaged with the public at all stages of our research programme. Within the research group, a lay member of the team has commented on all research plans, patient materials and final documents. We have fed back to service user groups from the study clinics when appropriate and a service user representative has been present at all presentations to the clinical teams involved in the research so that our work can be fed back to the wider service user communities. We will continue with this dissemination activity through University College London's website (www.ucl.ac.uk/iph), on which will be placed links to all publications and this final report in due course.

Public involvement was particularly important in workstream 3. We have summarised below key areas in which we have worked together for the whole duration of the research.

To aid in the design and implementation plan of the SPORTSMART interventions for the pilot RCT, preclinical patient and public involvement (PPI) work was conducted in London. This work included qualitative research and potential participant and stakeholder consultation:

1. Initial stakeholder consultation with members of various community groups within sport, antiracial discrimination and men's health: Sporting Equals, Premier League Health, Men's Health Forum and the Football Foundation. This consultation provided useful information on lessons learned (by some of the community groups) from previous sporting-based health promotion campaigns.
2. Qualitative research conducted with potential participants in the London area – men who played football and who came from groups that we would wish to target in the forthcoming research. This allowed us to assess the potential acceptability of offering STI test kits at amateur football clubs in London. The data from these interviews provided detailed information on the way in which these STI test kits should be offered to players in this setting, specifically:

    - Following preliminary market research conducted outside London (conducted in advance of application for funding for the Ballseye study) we anticipated that club members would value in-depth informational sessions on STI prevention as part of the coach-led and sexual HCP-led interventions. However, when this was presented to club members in London during qualitative interviews, participants strongly suggested a brief (< 5-minute) informal chat on the need for STI testing (i.e. many men infected with chlamydia do not have any symptoms; national recommendations for men aged < 25 years to be screened for STIs every year and after partner change).[186]
    - Interview participants suggested that discreet branding and packaging for the STI testing kits would encourage players to take part in screening and, if so desired, take home the test kits for return to the clinic by post.
    - Informal interviews with football club managers, captains, coaches and (in some cases) players who agreed to participate in the intervention prior to intervention implementation meant that we were able to incorporate suggestions given by gatekeepers in the clubs where we would be implementing the interventions. This allowed us to have a better understanding of the factors that might affect acceptability, specifically:

        - the time and place of screening promotion (e.g. promoting screening in changing rooms before or after the match)
        - identification of football coaches to lead the coach-led intervention.

    - Club manager and coach explanations of fixture schedules and match timings given to the trial co-ordinator. This allowed for a greater understanding of how much time we would have to run the pilot trial and what factors would affect this (e.g. weather).

- Brief interviews with the HCP and captains promoting STI test kits in the football clubs. These post-implementation enquiries allowed us to investigate factors affecting acceptability of the intervention, specifically:

    - health-care professionals' and coaches' comfort with delivery of the intervention
    - perception of club members' comfort with the intervention
    - account of the questions that club members raised with health-care professionals and coaches
    - length of intervention delivery.

3. Presentation of study findings. All participating clubs and stakeholders were presented with a report of the preliminary findings from the SPORTSMART study. Those involved in club liaison (including team captains, club managers and secretaries) and stakeholders were e-mailed a report to pass on to the club members either through the club e-mail or using printouts within 3 months of the completion of data collection. Each report also included an offer to present the study findings at their location by a SPORTSMART researcher.

As a result of these initiatives, we have generated sufficient interest from the public and community groups to establish a sustainable PPI programme for our research: the Barts Sexual Health Public Voice Research Group. This group of around 20 people forms our lay research panel, facilitating lay people to join the research team, comment on proposals, generate ideas for future research and help with dissemination of findings to the wider community.

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