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Abstract

The effectiveness and cost-effectiveness of behavioural interventions for the prevention of sexually transmitted infections in young people aged 13–19: a systematic review and economic evaluation

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Objectives: To assess the effectiveness and cost-effectiveness of schools-based skills building behavioural interventions to encourage young people to adopt and maintain safer sexual behaviour and to prevent them from acquiring sexually transmitted infections (STIs).
Data sources: Electronic bibliographic databases (e.g. MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, CINAHL, PsycINFO, CCRCT, NHS EED and DARE) were searched for the period 1985 to March 2008. Bibliographies of systematic reviews and related papers were screened and experts contacted to identify additional published and unpublished references.
Review methods: A systematic review of effectiveness and economic evaluation of cost-effectiveness were carried out. A descriptive map of studies that met inclusion criteria was produced, and keywords were developed and systematically applied to these studies to identify a policy-relevant subset of studies for the systematic review. Outcome data for variables including sexual behavioural were extracted. An economic model was developed to compare the costs and consequences of the behavioural interventions. A Bernoulli statistical model was constructed to describe the probability of STI infection.
Results: There were few significant differences between the interventions and comparators in terms of changes in sexual behaviour outcomes, although there were some significant differences for knowledge and some measures of self-efficacy. The studies included in this review conducted relatively short follow-up assessments at a time when many young people were becoming sexually active. It is therefore possible that favourable behaviour change may have occurred, and become more cost-effective, with time, as sexual activity becomes more routine in young people's lives. The quality of the intervention provider influenced whether or not young people found the interventions to be acceptable and engaging; enthusiasm and considerable expertise were important for effective class management and delivery of skills-building activities, and a supportive school culture was also helpful. Recognition of young people's individual needs in relation to sexual health was another important factor. No conclusions could be drawn on the impact of the interventions on sexual health inequalities due to a lack of relevant data on socioeconomic status, gender and ethnicity. The results of the economic evaluation were considered to be illustrative, mainly due to the uncertainty of the effect of intervention on behavioural outcomes. The results were most sensitive to changes in parameter values for the intervention effect, the transmission probability of STIs and the number of sexual partners. The costs of teacher-led and peer-led behavioural interventions, based on the resources estimated from the relevant randomised controlled trials in our systematic review, were £4.30 and £15 per pupil, respectively. Teacher-led interventions were more cost-effective than peer-led interventions due to the less frequent need for training. The incremental cost-effectiveness of the teacher-led and peer-led interventions was £20,223 and £80,782 per quality-adjusted life-year gained, respectively. An analysis of individual parameters revealed that future research funding should focus on assessing the intervention effect

for condom use from a school-based intervention.
Conclusions: School-based behavioural interventions for the prevention of STIs in young people can bring about improvements in knowledge and increased self-efficacy, but the interventions did not significantly influence sexual risk-taking behaviour or infection rates. Future investigation should include long-term follow-up to assess the extent to which safer sexual behaviour is adopted and maintained into adulthood, and prospective cohort studies are needed to look at the parameters that describe the transmission of STIs between partners. Funding should focus on the effectiveness of the interventions on influencing behaviour.

Contents

List of abbreviations

AIDS	acquired immune deficiency syndrome
ANCOVA	analysis of covariance
CEAC	cost-effectiveness acceptability curve
CI	confidence interval
CLaSS	Chlamydia Screening Studies
CONSORT	Consolidated Standards of Reporting Trials
DALY	disability-adjusted life-year
DCSF	Department for Children, Schools and Families
DES	discrete event simulation
EVPI	expected value of perfect information
EVPPI	expected value of partial perfect information
FoK	Focus on Kids
GUM	genitourinary medicine
HAART	highly active antiretroviral therapy
HBSC	Health Behaviour in School-aged Children
HIV	human immunodeficiency virus
HPA	Health Protection Agency
HPV	human papillomavirus
HRQoL	health-related quality of life
HSV	herpes simplex virus
ICC	intracluster correlation coefficient
ICER	incremental cost-effectiveness ratio
ITI	intention to intervene
MSM	men who have sex with men
NAAT	nucleic acid amplification test
NATSAL	National Surveys of Sexual Attitudes and Lifestyles
NCSP	National Chlamydia Screening Programme
NHSP	National Healthy Schools Programme
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NNRTI	non-nucleoside reverse transcriptase inhibitor
NRTI	nucleoside reverse transcriptase inhibitor
NSU	non-specific urethritis
OR	odds ratio
PCR	polymerase chain reaction
PCT	primary care trust
PID	pelvic inflammatory disease
PSA	probabilistic sensitivity analysis
PSE	personal and social education
PSHE	personal, social and health education
PSS	Personal Social Services
PSSRU	Personal Social Services Research Unit
QALY	quality-adjusted life-year
QUOROM	Quality of Reporting of Meta-analyses
RCT	randomised controlled trial
RIPPLE	randomised intervention of pupil peer-led sex education
RR	risk ratio
SD	standard deviation

continued

SEAL	Social and Emotional Aspects of Learning
SES	socioeconomic status
SHARE	sexual health and relationships education
SRE	sex and relationships education
STI	sexually transmitted infection
TFI	tubal factor infertility
TREND	Transparent Reporting of Evaluations with Nonrandomised Designs

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

Background

Rates of sexually transmitted infections (STIs) continue to increase, particularly amongst young people. STIs can be either bacterial (e.g. chlamydia, gonorrhoea) or viral [e.g. human immunodeficiency virus (HIV), genital herpes, human papillomavirus]. Interventions to encourage young people to adopt and maintain safer sexual behaviour are one approach to preventing STIs and promoting sexual health. The prevention of STIs and teenage pregnancy is a high priority for health policy because of the adverse impact on individuals and on health service resources. We conducted a systematic review and economic evaluation to assess the effectiveness and cost-effectiveness of behavioural interventions for the prevention of STIs in young people.

Methods

Systematic review of effectiveness

A two-stage process was followed: (1) development of a descriptive map of the key characteristics of studies evaluating behavioural interventions, followed by (2) a detailed systematic review of a subset of interventions.

Search strategies Electronic bibliographic databases (for example, MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, PsycINFO and CINAHL) were searched for the period 1985 to March 2008. Bibliographies of systematic reviews and related papers were screened and experts contacted to identify additional published and unpublished references.

Study selection Titles (and abstracts, where available) were screened for eligibility by one reviewer using a priori inclusion criteria. Studies eligible for inclusion in the descriptive map were: controlled trials, evaluating a behavioural intervention (defined as any activity to encourage young people to adopt sexual behaviours that would protect them from acquiring STIs), in young people aged 13–19 years, which reported a sexual behavioural outcome. Full papers were obtained for those abstracts and/or titles that appeared relevant, and these were screened by two reviewers independently.

Descriptive map Keywords were developed and systematically applied to included studies to produce a detailed map of the evidence base that was used to prioritise a subset of studies for inclusion in the systematic review in consultation with stakeholders.

Data extraction and quality assessment Two reviewers independently quality assessed the studies included in the systematic review. Differences in judgement were resolved by discussion and involvement of a third reviewer if necessary. Outcome data from the studies that were judged to be methodologically sound were extracted by one reviewer and checked by a second. Process evaluation data were coded by two reviewers and classified into higher-order themes.

Data synthesis Studies were synthesised in both a narrative synthesis and meta-analysis.

Process evaluation Findings from process evaluations that had been conducted alongside the included original randomised controlled trials (RCTs) were summarised narratively.

Economic evaluation

A systematic review was conducted of economic evaluations of behavioural interventions for the prevention of STIs in young people. A number of electronic bibliographic databases (for example, CCRCT, MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, NHSEED and DARE) were searched for the period 1990 to February 2008, and references screened according to a priori inclusion criteria.

An economic model was developed to compare the costs and consequences of behavioural interventions for the prevention of STIs in young people. The cost-effectiveness of two types of behavioural intervention (teacher- and peer-led school-based intervention) compared with standard sexual health education was assessed.

A Bernoulli statistical model was constructed, which described the probability of STI infection based upon STI prevalence; single-act transmission probability; condom effectiveness and condom use; number of sexual episodes; and number of sexual partners. The parameters for the model were derived from a systematic search of the literature on the natural history and epidemiology of STIs; sexual behaviour and lifestyles; health-related quality of life; and costs. Costs were derived from primary data from previous studies, and national and local NHS unit costs. The analysis was conducted from the perspective of the NHS and Personal Social Services. In the model, the intervention effects last for 1 year, on the basis that the majority of the trials included in our systematic review assessed outcomes up to 1 year. The model estimates the lifelong costs and benefits from averted STI cases.

The model estimates the probability of becoming infected for the intervention and comparator groups according to changes in parameters that may be affected by the intervention (i.e. condom use, number of sexual partners, number of sexual episodes). The number of cases averted is estimated by multiplying the reduction in risk of STI infection by the number of people who receive the intervention. The total number of STI cases averted, and consequent quality-adjusted life-year (QALY) gain and saving in medical costs is estimated for males and females for all STIs for one year.

Results of the systematic review of effectiveness

A descriptive map of 136 studies meeting the inclusion criteria was produced. The results illustrated the predominance of North American trials of educational interventions conducted in schools with young people targeted primarily because of their age.

Discussion with the project's advisory group enabled the prioritisation of a policy-relevant subset of studies for systematic review. To be included studies had to be an RCT; evaluate a behavioural intervention including factual information on STIs, in addition to an element of skills development for negotiation of safer sex; be delivered in a school; and report a sexual behavioural outcome (in addition to other outcomes).

A total of 15 RCTs met the inclusion criteria for the systematic review. The majority were conducted in the USA, with only two in the UK. Of the 15 RCTs, 12 were judged to be methodologically sound and were included in the analysis of effectiveness. Studies reported on five main types of behavioural outcome: initiation of sexual intercourse; condom use; sexual intercourse; contraception and pregnancy; and sexual partners. Outcome data for variables that may mediate behavioural change were also often reported: knowledge; skills and self-efficacy; attitudes; and behavioural intentions. Rates of infection were not reported.

Five studies contributed data on sexual initiation. Three of the five studies found that there was no significant difference for this outcome between the intervention and the comparison group. Two studies reported a statistically significant difference in favour of the intervention, although in one the difference was only observed for girls in the peer-led group, which was compared with a teacher-led group. Data from four of these studies could be combined in a meta-analysis, the odds ratio (OR) of 1.03 [95% confidence interval (CI) 0.74 to 1.43] indicated no overall significant difference between groups.

A variety of condom use outcomes were reported. Statistically significant effects in favour of the intervention group over the comparison group were only reported by two of the studies, with one further study reporting a statistically significant effect in favour of the intervention for a subgroup of participants. A meta-analysis was conducted for the general outcome of condom use (an outcome incorporating some of the various measures of condom use). The fixed-effect OR for the combined effect was 1.07 (95% CI 0.88 to 1.30), again indicating no significant difference overall between groups.

For the remaining behavioural outcomes of sexual intercourse, contraception and pregnancy, and number of sexual partners there were very few statistically significant differences between intervention and comparators. The interventions did not lead to a significant increase in initiation of sexual activity by young people, or to an increase in the number of their sexual partners.

The success of the skills component of interventions was generally assessed by self-efficacy measures. Eight of the 12 studies reported a self-efficacy measure, most commonly condom use

self-efficacy which was reported by seven studies. Refusal or abstinence self-efficacy ($n = 6$ studies), communication/negotiation self-efficacy ($n = 4$ studies), and situational self-efficacy ($n = 2$ studies) were also reported by some studies. Statistically significant effects were reported for some, but not all, of the self-efficacy measures assessed. All the methodologically sound studies included a knowledge outcome measure, and statistically significant effects in favour of the intervention group over the comparison group were found by all but two of the studies.

Eight of the methodologically sound studies included an assessment of attitudes among their outcomes, and six studies reported participants' intentions, with a variety of different attitudes and intentions being assessed. However, few studies reported statistically significant effects in favour of the intervention group for these outcomes.

Nine of the 12 methodologically sound RCTs conducted a process evaluation. Synthesis of the process findings to explore reasons for the limited impact of school-based skill-development interventions revealed two sets of factors. Firstly, interventions were not always implemented as intended. Variation in implementation was affected by whether or not there was a supportive school culture, flexible school administration, and enthusiasm and expertise from teachers and peers for delivering interactive sexual health sessions such as role plays. Secondly, not all young people found the interventions as engaging or as acceptable as they might have done. The qualities of the intervention providers – namely enthusiasm, credibility and expertise (in content and in managing classrooms) – was one factor that influenced whether or not young people found the interventions to be acceptable and engaging. Other factors were whether the interventions met young people's own needs in relation to sexual health, including sexual feelings, emotions and relationships, the operation of gendered norms, the age appropriateness of the intervention and the level of discomfort felt in the classroom setting.

No conclusions could be drawn about the impact of the interventions on sexual health inequalities due to a lack of relevant data in the primary studies on factors, such as socioeconomic status (SES), gender and ethnicity.

Results of the economic evaluation

Systematic review of cost-effectiveness studies

Five economic evaluations of behavioural interventions for the prevention of STIs in young people were included. The studies were conducted in the USA and focused on the prevention of HIV. All studies used mathematical models extrapolating the changes in sexual behaviour. All interventions were effective at encouraging safer sexual behaviour in the study groups and thus led to cases of HIV averted. As the studies used a wide range of assumptions and parameter values in the mathematical models, substantial differences in the estimated cost-effectiveness of the behavioural interventions were reported.

Modelled cost-effectiveness analysis

An economic model was developed to assess the cost-effectiveness of behavioural interventions for preventing STIs in young people. However, as our meta-analysis did not show a statistically significant intervention effect, the results presented should be treated with caution and only be regarded as illustrative. The costs of teacher- and peer-led behavioural interventions, based on the resources estimated from the relevant RCTs in our systematic review, were £4.30 and £15 per pupil, respectively. We assumed the same benefit for teacher- and peer-led interventions. The teacher-led interventions were cheaper because of the need to train a new cohort of peers each year, whereas the teachers are only likely to need retraining after a number of years.

For a cohort of 1000 boys and 1000 girls, aged 15 years, the model estimated that the behavioural interventions would avert three STI cases and save 0.5 of a QALY. The incremental cost-effectiveness of the teacher- and peer-led interventions was £20,223 and £80,782 per QALY gained, respectively. Sensitivity analyses show the results were most sensitive to the intervention effect (condom use), the STI transmission probability, and the number of sexual partners in the base-case analysis. The model results were also sensitive to changes to the model parameters for chlamydia and especially for parameters related to tubal infertility. In a probabilistic sensitivity analysis, the

probability of the teacher-led intervention being cost-effective was 46%, where a decision-maker is prepared to pay £20,000 per QALY and 54% at a threshold of £30,000 per QALY.

At a cost-effectiveness threshold of £20,000 per QALY, the population expected value of perfect information (EVPI) is £12.5M, assuming a 10-year lifetime for the intervention (i.e. the time until a new intervention supersedes or replaces it). This constitutes an upper limit on research expenditure to reduce decision uncertainty. An analysis of the individual parameters used in the model revealed that research would be best funded to assess the intervention effect for condom use from a school-based behavioural STI intervention.

Conclusions

School-based behavioural interventions which provide information and teach young people sexual health negotiation skills can bring about improvements in knowledge and increased self-efficacy. However, in this systematic review there were few significant differences between the interventions and comparators in terms of changes in behavioural outcomes, such as condom use. The studies conducted relatively short follow-up assessments at a time when many young people were only just becoming sexually active. It is possible that favourable behaviour change may have occurred with time, particularly as sexual activity becomes more routine in young people's lives.

The results of the economic evaluation are considered illustrative primarily due to the uncertainty around the effect of intervention on behavioural outcomes, but also due to limitations in the data for other input parameters. The results were most sensitive to changes in parameter values for the intervention effect, the transmission probability of STIs and the number of sexual partners. Teacher-led interventions are likely to be cheaper than peer-led interventions due to less frequent need for retraining. Behavioural interventions for young people potentially may become more cost-effective as they get older and a greater proportion become sexually active.

Implications for practice

Policy-makers and practitioners should be cautious in their expectations about the impact of such interventions on sexual behaviour and incidence of infection. Nonetheless, school-based skills-building behavioural interventions can be effective in influencing behaviour-mediating outcomes, such as knowledge, attitudes and self-efficacy. This is in accordance with current UK government health policy, which stresses the need to provide high-quality information to enable young people to make informed decisions. Interventions need to be culturally relevant and context specific, taking into account the needs of subgroups of young people (e.g. young men, young women) and, where possible, be part of a whole school approach to sexual health promotion. Young people will benefit from being involved as equal stakeholders in the design and delivery of interventions. Providers of school-based interventions need to be enthusiastic and credible, with considerable expertise in classroom management and the delivery of skills-building activities, such as role plays and group discussions. A supportive school culture is also important.

Implications for research

If further primary evaluation of behavioural interventions is to be conducted there should be long-term follow-up to assess the extent to which safer sexual behaviour is adopted and maintained into adulthood. The impact of booster sessions should be further evaluated. All trials should be accompanied by rigorous process evaluation to assess the factors that contribute to success or failure, and economic evaluations to assess cost-effectiveness. Where appropriate, trials should collect, analyse and report data on the likely effects of the intervention on sexual health inequalities. Other markers of risk reduction (e.g. STI testing) should be measured.

For many of the parameters for the economic evaluation there were no available data for the < 16-year-old age group and we have had to make assumptions to extrapolate data from older age groups. Data on the sexual behaviour of under-16s is therefore needed. Furthermore, there is a need for prospective cohort studies to determine the parameters that describe the transmission of STIs between partners. The analysis of EVPI suggested an upper limit of £12.5M on funding for further research to reduce decision uncertainty, which should focus on the effectiveness of interventions on changing behaviour (e.g. increasing condom use).

Chapter 1
Background

Sexual health is influenced by a complex interplay between a number of factors, including the individual, their sexual partners, and their social and economic environment. The mechanisms by which the social and economic environment in which young people live influence the risk of acquiring a sexually transmitted infection (STI) remain complex and unclear. However, it is clear that some groups of young people are disproportionately affected by STIs. These groups are often characterised by factors that are also associated with the broader determinants of social and health inequalities, such as gender, ethnicity and sexuality. For example, young women (aged 16–19 years) have the highest incidence of both chlamydia and genital warts; young men who have sex with men remain at high risk of acquiring human immunodeficiency virus (HIV) in the UK, and rates of diagnosed STIs vary among young people of different racial and ethnic groups.[1] Little is known about which interventions are likely to reduce inequalities in sexual health.

Sexually transmitted infections are preventable, but individuals may put themselves at risk due to factors such as a lack of knowledge about STIs, low self-efficacy (the expectation that one can perform a particular task or activity, such as using condoms), poor condom use and/or sexual negotiation skills. Risk-taking by individuals may also be influenced by peer-group norms. Behavioural interventions have been developed which are designed to prevent or reduce risk behaviour, for example, by providing factual information and skills training.[2,3]

For young people, information about STIs is available from a wide range of sources that have varying degrees of reliability. Informal information sources about STIs and sex more generally may come from friends, family, the internet, magazines and other media. Most formal information and skills development around STIs is likely to come from sex education lessons provided in schools or from health services (see under Sexually transmitted infection prevention in the UK). The objective of school-based sex and relationships education (SRE) is to help and support young people through their physical, emotional and moral development – to help them learn to respect themselves and others, and to move with confidence from childhood through adolescence into adulthood. Effective SRE is essential for young people to be able to make informed decisions about their lives. However, there is uncertainty and sometimes controversy about how and when sex education should be taught. It should also be acknowledged that providing young people with information and skills does not mean that they will always choose the healthiest decisions, but, nonetheless, they have a right to high-quality sexual health promotion. At present, sex education is not compulsory in England and Wales; however, the introduction of a new personal, social and health education (PSHE) curriculum in 2010 will ensure that sex education is a compulsory element of the curriculum.

There is a need to base interventions to prevent STIs in young people, whether in school or any other setting, upon sound evidence of effectiveness. It is also necessary to assess the costs of such interventions and the gains to health in terms of the infections averted, associated gains in health-related quality of life (HRQoL), and lives saved.

The objective of this systematic review and economic evaluation, therefore, is to assess the effectiveness and cost-effectiveness of behavioural interventions for the prevention of STIs in young people.

Epidemiology and natural history of STIs

Rates of STIs continue to increase in the UK, particularly among young people. Increases in diagnoses may reflect greater ascertainment of cases through more testing and better diagnostic methods. They may also reflect an increase in unsafe sexual behaviour among young people. Most STIs are caused by either bacteria (e.g. chlamydia, gonorrhoea) or viruses [e.g. HIV, genital herpes, human papillomavirus (HPV)].

The impact of increases in the incidence and prevalence of STIs over recent years has placed great demand on health service resources for screening, treatment, and prevention of infections

and their complications. Data from the British National Surveys of Sexual Attitudes and Lifestyles (NATSAL) show an increase in the number of individuals attending genitourinary medicine (GUM) services over a 10-year period.[4] Between 1990 and 2000 there was an increase of 4.3–7.6% in men and 3.3–6.6% among women. This may be explained not only by increases in rates of STIs, but also by improvements in access to clinic services, and increased asymptomatic screening. STIs can lead to a range of serious long-term complications, such as infertility, pelvic inflammatory disease (PID) (in women), and epididymitis (in men), particularly if undiagnosed and untreated. HIV, though treatable, currently remains incurable, and, if not successfully managed, is associated with faster disease progression to acquired immune deficiency syndrome (AIDS) and related complications, and to mortality.

More detailed descriptions of the characteristics of individual STIs, including their causes, symptoms, treatment, incidence, prevalence and complications, are provided in the following subsections.

Chlamydia

Chlamydia is caused by the bacterium *Chlamydia trachomatis*, which is almost always transmitted through sexual intercourse, but can also be passed from an infected pregnant woman to her baby during delivery. In women, the symptoms of chlamydia tend to be non-specific and may include cystitis, change in vaginal discharge, post-coital and intermenstrual bleeding, and mild lower abdominal pain. In men, chlamydia is the most common identifiable cause of discharge from the penis. This may be accompanied by a mild irritation of the urethra that may disappear after two or three days. In both men and women, chlamydia infection may be asymptomatic (50% of male and 70% of female cases[5]) and persistent, and therefore a test is required to confirm infection. In women, the test can be carried out on a urine sample or from a swab taken within the vagina. In men, the test can also be carried out on a urine sample, but may sometimes be done on a swab taken from inside the tip of the urethra. Nucleic acid amplification tests (NAATs) are recommended for testing for chlamydia because of their high sensitivity and good specificity.[6] Chlamydia is treated with antibiotics, most commonly a macrolide, such as azithromycin, or a tetracycline, such as doxycycline. As with any STI it is important that sexual partners also receive treatment to avoid reinfection.

Chlamydia is the most common STI that is diagnosed and treated in the UK. In 2006 there were 113,585 new episodes seen at GUM clinics, and significant numbers of diagnoses originated from within the general practice setting.[7] The highest rates of undiagnosed infection, ascertained by the National Chlamydia Screening Programme (NCSP), and of GUM clinic-diagnosed chlamydia in 2006, were in young women (aged 16–19 years) and young men (aged 20–24 years).[8] In 2007 the NCSP in England performed 270,729 screens in under-25-year-olds: 9.5% of screens in women and 8.4% in men were positive for chlamydia. A further 79,557 diagnoses of genital chlamydia infection were made among young people in GUM clinics in the UK in 2007 (a rate of 1102 per 100,000 16- to 24-year-olds) – a rise of 7% on 2006.[1]

TABLE 1 *Incidence of newly diagnosed chlamydia in the UK in 2006*

	Incidence[7,10] [number (population rate per 100,000)]	
	Men	**Women**
Overall	113,585	
All adults	56,008 (190)	57,577 (187)
MSM	3239	–
Age < 15[a]	40	346
Age 15	120	1045
Age 16–19	8886 (544)	20,636 (1337)
Age 20–24	22,643 (1144)	22,059 (1145)

MSM, men who have sex with men.
a Incidence for all age groups: for 2006, 32 clinics did not report one-quarter or more of the KC60 returns.

Whilst the incidence of newly diagnosed chlamydia can be obtained from routine data (*Table 1*), estimates of the prevalence of undiagnosed chlamydia vary according to studies that have been conducted in diverse settings with different age groups. A review of prevalence studies conducted in the UK[9] found 25 studies that reported the prevalence of chlamydia. In males, estimates varied between 0% and 33%, and females between 0% and 41%.

Gonorrhoea

Gonorrhoea is caused by the bacterium *Neisseria gonorrhoeae*. The bacterium is highly infectious and mainly transmitted during sexual intercourse, but can also be passed from an infected pregnant woman to her baby during delivery. Like chlamydia, many women and men with gonorrhoea do not exhibit any symptoms. The most common symptom, if one is present, in men and women, is painful urination. In men this is accompanied by discharge from the urethra, whilst women experience an increase in vaginal discharge. Men and women who have anal sex can develop gonorrhoea in the rectum. Again, this infection may be asymptomatic or may lead to a painful discharge of blood and pus from the rectum. Men and women who have oral sex can develop gonorrhoea in the pharynx, which is usually asymptomatic. To confirm infection, the preferred test for routine use is culture of a specimen taken from the pharynx, urethra, cervix or rectum.[6] Other methods that can be used are NAATs and direct observation of the bacteria smeared on to a glass slide, Gram-stained and examined under a microscope. Gonorrhoea is treated with antibiotics, depending on local sensitivity patterns; most commonly a single dose of antibiotics is prescribed – usually ceftriaxone, cefiximine or spectinomycin.

Gonorrhoea is the second most common bacterial STI in the UK. In 2006, 19,007 new episodes were seen at GUM clinics. Gonorrhoea particularly affects certain population subgroups: young adults, men who have sex with men (MSM) and some ethnic groups.[8] Rates of gonorrhoea diagnosis in GUM clinics were highest among women aged 16–19 years (128 per 100,000) and men aged 20–24 (188 per 100,000). Of the women diagnosed with gonorrhoea, 40% (2147/5380) were teenagers (*Table 2*).[8]

HIV and AIDS

HIV is the virus that causes AIDS. The most common way for the virus to be transmitted is through sexual intercourse (vaginal or anal sex), but since it can be transmitted through the exchange of any bodily fluid it can also be spread by sharing needles and from a pregnant women to her baby (either during delivery or breastfeeding). HIV infects a type of lymphocyte known as a T-helper cell, which is a key component of the immune system. Because these cells express a protein called CD4 (cluster of differentiation 4) on their surface they are also known as CD4 cells.

Many people who become infected with HIV will not have any immediate symptoms, but about 60% of people will develop symptoms of primary HIV infection after about 2–6 weeks.[11] The symptoms are often mild and non-specific, such as fever, sore throat, swollen glands, joint and muscle pain, chest

TABLE 2 *Incidence of newly diagnosed gonorrhoea in the UK in 2006*

	Incidence[7,10] [number (population rate per 100,000)]		
	Men	**Homosexually acquired cases**	**Women**
Overall		19,007	
All adults	13,627	–	5380 (18)
MSM	4524 (967[a])	–	–
Age <15[b]	7	0	41
Age15	23	4	137
Age 16–19	1642	252	1969 (128)
Age 20–24	3723 (188)	810	1780

MSM, men who have sex with men.
a For MSM aged 15–44.
b Incidence for all age groups: for 2006, 32 clinics did not report one-quarter or more of the KC60 returns.

rash and tiredness. The immune system is not able to combat the virus, which continues to infect and destroy CD4 cells, but this phase of the infection often causes no further symptoms for many years.

An HIV infection can only be detected by testing a sample of bodily fluid (most commonly a blood sample, but plasma or saliva can also be tested). Current tests for HIV usually look for antibodies to HIV and these antibodies may take up to 3 months to appear following infection. Therefore, it cannot be assumed that a negative test result indicates no infection unless a second HIV test, taken at least 3 months later, is also negative.[6] HIV infection can also be detected by testing for protein components of HIV, or HIV nucleic acids. Testing for HIV antigens can provide a positive result 6 weeks after infection. Testing for HIV is important as this enables people with the infection to be identified, thus enabling them to benefit from early treatment with highly active antiretroviral therapy (HAART) and providing the opportunity for behavioural change to reduce onwards transmission. HAART has proved successful in slowing the progression of the HIV infection and prolonging life.

Human immunodefficiency virus and AIDS diagnoses observed at GUM clinics in 2006 are presented in *Table 3*, which shows that the total of new diagnoses was 6,137. The overall estimated new diagnoses of HIV are slightly higher, at 7800 (range: 7700–7950)[8] and over half were among heterosexuals, most of whom were infected abroad. Cases of sexually acquired HIV in those under 15 (if any) are not documented within a recent Health Protection Agency (HPA) report.[8] However, in 2006 there were 745 new diagnoses of HIV in the 16- to 24-year age group. About half of the new HIV diagnoses in young adults were in women (48%, 359/745[8]) and, where reported, most young adults were infected through heterosexual contact (55%, 374/686). Infection through sex between men resulted in 41% (281/686) of the new HIV diagnoses in young adults. Most of the children (aged under 15) in the UK diagnosed with HIV in 2006 acquired the infection perinatally, and about half of these were born abroad.

The estimated prevalence of HIV can be seen in *Table 4*. In the different population groups, between 25% and 39% were undiagnosed and therefore unaware of their infection. African-born people accounted for 35% of those with HIV and 31% of the total were unaware of their HIV status.

Genital herpes

Genital herpes is caused by the herpes simplex virus (HSV). There are two forms of this virus. Type 2 is more likely to cause herpes on the genitals, whilst Type 1 is more likely to cause herpes on the face (e.g. cold sores). It should be remembered that both types can cause herpes on either the face or the genitals. The virus is very contagious and is passed between people during skin-to-skin contact, such as during sexual activity (including orogenital contact in the case of HSV-1). The majority of cases of genital herpes are undiagnosed because they are not associated with any symptoms, or the symptoms are mild, for example a slight itching or red patch of skin in the genital area. If symptoms do occur

TABLE 3 *Incidence of new HIV and AIDS diagnoses in the UK in 2006*

	Incidence of new asymptomatic HIV diagnosis[7,10] [number (population rate per 100,000)]	**Incidence of new symptomatic HIV diagnosis (not AIDS)[7,10] [number (population rate per 100,000)**	**Incidence of new AIDS diagnosis (first presentation)[7,10] [number (population rate per 100,000)]**
All adults	4819 (8)	1035 (1.7)	283 (0.5)
Men (all)	2956 (10)	673 (2.3)	192 (0.6)
MSM	1400	256	63
Women	1863 (6)	362 (1.2)	91 (0.3)
Young adults (aged 16–24)	New diagnoses of HIV[a] 745 (11)	–	–

MSM, men who have sex with men. (It is not possible to provide population rates for MSM because information on sexual orientation is not collected by the UK census.)
Population rates for adults, men (all) and women have been calculated by the reviewer, based on mid-2006 population estimates.
a Not stated whether asymptomatic, symptomatic or at first presentation with AIDS.

TABLE 4 *Estimated HIV prevalence in the UK*

	Estimated HIV prevalence[a] (95% confidence interval, CI)[8]	Estimated population rate per 100,000
All adults[b]	69,400 (64,800 to 75,500)	115
MSM	30,100 (27,600 to 33,700)	151 (all men)
Heterosexual men	14,700 (12,700 to 18,400)	–
Heterosexual women	21,600 (20,000 to 23,700)	–

MSM, men who have sex with men. (It is not possible to provide population rates for MSM and heterosexual women because information on sexual orientation is not collected by the UK census.)
Population rates for all adults and a combined value for all men have been calculated by the reviewer, based on mid-2006 population estimates.
a Estimate includes both those diagnosed and those undiagnosed.
b Individuals aged 15–59 years.

they usually begin 2–7 days after infection and the initial phase of infection (primary infection) may last for up to 21 days.

Symptoms in this phase can be variable but may include mild fever, aches and pains, and swollen lymph glands in the groin. Some people may also experience painful red spots in the genital area, which gradually blister and then burst to leave painful ulcers. These ulcers will heal within about 10–14 days.

In women, genital herpes is usually localised to the vulva and, sometimes, the cervix. The infection may be accompanied by vaginal discharge and urination may be very painful. In men, the symptoms of infection are mainly present on the end and shaft of the penis, the foreskin, and, sometimes, the scrotum, and urination may also be painful. Some people experience recurrent episodes of genital herpes, occurring because the virus has not been completely cleared by the immune system and can lie dormant in nerve cells. The period between recurrences varies greatly between people, but recurrences generally become less frequent with age. Symptoms during a recurrence are not usually as severe as they are following the primary infection and they do not last as long. In order to diagnose genital herpes accurately a swab of the blisters should be taken during the active phase of infection. The fluid in the blisters or open sore that follows contains viral particles that can be detected in laboratory assays. During the active phase of the infection general advice for ameliorating the effects include using paracetamol or anaesthetic ointments as pain relief. Treatment with oral antiviral drugs may be indicated within 5 days of the start of the episode and while new lesions are still forming. For people who are prone to recurrent episodes of genital herpes antiviral medication may be prescribed as a suppressive therapy to help reduce the intensity and frequency of the recurrences.[12]

Genital herpes is the most common ulcerative STI in the UK. In 2006, 21,698 new diagnoses of a first attack of genital herpes were made in GUM clinics, with the number of diagnoses being 50% higher in women than in men (*Table 5*). In common with other STIs, such as chlamydia and gonorrhoea, genital herpes diagnoses were most common in young adults. Those in the 20- to 24-year age group had the highest rates of diagnosis in GUM clinics. The overall prevalence of genital herpes in the general population of England and Wales is estimated at about 3% for men and 5% for women.[13]

Syphilis

Syphilis is caused by the spirochaete bacterium *Treponema pallidum* and is mainly transmitted during sexual intercourse, but can also be transmitted during blood transfusions or by sharing infected needles during intravenous drug use. Additionally, infected pregnant women can pass the infection to their unborn child (congenital syphilis). There are three phases to the natural history of syphilis infection: primary (the incubation period is 9 – 90 days after exposure), secondary (3–6 weeks after the primary phase) and tertiary (a number of years after the primary phase).

Diagnosis of syphilis can be made by dark ground microscopy of specimens from any chancres of primary syphilis, but is more usually made following a blood test. Recommended regimes for the treatment of primary and secondary syphilis are

TABLE 5 *Incidence of genital herpes in the UK in 2006*

	First attack incidence[7,10] [number (population rate per 100,000)]		Recurrence incidence[7,10] [number (population rate per 100,000)]	
	Men	**Women**	**Men**	**Women**
Overall	21,698 (36)		16,354 (27)	
All adults	8392 (29)	13,306 (43)	7256 (24)	9098 (29)
MSM	604	–	573	–
Age <15[a]	1 (0.02)	33 (0.63)	–	–
Age 15	5 (1.2)	121 (31)	–	–
Age 16–19	610 (37)	2803 (181)	–	–
Age 20–24	2016 (102)	4014 (208)	–	–

MSM, men who have sex with men. (It is not possible to provide population rates for MSM because information on sexual orientation is not collected by the UK census.)
Population rates for overall group, all adults (recurrence rates only), age < 15, age 15 and age 16–19 have been calculated by the reviewer, based on mid-2006 population estimates.
a Incidence for all age groups: for 2006, 32 clinics did not report one-quarter or more of the KC60 returns.

benzathine penicillin as a single dose, or procaine penicillin for 10 days. Other antibiotic regiments may also be used.[14] Tertiary syphilis can also be treated with antibiotics, but any damage that has already been done to the heart or nervous system is irreversible. After treatment, a repeat blood test will be necessary to confirm that the infection has been cleared.

Syphilis is a relatively rare infection and diagnoses tend to be concentrated in large urban areas (e.g. London, the West Midlands and the north-west of England) and/or in particular core groups of the population. In 2006, the majority of diagnoses were in MSM, contributing to a ratio of 7 : 1 diagnoses of primary and secondary syphilis cases in men for every one case in women (*Table 6*). In contrast with some of the other STIs, patients with syphilis tended to be older, with the highest rates of primary and secondary syphilis in 35- to 44-year-old men (19 per 100,000) and 20- to 24-year-old women (4.3 per 100,000).

Researchers investigating characteristics of a recent outbreak of 21 cases of syphilis in Sheffield describe two major outbreak patterns that differed between groups of heterosexuals and MSM. Amongst the former they found a relatively straightforward and accessible cluster of cases, and more sporadic, 'starburst' network of non-connected cases in the latter.[15]

Human papillomavirus

The virus can cause genital warts. There are over 100 subtypes of HPV, of which about 40 infect the genital tract.[8] Genital warts are highly infectious because each wart releases virus particles. The virus is most commonly transmitted during sexual contact.

The symptoms of genital warts take at least 2–4 weeks to develop, but may not appear for several months. They may be flat or rough (rough warts are often described as being cauliflower-like in appearance), can be hard on dry hairy skin, or soft on moist hairless skin, may be very small (hardly visible) or larger, and there may be a single wart, a cluster of warts in one location or several warts in different places. In women, genital warts may develop on the vulva, inside the vagina, on the cervix, by the urethra and in, or around, the anus. In men, they may develop on the shaft of the penis, under the foreskin, on the perineum, in or at the tip of the urethra and in, or around, the anus. In general, warts are painless but flat warts may be accompanied by an itching or burning sensation. Genital warts can usually be diagnosed by clinical examination.

It is not possible to treat the underlying HPV infection that causes genital warts, but it is possible to treat the warts and there are several treatment options. The choice of treatment will depend on the size and location of the warts. In general, warts are easier to treat when they are small and few in number. Chemical treatments, such as podophyllotoxin, or, more rarely, tricholoroacetic acid, or immune response modifiers, such as imiquimod, are applied to the surface of the wart. With some treatments the surrounding uninfected skin must be protected from the treatment. These treatments can be used to treat only external warts.

TABLE 6 *Incidence of syphilis in the UK in 2006*

	Primary and secondary syphilis incidence[7,10] [number (population rate per 100,000)]		**Syphilis early latent (first 2 years) incidence[7,10] [number (population rate per 100,000)]**	
	Men	**Women**	**Men**	**Women**
Overall	2766 (5)		936 (1.5)	
All adults	2424 (8)	342 (1.1)	745 (2.5)	191 (0.6)
MSM	1417	–	456	–
Age <15[a]	0	1 (0.02)	–	–
Age 15	2 (0.5)	8 (2.1)	–	–
Age 16–19	61 (3.7)	51 (3.3)	–	–
Age 20–24	290 (14)	83 (4.2)	–	–

MSM, men who have sex with men. (It is not possible to provide population rates for MSM because information on sexual orientation is not collected by the UK census.)
a Incidence for all age groups: for 2006, 32 clinics did not report one-quarter or more of the KC60 returns.

Internal and external warts can be treated by cryotherapy (freezing), laser treatment or surgery. Because none of these treatments clears the underlying HPV infection there is a chance that the warts will re-occur after treatment.

Genital warts were the most common viral STI that was diagnosed in GUM clinics in 2006 and 2007. HPV subtypes 6 and 11 are the main causative agents of genital warts. In 2006 there were 83,745 diagnoses of first-episode genital warts in GUM clinics in the UK (*Table 7*). This represented 22% of all the new STI diagnoses made within this setting, with an additional 44,655 people attending GUM clinics for recurrent episodes, and a further 17,821 cases that required treatment for more than 3 months. Rates of newly diagnosed genital warts were highest in men aged 20–24 and in women aged 16–19.

In addition to the HPV subtypes that are commonly associated with genital warts, subtypes 16 and 18 are two of about 13 subtypes that are associated with human cancers (known as high-risk subtypes), particularly cervical cancer. The prevalence of the two key low- and high-risk subtypes of HPV are given in *Table 8*.

TABLE 7 *Incidence of HPV in the UK in 2006*

	HPV first attack incidence[7,10] [number (population rate per 100,000)]		**HPV recurrence[7,10] [number (population rate per 100,000)]**	
	Men	**Women**	**Men**	**Women**
Overall	83,745 (138)		44,655 (74)	
All adults	44,445 (151)	39,300 (128)	27,772 (94)	16,883 (55)
MSM	2691	–	1894	–
Age <15[a]	30 (0.55)	134 (2.6)	–	–
Age 15	70 (17)	497 (128)	–	–
Age 16–19	4846 (294)	11,845 (767)	–	–
Age 20–24	15,716 (794)	13,484 (682)	–	–

MSM, men who have sex with men. (It is not possible to provide population rates for MSM because information on sexual orientation is not collected by the UK census.)
Population rates for overall group, men (recurrence only), women (recurrence only), age < 15, age 15, age 16–19 (men only), and age 20–24 (women only) have been calculated by the reviewer, based on mid-2006 population estimates.
a Incidence for all age groups: for 2006, 32 clinics did not report one-quarter or more of the KC60 returns.

TABLE 8 *Prevalence of HPV subtypes in young women in England. Seroprevalences for females aged 10–29 (age standardised)*

Prevalence of HPV subtypes[16] (95% CI)
Low-risk subtype HPV 6: 10.7% (9.0 to12.3)
Low-risk subtype HPV 11: 2.7% (1.8 to 3.6)
High-risk subtype HPV 16: 11.9% (10.2 to 13.6)
High-risk subtype HPV 18: 4.7% (3.5 to 5.8)
Any of the four types: 20.7% (18.6 to 22.7)

Complications of STIs

Complications in women

In women, untreated chlamydia and gonorrhoea can lead to a number of complications including PID. PID is a syndrome that is believed to be caused by an infection that passes from the vagina through the cervix, the womb and up to the fallopian tubes and ovaries. When spread to the fallopian tubes, it causes inflammation (salpingitis) and narrowing of the tubes. This can result in fertilised eggs being unable to move along the fallopian tubes normally, thus increasing the risk of ectopic pregnancy and infertility. PID is difficult to diagnose by symptoms alone and diagnosis may require a combination of gynaecological examination, examination of vaginal and cervical swabs, blood tests, ultrasound scans and, in some cases, laparoscopy. Many women with PID experience few or no symptoms, whilst others may experience symptoms such as pelvic pain. If the infection remains untreated, the inflammation will eventually spread to the whole wall of the fallopian tubes, which can cause abscesses and adhesions to surrounding organs, such as the bladder and rectum.

Syphilis, if treated quickly, can be cured without causing any serious complications to health. However, if untreated it can progress to affect all areas of the body, including the joints, heart and lungs, spinal cord and brain. People with tertiary syphilis are at risk of blindness, deafness, muscle control problems, seizures and dementia. Complications of syphilis are similar for both men and women, though pregnant women are at increased risk of serious complications of pregnancy and childbirth (see Complications in pregnancy and childbirth).

Of all the viral STIs, HIV is associated with the most serious health complications, with significant morbidity and high costs of treatment and care. Whilst it remains an infection associated with significant mortality and a high number of potential years of life lost, disease progression to AIDS and death has been substantially reduced in the UK since the introduction of HAART in the mid- to late 1990s. The average lifetime treatment costs for an HIV-positive individual are estimated to be between £135,000 and £181,000.[17] HIV presents specific problems for women and babies both during and after pregnancy (see Complications in pregnancy and childbirth).

As described earlier, there are more than 100 types of HPV, 13 of which are 'high-risk' types that are associated with cervical cancer, the 12th most common cancer in females in the UK, and responsible for 949 deaths in the UK in 2006.[18] Around 70% of cervical cancers are attributed to two high-risk types: HPV 16 and 18. At least 10 other HPV types are also associated with a high risk of cervical cancer. In the autumn of 2008 the UK government introduced a national HPV immunisation programme for the routine vaccination of girls aged 12 to 13 years of age against cervical cancer. A catch-up campaign, targeting girls up to 18 years of age, will begin in Autumn 2009. The cost of the routine programme is expected to be in the region of £100M per year, with the catch-up programme costing up to £200M per year.[19]

Complications in pregnancy and childbirth

All bacterial STIs can transfer to the child when the mother gives birth, whereas syphilis can also cross the placenta during pregnancy. Both gonorrhoea and chlamydia can lead to pre-term birth, stillbirth and serious eye infections, and chlamydia can lead to neonatal pneumonia. Trichomoniasis is associated with both pre-term birth and low birth weight. Infective syphilis in pregnant women can lead to miscarriage, pre-term birth, stillbirth or a congenitally infected baby, which can result in physical deformity and neurological complications in children who survive. Maternal infection of all these STIs is detectable, however, treatment can prevent transmission to the baby.

Unlike the bacterial STIs, which can be treated and potentially cured during pregnancy, viral STIs cannot. The risk of transmission of genital herpes from mother to baby is greatest for babies born to a woman with first episode genital herpes around the time of delivery. Women with recurrent herpes prior to pregnancy are at very low risk of transmitting the infection to their babies. Herpes can be transferred in the birth canal during delivery, but rarely crosses the placenta during pregnancy. Transmission of the genital herpes virus can cause severe systemic disease in newborn

infants. However, whilst potentially life-threatening, neonatal herpes occurs very rarely in the UK.

In relation to conception, an HIV-positive woman with an HIV-negative partner may choose to conceive using artificial insemination to avoid transmission of the virus to her partner. Where a woman is HIV negative and her partner is HIV positive, options to avoid transmission of the virus include conception using artificial insemination or sperm-washing techniques. Pregnancy itself is not known to worsen the health of an HIV-positive woman.[20] Whilst it may slightly reduce her CD4 cell count, this is likely to return to pre-pregnancy levels shortly after the birth. An HIV-positive woman can transmit the virus to her baby during pregnancy, childbirth and breastfeeding. Antiretroviral medication can be given to the mother during pregnancy and labour to reduce or prevent transmission of the virus to the baby. If viral load on HAART is undetectable then elective vaginal delivery is supported.

Complications in men

Untreated chlamydia and gonorrhoea can cause epididymitis in men, and chlamydia can lead to Reiter's disease. Epididymitis is an inflammation of the tubular part (epididymis) of the testicle. The inflammation makes the testicle hot, swollen and extremely tender. It can lead to an accumulation of fluid in the area (hydrocele), abscesses and sterility. Reiter's disease is a condition that can affect both men and women; however, it mainly affects men. It usually occurs 1–3 weeks after infection with chlamydia. Symptoms include inflammation of the joints (arthritis), the urethra and, quite often, the eyes. It is the most common cause of arthritis in young men.

The complications of syphilis are similar for both men and women and have been described earlier (see Syphilis). Complications are rare with trichomoniasis, and mostly relate to pregnancy and childbirth. The genital herpes virus does not usually cause serious health problems for men. In men, high-risk HPV infections are associated with cancer of the penis, anus, mouth and oropharynx. These cancers are rare and much less common than cervical cancer. The serious health complications and impact of HIV are similar for men and women, excluding pregnancy and childbirth.

Sexually transmitted infection prevention in the UK

Sexually transmitted infection prevention for young people in the UK is provided by a number of agencies, including schools and colleges, the NHS, the youth service and non-statutory organisations. Sometimes prevention interventions are undertaken through multi-agency collaboration, such as school health clinics that are run by health professionals. [The subject of a separate systematic review and economic evaluation funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme – see www.hta.ac.uk.]

Policy context

The prevention of STIs and teenage pregnancy has been a high priority for health policy for some time. In 2001 the *National Strategy for Sexual Health and HIV* was published, demonstrating a commitment to tackling sexual ill-health and unintended pregnancies through improved prevention and treatment.[17] A key aim of the strategy was to address health inequalities and the needs of vulnerable groups, including (amongst others) young people, particularly those in, or leaving, care. Sexual health was also one of the priority areas of the public health strategy for England 'Choosing Health', with particular emphasis on addressing the needs of younger men and women.[21]

More recently the National Institute for Health and Clinical Excellence (NICE) has published public health guidance on sexual health for England and Wales.[22] The guidance covers one type of behavioural approach, one-to-one interventions, and it makes recommendations to NHS and non-NHS agencies with a role in the promotion of sexual health. There is particular emphasis on interventions for groups considered to be at higher risk, including MSM, vulnerable young people aged under 18 (including those from disadvantaged backgrounds, those in, or leaving, care, those with low educational attainment) and young women who are pregnant or already mothers.

The National Institute for Health and Clinical Excellence is also currently preparing guidance on NHS provision of contraceptive services for socially disadvantaged young people (up to the age of 25) – publication expected to be in October 2010. Teenage pregnancy is one of the issues covered by 'Every Child Matters: Change for Children', the strategy of the Department for Children, Schools and Families (DCSF) for the well-being of children and young people from birth to age 19.[23] A key feature of the strategy is effective co-ordination between services to ensure that all needs are met.

Non-governmental organisations also have a role to play in influencing the policy agenda. For example, the Sex Education Forum, part of the National Children's Bureau, brings together a wide range of stakeholders to promote and raise the profile of children and young people's entitlement to SRE through policy and advocacy work. The forum provides advice to the Government, discusses research evidence, and promotes best practice in the delivery of SRE.

Schools

Sex and relationships education is embedded within the secondary school curriculum in the UK through PSHE lessons [personal and social education (PSE) in Wales and Scotland]. Schools vary in the amount of time that they assign to SRE, with provision in some areas reported to be 'patchy'[24] (p. 5). Variability depends on a number of factors, including the time available within the curriculum, and the availability, skills and motivation of teaching staff. Schools usually assign particular teaching staff to deliver PSHE, and they may have different titles in different schools (e.g. the citizenship manager or the PSHE co-ordinator).

There is also variability in the topics covered and the format of the lessons. Some schools primarily provide factual information, whilst others supplement this with interactive learning, such as role play, condom use demonstrations and educational theatre, often with input from outside agencies (e.g. health promotion services). There are a wide variety of voluntary and statutory agencies that can work with schools around PSHE and SRE (see sections Health services and Non-statutory agencies). To date, schools have been largely autonomous in terms of which agencies they work with, and the depth to which sex education is covered. However, in 2008 it was announced that PSHE will become a compulsory part of the curriculum from Key Stage 1–4 (ages 5 to 16). There will be greater emphasis upon the role of healthy personal relationships, STIs and unplanned pregnancy, in addition to basic information on reproductive health.

Personal, social and health education is also one of the four core themes of the National Healthy Schools Programme (NHSP), which is run by the DCSF and the NHS. The other theme relevant to sexual health is 'emotional health and well-being'. The aim is to ensure that health education becomes an integrated part of the school curriculum and that the wider community is involved in its planning, implementation, and evaluation. It is intended that there will be measurable improvements in both health and education in the school and wider community. The NHSP represents a 'whole-school' approach to sexual health education, whereby everyone involved with the school (pupils, parents, teachers, governors) has a role to play in the promotion of health. There is particular emphasis in involving parents in the planning and delivery of the curriculum.

Another programme, used currently in 15% of secondary schools, with a growing take up, which is relevant to the promotion of sexual health is 'Social and Emotional Aspects of Learning' (SEAL). The programme operates a whole-school approach to promoting social and emotional health, through all aspects of the school (including the curriculum, teaching and learning, staff development, setting of policy, liaison with parents, promoting pupil voice, etc). The acquisition of the social and emotional skills of self-understanding, managing feelings, motivation, social skills and empathy is the heart of the SEAL programme. These generic skills that young people learn are central to their ability to manage themselves and their feelings, create a positive lifestyle for themselves and communicate effectively about drugs and alcohol, as well as sexual health. SEAL was implemented nationally in September 2007, based on the Social, Emotional and Behavioural needs pilot study.

Health services

At the local level, statutory health promotion services are the responsibility of primary care trusts (PCTs) in England. In Wales, services are overseen by the Welsh Assembly Government/NHS Wales, in Scotland by the Scottish Government/NHS Health Scotland, and in Northern Ireland by the Health Promotion Agency.

Sexual health promotion specialists employed by the NHS have a broad remit to work with a number of stakeholders on a variety of strategies. A PCT will commonly host a health promotion team comprising specialists in various areas, such as tobacco, healthy eating, physical activity and sexual health. Some of these run specialist projects that are set up to meet the needs of particular target groups, such as gay and bisexual men, young offenders, people with learning disabilities, commercial sex workers, or minority ethnic groups.

Sexual health promotion is also provided in primary care by general practitioners and practice nurses, on an opportunistic basis during

consultations and via targeted campaigns and specialist clinics. In the acute sector the promotion of sexual health is primarily the responsibility of GUM and family planning services. For example, in the GUM setting health advisors provide advice and information about STIs within the context of testing and treatment. For a number of years specialist sexual health/family planning clinics have been run for young people, at which they can receive confidential advice, receive testing, treatment (where necessary) and access resources such as condoms [including Brook drop-in centres (see Non-statutory agencies, below)]. These services, sometimes termed 'clinic in a box', can also be located in settings where young people socialise, such as youth groups, and sports and leisure facilities.

At a broader level, sexual health is promoted via Department of Health policy initiatives, such as mass media campaigns featuring television and radio adverts that are specifically targeted at young people around the need for safer sex to protect against STIs (e.g. the 'Condom Essential Wear' campaign during 2007–8).

Non-statutory agencies

A number of non-statutory agencies offer sexual health services to young people, often in partnership with statutory health, education and youth services. One of the most significant of these is Brook (formerly Brook Advisory), a national voluntary sector provider of free and confidential sexual health advice and services specifically for young people under 25. Brook has a network of 17 centres around the UK where young people can drop in and consult with a counsellor, nurse or doctor.

Other agencies in the UK which play a role in meeting young people's sexual health needs include the Terrence Higgins Trust and the National AIDS Trust. These agencies offer a number of services locally and nationally, including the provision of written resources, interactive internet advice, referral for STI screening (e.g. chlamydia screening) and media campaigns.

Agencies that look after the general needs of children and young people, such as Barnardo's, address sexual health issues amongst a range of other things, and refer young people to relevant statutory and non-statutory services when necessary.

Cost-effectiveness of behavioural interventions to reduce STIs

The rise in the number of STI diagnoses in the UK over recent years has led to greater burden on health services. As mentioned earlier, increases in the number of individuals accessing GUM services have been reported.[4] There are also costs associated with treating the long-term complications of infections that are asymptomatic and/or undiagnosed. The prevention of STIs is a key policy imperative, not only to reduce morbidity and mortality, but also to reduce health service costs. There is, therefore, a need to identify and focus on those interventions which are both effective and good value for money in reducing STIs.

One of the few relevant published cost-effectiveness analyses on the prevention of STIs from a UK perspective was the NIHR Health Technology Assessment (HTA) programme-funded economic evaluation of the cost-effectiveness of population screening for genital chlamydia.[25] It was found that proactive screening for chlamydia in women and men under 25 years of age, using home-collected specimens, was feasible and acceptable, but screening was not found to be cost-effective. A number of research recommendations were made to fill gaps in the evidence base, including a randomised controlled trial (RCT) of chlamydia screening.

The systematic review used to underpin the aforementioned guidance from NICE on the cost-effectiveness of one-to-one interventions to reduce STIs and teenage conceptions[26] found that most commonly evaluated interventions were chlamydia screening. Most of the interventions were found to be cost-effective and it was suggested that they may have been even more cost-effective if they had included the effects of reducing other STIs in their analyses. However, it was noted that there were few studies from the UK context, and that relatively few studies reported quality-adjusted life-years (QALYs), which made it difficult to compare across interventions. The cost-effectiveness of behavioural approaches to preventing STIs, particularly from a UK context, remains a priority to inform decision-making, given the paucity of cost-effectiveness assessments of this type of intervention that have been identified.[26]

Chapter 2

Methods for the mapping exercise and systematic review of effectiveness

The methods for the systematic review of effectiveness were described a priori in a research protocol (see Appendix 1) and adhered to accepted methodology for evidence synthesis as outlined in the Quality of Reporting of Meta-analyses (QUOROM) checklist.[27] A two-stage review was conducted.

The first stage was a descriptive mapping of included studies in order to prioritise a subset of the most policy-relevant studies in consultation with the project's Advisory Group of stakeholders (the results of which are reported in Chapter 3).

The second stage was a systematic review of the prioritised subset of studies (the results of which are reported in Chapters 4 and 5).

Search strategy

Searching for primary evaluations

Sensitive search strategies were developed and tested by an experienced information scientist (see Appendix 2 for search strategies). The finalised strategies were applied to the following electronic bibliographic databases:

- MEDLINE (via Ovid)
- MEDLINE In-Process & Other Non-Indexed Citations (via Ovid)
- EMBASE (via Ovid)
- PsycINFO (via Ovid)
- Educational Resources Information Centre (ERIC) (via CSA)
- CINAHL (via Ovid)
- Cochrane Central Register of Controlled Trials (CCRCT)
- Trials Register of Promoting Health Interventions [TRoPHI – the Evidence for Informed Policy and Practice Information and Co-ordination Centre (EPPI-Centre) register of RCTs and non-randomised controlled trials]
- Applied Social Sciences Index and Abstracts (ASSIA) (via CSA)
- Sociological Abstracts (SOCABS) (via CSA)
- POPLINE (POPulation information online).

ASSIA was searched from 1987 to March 2008. All other databases were searched for the period 1985 to March 2008. It was considered that evaluations of behavioural interventions to prevent STIs, notably HIV, would have started to be published from the mid-1980s onwards, hence the choice of 1985 as the start of the search period.

The following websites were also searched to identify relevant studies:

- The UK National Library for Health (NLH) – www.library.nhs.uk/Default.aspx
- UNAIDS (Joint United Nations Programme on HIV/AIDS) – www.unaids.org/en/
- CDC (Centers for Disease Control and Prevention) – www.cdc.gov/
- Google Scholar – http://scholar.google.co.uk

Google Scholar was searched from 1989 to 2007; UNAIDS and CDC were searched for the period 1998 to 2007. The NLH database does not permit restriction of searches to particular dates.

In addition, relevant articles were sourced from bibliographies of the studies included in the systematic review. For all searches, studies were limited to English-language articles. Full papers were obtained from University libraries, the British Library, and from the internet (e.g. Google). Search results were uploaded into the EPPI-REVIEWER database[28] (specialist systematic reviewing software developed by the EPPI-Centre), de-duplicated and stored, ready for screening.

Searching for systematic reviews

A separate search was conducted to identify other systematic reviews of behavioural interventions to prevent STIs. The aim was to scan the reference lists of relevant systematic reviews to identify studies, supplemental to those identified by our own searches, which might meet the inclusion criteria of our review. The systematic reviews

themselves were not subjected to data extraction and critical appraisal and their results were not assessed. However, some notable examples of these systematic reviews are discussed in relation to the findings of our review (see Chapter 8, Findings from other systematic reviews). The search for systematic reviews was based on those conducted for the Evidence briefings on STIs and HIV published by the (former) Health Development Agency (now the Centre for Public Health Excellence at NICE).[29,30] As these briefings searched up to 2003, we carried out further database searches for the period 2003 to March 2008 to identify more recent systematic reviews. The databases searched included: Cochrane Database of Systematic Reviews (CDSR); Centre for Reviews and Dissemination (CRD) (University of York) databases: DARE (Database of Abstracts of Reviews of Effectiveness) and HTA (Health Technology Assessment); MEDLINE (Ovid); MEDLINE In-Process & Other Non-Indexed Citations (Ovid); EMBASE (Ovid); CINAHL (Ovid); British Nursing Index; PsycINFO; ERIC (CSA); and SOCABS (CSA). The search identified 643 systematic reviews, of which 21 met the inclusion criteria [i.e. the review focused on behavioural interventions targeted at young people aged 13–19 years, and could be considered systematic (in that they provided evidence of: search strategy; application of inclusion criteria; and use of quality assessment)]. The 21 reviews yielded 76 references to studies that had not been identified from our search of bibliographic databases. These were screened for inclusion, along with all of the other references that had already identified from the databases.

Inclusion criteria for descriptive mapping (stage one)

An inclusion worksheet was used for the screening process (see Appendix 3). Each reference was screened on the basis of title and abstract for potential inclusion by one reviewer. Full reports were obtained for those references that appeared to meet the criteria or where there was insufficient information from the title and abstract. Inclusion criteria were then applied independently to each report by two reviewers, with any differences in opinion on the inclusion of a particular study being resolved through discussion and recourse to a third reviewer where necessary. The numbers of studies included and excluded at each stage of the review are documented in a QUOROM style flow chart[27] (Appendix 4). The inclusion criteria were based on the commissioning brief issued by the HTA programme. Further details of the criteria are set out below.

Participants

The participants were young people aged 13–19 years.

If the study included a broader age range (e.g. 17–22 years), but the mean or median age was within the specified age range, then the study was included.

Study design

Outcome evaluations (RCTs or non-randomised controlled trials) were used.

These were defined as studies designed to establish whether the intervention changes the outcomes specified in the aims of the study. Only trials that compared the intervention with a control or comparison group were included. Outcome evaluations that included an integral cost-effectiveness analysis and/or process evaluation were also included. Studies reported in abstract form only (e.g. conference proceedings) were only included if they were published in or after 2005. It was assumed that, in general, abstracts from before this date would have been fully published and hence identified by our search.

Intervention

Behavioural interventions that aim to prevent STIs were used.

The commissioning brief did not define what a behavioural intervention was, so we adopted an inclusive strategy that defined it as 'any activity to encourage young people to adopt sexual behaviours that will protect them from acquiring STIs'. Sex education studies were included provided there was some indication that prevention of STIs was addressed by the intervention.

Comparator

The commissioning brief specified 'standard practice' as the comparator. We therefore did not restrict inclusion of studies on the basis of any particular comparator. (See Chapter 4, Comparators, for a description of the various comparators used in the studies which were systematically reviewed.)

Outcomes

Studies that reported the impact of the intervention on a sexual behavioural outcome were included, for example:

- abstinence from sexual activity/delaying onset of sexual activity
- self-reported condom use (e.g. frequency of use)
- number of sexual partners
- age at first experience of sexual intercourse.

Studies that reported incidence/prevalence of STIs or pregnancy-related outcomes (e.g. rate of conceptions) were included, providing they also reported a sexual behaviour outcome. Since self-efficacy does not constitute a behaviour, studies that reported self-efficacy or sexual behavioural intentions were included only if they also reported a sexual behaviour outcome. Likewise, studies measuring variables considered to mediate behaviour change (e.g. knowledge, attitudes, beliefs, intentions) were included provided that a behavioural outcome was also measured.

The process of descriptive mapping

As mentioned, the purpose of the mapping exercise was to facilitate a description of the evidence base so that a subset of policy-relevant studies from the map could be identified and subjected to a detailed systematic review. This approach has been found to be useful in previously published EPPI-Centre systematic reviews.[31–35] Included studies were classified on the basis of their key characteristics, using the web-based systematic review software EPPI-REVIEWER.[28] Keywords to classify the characteristics of young people were allocated to each study, using a modified version of a classification system originally devised by Evans and Brown[36] and subsequently adapted for use in a previous systematic review.[37] The classification system is known as 'PROGRESS plus' [*P*lace of residence, *R*ace/ethnicity, *O*ccupation, *G*ender, *R*eligion, *E*ducation, *S*ocioeconomic status (SES) and *S*ocial Capital][38] and underwent a further modification for this review to accommodate keywords specific to sexual health. Application of 'PROGRESS plus' keywords enabled the identification of subgroups of young people based on markers of their risk of acquiring, or passing on, an STI.

Studies were also classified according to the STI under focus (e.g. HIV, chlamydia), the type of intervention evaluated (e.g. education, skills training, counselling), the intervention provider (e.g. teacher, peers, health professional), the setting, the country and location, and outcome measures. The interventions were also classified at the 'level(s)' at which they were delivered (individual, social, policy), based on a classification system used by a Cochrane Systematic Review of behavioural interventions to prevent HIV in racial and ethnic minorities.[39] Keywords for these factors were devised specifically for this project by the review team.

The classification instrument was piloted on a sample of five studies to refine the keywords and to establish good inter-rater reliability within the team. Some changes were made as a result of the piloting, mostly to the keywords relating to the characteristics of the young people studied. Once finalised, the instrument was applied to the included studies by one reviewer. A random sample of 20% of the studies were then checked by a second reviewer to ensure consistency.

Inclusion criteria for the systematic review (stage two)

Once all of the studies had been classified, analysis was performed to construct the descriptive map (for results of the map, see Chapter 3). The preliminary results of the descriptive map were presented to our advisory group in June 2008 for discussion. The group assisted us in prioritising a subset of studies for systematic review that most closely resemble current UK practice, and which are most likely to address current policy and practice needs. Several different subsets of studies for potential systematic review were discussed (according to different groups of young people, types of intervention, outcome measures, etc.). It was noted that although young people who are considered to be at greatest risk for STIs may not regularly attend school, school-based behavioural interventions had the potential to reach a large number of young people (and as will be seen in Chapter 3, in Characteristics of the interventions, school was the most common intervention setting as identified in the mapping). It was also considered that interventions that provide factual information about STIs, in addition to the teaching of skills to avoid catching and/or transmitting them, would be a useful focus for the review. Based on the discussion, the inclusion criteria for the systematic review were set as follows:

- Participants: young people aged 13–19 years.
- Intervention: behavioural interventions based in (but not restricted to) schools in which an element of the intervention included the development of sexual behavioural skills (e.g. how to use a condom, to negotiate safer sex with partners). Studies evaluating interventions teaching skills outside the context of sexual health (e.g. life skills) were not included.
- Study design: RCTs only.
- Outcomes: self-reported sexual behaviour (studies reporting other outcomes could be included providing that behaviour was also measured).

Once the criteria for the systematic review had been set, all of the studies classified in the map were checked to ensure that the keywords regarding the type of intervention were accurate. This ensured that all studies which were based in schools and in which skills development was a feature of the intervention were identified.

Data extraction in the systematic review

A data extraction and quality assessment instrument was devised for the systematic review and loaded into EPPI-REVIEWER software. The instrument contained 102 separate items and incorporated some of the items included in an existing EPPI-Centre quality assessment instrument[40] as used in several published systematic reviews.[33–35,41] Data were extracted from the included subset of RCTs using the EPPI-REVIEWER program. Data extraction was undertaken independently by two reviewers. EPPI-REVIEWER compared their data extractions and identified discrepancies in coding. Differences were resolved by discussion and involvement of a third reviewer where necessary.

For outcome evaluations that also conducted a process evaluation, additional data were collected on: the types of processes evaluated, the data collection methods used, the groups from which data were collected, and the findings and conclusions of the process evaluation. A broad definition of process evaluation was adopted, which covered any assessment of how well the intervention was implemented and the factors influencing this, the acceptability and accessibility of the intervention, the quality of intervention content and materials, collaborations and partnership working, and the skills and training of the intervention providers.

Where available, we extracted outcomes data for the pre-specified population subgroups that are outlined above (see The process of descriptive mapping).

Quality assessment

The quality assessment instrument was devised by the EPPI-Centre in consultation with a statistician[42] and was designed to assess key biases to the results of evaluations, based on empirical methodological research (Appendix 5). The quality of each study was assessed by two reviewers, independently, with differences in opinion resolved by discussion. For one study a third opinion was sought regarding judgement of methodological quality.[43] Included studies were categorised into two groups: 'sound' and 'not sound'. Methodologically 'sound' studies were those deemed to have avoided selection bias, attrition bias, and bias due to selective reporting. Studies failing one or more of these criteria could be judged 'sound despite discrepancy with the criteria' if there were extenuating circumstances that both reviewers agreed did not pose a significant risk of bias (e.g. a study that did not report results for all outcome measures, but the outcomes that were reported were not statistically significant; it was therefore unlikely that the authors were trying to conceal 'negative' results) (see Chapter 4, Overall judgements on study quality).

The quality of the process evaluations was assessed according to a set of criteria developed specifically for this review. These criteria were based on our own previous work assessing the quality of process evaluations and qualitative research[44–46] and the work of others in the field.[47]

- Steps were taken to minimise bias and error/ increase rigour in sampling. (For example, was the sampling strategy appropriate to the questions being asked? Were all stakeholders included?)
- Steps were taken to minimise bias and error/ increase rigour in data collection. (For example were data collection tools validated or piloted? Was data collection comprehensive, flexible and/or sensitive to provide a rich description of processes?)
- Steps were taken to minimise bias and error/ increase rigour in data analysis. (For exmple

were analysis methods systematic? Was diversity in perspective explored?)
- Findings were grounded in/supported by the data. (For example were enough data presented to show how the authors arrived at their findings? Do the data presented fit the interpretation provided?)
- There was good breadth and/or depth achieved in the findings. (For example were a range of processes issues covered in the evaluation? Were the perspectives of participants fully explored in terms of breadth – contrast of two or more perspectives – and depth – insight into a single perspective?)
- The perspectives of young people were privileged. (For example were young people included in the evaluation? Was there a balance between open-ended and fixed-response options?)

As a final step in the quality assessment of the process evaluations, reviewers were requested to assign the studies two types of 'weight of evidence'. First, reviewers were asked to assign a weight (low, medium or high) to rate the reliability or trustworthiness of the findings (the extent to which the methods employed were rigorous/could minimise bias and error in the findings). Reviewers were also asked to assign a second weight (low, medium, high) to rate the usefulness of the findings in terms of how well the intervention processes were described and whether or not the process data could illuminate why or how the intervention worked or did not work. Guidance was given to reviewers to help them reach an assessment on each criterion and the final weight of evidence.

Data synthesis

Both a narrative synthesis and a meta-analysis were performed to analyse the results of the RCTs. For the narrative synthesis data were systematically retrieved from EPPI-REVIEWER and summarised narratively and in tabular form.

Meta-analysis

Meta-analysis was conducted using EPPI-REVIEWER. A fixed-effect model was used, with a random-effects model reserved to explore any significant statistical heterogeneity observed. Statistical heterogeneity was assessed using the chi-squared test, with a p-value greater than 0.10 indicating significant heterogeneity.[48] The I^2-statistic was used to quantify the magnitude of statistical heterogeneity. This describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance).

As will be reported in more detail in Chapter 4 (see Methodological quality of the outcome evaluations), 9 of the 12 methodologically sound outcome evaluations randomly allocated clusters rather than individuals to study groups. An estimate of the intracluster correlation coefficient (ICC) was therefore required. This is necessary to account for the tendency for individuals within a cluster to be similar, thus reducing the variability in the responses.[49] The ICC is expressed as a value of between 0 and 1. The closer the figure is to 1 the greater the within-cluster correlation.[49] Five of the nine cluster RCTs reported an ICC, and these were entered into the meta-analysis. For studies that did not report an ICC we imputed a value of 0.2, based on that used for the power calculation in one of the trials included in the systematic review [the RIPPLE (randomised intervention of pupil peer-led sex education) trial].[50] This value was higher than ICC values reported by the other included studies. Therefore, the effects of imputing lower ICC values, and of omitting an ICC value when none was reported, were tested. It was found that they did not alter the pooled effect estimates (data not reported).

The mean cluster size was calculated by adding the total number of young people randomised to each study group and dividing this total by the number of clusters. The majority of outcome measures for which sufficient data were available were dichotomous. Odds ratios (ORs) were chosen as the summary effect estimate for these outcomes.

Behavioural outcomes were prioritised for meta-analysis because effect estimates of parameters such as condom use were required to inform the Bernoulli equation in our economic model (see Chapter 7, Methods for cost-effectiveness modelling of behavioural interventions for prevention of STIs in young people). The outcome measures reported by each of the RCTs judged methodologically sound in the systematic review were tabulated to determine whether sufficient data existed to permit meta-analysis. This was an intricate process, as there was much variability in the definition and reporting of behavioural outcomes, such as condom use. Once tabulated, specific behavioural outcomes were defined and data assembled into a format suitable for entry into the meta-analysis facility in EPPI-REVIEWER. If the

primary studies assessed outcomes at several time points (e.g. 6 months' follow-up, 12 months' follow-up), the data were entered for all of the reported follow-up time points.

Where possible, the outcome data were entered into the analysis based on an intention-to-intervene (ITI) analysis (i.e. based on all young people randomised). For some behavioural outcomes, data were reported for subgroups of young people who were sexually active/inactive. Where necessary, study authors were contacted for clarification on figures reported in their papers or to supply missing data. However, few of the authors responded, which meant that certain studies could not be included in the meta-analysis for some outcomes. It was decided that the study by Borgia and colleagues[51] would not be included in the meta-analysis as it compared two very similar behavioural interventions (the only difference between them being that one was teacher-led, while the other was peer-led), whereas the other studies generally compared a behavioural intervention with either a control or with standard practice. (Note: The trial by Stephenson and colleagues,[50] which also compared peer-led with teacher-led interventions, was included in the meta-analysis as the teacher-led intervention was standard practice – see Chapter 4, Synthesis of results of sound outcome evaluations.)

Where data allowed, we conducted separate meta-analyses for the subgroups based on gender (young men and young women). This was one of the subgroups specified in the protocol as a variable to be explored in the synthesis of outcome evaluations.

The feasibility of meta-analysis of behavioural mediators, such as knowledge and self-efficacy, was explored. Much of these data were measured using widely differing measurement scales, and in many cases no measure of variance was reported to allow meta-analysis of continuous data. Meta-analysis of these outcomes was therefore not considered feasible or appropriate.

Process evaluations

Narrative methods were used to synthesise findings from the process evaluations. These methods were based on those we have developed in previous work on the synthesis of process evaluations and qualitative research[44,52–54] and from other

Researcher 1 (AH) themes	Researcher 2 (EBP) themes
• Peer leader issues • Age appropriateness (of intervention) • Student engagement with intervention • Parent involvement not feasible • Intervention as extra demands on school teachers and administrators • School context • Implementation failure for interactive sessions • Gendered norms and mixed sex classes • Teachers, peers, health educators?	• Parents (as providers or their attitudes to the intervention) • Peer educators • School administration • School culture • Use of technology/computers • Fidelity • Mixed sex vs single sex groups • Timing of sex education • Interactivity
Jointly agreed themes	
Fidelity of implementation School administration School culture Student engagement Teacher engagement Interactivity Gendered norms and mixed sex teaching Peer leaders Parents Age and timing of sex education	

FIGURE 1 *Initial and jointly agreed themes.*

groups working on methods for synthesising process evaluations.[55–57] Detailed evidence tables were prepared, describing the methodological quality of the process evaluation, contextual details (e.g. intervention content, setting) and the findings of process evaluation (Appendix 6). This was undertaken by one researcher (EBP), with contributions from the second reviewer (AH), based on the data extracted using the instrument described in Appendix 5.

Findings were assigned to one or more of eight predetermined categories (accessibility/programme reach; collaboration and partnerships; content of the intervention; intervention implementation; acceptability; quality of intervention materials; skills and training of intervention providers; and 'other').

Both researchers independently read and re-read the tabulated details and noted down their initial thoughts on the main themes to arise from the findings. The two researchers met to discuss and compare their individual themes and compiled a jointly agreed list (*Figure 1*). These themes were used to generate hypotheses about intervention effectiveness and to illuminate issues around intervention acceptability as well as barriers and facilitators to implementation.

A narrative was written to describe and elaborate on these themes and this was reviewed and discussed by five members of the review team (AH, EBP, JS, JK and JP) to generate possible explanations for the effects of the outcome evaluations. The themes and notes from this meeting were reviewed again by two researchers (AH and EBP) who translated their initial themes across the process evaluations in order to answer two questions. Firstly, what factors facilitate or hinder the implementation of skills-based behavioural interventions in schools? Secondly, what factors impact on student engagement and intervention acceptability?

Chapter 3

Results of the mapping exercise

Results of the literature search

- A total of 11,548 references were identified through electronic database searches. Of these, 3511 were duplicate references and were removed.
- In total, 8037 titles (and, where available, abstracts) were screened, of which 7682 were excluded according to our criteria, primarily on the basis of irrelevant study population or study design.
- Full reports of the remaining 355 references were obtained:
  - According to our criteria, 158 of these were excluded, again primarily on the basis of irrelevant study population or study design.
  - In total, 36 reports were unable to be retrieved (mostly Master's and doctoral dissertations and unpublished reports).
  - An additional 16 papers were identified from checking reference lists and through contact with study authors.
  - A total of 136 separate evaluations were eligible for inclusion in the descriptive mapping exercise (as described by a total of 177 papers).
  - Of the 136, a subset of 15 RCTs were prioritised for inclusion in the systematic review (as described by a total of 45 papers). (See Chapter 4.)

Please refer to Appendix 4 for a QUOROM flow chart illustrating the flow of references through the various stages of screening and mapping, and the reasons for study exclusion.

The characteristics of the 136 studies included in the mapping exercise are reported in the following subsections.

Characteristics of the young people studied

The factors targeted by the studies, as classified using the PROGRESS-Plus system, can be seen in *Table 9*.

Although all of the studies were included because their participants were aged between 13 and 19 years, 71 of the studies were classified as targeting a particular age band within this age range. For example, some interventions were conducted to meet the specific needs of younger teenagers, whilst others were geared towards older teenagers who, it was considered, may be more sexually active. The next most frequently reported factors were ethnicity ($n = 26$) and place of residence ($n = 24$).

Gender was identified as an issue by some of the studies. Seventeen targeted young women, whilst half this amount targeted young men. Studies classified as targeting young people on the basis of sexual behaviour did so on the basis of self-reported risk behaviour (e.g. having multiple partners), or through other indicators of sexual risk in a particular area. Factors which were rarely targeted included occupation, religion, disability, having a previous history of STI, and being HIV positive. Factors in the 'other' category included runaway (homeless) youths, young people with a previous history of abuse, and teenage mothers. Just under a fifth of the studies ($n = 25$) did not specifically target any of the factors. These were studies that aimed to promote the sexual health of young people, but did not make explicit reference to any particular target group.

Types of studies

Table 10 shows the different types of study design included in the map. Of the 136 studies, 70 were non-randomised and 66 were RCTs. Sixteen of the studies included integral process evaluations (not shown in the table – refer to Chapter 5 for further details of the process evaluations that are integral to the trials included in our systematic review). They evaluated the delivery of the intervention or resources used, or measured the acceptability of the intervention to its recipients, amongst other things.

As can be seen from *Table 11*, only one study reported the economic costs of the intervention programme, albeit limited information. This study, carried out in Switzerland, reported the

TABLE 9 *Factors targeted by the studies included in the mapping exercise*

PROGRESS-Plus factors	Number of studies[a]
Age	71
Ethnicity	26
Place of residence	24
Gender – female only	17
SES	15
Gender – male only	8
Sexual behaviour	9
Offenders	6
Alcohol use	4
Drug use	4
Education	3
Existing STI (other than HIV)	2
Housing status	2
Disability	1
HIV positive	1
Looked-after young people	1
Occupation	1
Previous STI	1
Religion	1
Other factor	13
No factors explicitly mentioned	25

a Total exceeds 136 as studies could target more than one factor.

TABLE 10 *Types of studies included in the mapping exercise*

Study type	Number of studies
Non-randomised controlled trial	70
RCT	66

TABLE 11 *Reporting of economic costs by studies in the mapping exercise*

Whether cost data reported	Number of studies
No	135
Yes	1

total cost of the intervention and who funded the programme. No other details were reported. The fact that cost details were not reported in the vast majority of studies does not preclude the fact that some of the interventions may have been subjected to cost or cost-effectiveness analysis in separate publications that were not included in the map. Publications included in the map were not systematically assessed for cross-references to related publications (with the exception of those which were eventually included in our systematic review). However, at least one study which was subsequently included in the systematic review is known to have undergone economic evaluation.[58] The publication describing this economic evaluation was included in our systematic review of cost-effectiveness studies[59,60] (see Chapter 6).

Study location

Table 12 shows the location where the studies were conducted. Around three-fifths of the studies were carried out in the USA ($n = 81$), and 25 were based in Africa. Only six studies were carried out in the UK and a further seven in Europe. The remainder were carried out in South America, Asia or Canada.

Characteristics of the interventions

Table 13 shows the sexual health topics covered by the interventions. In over two-thirds of studies ($n = 97$), the aim of the intervention was to prevent young people from acquiring HIV. In nearly half of the studies, the aim was the prevention of STIs in general ($n = 64$). Thirty-six of these were classified as targeting both HIV and other STIs, but without any specific STI being mentioned (other than HIV) (not shown in table). Only two studies focused on a specific STI: chlamydia ($n = 1$) and genital herpes ($n = 1$). For the 26 studies in the 'other' category the intervention focused on reproductive health and prevention of pregnancy, and other risk factors such as alcohol, tobacco and drug use.

Table 14 shows the various different intervention components evaluated in the studies. The majority of studies ($n = 123$) incorporated an element of education and information relating to sex and sexual health into the intervention. These studies

TABLE 12 *Location of the studies included in the mapping exercise*

Location	Number of studies
USA	81
Africa	25
South America	9
Other Europe	7
Asia	6
UK	6
Canada	2
New Zealand	0
Australia	0
Other Australasia	0
Republic of Ireland	0

TABLE 13 *Number of studies included in the mapping exercise reporting sexual health topics*

Sexual health topic	Number of studies[a]
HIV	97
STIs in general	64
Chlamydia	1
Genital herpes	1
Gonorrhoea	0
HPV/genital warts	0
NSU	0
Pubic lice	0
Scabies	0
Syphilis	0
Trichomonas vaginalis	0
Other	26
Not stated	2

NSU, non-specific urethritis.
a Total exceeds 136 as studies could focus on more than one topic.

commonly provided training in how to use a condom or how to negotiate safe sex ($n = 81$). The majority of these studies also provided education and information ($n = 74$) (not shown in *Table 14*). In 33 studies, resources and services were provided to participants, such as pamphlets, brochures, tapes, videos, group discussions, lectures, seminars, youth clubs and free condoms. Very few studies provided

TABLE 14 *Number of studies included in the mapping exercise reporting intervention components*

Type of intervention component	Number of studies[a]
Education/information	123
Skills training	81
Provision of resources and services	33
Mass media	20
Professional training	14
Incentives	11
Counselling (group)	6
Social support	5
Policy and legislation	0
Screening	0
Other/unclear	18
Not stated	2

a Total exceeds 136 as studies could include more than one component.

a group counselling or social support element in the intervention. Interventions classified under 'Other/unclear' included a computer-based program, games/sports events, take-home exercises and role play.

Table 15 shows the different types of intervention provider in the studies. The intervention was provided most frequently by peers ($n = 44$) and teachers ($n = 39$). In 23 studies, the intervention was provided by a health-care professional (e.g. family planning clinic nurse, general practitioner). Parents were used infrequently ($n = 5$), as were researchers ($n = 9$). Least likely to provide the intervention were psychologists, school nurses, youth workers, community workers or social workers. In the 'other' category ($n = 45$), the intervention was given by such people as AIDS educators, counsellors, or other specially trained facilitators and health educators.

Table 16 reports the various locations in which the interventions were delivered. In more than half of the included studies, the intervention was provided in a school or college setting ($n = 77$), tying in with the finding that peers and teachers most commonly delivered the intervention (*Table 15*). Approximately one-quarter of the included

TABLE 15 *Number of studies included in the mapping exercise reporting intervention providers*

Person(s) providing intervention	Number of studies[a]
Peers	44
Teacher	39
Health-care professional	23
Researcher	9
Parent/carer	4
Community worker	3
Computer	2
Social worker	2
School nurse	2
Psychologist	1
Youth worker	1
Other	45
Not stated	21

a Total exceeds 136 as an intervention could have more than one provider.

TABLE 16 *Number of studies included in the mapping exercise reporting intervention locations*

Intervention location	Number of studies[a]
School/college	77
Community	37
Health-care setting	25
Home	7
Correctional institution	5
Workplace	2
Other	10
Not stated	8

a Total exceeds 136 as interventions could be provided in more than one location.

studies used a community setting ($n = 37$), whilst in 25 studies the intervention took place in a health-care setting (e.g. STI clinics, reproductive health clinics). The workplace was, not surprisingly, given the young age of the participants, infrequently used as a location ($n = 2$).

Table 17 reports the number of studies classified as different levels of behavioural intervention. The majority of studies ($n = 126$) were classified as evaluating an individual-level behavioural

TABLE 17 *Number of studies in the mapping exercise classified as evaluating different levels of behavioural intervention*

Intervention type	Number of studies[a]
Individual-level interventions	126
Social interventions	15
Policy interventions	5
Unclear	2

a Total exceeds 136 as studies could evaluate more than one type of intervention.

intervention, i.e. interventions in which the primary focus is on encouraging behaviour change in individuals rather than changing community or population norms. Components of this type of intervention included skills training, education, provision of resources and risk-reduction materials, and counselling. Fifteen studies were classified as social interventions, which aim to change not only individual behaviours, but also social norms or peer norms. Strategies such as community mobilisation, building networks, and structural and resource support were used in an attempt to bring about such changes. Very few studies ($n = 5$) were classified as evaluating policy interventions. These were defined as interventions that aim to change individual behaviour or peer/social norms or structures through implementation of legislation, administration and policy. Four of these were delivered in developing countries, with the fifth in the USA. The interventions featured the provision of youth-friendly sexual and reproductive health-care services, including condom availability schemes, and competitive voucher programmes. All of the five studies were evaluated using non-randomised controlled trial designs.

Table 18 presents the number of studies included in the mapping which reported various sexual behaviour outcomes. All of the studies included in the mapping exercise reported at least one sexual behavioural outcome measure, in accordance with our inclusion criteria. Condom use was the most frequently reported sexual behaviour outcome, reported in over 80% ($n = 113$) of included studies. Fifty-eight studies reported the number of sexual partners, whilst approximately one-third of studies ($n = 45$) presented data on abstinence from, or delaying the onset of, sexual activity.

A relatively large number of studies were classified as 'other' in their reporting of sexual behavioural

TABLE 18 *Number of studies included in the mapping exercise reporting various sexual behaviour outcomes*

Sexual behaviour outcome	Number of studies[a]
Abstinence from sexual activity/delaying onset of sexual activity	45
Age at first experience of sexual intercourse	12
Condom use for vaginal/anal intercourse	113
Number of sexual partners	58
Other	82

a Total exceeds 136 as studies could report more than one outcome.

outcomes. This was because the outcomes were heterogeneous and often ambiguous in definition, and did not appear applicable to our pre-existing categories. An example from one study was 'sex with a high-risk partner', with no definition of what a high-risk partner was. The two most common types of outcome classified under 'other' were the proportion of young people having sex/becoming sexually active, and the frequency of sex (protected and unprotected). These outcomes were not anticipated when the classification system was designed, hence they did not appear as categories in the mapping instrument.

Table 19 presents the number of studies included in the mapping exercise that measured STI outcomes. The majority of studies ($n = 109$) did not report the incidence of STIs as an outcome. Where incidence was an outcome it was reported for STIs in general, rather than a specific STI ($n = 19$). Only a handful of studies reported outcome data on specific STIs, such as chlamydia, gonorrhoea and genital herpes.

Table 20 reports the number of studies included in the map that reported other (non-behavioural, non-biological) outcome measures. Other outcomes that were reported by studies largely included variables that are considered to mediate behaviour change. For example, two-thirds of the studies ($n = 87$) reported knowledge of STIs as an outcome measure, and just under half ($n = 72$) measured young people's attitudes towards sex, STIs and safer sex. Self-efficacy, the expectation that one can perform a particular task or activity, was reported in 52 studies.

TABLE 19 *Number of studies included in the mapping exercise reporting STI outcomes*

STI	Number of studies
No STI incidence outcomes reported	109
STIs in general	19
Chlamydia	6
Gonorrhoea	2
Genital herpes	2
HIV	2
Pubic lice	1
Syphilis	1
Trichomonas vaginalis	1
Genital warts (including HPV)	0
NSU	0
Scabies	0

NSU, non-specific urethritis.

TABLE 20 *Number of studies included in the mapping exercise reporting other outcomes*

Outcome	Number of studies[a]
No other outcomes reported	17
Attitudes	72
Beliefs	24
Complications arising from STIs[b]	0
Conception rate	7
Behavioural intentions	41
Knowledge	87
Self-efficacy	52
Use of microbicides	0
Other	40

a Total exceeds 136 as studies could report more than one outcome.
b For example, PID, ectopic pregnancy, infertility.

Mapping exercise – summary of results

The most commonly mentioned factors targeted by the studies included age (e.g. the needs of younger teenagers), followed by ethnicity, place of residence (e.g. urban or rural) and SES. Around one-fifth of the studies did not mention targeting any particular risk factors.

Nearly one-half of the studies mapped were RCTs, with minimal reporting of costs and cost-effectiveness. The majority were North American studies (just under two-thirds), with very few studies from the UK. The vast majority of studies aimed to prevent HIV, and many specified targeting HIV and other STIs, but without mentioning any specific infections of interest. The prevention of pregnancy was an additional focus in less than 10% of the studies.

The provision of information about STIs and sexual health was a staple of the vast majority of interventions. Training in skills was an additional feature of just over half of these interventions. Just over a quarter of the interventions were classified as providing services or resources to young people, but there were very few interventions involving the setting of policy or legislation. The bulk of the interventions were delivered in schools or, less commonly, community settings and were mostly provided by teachers or peers.

Condom use was the most commonly reported behavioural outcome, and changes in STI incidence were reported in only a minority of studies. Commonly reported mediators of behaviour change included knowledge, attitudes and self-efficacy.

In summary, the mapping exercise illustrated the predominance of North American trials of educational interventions conducted in schools, with young people considered at risk due, primarily, to their age. These interventions were often delivered by teachers and peers, focusing mainly on the prevention of HIV and STIs generally. The effectiveness of these interventions was mainly measured in terms of behavioural outcomes, such as condom use and mediators of behaviour change. Biological outcomes were rarely measured.

As mentioned earlier in Chapter 2 (The process of descriptive mapping), the results of the mapping exercise were discussed with the project's advisory group. Various different inclusion criteria for the systematic review were discussed, based on the findings of the map. These discussions led to the identification of the following inclusion criteria for the systematic review:

- Participants: young people aged 13–19 years.
- Intervention: behavioural interventions based in (but not restricted to) schools in which an element of the intervention included the development of behavioural skills (e.g. how to use a condom, to negotiate safer sex with partners).
- Study design: RCTs only.
- Outcomes: self-reported sexual behaviour (studies reporting other outcomes could be included, providing that behaviour was measured).

Given that a number of RCTs and non-randomised trials of the relevant behavioural interventions (i.e. based in schools in which an element of the intervention included the development of behavioural skills) were identified, it was decided to restrict inclusion to just the RCTs as these were considered, generally, to provide more rigorous evidence.

Chapter 4

Results of the systematic review of effectiveness

A total of 15 RCTs met the inclusion criteria for the systematic review (see Appendix 7 for a bibliography of these, including all linked publications; see also Appendix 4 for the QUOROM flow chart showing the process of inclusion and exclusion of studies). The next three subsections of this report (Characteristics of the interventions, Characteristics of the young people and Methodological quality of the outcome evaluations) present the key characteristics of all 15 included studies. Subsequent sections present the outcome evaluation results of a subset of 12 studies that were judged to be methodologically sound (Synthesis of results of sound outcome evaluations), and the characteristics and results of the sounds studies that also included process evaluations (Chapter 5). Readers who are primarily interested in the results of the sound outcome evaluations may wish to prioritise the section 'Synthesis of results of sound outcome evaluations', whilst those interested in the characteristics of the wider evidence base, irrespective of methodological soundness, may wish to examine the sections 'Characteristics of the interventions', 'Characteristics of the young people' and 'Methodological quality of the outcome evaluations'.

Characteristics of the interventions

Table 21 provides an overview of the 15 RCTs.

TABLE 21 *Overview of the 15 RCTs included in the systematic review*

Study		Intervention	Comparator
Borgia *et al.*[51]			
Country: Italy Ethnicity: NR Sex: mixed SES: representative of general population		Not named, peer led: 5 sessions, 10 hours in total	Teacher led: same total length suggested over approximately 3 months
n	1295	613	682
Age[a]	18.3 (1.1)	18.2 (1.1)	18.2 (1.1)
Coyle *et al.*[58]			
Country: USA Ethnicity: mixed Sex: mixed SES: representative of general population		'Safer Choices' led by teachers and trained project staff: 10 sessions in each of 2 consecutive years[b]	Standard HIV prevention curriculum, presumably teacher led – length not stated
n	4310 (3677 for baseline characteristics)	1983[c]	1886
Age		13 – 4.4%; 14 – 57.2%; 15 – 28.1%; 16 – 8.6%; > 17 – 1.7%	13 – 4.6%; 14 – 57.4%; 15 – 27.7%; 16 – 7.9%; > 17 – 2.4%

continued

TABLE 21 *Overview of the 15 RCTs included in the systematic review (continued)*

Study		Intervention	Comparator
Coyle *et al.*[61]			
Country: USA Ethnicity: mixed Sex: mixed SES: NR		'All4You!' led by experienced health educators: 14 sessions, totalling 26 hours, over 6–8 weeks[d]	Usual HIV, STI and pregnancy prevention activities, typically led by presenters from community-based agencies – length not stated
n	988	597	391
Age		14 – 7.3%; 15 – 20.7%; 16 – 30.7%; 17 – 32.2%; 18 or older – 9.1%	14 – 11.3%; 15 – 27.4%; 16 – 33.6%; 17 – 21.8%; 18 or older – 5.9%
Jemmott *et al.*[43]			
Country: USA Ethnicity: black Sex: male only SES: low		Not named; single 5-hour session led by specially trained adult facilitators	Career opportunities: single 5-hour session led by specially trained adult facilitators
n	157	85	72
Age	14.64 (1.66)	NR	NR
Jemmott *et al.*[62]			
Country: USA Ethnicity: African-American Sex: mixed SES: low		Not named; single 5-hour session led by specially trained adult facilitators	General health promotion; single 5-hour session led by specially trained adult facilitators
n	496	269	227
Age	13.2 (0.94)	NR	NR
Karnell *et al.*[63]			
Country: South Africa Ethnicity: predominantly Zulu Sex: mixed SES: low		'Our Times, Our Choices': 10 units, each 30 minutes, delivered over approximately 8 weeks[e] by teachers and peer leaders (both trained)	Life orientation instruction, presumably teacher led; length not stated
n	661	325	336
Age	16 (median)	16 (median)	16 (median)
Klepp *et al.*[64]			
Country: Tanzania Ethnicity: NR Sex: Mixed SES: NR		'*Ngao*' (Swahili for 'shield'); about 20 hours of class time, over 2–3 months	Delayed intervention
n	1063	258 (for baseline characteristics)	556 (for baseline characteristics)
Age	13.6 (1.3)	13.5 (1.2)	13.6 (1.3)
Levy *et al.*[65]			
Country: USA Ethnicity: mixed Sex: mixed SES: low		'Youth AIDS Prevention Project (YAPP)' delivered by trained health educators; 10 sessions over 2 weeks; booster – 5 sessions over 1 week the following year	Basic AIDS education (current practice) presumably delivered by teachers; length not stated
n	2392	1459 (1001 for baseline characteristics)	933 (668 for baseline characteristics)
Age		12.5	12.6

TABLE 21 *Overview of the 15 RCTs included in the systematic review (continued)*

Study		Intervention	Comparator
Roberto *et al.*[66]			
Country: USA Ethnicity: predominantly European-American Sex: mixed SES: low		Not named: 6 computer activities for students, each approximately 15 minutes, over 7 weeks	Not described (no intervention)
n	378	164 (139 for baseline characteristics)	214 (187 for baseline characteristics)
Age		15.50 (0.63)	15.68 (0.73)
Schaalma *et al.*[67]			
Country: Netherlands Ethnicity: NR Sex: mixed SES: NR		Not named; 4 class sessions, teacher led, each 60–76 minutes on average	AIDS/STI education led by teachers (current practice); approximately 5 hours in total
n	3142	NR	NR
Age	School grade 9 (~age 15) or grade 10 (~age 16)	NR	NR
Stanton *et al.*[68]			
Country: Namibia Ethnicity: NR Sex: Mixed SES: NR		'My Future is My Choice': 14 sessions, each 2 hours, led by a volunteer teacher and a youth, administered over 7 weeks	Delayed intervention
n	515	262	253
Age	17 (median)	17 (median presumed)	17 (median presumed)
Stanton *et al.*[69]			
Country: USA Ethnicity: predominantly white Sex: mixed SES: low		'Focus on Kids (FoK)' and 'West Virginia FoK': 8 weekly sessions, each approximately 1.5 hours, led by specially trained local interventionists[f]; in community settings, 1 day or 2 half-day sessions	Training in environmental conservation: comparable length to FoK and presumably led by trained interventionists
n	1131	870 (combined intervention group)	261
Age	12–14: 46.9%; 15–16: 53.1%	NR (for combined group)	12–14: 48.28%; 15–16: 51.52%
Stephenson *et al.*[50]			
Country: England, UK Ethnicity: NR Sex: mixed SES: representative of general population		'RIPPLE': 3 peer-led sessions, each 1 hour, over the summer term	Teacher-led SRE (current practice); length not stated
n	8766	4516	4250
Age	13–14[g]	13–14	13–14

continued

TABLE 21 *Overview of the 15 RCTs included in the systematic review (continued)*

Study		Intervention	Comparator
Wight *et al.*[70]			
Country: Scotland, UK Ethnicity: NR Sex: mixed SES: representative of general population		'SHARE'; 10 teacher-led sessions in each of 2 consecutive years, plus teacher training	Usual teacher-led sex education (current practice): 7–12 lessons in total, over 2 years
n	7616	2867 (follow-up)	2987 (follow-up)
Age	13–14	13–14	13–14
Zimmerman *et al.*[71]			
Country: USA Ethnicity: mixed Sex: mixed SES: NR		'Reducing the Risk (RtR)', and a modified version: 16–17 class sessions during one school year, delivered by specially trained teachers and peer leaders; booster session (not described) the next year	Non-skills based, HIV prevention, presumably teacher-led; 0 to 15 class sessions (presume current practice)
n	2647 (1944 for baseline characteristics)	RtR: 681 Modified RtR 1149	851
Age	13–0.6%; 14–53.0%; 15–35.1%; ≥16–11.3%	NR	NR

n, number; NR, not reported.
a Age in years reported as mean (SD) unless otherwise stated.
b This intervention involves a whole-school approach that was not assessed in the reported RCT.
c Group '*n*'s do not sum to the baseline or follow-up *n* for the whole sample.
d Based on two previously evaluated interventions: 'Be Proud, Be Responsible' and 'Safer Choices'.
e Adapted from two previously evaluated interventions: 'Project Northland' and 'Reducing the Risk'.
f Included face-to-face and long-distance interactive televised delivery formats.
g Mean baseline age probably 14.1 years because mean age at the 6-month follow-up was 14.7 years.

Intervention provider

Table 22 presents the number of studies using different types of intervention providers. Just over half of the studies involved teachers as intervention providers and nearly as many involved peer educators. Five were delivered by both teachers and peers (not shown in *Table 22*).[51,58,63,68,71] Two of the studies, Levy and colleagues[65] and Coyle and colleagues,[61] which fell into the 'Other' category, used specially trained health educators. One study, Jemmott and colleagues,[43] used a specially trained 'adult facilitator'. Stanton and colleagues,[69] whose study took place in a number of rural locations, involved local people to deliver the intervention, including ministers, recreation centre directors, liaison officers, faculty members, graduate students and housewives.

Intervention setting

Table 23 presents the number of studies using various settings for the delivery of the intervention. All included studies took place in a school/college setting, in accordance with the inclusion criteria. Two studies, Stanton and colleagues[69] and Jemmott and colleagues[62] were also partly based in the community. In terms of country, eight interventions were delivered in the USA,[43,58,61,62,65,66,69,71] three in Africa (South Africa,[63] Tanzania[64] and Namibia[68]), two in Europe (Italy[51] and the Netherlands[67]) and two in the UK (Scotland[70] and central southern England[50]).

Type of intervention component(s)

Table 24 presents the number of studies using various intervention components. As can be seen, the interventions featured more than one component. All provided skills training, in addition to information (a consequence of our inclusion criteria).

All interventions provided education/information and skills training. Fewer studies were classified as

TABLE 22 *Intervention provider*

Provider	Number of studies[a]
Teacher	8
Peers	6
Health-care professional	2
Community worker	1
Computer	1
Parent or carer	1
Social worker	1
Other	5

a Total exceeds 15 as interventions could have more than one provider.

TABLE 23 *Intervention setting*

Setting	Number of studies[a]
School/college	15
Community	2

a Total exceeds 15 as interventions could be delivered in more than one setting.

TABLE 24 *Components of the interventions*

Component	Number of studies[a]
Skills training	15
Education/information	15
Professional training	3
Provision of resources and services	3
Mass media	2
Incentives	1
Other	5

a Total exceeds 15 as interventions could include more than one component.

providing resources and services. Two interventions included a mass media component: Wight and colleagues[70] included videos to trigger discussion, whilst Stanton and colleagues[69] used a long-distance interactive televised format to deliver their intervention to some of the participants. Components in the 'Other' category included the use of games (Stanton and colleagues,[68] Stephenson and colleagues[50]), a computer-based interactive program (Roberto and colleagues[66]) and the use of drama (Klepp and colleagues[64]).

Sexual health topics covered

Table 25 presents the sexual health topics that were addressed by the interventions. Most of the studies covered HIV, and just over half also covered other STIs. None targeted any one particular STI (other than HIV). The studies in the 'Other' category covered the prevention of unintended pregnancy, in addition to STIs.[58,61,66,70,71]

Content of the interventions

The majority of the interventions encouraged risk reduction. Although not always clear from the descriptions provided, seven studies mentioned risk reduction only and a further five studies aimed at both risk reduction and delayed sexual intercourse. Only one study, Klepp and colleagues,[64] focused solely on delayed initiation of sex. Two studies were not clear.

All studies aimed to increase knowledge of HIV and other STIs. Two-thirds of the studies covered negotiation/communication skills, one-third mentioned enhancing self-efficacy, and three studies mentioned attempting to alter peer norms regarding either the desirability of using protection during intercourse or of delaying intercourse. Most studies mentioned the promotion of condoms, and seven studies described actively modelling and practising condom use skills with the young people.

Three studies involved parents as part of the intervention, although the parents were not the official intervention providers. One further study aimed to increase young people's communication with their parents. Only one study, Wight and colleagues[70] mentioned including the promotion of local sexual health services (either by the

TABLE 25 *Sexual health topics covered*

Focus	Number of studies[a]
HIV	12
STIs generally	8
Other	5

a Total exceeds 15 as interventions could address more than one topic.

young people visiting the service or by a member of staff visiting the school), although Coyle and colleagues[61] arranged visits to local 'AIDS service organisations'. None of the interventions featured the distribution of contraception or referrals to sexual health clinics.

Additionally, the two UK-based studies (Wight and colleagues[70] and Stephenson and colleagues[50]) both aimed to improve the quality of young people's sexual relationships.

None of the interventions were described as having included either referrals to local sexual health services or the provision of contraception, although one (Coyle and colleagues[56]) required pupils to gather information on local resources and sexual health services. Furthermore, the studies did not tend to mention whether the interventions followed an empowerment or a directive approach to health promotion.

Length/intensity of the intervention

Although some authors provided only minimal details, the length/intensity of the interventions varied widely across studies. The shortest/least intense intervention was the single 5-hour session of Jemmott and colleagues.[26] The lengthiest/most intense intervention appeared to be Wight and colleagues' intervention,[70] consisting of 20 sessions over 2 years. Not so lengthy, but also intense, were the studies of Coyle and colleagues,[61] involving 26 hours of intervention over 5–7 weeks, and Stanton and colleagues,[68] comprising 14 2-hour sessions over 7 weeks.

Theoretical basis

Table 26 presents the number of studies that used specified theories of health-related behaviour in the conception of the interventions. All except two of the studies were explicitly informed by a named theory. Stephenson and colleagues[50] noted that the RIPPLE intervention was not based on any particular theory, but was designed to be a pragmatic approach to sex education. Zimmerman and colleagues[71] mentioned that their intervention was theory driven, but did not cite any specific theoretical models. The theories used in the studies were generally sociopsychological in origin. They included Social Learning Theory and Social Cognitive Theory (often associated with the work of Bandura[72–74]), the Theory of Reasoned Action (associated with the work of Ajzen and Fishbein[75]), as well as its successor the Theory of Planned Behaviour (associated with Ajzen[76]). These models predict how health-related behaviour can be influenced in social settings through role modelling to foster positive attitudes, intentions and self-efficacy around negotiating safer sex. Most studies cited more than one theory in the development of the intervention, such as the trial by Karnell and colleagues,[63] which included what the authors described as three overlapping theories (Social Learning Theory, Social Inoculation Theory and Cognitive Behaviour Theory).

TABLE 26 *Theoretical basis of the interventions*

Theory	Number of studies[a]
Social Learning Theory	6
Traditional education/reasoned action model	4
Theory of Planned Behaviour	3
Social Cognitive Theory	3
Cognitive Theory	2
Not stated	2
Other	8

a Total exceeds 15 as studies could use more than one theory.

A range of theories were classified as 'Other', including the Social Influences Model,[77] Inoculation Theory,[78] the Extended Parallel Process Model,[79] Protection Motivation Theory,[80] the Health Belief Model[81] and the Transtheoretical Model (stages of behaviour change).[82] These theories vary in their tenets, but, in common with the theories mentioned above, generally seek to predict health-related behaviour through the role of attitudes, skills, self-efficacy and social influences.

Origin of the interventions

Some of the interventions were derivations of other interventions, some of which were included in our review. For example, 'Safer Choices', reported by Coyle and colleagues,[58] was based on an intervention, in the USA, entitled 'Reducing the Risk' (originally evaluated by Kirby and colleagues,[83] but did not meet the inclusion criteria for this systematic review). 'Reducing the Risk' was one of the Centers for Disease Control's 'programmes that work'[84] and was subsequently replicated and modified by Zimmerman and colleagues[71] (included in this systematic review) for 'high sensation seeking and impulsive youth'. Similarly, the 'Our Times, Our Choices'

intervention evaluated by Karnell and colleagues,[63] which was delivered in South Africa, was also a modification of 'Reducing the Risk'.

'Safer Choices', itself, subsequently became one of six effective interventions selected by the National Institutes of Health in the USA for adaptation and replication in different settings.[85] Evaluation of 'Safer Choices 2', this time in an 'alternative' rather than a mainstream high school setting (e.g. for students with behavioural problems, truancy, poor educational attainment or pregnancy), has been conducted and results are awaited.[86,87]

Another of the six replication projects is the West Virginia Focus on Kids (FoK) intervention by Stanton and colleagues[69] (included in our systematic review). This is an adaptation of the original FoK intervention, which was originally evaluated with urban, low-income, predominantly African-American young people in Baltimore, MD, USA.[88] (Note: The original intervention is not included in our review as the mean age of the young people, 11 years, did not meet our inclusion criteria.). It was adapted to be relevant to the predominantly rural white population of West Virginia, with low HIV seroprevalence. The original FoK intervention has also been adapted for use outside of the USA – in Namibia.[68] (Note: This study was included in the systematic review, but was judged not to be methodologically sound.)

Comparators

Table 27 presents a classification of the comparators used in the studies. The majority of studies used 'standard' sex education as their comparator. This generally consisted of information provision and tended not to include active participation, exercises, role play and skills development. Nearly as many studies used an 'attention' control, in which an intervention of similar length and intensity, focusing on a non-sexual health-related topic, was provided.

TABLE 27 *Comparators used in the studies*

Comparator	Number of studies
'Standard' sex education	5
'Attention' control	5
Delayed intervention	2
No intervention control	1
Teacher led vs peer led	2

Characteristics of the young people

Age

Studies reported age in a wide variety of ways. Some gave a mean, some a median age, and some a breakdown across the age range of those in their sample (see *Table 21*, earlier). Some reported for intervention and control groups separately, some for the total sample. This makes it difficult to summarise data on age across the 15 included studies. However, studies largely targeted young people in their early- to mid-teens (i.e. up to, and including, 16-year-olds). The exceptions to this were the study of Borgia and colleagues[51] – the mean for the total sample was 18.3 years [standard deviation (SD) = 1.1] – and Stanton and colleagues,[68] who reported a median age of 17 years. The youngest to be targeted were 12 years old (for example, in Levy and colleagues[65] and Stanton and colleagues[69]).

Gender

Study samples were predominantly of mixed sex and were equally balanced between the sexes. The exceptions to this were the samples of Coyle and colleagues,[61] of which around two-thirds were male, and Jemmott and colleagues,[43] whose intervention was designed only for young men.

Race and ethnicity

Ten studies reported the racial/ethnic profile of the sample, but the level of detail given varied considerably.[43,50,58,61–63,65,66,69,71] The ethnicity of the samples was largely a function of either the country or the aim of the study. In North American studies, the young people were generally ethnically diverse. The exceptions to this were the studies by Stanton and colleagues,[69] whose sample was predominantly white (this study took place in a largely white, rural area of West Virginia, USA), and Jemmott and colleagues,[62] who specifically targeted African-American young men. In the case of the two UK studies, Stephenson and colleagues' sample was predominantly white,[50] whereas Wight and colleagues[70] did not report on the ethnic composition of their sample.

Socioeconomic status

Eight of the included studies reported on the SES of the sample, and again the level of detail given also varied considerably.[50,51,58,62,63,65,69,70] Typically, these samples were either representative of the general population (white, middle class, but including some young people of lower SES, for example studies by Borgia and colleagues[51] and Wight and colleagues,[70] or they specifically targeted young people of lower SES, for example studies by Jemmott and colleagues,[62] and Levy and colleagues[65]). In four studies, low SES was implicit.[43,63,66,69] A number of studies provided brief details about participants' education and occupation. Unlike measures of parental education and occupation, these are not commonly used as indicators of participants' SES.

Sexual behaviour

There was variability across the studies in terms of sexual experience and participation in risk behaviour. All but one of the included studies indicated what proportion of their sample was sexually active at baseline, with some studies reporting additional detail on sexual behaviours. The lowest proportion of sexually active participants were recorded by the two UK-based studies, where less than one-fifth of participants had ever had sex at baseline [6.7% in both study groups of the RIPPLE trial,[50] 15% in the control group and 19% in the intervention group of the SHARE (sexual health and relationships education) trial[70]]. Neither of these studies reported any further detail of the young people's sexual behaviour prior to the study, but it is likely that participants in these studies constituted relatively low-risk groups in terms of STIs.

In six studies between one- and two-fifths of the participants reported ever having sex.[58,63,65–67,71] Four of these studies also reported on condom use.[58,65,67,71] In one study,[65] over 70% of participants had ever used a condom, two studies reported condom use at last sex[58,67] of between 56.3% and 61%, and, in a further study,[71] 54.6% of participants reported always using a condom. The sexual behaviour of participants in these studies also appears to be fairly low risk.

In three studies, approximately half of the participants reported ever having sex.[51,62,68] In one of these studies[68] almost three-quarters of participants had ever used a condom and nearly one-fifth had experienced more than two sexual partners. In another study,[51] only about one-third of participants reported that they always used a condom, but only about 6% had experienced more than one partner. In the third study,[62] 17.7% of participants reported ever having anal sex, with 8.3% having had anal sex in the preceding 3 months. The participants in these three studies had baseline sexual behaviour that may have put them at some risk.

Coyle and colleagues[61] reported the highest proportion of participants who had ever had sex (82.0% in the intervention group, 84.7% in the control group). Although over three-fifths of the participants reported using a condom at last sex, about 20% of participants had ever had anal intercourse, and of these over two-fifths had not used a condom the last time they had anal sex. This group of participants was highly sexually active and some participants took part in risky sexual behaviour.

One study[64] did not report an overall figure for the proportion of the participants who were sexually active at baseline. Instead this was reported separately for boys and girls, which indicated a large difference between sexual experience according to gender (50.8% of boys had ever had sex versus 10.4% of girls). No other markers of sexual risk were reported by this study.

The study by Jemmott and colleagues[43] was the only one not to provide an indication of what proportion of their study participants (who were all males) were sexually active, but other measures of baseline sexual behaviour were reported, which indicated that this was a group with relatively high-risk sexual behaviour. Only about 30% of participants always used a condom, and over 30% had experienced more than one partner in the preceding month. Almost 13% had taken part in heterosexual anal sex in the previous 3 months.

Other characteristics

Eight studies took place in an urban setting,[43,51,58,61–63,65,71] two in a rural setting,[66,69] and two in a mixture of urban and rural settings.[50,64] The locations of the remaining studies were either unclear[67,68] or not stated.[70] Five studies collected data on drug use,[43,51,61,62,65] but only one suggested levels of use to be problematic.[61] Four studies reported alcohol use, in terms of ever having used it or frequency of use.[51,63,65,68] Surprisingly, only three studies reported explicitly on sexual orientation: Roberto and colleagues reported their sample to be exclusively heterosexual,[66]

Jemmott and colleagues,[26,62] reported low levels of homosexual experience in both of their studies. Religious affiliation was only reported by three studies, in which the samples comprised a mixture of Catholics, Protestants or Muslims.[64,67,68]

Only one study reported whether or not the young people had ever been considered as offenders;[61] in this study, 62% and 57% of the intervention and comparison groups, respectively, had offended. The respective figures for currently being on probation were 53% and 49%. None of the studies reported the HIV status of the young people or whether any currently had an STI, although Stanton and colleagues[69] did mention that their study took place in a low HIV seroprevalence setting.

None of the studies provided any information on the following: levels of social capital, disability status, whether any of the sample were commercial sex workers, and whether any of the sample were looked-after young people.

Methodological quality of the outcome evaluations

The following sections report the methodological characteristics and quality of the 15 outcome evaluations. The information below is synthesised in the section 'Overall judgements on study quality' in order to determine which of the studies are at least risk of selection bias, attrition bias, and bias due to selective reporting.

Method of randomisation

Three trials[43,62,68] randomised individuals to study groups. Stanton and colleauges[68] indicated that a random number table had been used as part of the randomisation process, Jemmott and colleagues[43,62] stated that the sample had been stratified before randomisation,[43] and indicated that both stratification and a random number table had been involved in the randomisation process.[62]

Twelve of the RCTs were cluster trials, 11 of which randomly allocated schools, with one allocating school districts. Six of the twelve studies did not provide details of the randomisation process,[63–67,69] although it should be noted that Roberto and colleagues[66] only involved two schools. Of the remaining six studies, the process of Zimmerman and colleagues[71] involved pairing clusters, Coyle and colleagues[58] ranked and paired clusters, whilst Coyle and colleagues,[61] Stephenson and colleagues,[50] and Borgia and colleagues[51] had used processes that involved stratifying or matching clusters. Wight and colleagues[70] stated that 'balanced randomisation' was used to allocate schools.

Allocation concealment/blinding

None of the studies stated whether allocation to intervention and comparison groups were concealed (blinded). It was also unclear in the majority (12 of the 15 studies) whether participants were aware or could have deduced which study group they had been allocated to.[43,51,58,61,63–69,71] Stephenson and colleagues[50] and Jemmott and colleagues[62] gave details that suggested either that the schools knew which group they had been allocated to[50] or that young people had been given sufficient information about the programme content for each group to have been able to deduce which group they were in.[62] It was clear in Wight and colleagues' study[70] that participants would have known which group they were in. Ten of the fifteen studies did not state whether outcome assessors were blind to group allocation[43,58,61,63–67,69,71] and in three studies it was not clear whether outcome assessors were aware of group allocation status.[50,51,68] Only Wight and colleagues[70] and Jemmott and colleagues[62] specifically stated that data checks[70] or data collection[62] had been carried out in a blinded fashion.

Comparability of study groups at baseline

More than half of the studies reported baseline sociodemographic and other sexual health-related characteristics for each study group, including all of the individuals who participated in the baseline assessment.[50,51,58,61,63,65,68–70] Wight and colleagues[65] and Levy and colleagues[70] also provided some baseline data for the individuals who remained in the study at follow-up. Roberto and colleagues[66] and Klepp and colleagues[64] only provided baseline data for the individuals who remained at follow-up, whilst Zimmerman and colleagues[71] restricted reporting to characteristics that differed between the study groups. Three studies did not report baseline characteristics for the intervention and control groups.[43,62,67] The two studies by Jemmott and colleagues[43,62] reported baseline values for the whole study population, but Schaalma and colleagues[67] reported no numerical data on baseline variables at all.

In five trials, the majority of sexual health-related characteristics were balanced between the study groups.[50,61,64,66,70] Three of these trials, Coyle and colleagues,[61] Stephenson and colleagues[50] and Wight and colleagues,[70] had reported data for all individuals in each study group at baseline. The other two trials, Roberto and colleagues[66] and Klepp and colleagues,[64] reported baseline data only for the individuals who remained at follow-up. Six studies reported that study groups were unbalanced for more than one of the reported characteristics – these were all studies that had reported baseline data for all individuals in each study group at baseline.[51,58,63,65,68,69] A further three trials did not report baseline data separately for intervention and comparison groups, so it was unclear whether the groups were balanced.[43,62,67] Zimmerman and colleagues[71] reported some differences between the study groups, and implied that the imbalances were not significant, but then appeared to make a correction for imbalances in the analyses (although this was not clearly explained).

Of the six trials that reported that study groups were not balanced at baseline, five reported making a correction for this in the analyses,[51,58,63,65,69] with Zimmerman and colleagues[71] also appearing to make a correction for baseline differences as noted above. Only Stanton and colleagues[68] reported imbalances between the groups at baseline, but did not report having corrected for this in the analyses.

Attrition

An overall attrition rate was reported by, or could be calculated from, data in 10 studies.[43,50,58,61–63,65,68,69,71] Attrition ranged from only 3.2% at 3 months in a study by Jemmott and colleagues[62] to 55% at 2 years in a study reported by Levy and colleagues.[65] Where studies reported on outcomes at more than one time point, attrition was generally seen to increase with increasing length of follow-up,[58,61,62,65,68,71] although there was one study in which attrition remained fairly constant at 3, 6 and 9 months.[69]

Twelve of the fifteen studies reported the attrition rate separately according to study group,[50,51,58,62–66,68,69–71] although Coyle and colleagues[58] did so only for the first of their three follow-up periods. The remaining three studies did not report a numerical value for attrition rate separately according to study group.[43,61,67] Attrition ranged from less than 5% in one or more study groups to over 50%, with greater attrition tending to occur after longer periods of follow-up.

Only two studies clearly reported that there was no statistically significant difference in attrition rates between the arms of the study, [61,62] and one study described attrition between study arms as fairly even.[63] Six studies reported that attrition differed between study groups,[50,51,64,68,69,71] with the differences being described as statistically significant in three studies,[50,64,68] and statistically significant at some but not all study follow-up points in a further two studies.[68,71] The remaining study[51] did not state whether the noted difference in attrition between the groups was statistically significant or not. Four studies did not report whether attrition differed between the study groups.[58,65,66,70]

Nine studies[51,58,61–65,68,71] commented on whether there were any differences between those participants who were lost to follow-up, and those who were retained. Only one study[51] reported that they did not detect any statistically significant differences between participants lost to follow-up, and retained participants. The remaining studies commenting on this noted at least one statistically significant difference between lost and retained participants.

Selective reporting

Eight studies reported outcomes for all individuals/groups,[43,50,58,61,63,65,68,70] although there were inevitably some outcomes that only applied to certain subgroups of young people (e.g. those who were sexually active at the start of the study, and those who became sexually active during the study). The remaining seven studies[51,62,64,66,67,69,71] reported outcomes only for some individuals/groups. Often these studies reported outcomes only for the subset of participants who contributed both baseline and follow-up data,[62,64,67,71] but in other cases it was not clear which individuals or groups were contributing outcome data,[51,66] and one study combined three intervention groups together in the reporting of outcomes.[69] All but two studies reported data for all outcome measures.[51,63]

Validation of outcome instruments

Outcome data were gathered, in all studies, by self-completion reports, diaries or questionnaires. In addition, one study also interviewed the young people to assess outcomes.[65] Seven of the fifteen studies reported that the questionnaire used to collect outcome data had been developed or tested in a pilot study[50,51,61–64,70] and 11 studies reported

a coefficient of reliability for some, or all, of the scales used within questionnaires.[43,58,61–67,69,71]

Length of follow-up

Stephenson and colleagues[50] assessed outcomes at four or more outcome assessment points. The remaining studies varied in reporting outcome data from either one,[51,63,66,67,70] two[43,64,65,71] or three[58,61,62,68,69] assessment points. The ways the studies reported the timing of the outcome assessments were variable: some reported the time elapsed since the baseline assessment, some reported time elapsed since completion of the intervention, and some reported both. Ten of the fifteen studies followed up participants for less than a year,[43,51,62,63,66–71] with the remaining five studies continuing to assess outcomes at 1–2 years,[61,64,65] 2–3 years,[58] and 3–7 years[50] after the intervention took place. However, it is worth noting that some studies reported high attrition at later time points (see below).

Unit of data analysis

The three trials[43,62,68] that randomised individuals to study groups also used individuals as the unit of data analysis. The remaining 12 trials randomised clusters of individuals to groups, but eight of these analysed data at the unit of the individual.[50,58,61,63,65,69–71] In the studies by Roberto and colleagues[66] and Borgia and colleagues,[51] the unit of data analysis was unclear, but was most probably the individual. Schaalma and colleagues[67] described a hierarchical linear model, analysing data at both the student (individual) and school (cluster) level. Stephenson and colleagues[50] analysed the primary outcome by age 16 years at the school level (cluster) but the primary outcome at age 20 years, and all secondary outcomes were based on individual participant data. Only the cluster randomised trial reported by Klepp and colleagues[64] used the cluster as the unit of data analysis for all of the study outcomes, with two others, Stephenson and colleagues,[50] and Schaalma and colleagues,[67] using the cluster as the unit of data analysis for some of the study outcomes.

Overall judgements on study quality

Five of the fifteen studies were considered to be methodologically sound (*Table 28*).[50,62,64,66,70] A further seven were judged to be methodologically

TABLE 28 *Summary of judgements on study quality*

Study	Selection bias avoided	Attrition bias avoided	Selective reporting bias avoided	Overall judgement
Borgia *et al.*[51]	Yes	No	Yes	Sound, despite discrepancy with criteria
Coyle *et al.*[58]	Yes	No	Yes	Sound, despite discrepancy with criteria
Coyle *et al.*[61]	Yes	No	Yes	Not sound
Jemmott *et al.*[43]	Yes	No	Yes	Sound, despite discrepancy with criteria
Jemmott *et al.*[62]	Yes	Yes	Yes	Sound
Karnell *et al.*[63]	Yes	Yes	No	Sound, despite discrepancy with criteria
Klepp *et al.*[64]	Yes	Yes	Yes	Sound
Levy *et al.*[65]	Yes	No	Yes	Sound, despite discrepancy with criteria
Schaalma *et al.*[67]	No	No	Yes	Not sound
Stanton *et al.*[68]	Yes	No	Yes	Not sound
Stanton *et al.*[69]	Yes	No	Yes	Sound, despite discrepancy with criteria
Stephenson *et al.*[50]	Yes	Yes	Yes	Sound
Wight *et al.*[70]	Yes	Yes	Yes	Sound
Zimmerman *et al.*[71]	Yes	No	Yes	Sound, despite discrepancy with criteria

TABLE 29 *Behavioural aims of included studies*

Study	Delaying initiation of sexual activity	Increase in condom use	Reduction in number of sexual partners	Increase in protective behaviours and/ or decrease in risk behaviours	Reduction in unintended pregnancy
Intervention vs standard sex education					
Coyle *et al.*[58]	✓	✓	✓		
Karnell *et al.*[63]	✓			✓	
Levy *et al.*[65]				✓	
Wight *et al.*[70]				✓	✓
Zimmerman *et al.*[71]				✓	
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)					
Jemmott *et al.*[43]				✓	
Jemmott *et al.*[62]				✓	
Klepp *et al.*[64]	✓				
Roberto *et al.*[66]	✓	✓	✓		
Stanton *et al.*[69]				✓	
Peer-led vs teacher-led interventions					
Borgia *et al.*[51]		✓	✓		
Stephenson *et al.*[50]	✓			✓	✓

sound despite a discrepancy with our quality assessment criteria (see Data extraction in the systematic review and Quality assessment, and Appendix 5), hereafter referred to as methodologically sound studies.[43,51,58,63,65,69,71] Of these seven studies, five failed due to high and/ or unbalanced attrition at later time points[65,71] or because attrition at later time points was not reported for each study group.[43,58,69] However, the earlier time point(s) provided data that could be considered sound according to our criteria and hence were used in our analysis (but data from the later time points were not).[58,65,69,71] One other study did not provide clear details about attrition but did state that an ITI analysis had been conducted.[51] We therefore considered that attrition bias was unlikely. Karnell and colleagues[63] failed to report on all of the outcomes described in their methods; however, it appeared unlikely that reporting bias would have been introduced, as the majority of outcomes were reported and for many of these there were no statistically significant differences between the groups.

In summary then, the results of the systematic review of effectiveness as presented in the following sections are based on a total of 12 RCTs[43,50,51,58,62–66,69–71] (of which nine were cluster RCTs), hereafter referred to as being methodologically sound. Three studies were not judged to be methodologically sound and their results are not analysed in this review.[61,67,68]

Synthesis of results of sound outcome evaluations

The following sections present the results of the 12 methodologically sound studies according to the outcomes measured. The results are stratified by the comparator used, grouped into three categories: (1) behavioural intervention compared with a standard sex education comparison group; (2) behavioural intervention compared with a control group (i.e. no intervention, delayed intervention, non-sex education intervention); and (3) peer-led behavioural intervention compared with teacher-led behavioural intervention. It should be noted that there is a key difference between the two studies that included a peer-led trial arm. In one study (Stephenson and colleagues[50]) the peers delivered the behavioural intervention, whilst the teachers delivered standard sex education (i.e. current practice). By contrast, in the study

by Borgia and colleagues,[51] peers and teachers delivered very similar behavioural interventions, neither of which were standard practice. It is for this reason that the study by Borgia and colleagues was not included in our meta-analysis, as mentioned earlier in Chapter 2, Meta-analysis.

Sexual behaviour

In accordance with our inclusion criteria all of the methodologically sound studies reported on at least one behavioural outcome (the tabulated numerical results for each study are presented in Appendix 8).

The behavioural aims of the studies varied, and about half described more than one behavioural aim (*Table 29*). Eight studies stated that the aim of the intervention was to impact on risk and/or protective behaviour.[43,50,62,63,65,69,70,71] One of these, Karnell and colleagues,[63] was also one of five studies that assessed whether or not the intervention delayed sexual initiation.[50,58,63,64,66] The authors of three studies hoped to see both an increase in condom use and a decrease in the number of sexual partners.[51,58,66] The effect on rates of unintended pregnancy was assessed by two studies.[50,70]

The extent to which the active comparators, i.e. standard sex education or teacher-led interventions, aimed to affect behaviour was generally not well described.

The majority of the studies reported more than one behavioural outcome, with some reporting on a wide range of behavioural outcomes. The study by Klepp and colleagues[64] was the only one to report a single behavioural outcome (*Table 30*), and this was also the only study that did not report a condom use outcome.[64] All of the other included studies reported on at least one of nine different condom use outcomes: last intercourse with a condom,[50,58,63,66,69,71] last intercourse without a condom,[70] first intercourse with a condom,[50,58] first intercourse without a condom,[70] frequency of condom use,[43,51,70] frequency of intercourse with a condom,[69] frequency of intercourse without a condom,[43,58,62] ever used a condom[65] and condom use with foam.[7] As indicated in *Table 30*, other behavioural outcomes included initiation of sexual activity, episodes of sexual intercourse (primarily vaginal), use of contraception and/or pregnancy rates, and number of sexual partners.

Each of the main types of behavioural outcomes reported by the included studies are presented below.

Initiation of sexual intercourse

Seven studies reported this outcome.[50,58,64,66,69–71] However, Zimmerman and colleagues,[71] and Stanton and colleagues[69] only reported data on this outcome for their final time points (12–18 months and 9 months, respectively). These data were not included in our review because they did not meet our criteria for methodological soundness at these time points due to attrition bias. In the study by Stanton and colleagues[69] the differential attrition rate between study groups was not clear, and in the study by Zimmerman and colleagues the attrition rate exceeded 70% (see Chapter 2, Quality assessment, and Appendix 5). Therefore, five studies contribute data to this outcome, which was assessed with reference to participants' status at baseline[50,58,64,66,70] (Appendix 8, *Table 70*). The time between baseline and the reported follow-up ranged between 5 and 18 months, but it should be noted that in two cases the intervention had not been completed[70] or had been completed only 10 weeks before follow-up[66] when data were collected.

Three of the five studies, Coyle and colleagues[58] Wight and colleagues[70] and Klepp and colleagues,[64] found that there was no significant difference between the intervention and comparison group in the initiation of sexual activity among those who were virgins at baseline. The other two studies[50,66] did report a statistically significant difference between groups. Roberto and colleagues[66] found that young people in the control group were nearly three times more likely to have initiated sexual activity, in the 5 months since the pre-test questionnaire, than students in the intervention group. Stephenson and colleagues[50] found that of those who were virgins at baseline, girls in the peer-led group were significantly less likely to report having had sex by age 16 years than were those in the comparison group, but there was no statistically significant difference for boys.

The impact of the interventions on sexual initiation is summarised in *Table 31*. Data were in a suitable format for meta-analysis in three of the five studies.[50,58,70] Roberto and colleagues[66] did not provide the denominators for each group, but these were calculated (using the reported numerators and percentage values) in order to complete the 2×2 table of data so that this study could also be included in the meta-analysis. It should be noted, however, that there appeared to be a reporting error in the paper published by Roberto and colleagues:[66] once denominator values had been calculated, it was apparent that they did not sum to the reported total number of participants in the

TABLE 30 *Summary of types of behavioural outcomes reported*

Study	Initiation	Condom use	Intercourse	Contraception/ pregnancy	Partners	Other
Intervention vs standard sex education						
Coyle *et al.*[58]	✓	First intercourse with[a] Frequency without Last intercourse with	Frequency With alcohol and drugs	Last intercourse with contraception	*n* without; *n* overall	Test HIV Test other STIs
Karnell *et al.*[63]		Last intercourse with[b]	With alcohol			
Levy *et al*[7]		Ever With foam	Frequency		*n*	
Wight *et al.*[70]	✓	First intercourse without[a] Frequency Last intercourse without		Last intercourse with oral contraception Unintended pregnancy		Unprotected sex
Zimmerman *et al.*[71]	✓	Last intercourse with	✓ With alcohol			
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)						
Jemmott *et al.*[43]		Frequency Frequency without	✓ (coitus) Frequency (coitus) ✓ (anal) Frequency (anal)		*n* (coital) *n* (anal sex)	Behaviour risk index
Jemmott *et al.*[62]		Frequency without	✓ (coitus) ✓ (anal) Frequency (anal)		*n* (coital) *n* (anal sex)	Behaviour risk index
Klepp *et al.*[64]	✓					
Roberto *et al.*[66]	✓	Last intercourse with			*n*	
Stanton *et al.*[69]	✓	Frequency with Last intercourse with	✓	Last intercourse with contraception		
Peer-led vs teacher-led interventions						
Borgia *et al.*[51]		Frequency			*n*	
Stephenson *et al.*[50]	✓	First intercourse with[a] Last intercourse with	✓ (> once)	First intercourse with contraception No unintended pregnancy Abortions and live births		

n, number of partners.
a Sexually naive participants' behaviour the first time they had intercourse.
b The questionnaire used in the study by Karnell and colleagues asked about frequency of condom use but the outcome was not reported.
✓ Study reports the outcome indicated by the column heading.

study who were sexually naive at baseline. Data from Klepp and colleagues study[64] could not be included in the meta-analysis because details were not provided that were necessary for calculating the numerators and denominators corresponding to the reported percentage values of those becoming sexually active in each group.[64]

Two of the studies[50,70] reported data separately for young women and young men. The data for young men and young women were therefore combined for each group to provide an overall study value for use in the meta-analysis. The fixed-effect pooled OR was 1.03 [95% confidence interval (CI) 0.74 to 1.43] indicating no significant difference between intervention and control (*Figure 2*). No statistically significant heterogeneity was detected ($p = 0.929$, $I^2 = 0\%$).

Condom use

All but one study, Klepp and colleagues,[64] reported on condom use. Outcome measures included whether a condom was used at first sex,[50,58,70] whether a condom was used at the most recent episode of sexual intercourse[50,58,63,66,69–71] and frequency of condom use,[43,51,58,62,69,70] and one study reported whether condoms had ever been used and the use of foam (the term foam was used for any product containing the spermicide nonoxynol-9) with condoms.[65] The numerical results are presented in Appendix 8, *Table 71*.

Statistically significant effects in favour of the intervention group over the comparison group were only reported by two of the studies. Coyle and colleagues[58] found that participants in the intervention group significantly outperformed the comparison group, statistically, on the outcome of condom use at last sex[58] (but there was no statistically significant difference in condom use at first sex) and frequency of condom use.[58] A statistically significant reduction in unprotected sex (i.e. increase in frequency of condom use) was also observed by Jemmott and colleagues.[62] This study was one of four studies with a control group that reported on condom use. Outcomes measurement that we considered methodologically sound took place at 6 months[62] and 7 months,[58] but, due to high attrition in the study by Coyle and colleagues,[58] at later time points (19 and 31 months) these outcomes were considered unsound and therefore were not data extracted. Whether improvements made in condom use behaviour can be maintained long term is therefore unknown.

Studies commonly reported either that there was no significant difference in condom use outcomes between the groups, or did not report whether a statistical comparison had been made. Of the studies comparing a behavioural intervention to standard sex education, statistically significant differences were not observed for condom use at first sex by Coyle and colleagues[58] as noted above,

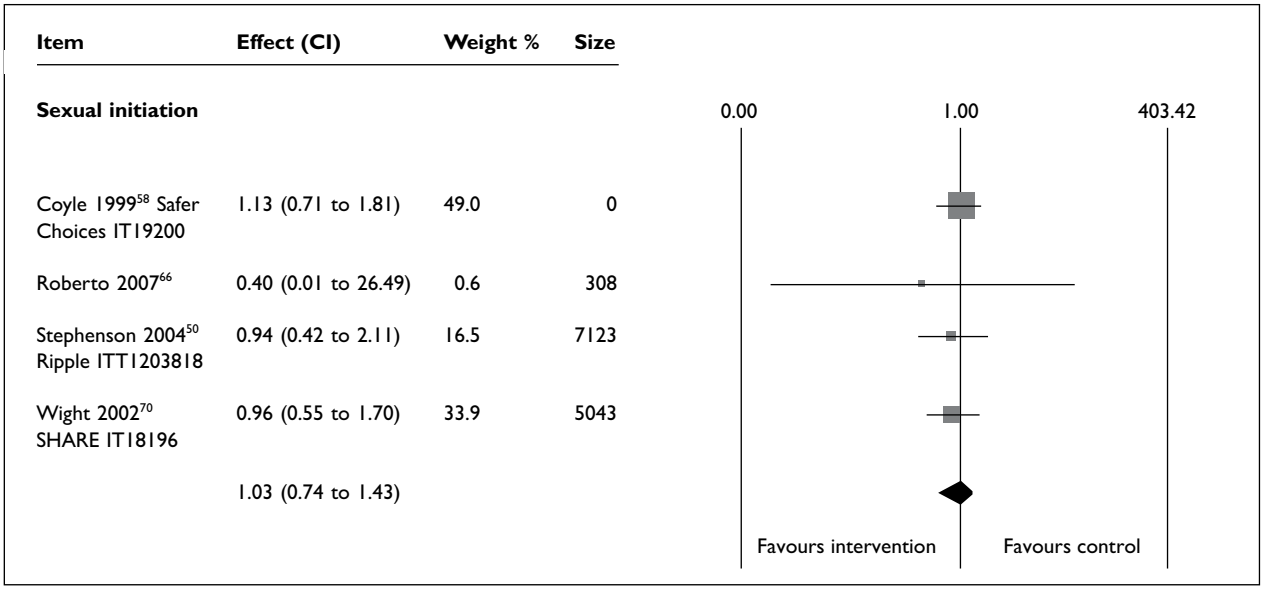

FIGURE 2 *Meta-analysis forest plot for outcome: 'delaying sexual initiation' (OR). Note: The zero value for Coyle and colleagues' sample size was due to slightly different data entry for this study. The sample size was 2565. Coyle and colleagues did not report data that could be entered into a 2 × 2 table, but did provide an effect size and its standard error, which were entered directly into the* EPPI-REVIEWER *software for meta-analysis.*

and this was also true for the study reported by Wight and colleagues.[70] The differences between the groups for outcomes of condom use at last sex,[70,71] and frequency of condom use,[70] were not significantly different, and Karnell and colleagues[63] did not report a statistical comparison for condom use at last sex. Two of the four studies with a control group reporting condom use outcomes also reported that there was no difference between the groups for the outcomes of condom use at last intercourse[66,69] and frequency of condom use.[69] The remaining study, Jemmott and colleagues,[43] did not report a statistically significant effect for the intervention on either of the condom use outcomes reported (frequency of condom use, and number of days a condom was not used during coitus).

Of the two studies that compared peer-led with teacher-led interventions (Stephenson and colleagues[50] and Borgia and colleagues[51]), neither demonstrated any statistically significant differences between the study groups for condom use at first sex,[50] condom use at last sex[50] or frequency of condom use.[51] However, statistically significant improvements between the pre-test and post-test were observed in both groups for the frequency of condom use outcome.[51]

Levy and colleagues[65] limited the reported findings on condom use to the subgroup of young people who had become sexually active in the period between the pre-test and first post-test measure. For one outcome, ever used condoms with foam, a statistically significant difference in favour of the intervention group over the comparison group was observed. But this was not the case for the remaining condom use outcomes of ever used condoms, used condoms in the past 30 days, and used condoms with foam in the past 30 days.

The effects of the interventions on condom use are summarised in *Table 31*. Although condom use was a commonly reported outcome, there were many different ways that this outcome could be measured. In order to obtain an overview of all possible condom use outcomes, a meta-analysis was conducted for the 'general' outcome of all condom use (shown below in *Figure 3* – see also additional forest plots in Appendix 9 for some of the constituent condom use outcomes that were used in the general condom use outcome).

The fixed-effect pooled OR was 1.07 (95% CI 0.88 to 1.30), with no statistically significant difference between intervention and comparator. No

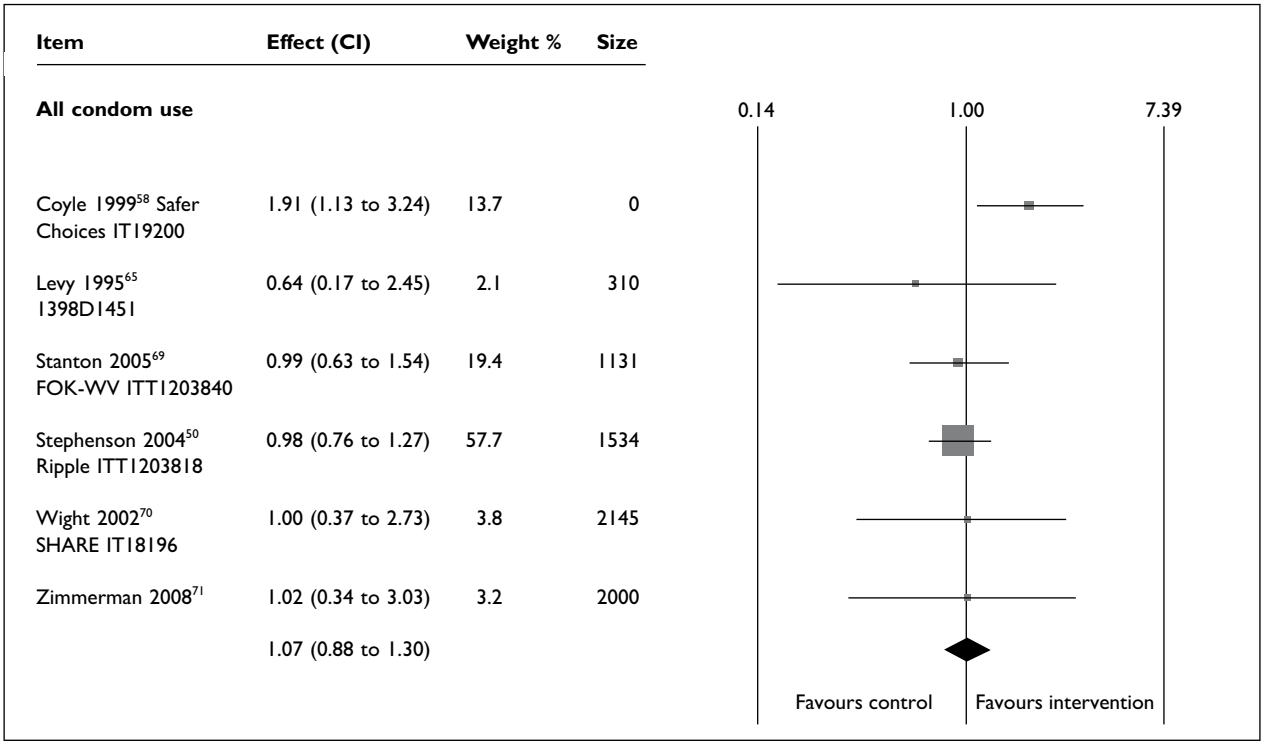

FIGURE 3 *Meta-analysis forest plot for the outcome: 'all condom use' (OR). Note: The zero value for Coyle and colleagues was due to slightly different data entry into the meta-analysis software for this study. The sample size was 1018 (see Appendix 12 for more detail).*

statistically significant heterogeneity was detected ($p = 0.333$, $I^2 = 12.9\%$).

Sexual intercourse

Several different outcomes relating to sexual intercourse were reported (*Table 30* and Appendix 8, *Table 72*). Three studies, Coyle and colleagues,[58] Levy and colleagues[65] and Jemmott and colleagues,[43] reported on the frequency of sexual intercourse, whilst both studies by Jemmott and colleagues reported on abstinence.[43,62] Jemmott and colleagues' studies were also the only ones to report whether participants had engaged in anal sex, along with the frequency of anal sex. In one of the papers, Jemmott and colleagues,[43] only heterosexual anal sex was reported, whereas the later paper (Jemmott and colleagues[62]) reported on anal sex without distinguishing a particular type. Zimmerman and colleagues[71] reported whether participants had ever had sex, and Stanton and colleagues[71] reported those who had had sex in the last 6 months.[69] Stephenson and colleagues[50] reported the percentage of students who had sex more than once. Three studies also reported on the use of alcohol prior to or during sexual intercourse.[58,63,71]

Coyle and colleagues,[58] and Levy and colleagues[65] found no significant differences between the intervention and comparison groups for the frequency of sexual intercourse. However, amongst those who became sexually active during the course of the study reported by Levy and colleagues (the subgroup termed 'Changers'), there was a trend towards students in the intervention group being sexually active less often, although this was a statistically marginal result ($p < 0.10$).[65] Jemmott and colleagues[62] found that the intervention group were not more likely to practise abstinence,[43,62] but in the later (1999) paper statistically significant differences in favour of the intervention group were reported for anal intercourse, and the frequency of anal intercourse.[62] The remaining three studies that reported the proportion of participants engaging in sexual intercourse found no significant differences between the groups.[50,69,71]

The three studies that reported on the use of alcohol during or before sexual intercourse[58,63,71] found that there was no significant difference in this outcome between the intervention group and the comparison group receiving standard sex education. Karnell and colleagues[63] reported a statistically significant difference between study groups in favour of the intervention for reducing the consumption of alcohol at last sex, but only amongst the subgroup who had not had sex at the pre-test. There were no significant differences between the intervention and comparison groups by gender, or for those who were already sexually active at the pre-test.

The effects of the interventions on sexual intercourse outcomes are summarised in *Table 31*. It was not possible to meta-analyse any of these outcomes due to heterogeneity in the types of outcome reported and incomplete reporting of data necessary to enter into meta-analysis.

Contraception and pregnancy

Four studies included an outcome measure that assessed broader methods of contraception use[50,58,69,70] and two included a pregnancy outcome.[50,70] One study reported on abortions.[50] The effects of the interventions on these outcomes is summarised in *Table 31*. Only Coyle and colleagues[58] reported a statistically significant effect in favour of the intervention group for the outcome of protection against pregnancy at last sex (use of condom, oral contraceptive or both). The other three studies used slightly differing outcomes: Wight and colleagues[70] found no significant difference between the groups on use of a condom with or without concomitant use of oral contraceptives, Stanton and colleagues[69] did not report a statistical comparison between groups for use of a condom and oral contraceptive, and Stephenson and colleagues[50] reported no significant difference in contraception use (a condom or other method of contraception) at either first or last sex. At the 18-month follow-up, girls in the peer-led arm reported slightly fewer unintended pregnancies, but the difference was not significant. By age 20 there was no significant difference between the groups in the proportion who had had an abortion, and although the proportion of girls in the peer-led group who had had one or more live births by age 20.5 was lower than that in the teacher-led group, the difference was not statistically significant[89] (Appendix 8, *Table 73*).

It was not possible to meta-analyse contraception and pregnancy outcomes due to heterogeneity in the types of outcome reported and incomplete reporting of data necessary to enter into meta-analysis.

Sexual partners

Six studies assessed intervention effect on the number of sexual partners,[43,51,58,62,65,66] although one of these limited the reporting of this outcome

to the subgroup of participants who had become sexually active during the course of the study.[65] One study reported separately on the number of anal sex partners,[62] and one on the number of female anal sex partners.[43] The effects of the interventions on these outcomes are summarised *Table 31* and full results are presented in Appendix 8, *Table 74*.

Only one of the studies by Jemmott and colleagues,[62] which reported the number of anal sex partners, found a statistically significant difference between the groups in favour of the intervention at the 6-month post-intervention follow-up. However, there was no significant difference in the number of heterosexual (coital) sex partners in this study. Similarly, the other studies that reported on number of sexual partners also stated that there was either no significant difference or did not report a statistical comparison between intervention and comparison groups.[43,51,58,66] The study that limited reporting to the subgroup of participants who had become sexually active during the study[65] also found no statistically significant differences between the groups. Borgia and colleagues[51] did report some significant differences between the number of partners reported pre-test and the number reported post test within the teacher-led arm of the studies.

Other behavioural outcomes

Four studies reported on additional behavioural outcomes not applicable in the previous sections. The effects of the intervention on these outcomes are summarised in *Table 31*.

Coyle and colleagues[58] reported on whether participants had been tested for HIV or another STI but found that there were no statistically significant differences between the study groups. Wight and colleagues[70] identified participants who made any report of sex without condoms for three specific events of intercourse, or reported a pregnancy (or a girlfriend's pregnancy), or who had not answered 'always' or 'most of the time' to the question 'How often did you ever use a condom?'. This composite outcome was described as 'Any evidence of sex unprotected against STDs ever' and no statistically significant differences were found between the study groups. Jemmott and colleagues[43,62] also reported a composite outcome measure – a risk behaviour index. The risk behaviour index was created from responses to questions within a questionnaire about sexual practices, for example unprotected sexual intercourse, number of sexual partners, intercourse and anal intercourse. These outcomes were converted and averaged to form a value on the 'risk behaviour index'. Jemmott and colleagues[43] found that after controlling for pre-intervention risk behaviour, participants engaged in significantly less risky sexual behaviour, statistically, in the 3 months following the intervention than the participants in the control group. Jemmott and colleagues[62] found that 3 months after intervention delivery there was no significant difference between the study groups, but at the 6-month follow-up results of analysis of covariance (ANCOVA) on the risk behaviour index scores revealed that young people in the HIV risk-reduction condition reported significantly less HIV risk-associated sexual behaviour, statistically, than the participants in the control group (Appendix 8, *Table 75*).

Summary – sexual behaviour

The impact of the interventions on the range of behavioural outcomes discussed above is summarised in *Table 31*. Few statistically significant effects on behaviour in favour of the intervention were reported by the included studies. Seven of the twelve studies reported that the intervention had at least one statistically significant effect on a behavioural outcome. However, in three cases this only applied to a subgroup of the participants[50,63,65] and for each study there were other behavioural outcomes for which no significant differences between groups were observed.[43,50,58,62,63,65,66]
The other five studies did not report that the intervention had any statistically significant behavioural effects.[51,64,69–71] The interventions did not lead to a significant increase in initiation of sexual activity by young people or to an increase in the number of their sexual partners.

Skills and self-efficacy

It was a condition of inclusion in our review that interventions had a skills component. However, not all the sound studies reported on whether participants felt that they had gained skills or increased in self-efficacy (their belief in their abilities) to perform certain skills. Where studies did report self-efficacy outcomes these varied depending on the focus of the skills component of the intervention employed in the study. The scales used to quantify self-efficacy varied among studies. Within studies, scales were often different for the various self-efficacy outcomes (the tabulated numerical results for each study are presented in Appendix 8, *Table 77*).

All twelve sound studies included a skills component within their intervention. These

TABLE 31 *Summary of intervention effects on behavioural outcomes*

	Sexual initiation	Condom first sex[a]	Condom last sex	Frequent condom use	Freq. sexual intercourse	Had sex	Abstinence	Use of drugs and/or alcohol	Contraception	Pregnancy (♀ only)	Number of sexual partners	Other
Intervention vs standard sex education												
Coyle *et al.*[58]	◆	◆	✓[b]	✓[b]	◆			◆	✓		◆	◆ HIV/STI tests
Karnell *et al.*[63]			◆					++				
Levy *et al.*[65]				++	++						◆[b]	
[c]Wight *et al.*[70]	◆	◆	◆	◆					◆	◆		◆ Any unprotected sex
Zimmerman *et al.*[71]	US		◆			◆		◆				
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)												
Jemmott *et al.*[43]				◆	◆[d]	◆[d]					◆[d]	✓ Risk behaviour
Jemmott *et al.*[62]				✓	✓[b]	✓[b]	◆				++	✓ Risk behaviour
Klepp *et al.*[64]	◆											
Roberto *et al.*[66]	✓		◆								◆	
Stanton *et al.*[69]	US		◆	◆		◆			◆			
Peer-led vs teacher-led interventions												
Borgia *et al.*[51]				◆							◆	
[c]Stephenson *et al.*[50]	‡	◆	◆			◆			◆	◆		◆ ♀ Abortions by age 20

US, unsound data reported but not data extracted.
a For subgroup of sexually inexperienced (virgins) at baseline.
b Reported for a subgroup of participants only.
c Reported all outcomes separately for young men and young women.
d Reported for both coitus and heterosexual anal sex.
◆, No significant difference between the study groups (assumed for studies not reporting significance or any *p*-value).
✓, Outcome favoured the intervention group.
‡, Outcome favoured the intervention for one subgroup of participants, but for one or more subgroups of participants there was no significant difference between the study groups.

TABLE 32 *Skills interventions*

Study	Skill component				
	Communication and/ or negotiation	**Decision-making**	**Risk avoidance**	**Refusal or abstinence**	**Condom use**
Intervention vs standard sex education					
Coyle *et al.*[58]	✓			✓	✓
Karnell *et al.*[63]			✓	✓	
Levy *et al.*[65]	✓	✓		✓	
Wight *et al.*[70]					✓
Zimmerman *et al.*[71]				✓	✓
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)					
Jemmott *et al.*[43]					✓
Jemmott *et al.*[62]	✓				✓
Klepp *et al.*[64]				✓	
Roberto *et al.*[66]				✓	
Stanton *et al.*[69]	✓	✓		✓	(✓)
Peer-led vs teacher-led interventions					
Borgia *et al.*[51]	✓	✓			
Stephenson *et al.*[50]	✓				✓

✓, Study reported this outcome.
(✓), Ninety per cent of sites did not include this type of skill training.

skills components were described as focusing on communication and negotiation, decision-making, risk avoidance, sex refusal or abstinence, and condom use (*Table 32*). The most commonly described skill was a refusal skill or abstinence skill component, present in seven of the twelve studies; communication and/or negotiation skills training were included by six studies; and six studies included condom use skills training. Condom use skills training involved participants handling condoms in three studies,[58,62,70] but it was not clear whether participants handled condoms in the other three studies that included condom skills training.[43,50,71] The intervention reported by Stanton and colleagues[69] was to have included exercises relating to condom use. However, during intervention adaptation, communities or schools requested that this element should be removed and therefore over 90% of sites did not include this type of skills training. Decision-making skills were a component of three interventions[51,65,69] and two studies taught risk avoidance skills.[63,71]

Four studies had interventions that were described as having only one skill component,[43,64,66,70] but most studies described an intervention that contained either two[50,51,62,63] or three [58,65,69,71] skill components.

The self-efficacy outcomes reported by the included studies did not always correlate with the skills components included within the interventions (*Table 33*), and four studies did not report a self-efficacy outcome.[43,64,65,70] The most commonly reported self-efficacy measure was condom use self-efficacy, which was reported by seven of the eight studies that reported a self-efficacy outcome.[50,58,62,63,66,69,71]

Six studies reported refusal or abstinence self-efficacy,[50,58,63,66,69,71] four reported communication/ negotiation self-efficacy,[50,51,58,66] and two reported situational self-efficacy (the negotiation of potentially risky situations).[66,71] Five studies assessed self-efficacy at more than one time point,[50,58,62,69,71] but the high attrition rate in two of these studies at the later time point meant that the data were not extracted.[58,71]

Two of the three studies that compared a behavioural intervention with standard sex education found there were no statistically

TABLE 33 *Self-efficacy outcomes*

Study	Communication and/or negotiation self-efficacy	Refusal or abstinence self-efficacy	Condom use self-efficacy	Situational self-efficacy
Intervention vs standard sex education				
Coyle *et al.*[58]	✓	✓	✓	
Karnell *et al.*[63]		✓	✓	
Zimmerman *et al.*[71]		✓	✓	✓
Intervention vs control				
Jemmott *et al.*[62]			✓	
Roberto *et al.*[66]	✓	✓	✓	✓
Stanton *et al.*[69]		✓	✓	
Peer-led vs teacher-led interventions				
Borgia *et al.*[51]	✓[a]			
Stephenson *et al.*[50]	✓	✓	✓	

a Described as prevention skills, but the questions assessing this outcome included prevention (not further defined), communication and negotiation skills.

significant differences in self-efficacy outcomes between the groups.[63,71] Coyle and colleagues[58] reported a statistically significant effect for condom use self-efficacy, but not for the other two self-efficacy items they assessed. Karnell and colleagues[63] reported a statistically significant intervention effect for refusal self-efficacy, but only in one subgroup: young women in the intervention group had greater refusal self-efficacy than young women in the comparison group. Conversely, the three comparisons between behavioural intervention groups and control groups (receiving no intervention) demonstrated a greater number of statistically significant intervention effects. Jemmott and colleagues[62] found that the intervention group had significantly greater condom self-efficacy, statistically, immediately after the intervention, and at 3 and 6 months post intervention, than the control group. Similarly, a statistically significant difference in favour of the intervention group 6-months' post intervention (but not at 3 months post intervention) was reported by Stanton and colleagues[69] for both condom self-efficacy and abstinence self-efficacy. Roberto and colleagues,[66] who reported four different self-efficacy outcomes, found statistically significant benefits of the intervention on condom negotiation and situational self-efficacy, but did not report any statistically significant effects for the other two measures – condom use and refusal self-efficacy.

Of the two studies that compared peer- with teacher-led interventions, one (Borgia and colleagues[51]) reported a statistically significant improvement in prevention skills (including communication and negotiation skills) in both groups following the intervention in comparison to pre-intervention scores. However, there were no statistically significant differences between the groups. The other study to compare peer- with teacher-led interventions, Stephenson and colleagues,[50] also reported that there were no differences between the groups for the communication measure (confidence about discussing sex and contraception with a partner). Statistically significant differences were found for girls, at the 18-month follow-up, who were less confident in the peer-led arm than those in the teacher-led arm about refusing to do something they did not want to do sexually, but who became more confident about using condoms.

Skills and self-efficacy outcomes in subgroups

Stephenson and colleagues[50] reported all of their results separately by gender. Three other studies also reported findings on self-efficacy according to one or more subgroups;[51,63,69] however, none of the reports stated whether the study had been powered to detect an effect in the subgroups (and the three studies reporting on self-efficacy subgroups are

different from the three studies that reported subgroup analyses for knowledge – see Knowledge, later). Three of the studies that analysed subgroups reported on differences according to gender.[50,51,63] Borgia and colleagues[51] found that, regardless of trial arm, female participants improved their prevention skills more than males (no statistical significance reported). Karnell and colleagues[63] found that female students in the intervention group were significantly more confident, statistically, about their ability to refuse sex than female students in the comparison group, but there was no statistically significant difference for the intervention group versus comparison group as a whole, as noted above. Stephenson and colleagues,[50] as noted above, found two statistically significant differences for girls (but not boys) at the 18-month follow-up, which favoured the teacher-led intervention in one case, and the peer-led intervention in the other.

Two studies also reported on subgroups of participants according to sexual experience.[51,69] Borgia and colleagues[51] found that participants who were already sexually active at baseline had a greater improvement in prevention skills (a prevention skill was not defined) than those not sexually active at baseline but no statistical significance was reported. Similarly, Stanton and colleagues[69] found that youth sexually experienced at baseline in the intervention group had a statistically significantly greater condom use self-efficacy at the 6-month follow-up than those in the control group. Stanton and colleagues[69] also reported that youth in the intervention group who were virgins at baseline demonstrated significantly greater perceptions, statistically, of abstinence self-efficacy 6 months after the intervention than those in the control group, whereas there was no difference in abstinence self-efficacy between the groups for the youth who were already sexually experienced at baseline.

The duration of most studies was 12 months or less.[51,62,63,66,69] Of those with a longer follow-up, attrition was too great at the later time point in two studies to consider the results would be sound.[58,71] Therefore only Stephenson and colleagues[50] provide any evidence that an intervention effect on self-efficacy can be sustained for 18 months post intervention.

Summary: skills and self-efficacy

The effects of the interventions on self-efficacy outcomes are summarised in *Table 34*. A third of the included studies did not report a self-efficacy outcome, although their intervention included a skills component.[43,64,65,70] Only two studies reported that their intervention had no statistically significant effect on any of the self-efficacy items assessed.[51,71] The other six studies report mixed results with either statistically significant effects being reported in a subgroup of participants for one or more self-efficacy outcomes[50,63,69] or statistically significant effects being reported for some, but not all, of the self-efficacy measures assessed,[58,66] with one study reporting a statistically significant effect of the intervention on the single self-efficacy measure that was reported.[62]

Knowledge

All 12 sound studies attempted to measure participants' knowledge, but the knowledge items that were measured varied depending on the focus of the educational component of the intervention employed in the study. The extent to which knowledge outcomes were reported also varied (the tabulated numerical results for each study are presented in Appendix 8, *Table 76*).

The majority of the studies tested participants' knowledge of HIV[51,64,65] or their knowledge of HIV and STIs more generally.[43,50,58,62,63,69] Zimmerman and colleagues[71] also tested knowledge of pregnancy prevention as well as HIV and STIs. Wight and colleagues[70] tested practical knowledge of sexual health, though this was not further defined. The knowledge tested in the remaining study, Roberto and colleagues,[66] was not clear as no description was provided.

Knowledge was tested at the same time as other outcomes at periods, ranging from immediately after the intervention to 18 months following intervention. Seven studies assessed knowledge at more than one time point,[43,50,58,62,65,69,71] but the high attrition rate in three of these studies at the later time point meant that only the data for earlier time points were extracted, whereas the later time points did not meet our quality assessment criteria for being methodologically sound.[58,65,71]

Statistically significant effects in favour of the intervention group over the comparison/control group were found by all but two of the studies. Four of the five studies that made a comparison with standard sex education found that participants in the intervention group significantly outperformed the comparison group, statistically, in the knowledge test.[58,65,70,71] Only Karnell and colleagues[63] reported that there was no intervention

TABLE 34 *Summary of intervention effects on self-efficacy*

	Sex refusal self efficacy	Condom use self-efficacy	Communication self-efficacy	Situational self-efficacy	Abstinence self-efficacy	Condom negotiation self-efficacy
Intervention vs standard sex education						
Coyle *et al.*[58]	◆	✓	◆			
Karnell *et al.*[63]	‡	◆				
Zimmerman *et al.*[71]	◆	◆		◆		
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)						
Jemmott *et al.*[62]		✓				
Roberto *et al.*[66]	◆	◆		✓		✓
Stanton *et al.*[69]		✓			✓	
Peer-led vs teacher-led interventions						
Borgia *et al.*[51]			◆			
Stephenson *et al.*[50a]	◆ X ♀	✓ ♀	◆			

a Reported all outcomes separately for young men and young women.
◆, No significant difference between the study groups (assumed for studies not reporting significance or any *p*-value).
✓, Outcome favoured the intervention group.
‡, Outcome favoured the intervention for one subgroup of participants, but for one or more subgroups of participants there was no significant difference between the study groups.
X, Outcome favoured the comparison group.
♀, For the subgroup of females.

effect. Similarly, compared with control groups (e.g. no intervention, a delayed intervention or a non-sex education intervention), four of the five studies reported that the intervention group statistically significantly outperformed the control group in the knowledge test,[43,62,64,66] whilst Stanton and colleagues[69] did not report on whether there was any difference between the groups.

Both studies that compared peer- with teacher-led interventions[50,51] reported that participants in the peer-led groups scored statistically significantly better on the knowledge outcomes than participants in the teacher-led groups.

The impact of the interventions on knowledge outcomes is summarised in *Table 35*.

Knowledge outcomes in subgroups

Stephenson and colleagues[3] and Wight and colleagues[4] reported all of their results separately by gender. In addition, three studies that reported an intervention effect for a knowledge outcome also reported findings according to one or more subgroups;[51,58,62] however, none stated whether the study had been powered to detect an effect in the subgroups reported. Three of the studies reporting on subgroups reported on differences between young men and young women. Wight and colleagues[70] and Borgia and colleagues[51] reported that young women were more knowledgeable than young men, but neither study reported whether the difference between the genders was statistically significant or not. Stephenson and colleagues[50] reported that knowledge in the peer-led group

was statistically significantly better at the 6-month follow-up for girls, but the reverse was true at the 18-month follow-up, when knowledge of methods to prevent STIs was significantly better, statistically, for boys who had received the peer-led intervention.

The other subgroups for which knowledge outcomes differed were previous sexual activity (Jemmott and colleagues[62] reported that the intervention effect was statistically significantly greater among young people who reported having coitus in the previous 3 months in the pre-intervention questionnaire); SES (Borgia and colleagues[51] found the highest SES group outperformed the lowest SES group but statistical significance not reported); school type (Borgia and colleagues[51] reported that humanistic/scientific school pupils scored more highly than pupils at technical or vocational schools, but again did not report whether this was statistically significant); and school location (a statistically significant greater intervention effect on knowledge was reported by Coyle and colleagues[58] for schools in Texas than schools in California).

The duration of most studies was 12 months or less.[43,51,62–64,66,69,70] Of those with a longer follow-up, attrition was too great at the later time point in three studies to consider that the results could be sound according to our quality assessment criteria.[58,65,71] Therefore, only Stephenson and colleagues[50] provide evidence that the intervention effect on knowledge can be sustained in the longer term (i.e. up to18 months post intervention).

Summary – knowledge

Ten of the twelve included studies reported that the intervention had a statistically significant effect on increasing knowledge, as summarised in *Table 35*. Only two studies did not demonstrate a statistically significant difference in knowledge between young people in the intervention and comparison[63] or control[69] groups.

Attitudes

Eight of the included studies had an assessment of participants' attitudes among their outcomes.[43,50,51,58,63,64,66,71] Six of these investigated participants' attitudes towards risky sexual behaviour or sexual intercourse,[43,50,58,64,66,71] with two specifically focused on attitudes towards waiting to have sex.[66,71] Three studies reported on attitudes towards condom use[50,58,63] – two on attitudes relating to people with AIDS[51,64] and one included positive and negative attitudes towards alcohol[63] (see Appendix 8, *Table 78*).

Jemmott and colleagues[43] reported statistically significantly less favourable attitudes towards risky sexual behaviours among the intervention group immediately following the intervention, but 3 months after the intervention this effect had waned to a non-statistically significant trend in favour of the intervention group over the control group. Roberto and colleagues[66] were the only authors to report a statistically significant effect in favour of the intervention group over the control group for participants' attitude towards waiting to have sexual intercourse. The other study to focus specifically on attitudes to waiting to have sexual intercourse reported that there was no significant difference between the groups,[71] and the other three studies that reported attitudes towards sexual intercourse also found no significant difference between the groups.[50,58,64] Similarly, only one of the three studies reporting on attitudes towards condom use (Coyle and colleagues[58]) found a statistically significant effect in favour of the intervention group, whereas the other two studies, Stephenson and colleagues[50] and Karnell and colleagues,[63] found no significant difference between the groups[50] or did not report a statistical comparison.[63] Both of the studies reporting on attitudes of participants towards people with AIDS reported significant changes. Klepp and colleagues[64] found a statistically significant effect in favour of the intervention group over the control group, whereas as Borgia and colleagues,[51] assessing peer- and teacher-led interventions, found that whilst statistically significant improvements were observed in both groups between the pre-test and the post-test, a post-test difference between the two groups was not reported. The single study that assessed both positive and negative attitudes to alcohol did not report on any statistical comparison between the groups.[63]

Summary – attitudes

The effects of the intervention on attitudes is summarised below in *Table 36*. A greater number of interventions that were assessed in relation to a control group, rather than those interventions assessed in comparison with standard sex education or to teacher-led interventions, found statistically significant effects. Three studies did not report any outcomes relating to attitudes.[65,69,70]

TABLE 35 *Summary of intervention effects on knowledge outcomes*

	HIV and/or AIDS knowledge	STI knowledge	HIV, AIDS and STI knowledge[a]	Sexual health knowledge
Intervention vs standard sex education				
Coyle *et al.*[58]	✓	✓		
Karnell *et al.*[63]			◆	
Levy *et al.*[65]	✓			
[b]Wight *et al.*[70]				✓
Zimmerman *et al.*[71]			✓	
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)				
Jemmott *et al.*[43]			✓	
Jemmott *et al.*[62]			✓	
Klepp *et al.*[64]	✓			
Roberto *et al.*[66]			✓	
Stanton *et al.*[69]	◆			
Peer-led vs teacher-led interventions				
Borgia *et al.*[51]	✓			
[b]Stephenson *et al.*[50]		✓		

a Zimmerman *et al.*[71] and Roberto *et al.*[66] also included pregnancy prevention knowledge.
b Reported all outcomes separately for young men and young women.
◆, No significant difference between the study groups (assumed for studies not reporting significance or any *p*-value).
✓, Outcome favoured the intervention group.

Behavioural intentions

Outcomes relating to participants' intentions were reported by six studies,[7,43,62–64,71] although one of these, by Levy and colleagues,[65] only reported intention outcomes for the subgroup of participants who had become sexually active during the course of the study. Four of the six studies reported on participants' intentions to have sex,[63–65,71] one reported on intentions to engage in risky sexual behaviour,[43] three reported on intentions to use condoms[62,63,65] (one further study, by Zimmerman and colleagues,[71] indicated that condom use intentions formed part of their participant questionnaire but did not report on this outcome), and the study by Levy and colleagues[65] reported on participants' intention to use condoms with foam (Appendix 8, *Table 79*).

Only one of the studies reporting on participants' intention to have sex. Klepp and colleagues[64] found a statistically significant difference in favour of the intervention group at follow-up. Participants in the intervention group had a reduced intention to have sex in comparison to the control group. The three other studies reporting on this outcome either reported no significant differences between the groups[71] or did not report a statistical comparison.[63,65]

The only study reporting intentions to engage in risky sexual behaviours found a statistically significant effect in favour of the intervention participants (participants had weaker intentions than the control group to engage in risky sex behaviours) both immediately after the intervention, and at the three month follow-up.[43] In terms of intention to use condoms, only one study reported a statistically significant difference between study groups in favour of the intervention group for the intention to use condoms.[62] Karnell and colleagues[63] found that overall there was no difference between intervention and comparison groups, but there was a statistically significant difference in favour of the intervention group for the subgroup of participants who were already sexually active at baseline. The third study reporting on the intention to use condoms, by Levy and colleagues,[65] did not report a statistical comparison for this outcome, but did report that the subgroup of participants who had become

TABLE 36 *Summary of intervention effect on attitudes*

	Attitude towards risky sexual behaviours	Attitude towards sexual intercourse	Attitude towards condom use	Attitude towards alcohol	Attitude towards people with AIDS
Intervention vs standard sex education					
Coyle *et al.*[58]		◆	✓		
Karnell *et al.*[63]			◆	◆	
Zimmerman *et al.*[71]		◆			
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)					
Jemmott *et al.*[43]	✓				
Klepp *et al.*[64]		◆			✓
Roberto *et al.*[66]		✓			
Peer-led vs teacher-led interventions					
Borgia *et al.*[51]					◆
[a]Stephenson *et al.*[50]		◆	◆		

a Reported all outcomes separately for young men and young women.
◆, No significant difference between the study groups (assumed for studies not reporting significance or any *p*-value).
✓, Outcome favoured the intervention group.

sexually active during the course of the study in the intervention group were more likely than participants in the comparison group to express an intention to use condoms with foam.[65]

Summary – behavioural intentions

Half of the included studies reported on the effects of the intervention on behavioural intentions and these are summarised in *Table 37*. An intervention effect was most likely to be reported by studies with a control group rather than a comparison group.

Infection rates

None of the included studies reported infection rates. Coyle and colleagues[58] reported whether participants had had a HIV or STI test, but the outcome of these tests is not known.

Summary of the results of sound outcome evaluations

- Sexual behaviour:
  - Outcomes related to the included sexual behaviours were reported under the headings: initiation of sexual intercourse; condom use; sexual intercourse; contraception and pregnancy; sexual partners; and other behavioural outcomes.
  - Interventions resulted in few statistically significant effects on sexual behaviour. Statistically significant effects on at least one behavioural outcome were reported by seven of the twelve studies. However, in three cases the effect was limited to a subgroup of participants, and in all studies no statistically significant effect was observed for some or all of the other behavioural outcomes reported on.
  - Five of twelve studies did not report that the intervention had any statistically significant behavioural effects.
- Skills and self-efficacy:
  - Two-thirds of the included studies reported a self-efficacy outcome, although all studies included a skills component within their intervention.
  - Most studies reported on more than one self-efficacy outcome and reported mixed results, statistically significant effects for some, but not all participants, or statistically significant effects for some, but not all self-efficacy outcomes.
  - One study reporting on a single self-efficacy measure reported a statistically significant intervention effect.
  - Two studies, one of which reported a single measure, found that the intervention had

TABLE 37 *Summary of intervention effects on behavioural intentions*

	Intention to engage in risky sexual behaviour	Intention to have sex	Intention to use condoms	Intention to use condoms with foam
Intervention vs standard sex education				
[a]Levy *et al.*[65a]		◆	◆	✓
Karnell *et al.*[63]		◆	‡	
Zimmerman *et al.*[71]		◆		
Intervention vs control (no intervention, delayed intervention, non-sex-education intervention)				
Jemmott *et al.*[43]	✓			
Jemmott *et al.*[62]			✓	
Klepp *et al.*[64]		✓		

a Reported for sexually inexperienced (virgins) subgroup.
◆, No significant difference between the study groups (assumed for studies not reporting significance or any *p*-value).
✓, Outcome favoured the intervention group.
‡, Outcome favoured the intervention for one subgroup of participants, but for another subgroup of participants there was no significant difference between the study groups.

no statistically significant effect on the reported self-efficacy measures.

- Knowledge:
  - Ten of the twelve included studies reported that the intervention had a statistically significant effect on increasing knowledge.
- Attitudes:
  - Nine studies reported attitude outcomes. Statistically significant effects of the intervention were reported by more of the studies that assessed an intervention in relation to a control group than those that assessed an intervention against standard sex education or teacher-led education.
- Behavioural intentions:
  - Half of the studies reported on behavioural intentions. As noted above for attitudes, a statistically significant intervention effect was more likely to be reported by studies with a control group rather than those with a comparison group.
- Infection rates:
  - None of the included studies reported on a biological outcome relating to infection with STIs. One study reported whether participants had undergone an HIV or STI test, but the outcome of the tests was not reported.

Chapter 5

Synthesis of process evaluations

This chapter presents the results of our synthesis of the process evaluations included in the systematic review of effectiveness reported in Chapter 4. Nine of the twelve sound outcome evaluations included an integral process evaluation (Borgia and colleagues,[51] Jemmott and colleagues,[43,62] Karnell and colleagues,[63] Levy and colleagues,[65] Roberto and colleagues,[66] Stephenson and colleagues,[50] Wight and colleagues,[70] Zimmerman and colleagues[71]).

Where authors had published additional papers reporting the process evaluations, we incorporated this additional information into account in the synthesis. Details of these 'linked' papers can be found in Appendix 7.

Methodological characteristics

A range of processes were evaluated (*Table 38*). All studies, except Borgia and colleagues,[51] evaluated both the acceptability of the intervention to providers or recipients, and all studies asked how well interventions were implemented (but Jemmott and colleagues[43,62] did not report findings on this). A third of the studies examined: accessibility or how many participants the intervention reached; the actual content of the intervention; and the skills and training of the intervention providers. Two studies assessed the collaboration and partnerships involved in developing or delivering the intervention, and only one evaluated the quality of the programme materials. The 'other' processes evaluated were: the duration of the intervention;[51,62] the assimilation of the intervention into classrooms;[51] how much the young people learned, whether the intervention would help them in the future and whether they would recommend the intervention to other peers,[43] and monitoring of sex education in comparison schools.[50]

Whilst some studies evaluated a wide range of processes others focused on just two or three. For example, in the UK-based RIPPLE trial, Stephenson and colleagues[50] examined the

TABLE 38 *Processes evaluated within the sound outcome evaluations that included an integral process evaluation* (n = 9)

	Accessibility/ programme reach	Collaboration and partnerships	Content	Implementation	Acceptability	Quality of materials	Skills and training of providers	Other
Borgia *et al.*[51]				✓		✓		✓
Jemmott *et al.*[43]	✓			✓	✓			✓
Jemmott *et al.*[62]				✓	✓		✓	✓
Karnell *et al.*[63]				✓	✓		✓	✓
Levy *et al.*[65]				✓	✓			
Roberto *et al.*[66]	✓			✓	✓			
Stephenson *et al.*[50]	✓	✓		✓	✓		✓	✓
Wight *et al.*[70]		✓	✓	✓	✓		✓	
Zimmerman *et al.*[71]			✓	✓	✓			
TOTAL	3	2	2	9	8	1	4	5

proportion of students who reported that they received the peer-led sex education ('accessibility and programme reach'); the contextual factors influencing the ability of teachers to co-ordinate the peer-led programme in schools ('collaboration and partnerships'); student evaluations of the peer-education ('acceptability'); the individual and structural factors influencing the extent of implementation of peer-led sex education ('implementation'); observation of peer leaders to assess their enthusiasm and organisational skills ('skills and training of intervention providers'); and the type and extent of sex education delivered in the control schools ('other').

The most common method used to collect data on process was a self-completion questionnaire (*Table 39*). Just over half of the studies also used observation (e.g. researchers observing the lessons). Both these methods of data collection were used to assess intervention implementation and the skills and training of intervention providers. Self-completion questionnaires were also used to assess intervention acceptability and accessibility, as were interviews and focus groups. A range of 'other' methods were used: website logs in a computer-based intervention (Roberto and colleagues[66]), researcher field notes from site visits (Stephenson and colleagues[50]) and group discussion (Wight and colleagues[70]).

All but two studies collected data from intervention providers, and all but two collected data from intervention participants themselves (*Table 40*).

Levy and colleagues[65] tested the effect of involving parents in a 10-lesson curriculum for the prevention of pregnancy and STIs. The process evaluation therefore monitored the participation of parents in the intervention. Other groups sampled in the process evaluations were: head teachers and other school staff responsible for sex education (Stephenson and colleagues[50], Wight and colleagues[70]), teacher trainers (Wight and colleagues[70]) and unspecified 'project staff' (Zimmerman and colleagues[71]).

Methodological quality

The methodological quality of the process evaluations was mixed (*Table 41*) (see Appendix 5 for the criteria used).

Six studies were judged to have taken at least a few steps to increase rigour in the sampling process.[43,50,62,63,70,71] Two studies were judged to have made a thorough attempt having sampled a range of stakeholders at several time points throughout the intervention period.[50,70] Half of the studies were judged to have taken a least a few steps to increase

TABLE 39 *Methods used to collect data on intervention processes within the sound outcome evaluations that included an integral process evaluation (*n = *9)*

	Documentation	Focus group	Interview	Observation	Self-completion questionnaire	Other	Not stated
Borgia *et al.*[51]		✓			✓		
Jemmott *et al.*[43]					✓		
Jemmott *et al.*[62]					✓		
Karnell *et al.*[63]				✓	✓		
Levy *et al.*[65]							✓
Roberto *et al.*[66]					✓	✓	
Stephenson *et al.*[50]		✓	✓	✓	✓	✓	
Wight *et al.*[70]	✓	✓	✓	✓	✓	✓	
Zimmerman *et al.*[71]				✓	✓		
TOTAL	1	3	2	4	8	3	1

TABLE 40 *Groups sampled in the process evaluations (n = 9)*

	Intervention participants	Intervention providers	Other
Borgia *et al.*[51]		✓	
Jemmott *et al.*[43]	✓	✓	
Jemmott *et al.*[62]	✓	✓	
Karnell *et al.*[63]	✓	✓	
Levy *et al.*[65]			✓
Roberto *et al.*[66]	✓		
Stephenson *et al.*[50]	✓	✓	✓
Wight *et al.*[70]	✓	✓	✓
Zimmerman *et al.*[71]	✓	✓	✓
TOTAL	7	7	4

rigour in data collection.[43,50,63,70,71] One study was judged to have made a thorough attempt.[70] This study used a diverse range of data collection methods, which included a balance between open-ended and closed techniques.

Researchers spent extensive periods of time collecting data at intervention and control sites and supplemented more formal data collection techniques (e.g. interviews, observation), with documentation of more informal conversations with teachers and pupils. Only two studies had taken at least a few steps to increase rigour in the analysis of the process data (Stephenson and colleagues[50] and Wight and colleagues[70]). These studies had provided a description of the data analysis process, had explored diversity in perspective and allowed concepts and themes to emerge from the data analysis, as well as exploring pre-determined themes and categories. The majority of the remaining studies had provided no detail at all on the methods used to analyse data, making it difficult to judge whether steps were taken to increase rigour.

Only the findings in one-third of studies were judged to have been at least fairly well grounded in or supported by the data (Stephenson and colleagues,[50] Wight and colleagues,[70] and Zimmerman and colleagues[71]).

All of these studies reported the findings in separate linked papers or had dedicated sections within the outcome paper to report findings. In other studies, data to support authors' conclusions about process were extremely limited or in some cases completely absent. The same three studies were also the only ones to have been judged as providing both good breadth and depth in their findings. Again, in other studies the limited scope and reporting of findings made it difficult to assess breadth and depth favourably.

The remaining quality criteria in *Table 41* assessed the extent to which young people's own perspectives had been considered in the process evaluation. Only three studies had been judged to have a least privileged young people's perspectives 'a little' (Stephenson and colleagues,[50] Wight and colleague,[70] and Zimmerman and colleagues[71]). These studies were judged to have given equal weight to young peoples' perspectives alongside the views of other stakeholders. Of the remainder, Borgia and colleagues[51] and Levy and colleagues[65] did not collect any data from the young people receiving the interventions.

A final step in the quality assessment process was for reviewers to assign two types of 'weight of evidence' to studies. Firstly, a weight (low, medium or high) was assigned according to the reliability or trustworthiness of the findings (the extent to which the methods used were rigorous/could minimise bias and error in the findings). A second weight (low, medium, high) was assigned according to the usefulness of the findings in terms of how well the intervention processes were described and whether or not the process data could illuminate why or how the intervention worked or did not work.

All but four studies were assigned a low weight of evidence for the rigour of their findings and all but three were assigned a low weight of evidence for the usefulness of the findings (*Table 42*). Three

TABLE 41 *Methodological quality of process evaluations (n = 9)*

	Number of studies			
	Not at all/not stated	**A few steps**	**Several steps**	**A thorough attempt**
1. Were steps taken to minimise bias/increase rigour in sampling?	3	3	1	2
2. Were steps taken to increase rigour/ minimise bias and error in the data collected?	4	3	1	1
3. Were steps taken to increase rigour/ minimise bias and error in the analysis of the process data?	7	1	0	1
	No grounding/ support	**Limited grounding/ support**	**Fairly well grounded/ supported**	**Good grounding/ support**
4. Findings of the process evaluation grounded in/supported by the data	0	6	1	2
	Limited breadth and depth	**Good/fair breadth, limited depth**	**Good/fair depth, limited breadth**	**Good breadth and depth**
5. Breadth and depth of findings	6	0	0	3
	Not at all	**A little**	**Somewhat**	**A lot**
6. Does the process evaluation privilege the perspectives and experiences of young people?	6	2	0	1

studies stand out overall as they were judged to be medium or high weight of evidence for both trustworthiness and usefulness – Stephenson and colleagues,[50] Wight and colleagues[70] and Zimmerman and colleagues.[71]

Synthesis of findings

As mentioned earlier (Chapter 2, Process evaluations), the synthesis of process evaluation studies addressed two principal questions. Firstly, what factors facilitate or hinder the implementation of skills-based behavioural interventions in schools? Secondly, what factors impact on student engagement and intervention acceptability? These are explored in the following subsections.

Fidelity of implementation

The fidelity of intervention implementation (i.e. the extent to which the intervention was delivered as intended) was assessed by all studies, but only seven reported findings on this.[50,51,63,65,66,70,71] As a number of these were multisite cluster RCTs they involved the implementation of a standardised programme across a number of schools.

Three studies found that implementation fidelity varied across and within schools. In the UK, Stephenson and colleagues[50] found that overall, 84% of the intended recipients of RIPPLE reported that they had received at least some peer education, but this varied between 51% and 97% across schools. Wight and colleagues[70] found that although the Scottish-based teacher-delivered SHARE programme was implemented in all 12 experimental schools, there was variation in the extent to which all 20 sessions of the programme were covered (from 38% to 88% across schools). In the USA, Zimmerman and colleagues[71] also found that implementation of the 16–17 session teacher- and peer-delivered 'Reducing the Risk' programme varied somewhat across schools and classrooms.

The factors influencing the implementation of the intervention are discussed in detail below, but a particular challenge was consistent implementation of some of the interactive and 'novel' elements of the programmes. In the RIPPLE trial,[50] whilst most students reported that the intervention had covered topics such as HIV, STIs, where to get contraception/condoms and medical advice, and had looked at condoms, fewer students reported that they had practiced putting a condom on

TABLE 42 *Weight of evidence judgements for (1) trustworthiness of findings and (2) usefulness of findings*

	Weight of evidence					
	Trustworthiness of findings			Usefulness of findings		
	Low	Medium	High	Low	Medium	High
Borgia *et al.*[51]	✓			✓		
Jemmott *et al.*[43]	✓			✓		
Jemmott *et al.*[62]	✓			✓		
Karnell *et al.*[63]		✓		✓		
Levy *et al.*[65]	✓			✓		
Roberto *et al.*[66]	✓			✓		
Stephenson *et al.*[50]			✓		✓	
Wight *et al.*[70]			✓			✓
Zimmerman *et al.*[71]		✓			✓	
TOTAL	5	2	2	6	2	1

(76%), discussed how to use condoms with a partner (39%) or practiced resisting pressure to have sex (55%). (However, greater numbers of students in the experimental schools reported that they had received skill-based activities than in the control schools.) In the SHARE trial[70] teachers reported making 'considerable changes' to five of the 20 lessons in the programme. These tended to be those lessons that involved role playing to develop communication and resistance skills and one lesson in which young people got the chance to visit a family planning clinic. Parental involvement was a novel element of the US-based Youth AIDS Prevention Project (YAPP) programme, but Levy and colleagues[65] reported that, despite substantial cost and effort, it was not possible to get parents to attend on-site school activities.

From the synthesis, a hierarchy emerged (*Figure 4*), incorporating a number of factors that may impact on fidelity of implementation.

School culture

School culture was identified as an overarching factor impacting on fidelity of implementation. School culture was determined by a range of key elements, and most clearly emerged as being significant from the SHARE study.[70] One element that Wight and colleagues[70] identified was the involvement of key players at a number of levels, from the Health Education Board of Scotland (HEBS), to guidance teams, sex education co-ordinators and senior management. Higher levels of involvement tended to facilitate implementation. Motivation of these key players was also important, as was communication between teachers and, importantly, communication style: in one school that was involved in the SHARE trial, the senior management imposed the programme (in all other schools there had been consultation with staff) and teachers felt unhappy with this 'imposition', which impacted negatively on implementation. A teacher having sufficient time to organise or deliver sessions was dependent on whether PSHE was considered enough of a priority in the face of competing subjects. If management support was low, cover for teacher sickness or absence was less likely to be supplied and, consequently, intervention sessions were missed. Low morale was also found to be a barrier against implementation: one of the two schools in the RIPPLE trial[50] in which some classrooms did not receive the peer-led intervention there was low morale because the sixth form facility for 16- to 18-year-old students was closing down.

School administration

Factors relating to school organisation also impacted on implementation. Staff absence and turnover, timetabling issues and time shortages led, generally, to lessons being missed or cut short.[50,70] In the SHARE study, schools found it hard to set aside 20 lessons for sex education and, even when they felt sex education was a priority, they were all too aware that other topics competed with the programme. As one teacher put it: '… this really has distorted my whole programme … I've not done any study skills, I've not done anything

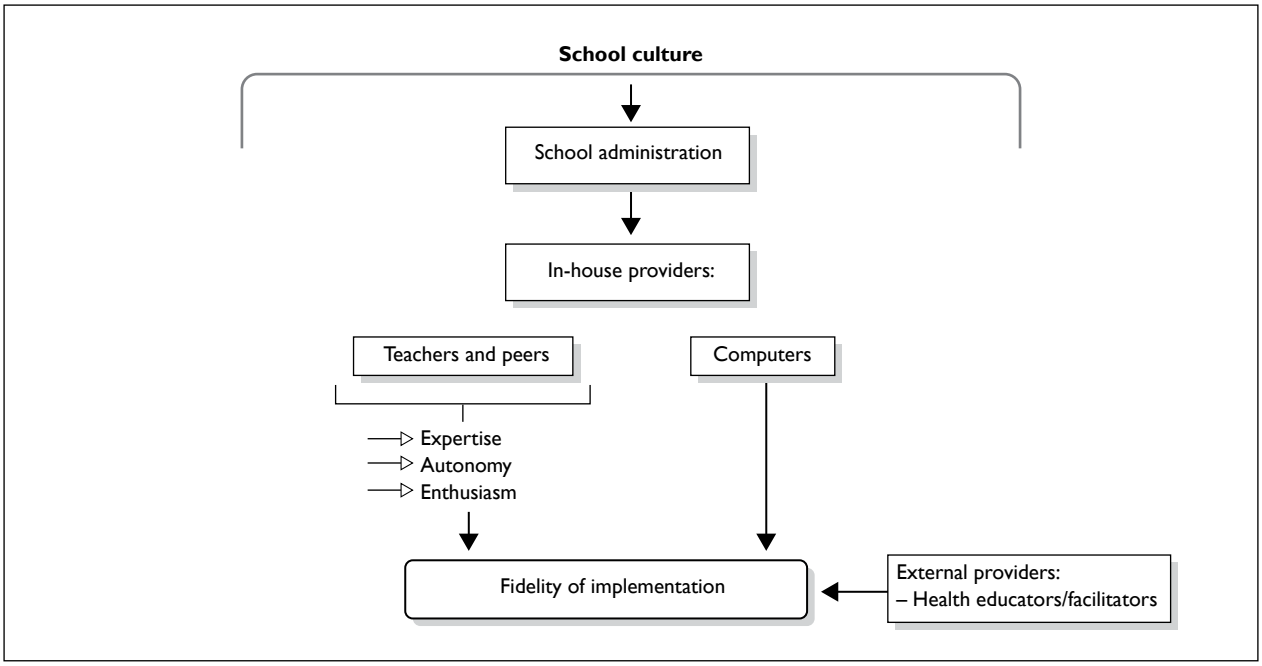

FIGURE 4 *Factors impacting upon fidelity of implementation.*

on drugs and alcohol, I've hardly done any work experience … it's blocked up a lot of my programme' (Buston and colleagues,[90] p. 66). Although the lessons had been designed to last for 40 minutes each, this was found to be rather optimistic and around one-third of the sessions 'could not be completed'. There were also problems with making the trained teachers available for the appropriate slots, resulting in some sessions being delivered by untrained teachers. This was a particular problem in one case, because of the inflexibility of the head teacher over timetabling.

Teachers – enthusiasm, expertise, autonomy

All of the findings on teachers as intervention providers come from Wight and colleagues,[70] who found that the process of actively cultivating teacher expertise and enthusiasm was vital in the delivery of SHARE. The SHARE teacher training was particularly important in this regard and was viewed very positively by teachers. Wight and colleagues[91] evaluated the training extensively and found that, in the post-training questionnaire, 86% reported that they were 'very glad' to have attended the course and 13% reported they were 'glad'. In interviews, teachers compared the SHARE training very favourably with other in-service training that they had received. For example, a typical comment from a teacher was: 'Without a doubt, yes, the training was actually one of the – and colleagues would say this as well – it was one of the best training courses that I've ever been on' (p. 528). Wight and colleagues[91] noted that the perceived success of the training was largely attributed to the trainer, who was an experienced sexual health educator, and who was felt to be clear and in control and able to put teachers at their ease. Wight and Abraham[92] also note that the training succeeded in ensuring that teachers' own self-efficacy was enhanced, so as not to appear to threaten their current expertise by introducing new methods.

However, despite high levels of acceptability of the teacher training, a number of problems with the teachers' implementation of the intervention persisted. Some failed to engage with the theoretical basis for the intervention, in particular the mechanism for behavioural change, via the modelling and practising of skills. Wight and colleagues[91] report that, in interviews, teachers seldom referred to skills development unprompted, and when interviewers raised the issue they talked about this only briefly. They comment that 'only one teacher referred to the mechanism by which the programme was intended to influence behaviour, that is the social-psychological theory behind it, and then only obliquely' (p. 536). In the interviews, the teachers never mentioned the theoretical aspects of the training that Wight and colleagues[91] had hypothesised were fundamental to achieving behavioural change and which distinguished the course from traditional sex

education. The authors concluded that 'many teachers saw the skills and tactics required to apply the theoretical principles of the SHARE programme to be so far removed from their established repertoires that it was too great a risk to try and develop them' (Wight and colleagues,[91] p. 540). In practice, this meant that many teachers failed to persevere with skills development and role play activities. In the words of one teacher: 'I turned round to 3A on Tuesday … I said "you're not going to do this [role play] are you now?" in a way that let them opt out because they went "no", but I knew they weren't going to do it and I didn't have a strategy really for thinking "right, I've hit a wall, what do I do with them?"' (Buston and colleagues,[90] pp. 67–8).

This failure to engage with the theory behind an intervention was experienced in a different way by Borgia and colleagues,[51] who suspected teachers of selecting the peer leaders who delivered their intervention for their academic skills rather than for the qualities that are hypothesised to make a good peer leader.

As well as issues relating to teachers' expertise, there were also issues of enthusiasm. Teachers were sometimes uncomfortable with talking explicitly about sexual issues and some were wary about how to handle the question of same-sex relationships. Some teachers simply did not see sex education as a priority.

There was also some conflict between issues of fidelity and issues of professional autonomy: some teachers made amendments to the programme without consulting the intervention developers, as they felt they had the skills and experience to do so. Buston and colleagues[90] looked at the extent to which teachers delivered the intervention as intended and found that for 71% of sessions, teachers reported having followed the pack 'very closely', for 23% teachers reported modifying the session 'slightly' and for 6% they reported making 'considerable' modifications. 'Considerable' modifications included missing out sessions or key exercises, amalgamating sessions, abandoning exercises when pupil resistance was experienced and modifying teaching methods. Ten teachers reported making modifications which they viewed as 'slight' but which, in the opinions of the packs' authors, would compromise the intervention in important ways, for example missing out or not completing key exercises.

Peers

Four of the studies that included process evaluations used peer educators. Karnell and colleagues[63] and Zimmerman and colleagues[71] used peer educators alongside teachers; and Borgia and colleagues[51] and Stephenson and colleagues[50] only used peers to deliver their intervention. In none of the studies was the age of the peer leader clear except in that of Stephenson and colleagues, in which they were 16–17 years old.

Only Zimmerman and colleagues[71] offer a justification for using peer educators, which was that they were specifically targeting high sensation seekers and impulsive decision-makers, whom they presumed relied more on peers than on adults when making decisions about their behaviour. Borgia and colleagues[51] did not offer a rationale for employing peer educators, other than wanting to see whether it conferred advantages that standard practice (i.e. teacher-led sex education) did not.

The process evaluation data showed that selection of peer leaders was clearly important. As seen above, Borgia and colleagues[51] hypothesised that there were problems with the criteria by which the teachers in their intervention selected peer leaders (i.e. they were selected for academic skills rather than for the qualities that make an effective peer leader). This, they believed, compromised the 'trustfulness and communication' (p. 514) between educators and pupils. Stephenson and colleagues[50] had other problems with selection: one school was unable to recruit enough peer leaders to implement the intervention.

Like Borgia and colleagues,[51] Stephenson and colleagues[50] questioned the aptitude of some of the recruited peer educators. They report that in two schools some classes failed to receive peer-led sex education due to the disorganisation and lack of enthusiasm of the peer educators for the programme. Zimmerman and colleagues[71] noted that although the peer educators performed the tasks assigned to them, they did not achieve the level of involvement hoped for, 'making this component of the modified curriculum less than ideal' (p. 49). Some peer leaders in Stephenson and colleagues' RIPPLE trial were hampered by structural factors, including long gaps between training and delivery of sex education and timetable clashes for peer educators taking examinations.

Researchers' observations in Stephenson and colleagues'study[50] show that some important topics may not have been addressed in many of the peer-led sessions (e.g. emergency contraception).

It is not clear across the studies whether intervention fidelity was more problematic in peer-led interventions than in those delivered by teachers or other adults. Although Stephenson and colleagues[50] report that RIPPLE was not implemented at all in one school because the school could not recruit enough peer educators (as opposed to the teacher-delivered SHARE programme, which was implemented in all schools), and Zimmerman and colleagues[71] found that peer facilitators were rarely used in the modified 'Reducing the Risk' programme, Borgia and colleagues[51] found that whilst their peer-led intervention achieved the suggested length (median across schools was equal to 10 hours) the teacher-led intervention was significantly shorter (median across schools was only 8 hours). Borgia and colleagues did not explore this finding any further.

Parents

Only one of the studies that included a process evaluation involved parents as providers of the intervention (Levy and colleagues[65]). This process evaluation shows that, although parents seemed satisfied and participatory during meetings, they only really became actively involved with the intervention through the interactive homework assignments. The authors reflect that interactive homework assignments 'may provide a practical way to involve parents in school-based prevention efforts' (p. 151). However, they also note that parents largely failed to attend on-site school activities. It is hypothesised that this was a function of parents (particularly those on a low income) having to balance work and life stresses, but this does not seem to be based on empirical data.

Health educators/facilitators

Levy and colleagues' intervention[65] utilised 'health educators', who were educated to 'professional master's level' and who had received extensive training in delivery of the programme and HIV/AIDS. Jemmott and colleagues[62] used 'facilitators' to deliver their intervention, but no details are given about their expertise or training or their impact on fidelity of implementation.

Computer

One study, that of Roberto and colleagues,[66] delivered the intervention by computer.

The authors note that 'the nature of the intervention provided a very high level of control over the implementation' (p. 68) and that the process evaluation showed the intervention had been implemented as intended.

Student engagement and intervention acceptability

The interventions evaluated by the studies included in this review shared two common features. Firstly, all interventions were designed to engage young people actively in their own learning through interactive exercises, such as role plays, discussions and small group work. Secondly, all interventions were designed to be relevant and appealing to young people in general or particular groups of young people. The latter was attempted in various ways including the use of peer leaders to deliver the intervention and attempts to make curriculum materials interesting, fun and relevant through, for example, the use of fictional teenage characters. Although there was evidence from the process evaluations to confirm that interventions did engage and appeal to many of the young people involved, this was not always the case.

Six of the process evaluations contributed findings that illuminated issues of student engagement and intervention acceptability.[50,51,63,66,70,71] A number of factors emerged as influences on this issue (*Figure 5*).

Appeal of intervention content

Attempts to design interventions that were appealing to young people were met with some success in the three studies with relevant findings. Three-quarters of the participants rated the four animated characters who modelled skill development in the South-African based intervention delivered to (predominantly) Zulu youth, evaluated by Karnell and colleagues,[51] as seeming 'very' or 'extremely' real to them, and 74% found the curriculum, delivered by peers and teachers, 'very' or 'extremely' interesting. A positive evaluation was also received for the intervention delivered by a computer to young people living in a rural Appalachian community in the USA, evaluated by Roberto and colleagues.[66] Young people found the programme to be informative, clear, useful and interesting and did not rate the programme as 'boring' or 'preachy'. Similarly, a large proportion of the young people participating in the US-based 'Reducing the Risk' intervention, evaluated by Zimmerman and colleagues,[71] an intervention delivered by teachers and peers to

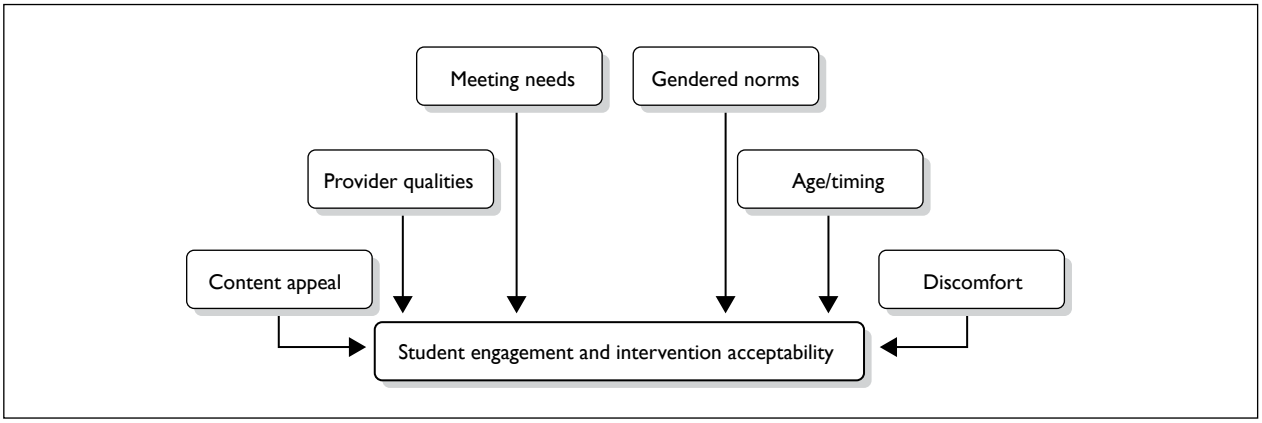

FIGURE 5 *Factors related to student engagement and intervention acceptability.*

ethnically diverse 'high sensation seeking youth', rated the programme as very interesting, easy to pay attention to and fun. However, not all parts of the intervention were evaluated positively in this study. The animated POWERPOINT presentations that introduced the curriculum were not judged to be particularly novel and researchers noted increasingly negative reactions to this part of the intervention. They concluded that it may be difficult to 'yield a high level of sensation value in a classroom intervention' (p. 49).

Qualities of intervention providers

The qualities and expertise of intervention providers was another factor that impacted upon student engagement and acceptability. The focus group data collected by Stephenson and colleagues[50] as part of the RIPPLE trial conducted in schools in central and southern England revealed that students receiving peer-led sex education were considerably more positive about their experience than those in the control schools who received the teacher-led sex education that was usually delivered in their schools. Those who did report greater satisfaction with peer-led sex education perceived peer educators as having 'greater relevant expertise and respect for pupils, holding more similar values about sex, using familiar language, being less moralistic and making the sessions fun' (p. 343). The peer educators were felt to be more 'in touch' with participants as young people. However, data from questionnaires show that around a third of students receiving peer-led sex education did not evaluate it positively. Those who found the peer-led component less acceptable reported that participation became difficult when peer educators were not able to engage boys or manage their behaviour.

Peer leaders also encountered difficulties in engaging young people in the evaluation conducted by Zimmerman and colleagues.[71] Delivering school-based programmes to develop skills around practising safer sex is clearly a role that requires considerable expertise. As already noted in the previous section on fidelity of implementation, teachers often struggled to engage young people in the interactive elements of the SHARE programme[70] and teacher control over student behaviour and engagement during the interactive elements of the 'Reducing the Risk' curriculum also emerged as a significant issue in the evaluation conducted by Zimmerman and colleagues.[71]

Meeting needs

It is important to recognise that whilst many of the young people surveyed in the process evaluations rated interventions favourably, there was a minority of young people for whom interventions were less than appealing. As noted above, Stephenson and colleagues[50] highlight this point in relation to the RIPPLE study, with their findings that one-third of young people did not evaluate peer-led sex education in a positive way. They argue that dissatisfaction or lack of engagement may be related to the possibility that the intervention, despite being designed to appeal to young people, did not, in fact, meet their own self-identified needs. Their process evaluation examined this issue directly and found that overall participants felt that topics such as sexual feelings, emotions, and relationships were not covered well by either teachers or peers. Researchers' observations in the RIPPLE trial revealed that some important topics may not have been addressed in many of the peer-led sessions (e.g. emergency contraception). The issues discussed below around the format

and timing of interventions also highlight how the failure of school-based interventions may be explained by a failure to respond to/acknowledge young people's self-identified needs

Gendered norms and mixed-sex versus single-sex groups

The interventions varied according to whether activities were delivered in mixed-sex or single-sex groups. The RIPPLE trial[50] was delivered in mixed-sex groups, but some of the participants said they would have preferred single-sex sessions. However, observation data from the evaluation of the SHARE trial[92] revealed problems with the single-sex classes they delivered, in particular for young men. Gendered norms dominated particularly in all male groups, and impaired discussion and reflexive insight. Boys tended to conform to macho stereotypes or practiced self-censoring. It was observed that boys tended to work better in mixed sex groups as they were 'liberated from defensive masculine norms' (p. 31) and became interested in the perspectives of young women. Wight and Abraham noted that these mixed-sex groups could engender confidence amongst young men for talking about sex to young women.

Age/timing

Three studies raised the question of the age-appropriateness of the interventions. Wight and Abraham[92] concluded that their content was too advanced for the pupils in their intervention, as pupils' lack of sexual experience at age 13–14 years meant that they failed to identify with the vignettes presented to them, which were designed to make pupils more aware of gendered interaction and power dynamics in sexual relationships, and/or found them alien. Pupils were unfamiliar with this kind of analysis and, in addition, were concerned about disclosing details of their own relationships. Wight and Abraham[92] modified the intervention because of this, but this was judged partially to undermine the effectiveness of the intervention. The question of age appropriateness also arose in the study conducted by Borgia and colleagues,[51] who report that the 'work groups' that evaluated their programme judged it to be more suitable for younger populations (the participants in this study were 17–18 years of age).

However, if content can be successfully matched to the age of the participants, a related issue is appropriate timing: at what age should school-based sex education start? Stephenson and colleagues[50] reported that more than half of students in both arms of their trial – who were the same age as the pupils in the SHARE trial evaluated by Wight and colleagues[70] – would have liked their sex education earlier, although it is not reported when exactly they would have liked it to start.

Discomfort

One final reason why the interactive, skills-building exercises in the SHARE intervention failed was the evident discomfort felt by pupils in engaging with issues relating to sex in a classroom setting. This discomfort expressed itself either in disruptive hilarity or in embarrassment. Wight and Abraham[92] comment: 'An important underlying problem was the embarrassment pupils felt at having to improvise sexual roles with a class mate under peer surveillance. The anticipated interpersonal consequences of having one's words and actions attributed to oneself rather than one's character inhibited acting-the-part and reflecting on the scripts in the abstract.' (p. 33). So the very element of the intervention that was considered by the developers to be its 'active ingredient' – the interactive nature of many of the sessions – combined with the sensitive subject matter, in fact worked against its success in a classroom context.

Summary of process synthesis findings

- *Fidelity of implementation* Three of the process evaluations (including the two most extensive evaluations – Stephenson and colleagues[50] and Wight and colleagues[70]) reported variation in fidelity of implementation. In some cases, fidelity was greatly compromised.
- *School culture* School culture (the involvement and commitment of key stakeholders, management support, the prioritisation of PSHE, overall morale) was vital in providing an accommodating context for the implementation of the intervention. Again, this was found to vary widely across schools.
- *School administration* Staff absence and turnover, timetabling issues and shortage of time acted as important barriers to fidelity of implementation.
- *Teachers – enthusiasm, expertise, autonomy* Wight and colleagues[70] found that enthusiasm, expertise and autonomy of teachers were vital to the delivery of the intervention. Despite thorough and highly acceptable training, teachers often failed to engage with the more interactive elements of the SHARE intervention and with the theory that underpinned it.

- *Peers* Selection of peers with the qualities that make an effective leader was important; this did not always happen. Some of the peer leaders were found to lack enthusiasm, organisation and the skills to manage and engage participants.
- *Parents* It is feasible to involve parents in homework tasks, but less so in attendance of on-site activities.
- *Health educators/facilitators* The studies did not report on the impact on fidelity of implementation of employing health educators or other facilitators.
- *Computer* The one study[66] that used a computer to deliver the intervention reported high fidelity of implementation.
- *Content appeal* It is both feasible and important to develop sexual health interventions with content that is highly acceptable to young people. However, acceptability alone does not guarantee effectiveness.
- *Provider qualities* It is vital to the success of any skills-based intervention that providers, whether teachers, peers or other facilitators, have sufficient expertise to deliver the intervention effectively. Process evaluations showed that this was not the case in many of the interventions reported on.
- *Meeting needs* It is less likely that interventions will impact on behaviour if they do not meet young people's self-identified needs. According to Stephenson and colleagues,[50] in the case of sex education these include sexual feelings, emotions and relationships, which were often addressed only partially or not at all.
- *Gendered norms* Gendered norms, especially the pressure on boys to conform to accepted notions of masculinity, inhibit and disrupt discussion of sexual issues in the classroom. Mixed-sex groups were more successful for boys than single-sex groups.
- *Age/timing* Some of the reviewed interventions were not age appropriate, either because they were felt to be more suitable for a younger age group or – due to the sexual inexperience of the participants – an older one.
- *Discomfort* Pupils can experience discomfort in engaging with interactive interventions in the classroom relating to sexual behaviour.

Chapter 6

Systematic review of cost-effectiveness studies

Introduction

A systematic review was conducted of the literature to identify economic evaluations of behavioural interventions to prevent STIs in young people. The purpose was to assess the current evidence base for the cost-effectiveness of behavioural interventions, and whether there is a need for further economic modelling. If further modelling is necessary, the methods used in previous cost-effectiveness studies will be analysed and appraised to inform the most appropriate approach.

Methods for the systematic review

Search strategy

A systematic literature search was undertaken to identify economic evaluations for behavioural interventions for sexually transmitted interventions for young people. Sensitive search strategies were developed and tested by an experienced information scientist [see Appendix 10 for the MEDLINE (Ovid) search strategy]. These strategies were used to search the following electronic bibliographic databases:

- The Cochrane Central Register of Controlled Trials (CCRCT) (Issue 1, 2008)
- MEDLINE (via Ovid)
- MEDLINE In-Process & Other Non-Indexed Citations (via Ovid)
- EMBASE (via Ovid)
- Science Citation Index
- NHS Economic Evaluation Database (NHS EED, via NIHR CRD)
- Health Technology Assessment Database (via Cochrane Library)
- Database of Abstracts of Reviews of Effectiveness (DARE) (via Cochrane Library)
- Econlit

Searches were limited to the period 1990 to February 2008.

Inclusion criteria

Titles and (where available) abstracts of references identified by the search strategy were assessed for potential eligibility against inclusion criteria (*Table 43*) by a health economist. Full papers of those which appeared relevant on title or abstract were retrieved and independently screened by two health economists. Any differences in judgement were resolved through discussion.

The quality of these economic evaluations has been assessed using a standard checklist adapted from Drummond and Jefferson[93] (*Table 44*).

Results

A total of 788 references were identified, of which 21 full papers were retrieved. Most of these papers were excluded because the participants were above the upper age limit of the inclusion criteria. Five economic evaluations met the inclusion criteria. The characteristics and results of the evaluations are discussed in more detail below.

Table 45 provides a summary of the characteristics and base-case findings of the five published economic evaluations (for the results of these

TABLE 43 *Inclusion criteria for the systematic review of cost-effectiveness studies*

	Inclusion criteria
Population	Young people aged 13–19
Intervention	Behavioural intervention, defined as: 'Any activity to encourage young people to adopt sexual behaviours that will protect them from acquiring STIs'
Outcomes	Cost per STI avoided; cost per QALY gained
Design	Economic evaluations, modelling studies

TABLE 44 *Methodological quality of reporting of the studies assessing the costs and cost-effectiveness of interventions to prevention HIV in young people*

Quality criteria	Tao and Remafedi[94]	Wang et *al.*[59]	Pinkerton et *al.*[95]	Cohen et *al.*[60]	Hogan et *al.*[96]
Is there a well-defined question?	✓	✓	✓	✓	✓
Is there a clear description of alternatives (i.e. who did what to whom, where, and how often)?	✓	✓	✓	✓	✓
Has the correct patient group/population of interest been clearly stated?	✓	✓	✓	✓	✓
Is the correct comparator used?	✓	✓	✓	✓	✓
Is the study type reasonable?	✓	✓	✓	✓	✓
Is the perspective of the analysis clearly stated?	✓	✓	✓	✓	✓
Is the perspective employed appropriate?	?	?	?	?	?
Is effectiveness of the intervention established?	✓	✓	✓	✓	✓
Has a lifetime horizon been used for analysis? If not, has a shorter time horizon been justified?	✓	✓	✓	✓	✓
Are the costs and consequences valued credibly?	?	X	?	?	?
Is differential timing considered?	✓	✓	✓	✓	✓
Is incremental analysis performed?	✓	✓	✓	✓	✓
Is sensitivity analysis undertaken and presented clearly?	✓	✓	✓	✓	X
Were credible conclusions drawn from the results	?	X	✓	✓	✓

✓,; ?, unclear; X,.

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TABLE 45 *Characteristics of economic evaluations of the prevention of STIs*

	Tao and Remafedi[94]	Wang *et al.*[59]	Pinkerton *et al.*[95]	Cohen *et al.*[60]	Hogan *et al.*[96]
Publication year	1998	2000	2000	2004	2005
Country	USA	USA	USA	USA	USA
Study type	Cost utility	Cost-effectiveness	Cost utility	Cost-effectiveness	Cost utility
Perspective	Societal	Societal	Societal	Not reported	Not reported
Study population	501 male gay/bisexual volunteers, 13–21 years (mean age 19 years)	10 schools in northern California and 10 schools in south-east Texas 3677 US 9th grade school children (14–15 years old)	157 African-American males (mean age 14.6 years)	Not reported	Not reported
Intervention(s)	HIV prevention intervention (individualised risk assessment and counselling, peer education, optional HIV testing and referrals services)	The 'Safer Choices' intervention 2-year, theory-based, multi-component HIV/STI prevention intervention Effectiveness established in an RCT	1-day cognitive behavioural HIV risk-reduction intervention	26 HIV prevention interventions including school-based education intervention with multiple sessions, group counselling for youth, and youth supervision programmes	8 HIV prevention interventions, including school-based education for two regions, sub-Saharan Africa and South East Asia
Intervention effect	*Compared with the initial risk assessment*: 60% fewer participants reported unprotected anal intercourse with recent partners 50% increase in the consistent use of condoms 4.5 months after the intervention	15% increase in condom use (52% in control group vs 67% in intervention group)	*Compared with the control group*: Intervention participants engaged in vaginal intercourse on fewer days (2.15 vs 5.48) With fewer partners (0.85 vs 1.79), Used condoms more frequently (4.35 vs 3.5)	*School-based intervention*: 15% increase in condom use (52% control group vs 67% in intervention group) Group counselling intervention (before vs after intervention): 1.05 vs 0.6 number of sexual partners; 24 vs 8 sexual encounters	*School-based intervention*: Reduction in condom non-use: 17% Reduction in non-treatment of STI: 18% Reduction in number of partners: 33% Increase in age of sexual debut: 0.1
Currency base	1994 US$	1994 US$	1997 US$	Year not stated US$	Year not stated US$

continued

TABLE 45 *Characteristics of economic evaluations of the prevention of STIs (continued)*

	Tao and Remafedi[94]	**Wang et *al.***[59]	**Pinkerton et *al.***[95]	**Cohen et *al.***[60]	**Hogan et *al.***[96]
Model type	HIV transmission model – projects HIV seroprevalence over a 10-year period 8 parameters including the number of risky partners, HIV prevalence and probability of HIV transmission	Previously developed Bernoulli model of HIV transmission adapted to translate the increase in condom use into cases of HIV and other STIs averted Model estimates the probability of HIV infection based on four variables: Number of sexual partners Number of sexual episodes with each partner HIV prevalence Probability of transmission	Existing Bernoulli model adapted to translate observed changes in sexual behaviour into number of HIV infections and future medical costs averted, and QALYs gained	Previously developed Bernoulli model adapted Model estimates probability of new infection with given sexual behaviours. Number of new HIV cases determined by size of the population, number of discordant partnerships and probability of transmission	Mathematical model of HIV/AIDS, adapted from the Goals model Model includes: Underlying demography Sexual mixing between defined risk groups Transmission of HIV infections Progression from HIV to AIDS and AIDS to death, and transmission of other STIs
Time horizon	10 years	1 year	1 year	1 year	10 years
Baseline HIV prevalence rate	0.02	0.001	0.006	0.002	Not reported
Single-act transmission probability	HIV: 0.06	HIV: 0.016 Chlamydia: 0.45 Gonorrhoea: 0.53	HIV: 0.0006–0.0014	HIV: 0.001	HIV: Male to female 0.0028 Female to male 0.001

studies, see *Table 46*). All estimated the cost-effectiveness of interventions to prevent HIV, but only one considered other STIs.[59] The studies varied in terms of the characteristics of the young people included. In terms of sexuality, one study included only young gay and bisexual men.[94] In terms of ethnicity/race, one study included African-American young people,[95] whilst another included sub-Saharan African and South East Asian young people.[96]

Four of the studies were conducted in the USA[59,60,94,95] and the remaining study was conducted in two regions: sub-Saharan African and South East Asia.[96] Three of the studies reported the cost-effectiveness of specific interventions that had previously been evaluated in a trial or cohort study.[59,94,95] The other two studies compared the cost-effectiveness of a range of interventions, including interventions for young people and adults.[60,96] The duration of the interventions varied from 1 day to 2 years. The interventions were associated with favourable changes in the number of partners, or frequency of condom use.

Pinkerton and colleagues[95] evaluated an RCT of an intensive one-day sexual risk-reduction intervention for African-American males. (Note: This trial, by Jemmott and colleagues, was included in our systematic review of effectiveness, see Chapter 4.[43]) The intervention was designed to increase knowledge of HIV/AIDS and reduce risky sexual behaviours and used videos, games, role plays and exercises to convey information. Participants in the control group attended a careers opportunities workshop. Wang and colleagues[59] evaluated a school-based education programme 'Safer Choices' (also included in our systematic review of effectiveness).[58] Tao and Remafedi[94] evaluated an intervention for gay or bisexual men, which included individual risk assessment and risk-reduction counselling, peer education and referral to further medical services as needed. The original study compared sexual behaviour 4.5 months after the intervention with that at the initial risk assessment.[97] Cohen and colleagues[60] evaluated a number of interventions for adults and young people. They evaluated school-based education,[58] group counselling for youth[98] and a youth supervision programme.[99]

All studies clearly defined the study question and explained the competing alternative. They each used the correct comparator and the patient group of interest was clearly stated. Furthermore, the study type appeared to be reasonable. All studies were conducted in the USA and so it is unclear how these studies relate to the UK NHS. The studies evaluated previous trials that had found the interventions to be effective. All studies estimated the cost-effectiveness of the intervention by considering the long-term discounted costs and consequences of HIV infection. Except for Hogan and colleagues,[96] all studies presented sensitivity analyses to discuss the impact of key parameters on model results.

It is unclear whether the studies valued the costs and consequences appropriately. Except for the Wang and colleagues study, the studies did not include the effect of the intervention on infection from other STIs or on unintended pregnancy, and this will underestimate the effect of the intervention. There are a range of assumptions and parameter values used. In particular, transmission probability has a large effect on the results and the values used by Tao and Remafedi[94] and Wang and colleagues[59] are much higher than the other studies. Finally, Wang and colleagues[59] have included the effects of reducing unintended pregnancy, but these results do not appear credible. Based on the results presented, the conclusions from three of the studies[59,95,96] appear credible.

Hogan and colleagues[96] evaluated several interventions in developing countries, including school-based education provided during regular lessons to all students. The effectiveness of this intervention was based upon an earlier review of the literature.[100]

Mathematical models were used to translate changes in sexual behaviour into the probability of HIV transmission. Four of the studies adapted a previously published model of HIV transmission (the 'Bernoulli' model[101]) to estimate the number of HIV infections averted in the subsequent year.[59,60,95,96] Tao and colleagues[94] developed a mathematical model to project the number of HIV infections averted over a 10-year period. All of the models predicted HIV cases averted following an intervention using parameters for number of sexual partners, number of sexual episodes, HIV prevalence and the probability of HIV transmission for an unprotected sexual episode. The sexual behaviour parameters were derived from evaluation of the interventions, for example an empirical study. The models incorporated the direct cost of the intervention, including staff training. The models differed in the way they dealt with medical and productivity costs. Three of the models included the medical costs for treating future HIV

infections.[59,94,95] Only one of the models included the loss in producti

vity costs.[59] Three of the models estimated the QALYs associated with averting an HIV infection.[94–96] The other two models estimated the cost per case of HIV averted.[59,60]

Estimation of outcomes within economic evaluations

Four of the studies used a model developed by Weinstein and colleagues.[101] The Bernoulli model of HIV transmission is a cumulative probability equation that describes the probability of HIV infection based upon HIV prevalence (π), single act transmission probability (α), condom effectiveness (e) and condom use (f), number of sexual episodes (n) and number of sexual partners (m). For example, the estimated probability of an uninfected person becoming infected is P,

$$P = 1 - \left\{ (1-\pi) + \pi \left| 1 - \alpha(1-ef) \right|^{n} \right\}^{m}$$

The model estimates the probability of becoming infected for the intervention and comparator groups according to changes in parameters that may be affected by the intervention, i.e. condom use, number of sexual partners and number of sexual episodes. The number of cases averted is estimated by multiplying the results by the number of people who receive the intervention.

Wang and colleagues[59] estimated the probability of infection during a 3-month period and then converted this 3-month probability into a 1-year probability. They used the following equation to calculate the total number of cases averted for primary transmission:

$$X = N\left[(1-P_i)^4 - (1-P_c)^4 \right]$$

where X is the total number of cases averted, N is the number of uninfected students, and P_i and P_c are the probability of infection for the intervention and control groups, respectively.

In addition, the number of secondary transmissions is estimated. Secondary transmissions are those transmissions from infected intervention students to non-infected sexual partners. In this case the probability of infection, P, is

$$P = 1 - \left| 1 - \alpha(1-ef) \right|^{n}$$

where α is single act transmission probability, e is condom effectiveness, f is frequency of condom use and n is number of sexual episodes.

Pinkerton and colleagues[95] used similar expressions to estimate the number of primary and secondary infections associated with anal intercourse. Cohen and colleagues[60] used this model to estimate the cost-effectiveness of a range of behavioural interventions. In addition to HIV infections, Wang and colleagues used the equations presented to estimate the cases of other STI infections avoided, i.e. chlamydia, gonorrhoea and pelvic inflammatory disease. They also developed a pregnancy model to translate contraceptive use into cases of pregnancy averted.

Hogan and colleagues[96] developed a mathematical model of HIV/AIDS, based on the Bernoulli model described above, combined with the progression from HIV to AIDS and AIDS to death and transmission of other STIs.

Tao and Remafedi[94] used a dynamic mathematical model to estimate the cost-effectiveness of HIV prevention for gay and bisexual young people. They modelled HIV transmission by calculating changes in the number of risky partners (i.e. unprotected) and then projected quarterly prevalence of HIV in the target population for a control and intervention population over 10 years. They assumed that without intervention, risky behaviour in the target population would not change during the 10-year period. Participants maintained less risky behaviour for only 1 year before relapsing to the previous level of risk. The target population was classified by participants, non-participants, infected and uninfected subgroups. The model calculated HIV prevalence after 10 years and used parameters for the number of risky partners, initial HIV prevalence, the probability of HIV transmission in each infected–uninfected partnership, and the percentage of gay and bisexual adolescents recruited into the intervention.

The studies used a range of values for the input parameters. HIV prevalence rates varied between 0.1% and 0.6% for US heterosexual adolescents, and 2% for gay and bisexual adolescents in the USA. The probability of transmission of HIV varied between 0.1% to 1.6% for US heterosexual adolescents and 6% for gay and bisexual adolescents. The increase in condom use varied between 11% and 24% for heterosexual adolescents, with a 50% increase in gay and

bisexual individuals. Wang and colleagues[59] did not report any change in the number of sexual partners and episodes, whilst Pinkerton and colleagues[95] found intervention participants engaged in vaginal intercourse on less than half the number of days and with half the number of partners.

Estimation of quality-adjusted life-years

Tao and Remafedi[94] and Pinkerton and colleagues[95] estimated that 16.9 QALYs and 14 QALYs, respectively, would be lost by an HIV-infected young person based on previous work by Holtgrave and colleagues.[102] These estimates were based upon the person receiving standard HIV-related medical treatment (including antiretroviral treatment). Hogan and colleagues[96] used a life expectancy estimate of between 8.5 and 16 years with HIV for males, depending on whether or not they received treatment.

Estimation of costs

Each of the studies estimated the intervention costs, including staff training, renting space, condoms, administration and monetary incentives for the participants. Wang and colleagues estimated costs of US$26 per participant, Pinkerton and their colleagues £89. Tao and Remafedi[94] reported much higher costs of over US$440 per participant. The costs for the group counselling and youth supervision programmes in the study by Cohen and colleagues[60] were US$300 and US$57 per participant, respectively. Hogan and colleagues[96] reported annual costs of school-based education from US$58M to US$77M for 50–95% coverage in the sub-Saharan Africa region. The differences in the costs were mainly due to staffing costs. For example, Tao and Remafedi[94] employed several staff, including a full-time case manager, two directors, a secretary and field worker at a total cost of US$184,006, in order to provide an intervention for about 500 participants. On the other hand, Wang and colleagues included costs for only teaching, teacher training and site co-ordination costs at a total cost of US$85,599 for almost 4000 participants.

Three of the studies included the cost of future medical care for HIV in the cost-effectiveness analyses. Wang and colleagues[59] and Pinkerton and colleagues[95] applied discount rates of 5% and 3%, respectively, to estimate the cost of medical care based on a previous study by Holtgrave and colleagues. The cost used for future medical HIV care varied between US$78,425 and US$195,188 per person with HIV. Wang and colleagues[59] also estimated the medical costs for chlamydia and gonorrhoea treatments, based upon costs from the public sector analysis from the California Medicaid Program. Wang and colleagues estimated the social cost of HIV infection in terms of lost productivity or foregone wages of US$430,000 per patient. It included the costs of earning-related outcomes, public assistance and other consequences.

Comparison of results

The base-case results of the cost-effectiveness studies are presented in *Table 46*. A comparison of the studies shows a wide range of cost-effectiveness estimates depending upon the assumptions and parameter values used. For example, Cohen and colleagues[60] found one of the interventions ('Safer Choices') to be not cost-effective, with a cost per case averted > US$39M. In contrast, Wang and colleagues[59] found the same intervention to be cost saving. Wang and colleagues included the effect of other STIs and unintended pregnancy. In particular, unintended pregnancy had a large effect on the results, with the medical and social costs for pregnancy comprising over half the total averted costs. However, the effects of the intervention in preventing pregnancy appear to have been overestimated. They estimated that 18.5 pregnancies were prevented in 345 ninth-grade students (aged 14–15), but this is likely to be higher than the conception rate in this age group. The under-16 conception rate for England in 2005 was 7.7 per 1000 girls aged 13–15. Furthermore, there were differences between the studies for the values for the probability of HIV transmission from 0.001 to 0.016.

Several of the studies conducted sensitivity analyses on the main model parameters. The most influential parameters were found to be baseline HIV prevalence, baseline number of risky partners, cost per person reached by the intervention, duration of the effect of the intervention and the single sex act transmission rate.

Published economic evaluations – summary of methods

A systematic review of cost-effectiveness studies identified five economic evaluations of behavioural interventions for prevention of HIV, published between 1998 and 2005. Only one study evaluated other STIs in addition to HIV. All studies used mathematical models extrapolating the changes

TABLE 46 *Base-case results and conclusions of the cost-effectiveness studies*

Author	Tao and Remafedi[94]	Wang *et al.*[59]	Pinkerton *et al.*[95]	Cohen *et al.*[60]	Hogan *et al.*[96]
Base-case results	16.9 QALYs saved per HIV infection averted Total intervention costs including medical treatment were US$1.1M for 10 years ICER was projected to US$6180 per QALY saved	0.12 cases of HIV, 24.37 cases of chlamydia, 2.77 cases of gonorrhoea, 5.86 cases of PID and 18.5 pregnancies prevented Intervention was cost saving, with US$2.65 saved for every dollar spent on the programme	0.8 of an infection averted and saved 0.1 QALY at cost of US$7548 Averted US$1478 in future medical care Cost–utility ratio was US$57,000 per QALY saved when training costs included and US$41,000 per QALY saved when they were excluded	*Cases HIV prevented*: School-based education 0.0027; group counselling for youth 0.0044; youth supervision programme 0.0023 *Cost per person (US$)*: School-based education US$305 Group counselling for youth US$300 Youth supervision programme US$57 *Cost per HIV case averted (US$)*: School-based education US$39M Group counselling for youth US$15M Youth supervision programme US$6.2M	*For African region*: Yearly infections averted (millions) 0.01 Yearly costs (US$ millions) 58 at 50% coverage Cost-effectiveness ratio of US$530 per DALY averted
Author's conclusions	The intervention was cost-effective even though the effects on behaviour were partial and short term	School-based prevention programmes should be considered by policy-makers	The authors suggest selectively implementing the intervention in high-risk HIV prevalence communities	Comparing estimates of the cost-effectiveness of HIV interventions provides insight that can help local communities maximise the impact of their HIV prevention resources	School-based education is cost-effective according to international benchmarks

DALY, disability-adjusted life-year; ICER, incremental cost-effectiveness ratio.

in sexual behaviour to number of cases of HIV averted. With the exception of one study for developing countries, all studies evaluated the interventions on a US population. All interventions were effective at encouraging safer sexual behaviour and were estimated to avert cases of HIV transmission through modelling. There was a range in assumptions and parameter values used in the mathematical models, and this led to substantial differences in the estimated cost-effectiveness of the behavioural interventions. Therefore, no existing model was appropriate for this study and so we developed a de novo model.

Chapter 7
Economic evaluation

An economic model was developed to assess the cost-effectiveness of behavioural interventions. The following subsections outline the components of this economic evaluation, including the structure of the economic model, the sources of information for costs and benefits, and results of the analysis.

Selecting a model type

There has been much debate in the literature on the most appropriate types of economic model to assess the cost-effectiveness of interventions to prevent STIs, particularly chlamydia screening.[103] In this section, we discuss the advantages and disadvantages of the different types of model.

A review of guidelines for good practice in decision-analytic modelling in health technology[104] concluded that 'Most experts agree that a model should be as simple as possible to address adequately the decision problem' (p. 10). Barton and colleagues[105] and Cooper and colleagues[106] provide overviews of the reasons for selecting between the different modelling techniques. They advocate the use of decision trees and Markov chains where possible, and recommend that discrete event simulation (DES) be used if the interaction between individuals or between individuals and the environment is important. DES is a powerful technique for modelling complex and dynamic systems.[107,108] It can describe interactions when, for example, the use of resources is dependent on decisions about individuals or interaction between individuals or when comparing different queuing systems or identifying bottlenecks in a system.[106,108] However, DES models often require more data than other models and are more computationally complex.

Static versus dynamic modelling

In the epidemiology of infectious diseases, the force of infection is the rate at which susceptible individuals become infected. Vaccination against infectious disease not only reduces the incidence of disease in those immunised, but also indirectly protects non-immunised susceptible people,[109] a concept known as herd immunity. Static models assume a constant force of infection and cannot take into account reinfection. On the other hand, dynamic models are able to capture herd immunity effects.

Barham and colleagues[26] systematically reviewed and critically appraised the economic evaluation of one-to-one interventions to reduce STIs and teenage conceptions. The review was conducted to underpin NICE's guidance in this area.[22] The majority of studies examined the cost-effectiveness of chlamydia and HIV screening programmes in various settings. There were fewer published studies of other STIs, and of behavioural interventions. The vast majority of studies used static modelling techniques. However, three studies (out of 55) employed dynamic approaches for the cost-effectiveness of chlamydia screening.

Welte and colleagues[110] compared a dynamic (stochastic network simulation model) with a static (decision–analysis) model for evaluating an opportunistic screening programme for chlamydia. The dynamic model required much more detailed data about sexual behaviour and the infectious disease than the static model, such as duration of partnerships, frequency of sexual intercourse in partnerships and transmission probability per sexual episode. It produced results that were more favourable in terms of cost-effectiveness than the static model.

Welte and colleagues[110] suggest that dynamic, rather than static, models are appropriate for the economic evaluation of chlamydia screening programmes that might affect the force of infection. They state that static models have frequently been applied in the past, and these did not include the risk of reinfection resulting from failed partner referral (*Table 47*). The only reasons against using the dynamic approach were its higher complexity, data demand, time and monetary costs and need of mathematical modelling expertise. On the other hand, static models might be the preferred option for estimating the cost-effectiveness of screening programmes that have no impact on the force of infection.

TABLE 47 *Advantages and disadvantages of dynamic versus static modelling for* Chlamydia trachomatis *prevention (from Welte and colleagues[110])*

	Dynamic model	Static model
Advantages	Takes the infectious character of chlamydia appropriately into consideration Includes the effect of screening on the force of infection Enables the full inclusion of indirect protection effects Enables the assessment of the optimal screening duration and target group	Requires fewer data Can be built quickly at low cost Easy to understand
Disadvantages	Requires detailed data about sexual behaviour that are often not available Very time consuming to build and thus more expensive Rather complex and thus more difficult to understand	Limited consideration of the infectious character of chlamydia Assumes constant force of infection Indirect protection effects are very limited May render incorrect results with respect to optimal screening duration and target group
Recommended uses	Prevention measures that have an impact on the chlamydia incidence in the population, such as large-scale screening programmes	Prevention measures that have no impact on the chlamydia incidence in the population

Kretzschmar and colleagues[111] developed a stochastic simulation model for chlamydia screening in the Netherlands. They made several assumptions to derive data for the model and had limited knowledge about disease-specific parameters, such as the probability of transmission per sexual episode, the average duration of the infectious period, and the fraction of asymptomatically infected persons. They suggested that their results should be interpreted mainly in a qualitative sense and not too much importance should be attached to the absolute numbers due to the uncertainties in parameter values.

Roberts and colleagues,[103] funded by the NIHR HTA programme, reviewed economic evaluations of various forms of chlamydia screening. They found that the majority of studies, all since 2000, had used static models. They suggested that this reflects the view that the simplicity of static models outweighs the limitations of violating the assumption of independence. They recommended the use of either DES or system dynamics models which provide more realistic representations of complex systems. These models 'can take into account the full economic consequences of interpersonal interactions' (p. 198). These interactions mean that the risk of infection depends upon the background STI prevalence, and that screened and treated individuals will not transmit infection but are susceptible to re-infection. Screened partners that remain untreated can also continue to transmit infection.

Turner and colleagues[112] developed a stochastic, individual-based network model to evaluate the effectiveness of opportunistic chlamydia screening ('The National Chlamydia Screening Programme'). They chose to use an individual-based dynamic model because population-based models 'fail to capture important individual level effects in the sexual network. For example, reinfection is dependent on the infection and treatment status of current partners, not the average level of infection in the community' (p. 4). For many of the model parameters the values were highly variable, the parameters of interest could not be measured directly or few data were available at all. They estimated some of these parameters by fitting the model to data. Several parameters were unknown: the proportion of individuals desiring short partnerships, the proportion of individuals changing from wanting short partnerships to long partnerships each year, the average duration of long partnerships, the annual increase in preferred partnership duration and the average gap between partnerships. Other parameters that were subject to high uncertainty were duration of chlamydial infection and transmission probability, the proportion seeking treatment and the level of partner notification.

Low and colleagues[25] developed a dynamic model to estimate the cost-effectiveness of active population screening for chlamydia. The model took into account the effects of ageing and replacement (i.e. new young people entering the model), partnership formation and dissolution, chlamydia transmission and progression, testing and treatment, and the complications from chlamydia. The authors stated there were no data available on the activity groups to estimate the propensity to form new partnerships and the mixing between activity groups. Instead of direct incorporation of data as input parameters, it was necessary to adjust the input parameters until a reasonable fit to the available data were obtained.

The two models developed for chlamydia screening provided very different estimations of cost-effectiveness, even though both used similar modelling methods (£1350[112] versus £26,000[25] per major outcome avoided). The differences between these models were due to differences in assumptions and data values, and these differences far exceed the difference shown comparing the results from static and dynamic models (Welte and colleagues[110]).

Discussion and key points

Modelling guidelines suggest that DES is suitable for modelling disease process when interaction between individuals is important. However, almost all previously published studies have used a static approach. Dynamic models are considerably more complicated, time consuming and require more data, which is often not available. Much of the discussion on type of modelling has focused upon chlamydia screening, as opposed to primary prevention, and even in these studies there were few data for key model parameters. The additional time, expense, and complexity involved in dynamic modelling may not actually provide a gain in precision.

In view of these points, and the lack of impact of school-based behavioural interventions on sexual behaviour (and therefore the low probability of altering rates of infection) demonstrated in our systematic review, we chose to construct a static economic model to explore the potential cost-effectiveness of behavioural interventions under various assumptions.

Methods for cost-effectiveness modelling of behavioural interventions for prevention of STIs in young people

Overview

A comparison of the costs and benefits of behavioural interventions for the prevention of STIs in young people was made using decision-analytic models.

The cost-effectiveness of two types of school-based behavioural intervention were assessed:

1. A teacher-led curriculum, spread over 20 sessions (based on the Scottish SHARE trial[70]).
2. A brief peer-led classroom curriculum, spread over three sessions (based on the RIPPLE trial in Central and Southern England[50]).

Both interventions provide factual information about STIs in addition to the teaching of skills associated with the practice of safer sex. These two interventions were considered to be broadly representative of the interventions included in our systematic review. However, they were prioritised for economic modelling because, in terms of costs and resources, they were considered to be more reflective of UK practice than many of the other (mostly US) studies in our review. This is particularly the case for the SHARE programme, which has been implemented by NHS Health Scotland.

The comparator was standard sexual health education, which is generally provided by teachers in schools as part of the PSHE curriculum. In the studies included in our systematic review of effectiveness (Chapter 4), standard sexual health education tended to provide basic information on STIs and sexual health, but did not teach skills. It is therefore the teaching of safer sex skills and other broader activities that distinguishes between the behavioural intervention and standard education.

Models were constructed in Microsoft EXCEL according to standard modelling methods (NICE[113]). To identify data to populate the model, systematic searches were conducted to locate studies on the natural history and epidemiology of STIs, sexual behaviour and lifestyles, HRQoL, and costs. Various websites of relevant organisations

were also searched (e.g. HPA) and contact made with experts to identify data.

The quality of data used for the model varied. Generally, there were few data for children aged under 18 years old, and, where there were no data, assumptions were made from existing data. The baseline clinical data were estimated from administrative databases for the UK, and prospective studies. The HRQoL data have been taken from previous utility studies using validated tools for groups of patients with the condition of interest.

Costs were derived from published studies (where available), and from national and local NHS unit costs. Only direct NHS and PSS costs were included and hence the model was from the perspective of the NHS and PSS.

In the model, the intervention effects last for 1 year, on the basis that the majority of the trials included in our systematic review assessed outcomes up to 1 year (see Chapter 4, Length of follow-up). The model estimates the lifelong costs and benefits from averted STI cases. The intervention effect (condom use) was derived from the systematic review of effectiveness reported in Chapter 4. The economic evaluation focused on estimating the number of cases of STI and associated complications averted. The outcome is reported as cost per QALY gained.

Model structure

We adapted the Bernoulli model, previously developed by Weinstein and colleagues,[101] as it estimates the effect of changes in sexual behaviour in terms of STIs averted. This model has been described earlier in Chapter 6 (see Results). The Bernoulli model of HIV transmission is a cumulative probability equation that describes the probability of HIV infection based upon HIV prevalence (π), single act transmission probability (α), condom effectiveness (e) and condom use (f), number of sexual episodes (n), and number of sexual partners (m). The equation described in Chapter 6 is an approximation to the original equation, but this approximation is only close when the proportion of condom use is either very low or extremely high, or when the infectivity is minimal ($\alpha < 0.001$). Consequently, that equation is not appropriate for chlamydia, gonorrhoea and genital warts. For this reason we split the equation for condom users (c) and non-condom users (nc) so that, the estimated probability of an uninfected person becoming infected is $P = fP_c + (1-f)P_{nc}$, where risk for a condom user P_c is:

$$P_c = 1 - \left\{(1-\pi) + \pi \,|\, 1 - \alpha(1-e)\,|^n\right\}^m$$

and risk for a non-condom user, P_{nc} is,

$$P_{nc} = 1 - \left\{(1-\pi) + \pi \,|\, 1 - \alpha\,|^n\right\}^m$$

The model estimates the probability of becoming infected for the intervention and comparator groups according to changes in parameters that may be affected by the intervention, i.e. condom use, number of sexual partners and number of sexual episodes. The number of cases averted is estimated by multiplying by the number of people who receive the intervention.

These cases averted, in turn, would have infected further individuals, i.e. through secondary transmission. The estimated probability of an uninfected person becoming infected is $P = fP_c + (1-f)P_{nc}$, where risk for a condom user P_c is,

$$P_c = m(1-\pi)\,|\,1 - (1 - \alpha(1-e)\,|^n)$$

and risk for a non-condom user, P_{nc} is,

$$P_{nc} = m(1-\pi)\,|\,1 - (1 - \alpha)\,|^n)$$

The number of cases averted through secondary transmission is estimated by multiplying the risk of becoming infected by the number of cases averted through primary transmission.

The model estimates the number of STI cases averted for HIV and also for chlamydia, gonorrhoea and genital warts, according to the risk of infection as shown above and the proportion of sexually active individuals who receive the intervention. For each STI case averted there was a HRQoL loss and resource use cost associated due to complications, such as PID or infertility. The data and assumptions used to derive the model parameters are described in the following sections.

The total number of STI cases averted, and consequent QALY gain, cost of the intervention and the saving in medical costs is estimated for males and females for all STIs for 1 year. Thus the cost-effectiveness is calculated,

$$\text{Cost-effectiveness} = \frac{\left(\begin{array}{c}\text{Cost of}\\ \text{intervention}\end{array} - \begin{array}{c}\text{Saving in}\\ \text{medical costs}\end{array}\right)}{\text{QALYs gained}}$$

The cost-effectiveness results are shown later (see Results of the modelling, below). For the base-case analysis, a cohort of children aged 15 years old receive the teacher-led intervention.

Assessment of uncertainty

The evaluation of the cost-effectiveness of behavioural interventions for preventing STIs is based on uncertain information about variables, such as clinical effect, HRQoL and resource use. This uncertainty was evaluated using deterministic and probabilistic sensitivity analyses. One-way deterministic sensitivity analyses were conducted to evaluate the influence of individual parameters on the model results and test the robustness of the cost-effectiveness results to variations in the structural assumptions and parameter inputs (see Sensitivity analysis).

Multiparameter uncertainty in the model was addressed using probabilistic sensitivity analysis (PSA) (see Probabilistic sensitivity analysis).[114] In PSA, probability distributions are assigned to the point estimates used in the base-case analysis. The model is run for a number of iterations (in this case 1000) according to a different set of parameter values, using Monte Carlo simulation methods, to give a range of results. The main parameters were varied according to the ranges used in the one-way deterministic sensitivity analysis. For each iteration, parameter values are sampled at random from their probability distributions. The uncertainty surrounding the cost-effectiveness of the behavioural intervention is represented on a cost-effectiveness acceptability curve (CEAC) according to the probability that the intervention will be cost-effective at a particular willingness-to-pay threshold. Appendix 11 reports the parameters included in the PSA, the form of distribution used for sampling each parameter, and the upper and lower limits assumed for each variable.

Finally, value of information analyses were conducted to investigate the expected pay-off from further research (see Expected value of perfect information for the prevention of STIs).[114,115] When decisions are based on imperfect or uncertain information, there is a risk that a wrong decision will be made and there will be a loss in costs and health benefits. The expected value of perfect information (EVPI) shows the value of reducing the uncertainty around the decision of whether or not to adopt the intervention. The EVPI is estimated for different cost-effectiveness thresholds and this gives an indication of an upper bound for further research at these thresholds. In order to determine where further research would have the most effect in reducing uncertainty, a partial EVPI (EVPPI) is conducted. In this analysis, the uncertainty around particular input parameters in the model is investigated.

Data synthesis

STI epidemiology

STI incidence rate

Table 48 shows the incidence rates for young people in GUM clinics in the UK in 2006. The diagnosis rates of STIs are likely to be an underestimation of the true rate of infection incidence, given that for many infections, such as chlamydia and HIV, a proportion of asymptomatic infections remain undiagnosed. In addition, not all young adults are diagnosed in the GUM clinic setting. Furthermore, we are interested in the prevalence of each of these conditions.

We decided that it was not realistic to include syphilis or genital herpes in the model. This is due to their relatively lower incidence, and the paucity of data on their epidemiology and natural history, particularly long-term complications. Few other economic evaluations have attempted to model the effectiveness of preventing these STIs.

Chlamydia

Chlamydia is the most commonly diagnosed bacterial STI in UK GUM clinics, constituting 30% of all new STI diagnoses in 2006. At least 70% of women and 50% of men with chlamydia infections show no symptoms and may remain undiagnosed

TABLE 48 *STI incidence from HPA GUM diagnoses in the UK per 100,000 population in 2006*[116]

	Chlamydia		Gonorrhoea		Genital warts	
Age (years)	Male	Female	Male	Female	Male	Female
< 16	13.1	121	2.5	15.5	8.2	54.8
16–19	544	1337	100.6	127.6	296.8	787.4

in the absence of screening for asymptomatic infection.[8]

The Department of Health in England has commenced the NCSP, which opportunistically screens for chlamydia in sexually active young men and women attending a range of health-care services, including general practice and family planning clinics, regardless of whether they have symptoms.[117] The prevalence of chlamydia in England in 2003–4 was 10.0% and 12.1% among men and women aged 16–19 years old, and 1.5% and 7.5% among men and women less than 16 years old, respectively[117] (*Table 49*).

The Uppsala Women's Cohort study[118] analysed data from 43,715 women in Uppsala, Sweden, aged 15–24 years. It was estimated that the cumulative incidence of chlamydia-associated complications by age 35 for those women who tested positive for chlamydia would be 5.6%, 2.7% and 6.7% for PID, ectopic pregnancy and infertility, respectively (*Table 50*). The authors noted that estimates from this study were lower than found in previous hospital- and clinic-based studies.

We used an estimate, from Ness and colleagues,[119] that 34% of women with PID had long-term chronic pelvic pain. Trei and colleagues[120] estimated the incidence of orchitis/epididymitis, prostatitis, infertility and urethral stricture among male US Air Force officers with and without prior chlamydia infections. Among chlamydia-positive men, the cumulative incidence of orchitis/epididymitis was 4.28%.

The data for transmission probability was generally of poor quality, based upon old case series. The transmission probability of chlamydia has been estimated to range from 0.0375[112] to 0.45[59] per sex episode, and from 0.2[122] to 0.68[123,124] per sexual relationship. Quinn and colleagues[124] determined the frequency of *Chlamydia trachomatis* genital infection within sexual partnerships using highly sensitive polymerase chain reaction (PCR) amplification. In a 4-year period, 494 sexual couples were enrolled. Participants were predominantly young African-Americans. In the 78 couples that included female partners who tested positive for chlamydia by PCR, 53 male sexual partners (68%) also tested positive by PCR. In the 76 couples with male partners who tested positive by PCR, 53 female sexual partners (70%) also tested positive by PCR.

We assumed that the transmission probability per relationship was 68% (*Table 51*). In a similar way to Low and colleagues[25] and Turner and colleagues,[112] we estimated the per-episode transmission probability to be 0.11, based on assuming that the infection would be transmitted within 10 sexual episodes per relationship (n), i.e. $1-(1-tp)^{1/n}$.

TABLE 49 *Prevalence of STIs (%)*

	< 16 years old		> 16 years old		
	Male	**Female**	**Male**	**Female**	**Source**
Chlamydia	1.5	7.5	10	12.5	NCSP[117]
Gonorrhoea[a]	0.03	0.16	1.25	1.3	NCSP South London[121]
Genital warts[a]	0.1	0.65	0.53	1.4	HPA[116]
HIV[a]	0.13	0.06	0.26	0.12	HPA[8]

a Figures have been adjusted to be representative of the UK from original sources as discussed in the following subsections.

TABLE 50 *Cumulative incidence of complications for chlamydia and gonorrhoea[118]*

	Cumulative incidence (%)	**Source**
PID	3.7	Low *et al.*[118], Ness *et al.*[119]
Chronic pelvic pain	1.9	Ness *et al.*[119]
Ectopic pregnancy	2.7	Low *et al.*[118]
Tubal infertility	6.7	Low *et al.*[118]
Epididymitis	4.3	Trei *et al.*[120]

TABLE 51 *STI transmission probabilities between discordant heterosexual couples*

	Per relationship	Per sex act	Source
Chlamydia	0.68	0.11	Quinn *et al.*[124]
Gonorrhoea	0.5	0.07	Rothenberg *et al.* [125]
Genital warts	0.65	0.1	HPA[126]
HIV		0.0015	Fisher *et al.*[127]

Gonorrhoea

Gonorrhoea is the second most common bacterial STI in the UK, and the majority of diagnoses are made in GUM clinics. In 2006, rates of diagnosis in GUM clinics were highest among women aged 16–19 years and men aged 20–24 years, and rates of diagnosis were highest in London.

The prevalence of gonococcal infection in young people was estimated for south-east London as part of the NCSP.[121] The tests were conducted for screening, diagnosis or through contacts with people with chlamydia or gonorrhoea. In the screened group the prevalence of gonococcal infection for male and females was 3% and 3.2%, respectively. The prevalence in London was 2.4 times higher than for the rest of the UK. We adjusted this prevalence, for the rest of the UK, for the 16– to 19-year-old age group. The adjusted prevalence was 1.25% and 1.3% for males and females, respectively (*Table 49*). In order to estimate the prevalence within the younger age group, we assumed the same relationship between age groups in the incident data reported in *Table 48*, i.e. the prevalence for UK for < 16-year-olds of 0.03% and 0.16% for males and females, respectively. As there were no available data, we assumed that the complication rate from gonorrhoea cases was the same as for chlamydia. We assumed that the transmission probability per relationship for gonorrhoea was 50% (*Table 50*).[122,125] We estimated the per-episode transmission probability to be 0.07, based on 10 sexual episodes per relationship in the same way as for chlamydia.

Genital warts

Genital warts are the most commonly diagnosed viral STI in GUM clinics.[8] If successfully treated, an individual's infection goes into remission, but may recur at a later date. Genital warts can be difficult to treat, and patients may experience frequent recurrent episodes. Genital warts are caused by HPV and 90% of cases of genital warts are attributable to HPV 6 and HPV 11.[126] HPV infection is the primary cause of cervical cancer, with the majority of cases attributable to HPV 16 and 18.

The majority of infections are acquired through heterosexual sex and the highest rates are among young people.[8] A study of antibodies to four types of HPV infection (HPV 16, HPV 18, HPV 6 and HPV 11) showed that the proportion of females who have been infected by HPV increases rapidly from 14 to 24 years of age.[16] The prevalence of HPV 6 and HPV 11 was 6.5% and 14% for females aged < 16 and 16 – 19 years, respectively. The prevalence of HPV 16 and HPV 18 was similar. About 10% of HPV infections develop genital warts[8] so we assumed that the prevalence of genital warts was one-tenth the prevalence of HPV 6 and HPV 11. The prevalence for males was estimated from female prevalence by using the same relationship between males and females as seen for incidence. Thus the prevalence was 0.1% and 0.53% for males aged > 16 years old and < 16 years old, respectively. As reported in a study of HPV epidemiology,[126] we assumed that the transmission probability per relationship for genital warts was 65%. We estimated the per-episode transmission probability to be 0.1, in the same way as for chlamydia, based on 10 sexual episodes per relationship.

HIV

HIV is a viral infection that is managed with lifelong antiretroviral treatment. There were estimated to be 73,000 people of all ages in the UK living with HIV in 2006.[8] The number of deaths among HIV-infected people has fallen from 749 in 1997 to 497 in 2006.[8] There were 167 men and 76 women living with HIV per 100,000 population in 2006. The prevalence of diagnosed HIV infection in 2006 was highest among London residents.[8] Based on the number of adults between the ages of 15 and 59 years old in the UK, we estimated the average HIV prevalence in the 16- to 19-year-old age group for men and women to be 0.26% and 0.12%, respectively. There are no data on prevalence of HIV for adolescents; we assumed

prevalence for the > 16-year-old age group to be half that of adult prevalence, as suggested by Wang and colleagues,[59] i.e. 0.13% for young men and 0.06% for young women.

Fisher and colleagues[127] developed the British Association for Sexual Health and HIV guidelines for post-exposure prophylaxis after sexual exposure to HIV. They undertook a literature review and reported the risk of HIV transmission following an exposure from a known HIV-positive individual to be 0.1% for vaginal intercourse. The probability of transmission increases to about 0.5%.[128,129] in the acute phase of the infection (days 20–54) when viral load levels are high. We combined these data to estimate a mean transmission probability over 1 year. Based on these studies, we assumed a mean transmission probability of 0.15% per sexual episode.

Sexual behaviour

Number of sexual partners per individual

The number of sexual partners that young people have has been estimated by the UK Office for National Statistics (ONS) Omnibus Survey.[130] The Omnibus Survey is a multipurpose survey with approximately 1200 adults (aged 16 or over) in private households in the UK each month. It reported the number of sexual partners for young people in the previous year (aged 16–19 years). We used a weighted average to estimate the mean number of partners for sexually active individuals for 1 year to be 2.1 for males and 2.0 for females for 16- to 19-year-olds, and assumed that those < 16 years old (i.e. aged 13–15 years old) would have a similar number of partners (*Table 52*).

Frequency of condom use for adolescents

According to the Omnibus Survey, 91% of young men and 79% of young women aged 16–19 years used a condom in the previous year.[130] The use of condoms was related to the number of sexual partners in the previous year. Among men aged 16–69, 85% of those who had multiple partners had used a condom in the past year compared with 36% of those who had a single partner. There was a similar variation for women – 77% of those with multiple partners used a condom compared with 45% of those with just one partner.

The Health Behaviour in School-aged Children survey[131] was a cross-national study conducted in collaboration with the World Health Organization. Thirty-five countries drew national samples of 11-, 13- and 15-year-olds, with approximately 1500 respondents in each age group for each country. In England, 69.1% of 15-year-old boys and 70.9% of 15-year-old girls reported using condoms the last time they had sexual intercourse (*Table 52*).

Number of episodes of sex

The UK NATSAL reported that the number of occasions of heterosexual sex (vaginal, oral or anal sex) in the past 4 weeks for 16- to 24-year-olds, among respondents who had one or more heterosexual partners in the year prior to interview, was 6.9 (SD = 9.1).[132] The Canadian Youth, Sexual Health and HIV/AIDS Study was undertaken to increase understanding of the factors that contribute to the sexual health of Canadian youth.[133] They questioned grade 9 and 11 (14- to 17-year-olds) sexually active teenagers on their sexual activity. In sexually active males in grade 11, 19% reported having had sexual intercourse once, 33% 'a few times' and 48% 'often'. We assumed lower sexual activity for the < 16-year-old age group and that it would be one-quarter of the rate seen in the 16- to 24-year-old group, i.e. 1.7 episodes per month (*Table 52*), based on clinical advice.

Sexual experience

According to a YouGov survey, commissioned for UK Channel 4 Television, 40% of all 14- to 17-year-olds are sexually active, one in three 15-year-olds is sexually active, nearly one-quarter of all 14-year-olds have had a sexual experience, and 20% of those surveyed had their first sexual experience at 13 or under.[134] The Adolescent Lifestyle Survey (ALS) provides a major benchmark of lifestyles and behaviours amongst 11- to 14-year-olds ($n = 3390$) in north-east Lincolnshire. By the age of 14 years, 35% of girls and 30% of boys were sexually active. Amongst the sexually active young people just over one-half reported using a condom, 25% reported using a condom some of the time and 16% never using a condom.[135] In the Health Behaviour in School-aged Children (HBSC) survey[131] in England, 35.7% of 15-year-old boys and 40.4% of 15-year-old girls reported ever having sexual intercourse (*Table 52*).

Condom effectiveness

Pinkerton and colleagues[136] estimated the effectiveness of condoms in reducing heterosexual HIV transmission to be 90%. A Cochrane systematic review by Weller and colleagues[137] estimated that consistent use of condoms results in an 80% reduction in HIV incidence. They noted

TABLE 52 *Sexual behaviour*

	Male	Female	Source
Sexually active (%)	35.7	40.4	HBSC[131]
Sexual episodes per month	1.7	1.7	Assumption
Sexual partners per year	2.1	2	ONS Omnibus Survey[130]
Condom use at last intercourse (%)	69	71	HBSC[131]

HBSC, Health Behaviour in School-aged Children survey; ONS, UK Office for National Statistics.

there was insufficient evidence to estimate the effectiveness of condoms in preventing other STIs. In 1 year, only two of every 100 couples who use condoms consistently and correctly will experience an unintended pregnancy.[138]

Fewer studies have estimated the effectiveness of condoms for preventing other STIs and effectiveness estimates vary widely.[139] In a systematic review the protective effect for chlamydia ranged from 10% to 90%, and for gonorrhoea ranged from 13% to 100%.[140] The authors reported that studies that were limited to individuals with known STI exposure were likely to estimate the protective effect of condom use more accurately. Niccolai and colleagues[141] estimated the effectiveness of condoms for the prevention of chlamydia among people who were exposed to the infection and found that consistent condom use was significantly associated with a 90% reduction in the prevalence of chlamydia. A longitudinal study by Winer and colleagues[142] suggested that consistent use of male condoms reduced the risk of genital HPV transmission by 70% in males and 50% in females. We assumed that condom effectiveness was 80% for HIV, 90% for chlamydia and gonorrhoea, and 70% for HPV.

Sexual mixing

According to the Chlamydia Screening Studies (CLaSS) prevalence study,[25] young men aged 16–19 years old, were 0.8 years older than their partners, whilst girls were 2.4 years younger than their partners. Therefore, we assumed that boys under the age of 16 would have partners also under the age of 16. On the other hand, girls under the age of 16 would have partners over the age of 16.

Pregnancy

Low and colleagues[25] estimated age-related pregnancy risk, defined per episode of unprotected intercourse, assumed to take into account variation in both fertility and use of non-barrier contraception. Risk of pregnancy was 0.00035 per day for women aged 17.5 years.

Health-related quality of life

Health-related quality of life utilities could have important implications on the cost-effectiveness of intervention to prevent STIs. Our review found many studies that estimated the HRQoL for HIV, but few studies have done so for the other STIs. We found only two studies that reported utilities for health states associated with PID. There were several studies for HPV, but these often reported values for health states not relevant to this study, for example cervical intraepithelial neoplasia grades 2 and 3.

Tengs and Lin[143] performed a meta-analysis to derive pooled utilities for HIV from 25 articles reporting 74 unique utility values from 1956 respondents. Pooling utilities, the authors estimate a utility of 0.7 for AIDS, 0.82 for symptomatic HIV, and 0.94 for asymptomatic HIV when the time trade-off method is used.

Smith and Tsevat[144] obtained health-state valuation from 56 women with and without PID history, using visual analogue scale and time trade-off methods. They assumed that PID was an acute condition with pain for about 7 days, and that ectopic pregnancy was a short-term state, with a possibility of long-term consequences. Infertility and chronic pelvic pain were assumed to be long-term health states. The definitions for each of the complications used in the analysis are shown in *Table 53*.

Hu and colleagues[145] estimated the cost-effectiveness of screening for chlamydia in the USA. They estimated the quality of life and duration of complications as shown in *Table 54*. Hu and colleagues assumed a quality disutility loss until age 50 years for infertility. We used the assumptions stated earlier for unit costs of

TABLE 53 *Definitions of STI complications[144] for a 25-year-old woman*

Complication	Definition of complication
Symptomatic acute PID	Woman does not require hospital stay; she has pain for about 7 days, with the pain mainly in the lower abdomen
Chronic pelvic pain	Woman has continuing pain in her lower abdomen and pelvic area; she is limited in moderate activities and has little energy and has low mood; the pain may slowly go away as time goes on but could also stay the same
Ectopic pregnancy	Woman has pregnancy not in the womb, she has pain in the abdomen and is treated to remove the pregnancy, either by minor operation or medicine; after the pregnancy is removed, she will soon be without pain
Tubal infertility	She has no pain but is unable to get pregnant; she feels less satisfied with her partner, her sex life and her overall quality of life

TABLE 54 *Costs and HRQoL for complications of chlamydia*

	HRQoL[144]	Unit cost (£)[146]	Duration (years)[145]
Symptomatic acute PID	0.9	137	0.03
Chronic pelvic pain	0.69	236	5
Ectopic pregnancy	0.79	762	0.076
Tubal infertility	0.76	10,798	15
Epididymitis	0.9	142	0.03

TABLE 55 *Costs and HRQoL for complications of HPV*

	Prevalence[8]	QALY loss[147]	Unit cost (£)[148,156]
Genital warts	1	0.03	222
Cervical cancer	0.033	6.4	10,464

TABLE 56 *Costs and HRQoL for complications per case of STI for females*

	Medical costs (£)	Source	QALY loss	Source
Chlamydia	753.37	Adams *et al.*[146]	0.27	Quality of life,[144] duration[145]
Gonorrhoea	753.37	Adams *et al.*[146]	0.27	Quality of life,[144] duration[145]
Genital warts	562.61	Brown *et al.*[149]	0.238	Chesson *et al.*[147]
HIV	408,654	Miners *et al.*[150]	8.4	Miners *et al.*[150]

infertility – that half would receive successful treatment for infertility[146] and so have assumed a lower estimate than Hu and colleagues[145] of 15 years' disutility for those with infertility.

We estimated the unit cost and QALY loss per cases of STI, based on the prevalence of complications of STI (*Table 54*).

Chesson and colleagues[147] described a simplified model for the economic and health effects of HPV, to estimate the cost-effectiveness of HPV vaccination of 12-year-old girls in the USA. The quality weights, and the estimated durations of these reductions in quality of life, were based on previously published estimates. They calculated the expected number of discounted lifetime QALYs lost as a result of HPV-related health outcomes for different age groups. The QALY loss was 6.4 for cervical cancer and 0.03 for genital warts for 15- to 19-year-olds (*Table 55*).

Estimation of costs

Cost of chlamydia and gonorrhoea treatment

As the analysis reflects an NHS perspective, it uses UK-specific resource use and costing data where available. Cost data were obtained from a number of primary and secondary sources. Unit costs for the complications of chlamydia and gonorrhoea are shown in *Table 56*. Adams and colleagues,[146] who evaluated the cost-effectiveness of the NCSP in England, estimated the cost of complications based on diagnosis and treatment. They assumed that only a small proportion of patients would have a hospital episode. Unit costs were also estimated by Low and colleagues,[25] who evaluated the cost-effectiveness of population screening for chlamydia, but these differed markedly from those used by Adams and colleagues,[146] and the rationale and assumptions used by Low and colleagues[25] were unclear and so were not used.

Adams and colleagues[146] made the following assumptions when estimating the costs of PID. All PID cases were assumed to have had one general practice clinic visit, including the cost of testing for chlamydia and gonorrhoea. It was assumed that 6.5% of PID cases were admitted to inpatient hospital care. An equal proportion was assumed to be treated as outpatient cases in hospital. The cost of an episode for an outpatient hospital gynaecology department and an inpatient episode of a non-elective, non-surgical treatment of a gynaecological condition were taken from the NHS reference costs.[151] It was assumed that all women with ectopic pregnancy were admitted to inpatient hospital care for a termination, of which 60% were assumed to be medical and the rest surgical.

It was assumed that half of women with tubal factor infertility (TFI) had an infertility investigation and treatment, either tubal surgery or in vitro fertilisation. The average cost of diagnosis and treatment was estimated to be the mean of that for mild and moderate TFI (£10,727 per live birth). Women without an infertility investigation or treatment had no costs. It was assumed that all men with epididymitis had a consultation in a GUM community clinic (general practice or GUM), and, of those, 10% were referred to hospital inpatient care. It was assumed that 36% of women with chronic pelvic pain would have an outpatient consultation.[152]

Cost of HIV treatment

Miners and colleagues[150] assessed the cost-effectiveness of HAART for adults with HIV in England compared with two nucleoside reverse transcriptase inhibitors (NRTIs). They developed a Markov model to describe the progression of HIV infection and 20 years of costs and effects. The model was run for 20 years with a cohort of infected individuals who were 18 years of age at the start. HAART was assumed to have a treatment effect of 5 years, although the cost was assumed to continue until the model ended or the individual died. However, a recent study by the antiretroviral therapy cohort collaboration[153] estimated that life expectancy in HIV-infected patients, who were treated with combination antiretroviral therapy, increased between 1996 and 2005. The average number of years remaining to be lived at the age of 20 years was about two-thirds of that in the general population.

We re-estimated the life expectancy of HIV patients using lower probabilities of death in each of the health states. We changed the discount rate to 3.5% for costs and benefits[113] and updated the health-care costs from 1999–2000 to 2005–06 using the inflation indices from the Personal Social Services Research Unit (PSSRU).[154] The British HIV Association guidelines[155] now recommend including an non-nucleoside reverse transcriptase inhibitor (NNRTI), such as efavirenz, and so we have included this in our reanalysis. The model was run for 50 years. Individuals with HIV have a lower than normal life expectancy. The model estimated that they would have 8.4 QALYs lower than an uninfected individual. The estimated discounted medical cost associated with an HIV infection was £408,657 (*Table 56*).

Cost of treatment of cervical cancer and genital warts

Brown and colleagues[149] estimated the costs of managing HPV-related disease. The first-year cost of cervical cancer was estimated to be £10,464 per patient, based on a previous study by Wolstenholme and Whynes.[148] These costs take into account all of the resources used, including treatments (surgery, radiotherapy and chemotherapy), drugs, inpatient palliative care, investigations and follow-up. The cost for treating genital warts was approximately £10.1M in 2003 for 76,457 incident cases (£132 per case) and for prevalent cases (55,657) was £12.3M (£221 per case). Langley and colleagues[156] estimated the cost of successfully treating genital warts in six GUM clinics in England and Wales in 2000. The cost per successful outcome was £222 for males and £211 for females. We assumed a unit cost of genital warts of £222 and of cervical cancer of £10,464 (*Table 56*).

Cost of behavioural intervention

The costs of peer- and teacher-led sexual education interventions are based upon the resources used in the RIPPLE trial[50] and the SHARE trial.[70] As mentioned earlier, these were the only two UK studies to meet the inclusion criteria for our systematic review of effectiveness (see Chapter 2). We have updated the costs to present day values using the NHS multiplier for Hospital & Community Health Services.[154] This method converts a cost in a base year to the current year by multiplying the base cost by a index that reflects changes in costs between these years.

Contact was made with both the RIPPLE and SHARE research teams to request data on costs and resources. Limited data were available from the teams, so most of the resources were estimated from systematically extracting data from the study publications. The extensive process evaluations conducted by both studies yielded some of the data we required (see Chapter 5).

For the teacher-led intervention, we used the resources from the SHARE trial (*Tables 57* and *58*), for which the teachers were taught, in groups of 13, on a 5-day training course run by a health promotion practitioner. We assumed that all teachers that taught SRE would receive training and would be retrained every 5 years.

For the peer-led intervention, we used the resources from the RIPPLE trial (*Table 59*), for which there was no training for the teachers involved, only for peer educators. Furthermore, the training was based upon groups of 12 people per training session for a 2-day intensive course led by a health promotion practitioner. Peer educators were assumed to only teach sex education for 1 year. These interventions were compared to current training for SRE, which we assumed consists of half a day per school per year for a PSHE co-ordinator.

The training costs for standard sex education were assumed to be minimal as the majority of the training would take place in house, for example during In-Service Training (INSET) days.

Results of the modelling

The model was run with the inputs shown in *Tables 49–56* for 1000 boys and 1000 girls aged 15 years old. In the base-case analysis, the costs from the

TABLE 57 *Costs for the peer- and teacher-led sexual education interventions*

	Unit cost (£)	Notes
Teacher's salary per annum	31,791	National Union of Teachers pay scales, band 6
Health promotion practitioner's salary	26,700	PSSRU[154]
Cost for SHARE, per teacher	1307	Updated cost, includes teacher cover, room hire and materials
Cost of one health promotion practitioner	960	Assumes 2-day course, half day before and after and 2-day preparation/administration
Cost of venue/day	200	For one room; includes lunch and tea/coffee

TABLE 58 *SHARE programme costs*

Costs	1997 price (£)	2008 price (£)
Full cost of SHARE teacher training, including supply cover, per teacher	900	1307
Total cost[a]	**62,100**	**90,161**
Total cost (per teacher)	900	1307
Total cost (per pupil)	14.8	21.5
Total cost (per school)	4777	6935

a The SHARE trial had 4197 pupils, 69 teachers and 13 schools.

TABLE 59 *RIPPLE programme costs*

	Cost (£)
Unit costs	
Cost of one health promotion practitioner (4 days)	1200
Cost of venue per room	200
RIPPLE teaching pack (not including video)	22
Total costs[a]	
Cost of health promotion practitioner (4 days)	46,300
Cost of venue	7717
Other costs (teaching pack)	6945
Total cost	**60,962**
Total cost (per pupil)	15
Total cost (per school)	4354

a The RIPPLE trial had 4063 pupils, 463 peer educators and 14 schools.

teacher-led intervention (SHARE) were used. The pooled OR from our meta-analysis for the outcome all condom use (see *Figure 3*, Chapter 4, Condom use) had to be converted into a risk ratio (RR) for the purposes of economic modelling, but this required imputation of the number of young people reporting condom use in the Safer Choices intervention[58]. More details of the methodology for deriving the RR effect size are shown in Appendix 12. This produced a pooled RR of 1.05 (95% CI 0.92 to 1.20). The pooled RR is not statistically significant and so caution is advised in the interpretation of these results.

The effect of the intervention was assumed to last for 1 year, due to the short follow-up in the trials (see Chapter 4, Length of follow-up). The base-case results for the teacher-led intervention (based on the SHARE trial) are shown in *Table 60*. This indicates that there would be two STI cases averted with a corresponding quality of life gain of 0.35 QALY and a net cost of £7146. This corresponds to an incremental cost-effectiveness ratio (ICER) of £20,223 per QALY gained. The results indicate that most of the cases averted are for chlamydia and the largest QALY gain would be for females who are not infected with chlamydia.

Using the same intervention effect estimate for the peer-led behavioural intervention (RIPPLE) results in the same health gains, in terms of cases averted and QALYs gained, but at a higher cost and would correspond to an ICER of £80,782 per QALY gained (*Table 61*).

Sensitivity analysis

The parameters in the STI model were varied in a series of sensitivity analyses for the base case and the results are shown in *Table 62* and *Figure 6*.

Where possible, the parameters were varied according to the ranges of the CIs of these parameters, otherwise a suitable range was chosen. Parameter values for all the STIs were altered by the same magnitude, but, for simplicity, only the input parameters for chlamydia are shown in *Table 62* and input parameters for the other STIs are shown in *Tables 63–66*. The results were most sensitive to the intervention effect, the transmission probability and the number of sexual partners.

The parameters are investigated in more detail in *Tables 63–67*. The model results are most sensitive to changes to the model parameters for chlamydia, whilst changes to the model parameters for the other STIs produce only small changes in the model results.

Table 67 shows the effect of changing parameter values for STI complications on the results. These indicate that the sensitive parameters are those related to tubal infertility, whilst those for the other complications have little effect on the results.

TABLE 60(a) *Base-case results for the teacher-led behavioural intervention (SHARE) compared with standard sex education: intervention effect estimate*

	HIV		Chlamydia		Gonorrhoea		Genital warts			
	Male	Female	Male	Female	Male	Female	Male	Female	Pregnancy	Total
Cases control	0.002	0.007	7.331	10.342	0.126	1.026	0.953	0.819	–	20.61
Cases intervention	0.001	0.006	6.572	9.222	0.113	0.915	0.895	0.768	–	18.49
Cases averted, total	0.000	0.000	0.76	1.12	0.01	0.11	0.06	0.05	0.05	2.11
QALY gained	0.00	0.00	0.00	0.30	0.00	0.03	0.00	0.01	0.00	0.35
Total medical costs averted (£)	38	184	5	844	0	84	13	29	257	1454

TABLE 60(b) *Base-case results for the teacher-led behavioural intervention (SHARE) compared with standard sex education: costs*

	Total (£)
Total cost of intervention	8600
Net cost	7146
Cost per case averted (all STI)	3382
Cost per QALY gained	20,223

TABLE 61 *Base-case results for the peer-led behavioural intervention (RIPPLE) compared to standard sex education*

	Total (£)
Total cost of intervention	30,000
Net cost	28,546
Cost per case averted (all STI)	13,508
Cost per QALY gained	80,782

Older teenagers

We investigated the effect of the intervention in older teenagers (aged 16–19 years). In this group there are more sexually active individuals and they have more sexual episodes per month (*Table 68*). The results for running the model with these parameters and STI prevalence from this age group for the teacher-led intervention are shown in *Table 69*. In this age group there are more STI cases averted, QALYs gained and medical costs averted than in the younger age group. The cost-effectiveness for this age group is £11,622 per QALY gained.

Probabilistic sensitivity analysis

The PSA was conducted for the base-case analysis for the teacher-led intervention (i.e. based on the SHARE trial). The main parameters were varied according to the ranges used in the deterministic sensitivity analysis. The PSA parameter values were sampled from appropriate distributions for these parameters as shown in Appendix 11. The model was run for 1000 iterations.

The teacher-led intervention was typically associated with increased costs (*Figure 7* – scatter plot of the incremental cost and QALYs), although there is a small proportion (1%) of simulations where costs are lower (associated with positive incremental outcomes). The percentile-based 95% CI for incremental cost is £341 to £12,060. There is a wide range for incremental QALYs, as shown in *Figure 7*, from –2.0 to 2.5, with poorer incremental outcomes typically being associated with higher incremental costs. In 23% of the simulations the teacher-led intervention was associated with a QALY loss. The percentile-based 95% CI for incremental QALYs is –0.7 to 2.

In addition to graphing the incremental cost and incremental QALYs for the teacher-led intervention, a CEAC was derived, representing the proportion of simulations where the teacher-led intervention is cost-effective for a range of willingness-to-pay thresholds, up to £100,000 (*Figure 8*). In this analysis the teacher-led intervention had a probability of being cost-effective of 46% at a willingness-to-pay threshold of £20,000, and 54% at a willingness-to-pay threshold of £30,000.

TABLE 62 *Sensitivity analyses for the STI model*

		Inputs		ICER (£/QALY)		
Variable	**Base case**	**Low**	**High**	**Low**	**High**	**Range (£)**
IE condom use	1.05	0.92	1.2	–19,325	1970	NA
Transmission probability	11[a]	3[a]	20[a]	71,391	13,390	58,001
IE number of sex partners	1	0.95	1.05	11,156	58,313	47,157
IE Sex episodes per partner	1	0.95	1.05	12,934	37,762	24,828
BC number of sexual partners	2	1.5	4	30,619	5975	24,644
STI prevalence	7.5[a,b]	5.3[a,b]	9.8[a,b]	28,802	10,830	17,972
Proportion sexually active	36	25	45	35,150	17,693	17,457
BC sex episodes per partner	10	6	14	31,954	15,654	16,300
Intervention cost	4.3	3	5.6	12,865	27,581	14,716
QALY loss per STI case	0.27[a]	0.19[a]	0.35[a]	28,890	15,556	13,334
Condom effectiveness	85[a]	70[a]	95[a]	24,748	18,407	6341
Condom use	70	60	80	22,607	18,686	3921
Unit costs	768.11[a,b]	537.68[a,b]	998.54[a,b]	19,211	21,235	2024

BC, base case; IE, intervention effect; NA, not available.
a Values shown for chlamydia. Parameters for other STIs were altered by the same magnitude.
b Values shown for females.

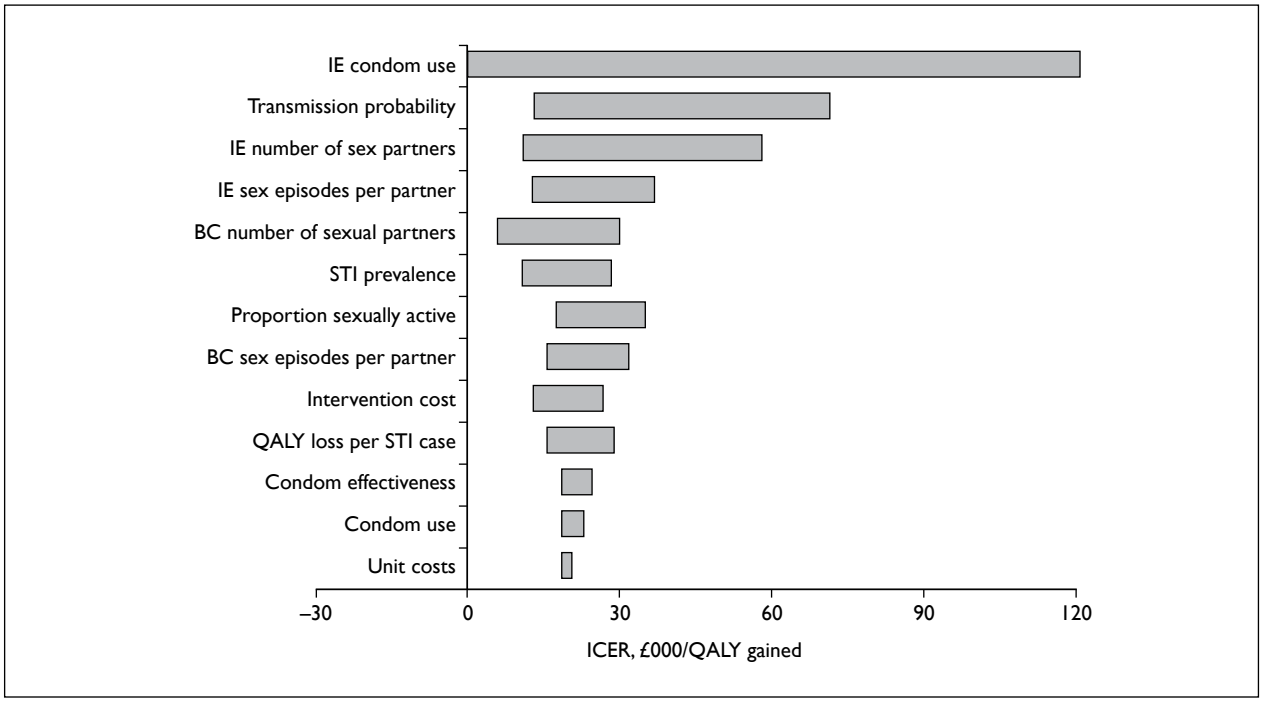

FIGURE 6 *Tornado plot for sensitivity analyses for the STI model. BC, base case; IE intervention effect.*

TABLE 63 *Sensitivity analyses for changes in STI single-sex transmission probability*

Variable	Base case (%)	Inputs		ICER (£/QALY)		
		Low	High	Low	High	Range
Chlamydia	11	3	20	52,726	14,688	38,038
Gonorrhoea	7	2	13	21,697	19,071	2626
HIV	0.15	0.04	0.3	20,882	19,338	1544
Genital warts	10	3	18	20,853	19,908	945

TABLE 64 *Sensitivity analyses for changes in STI condom effectiveness*

Variable	Base case (%)	Inputs (£)		ICER (£/QALY)		
		Low	High	Low	High	Range
Chlamydia	90	70	95	25,250	19,422	5,828
Gonorrhoea	90	70	95	20,593	20,148	445
HIV	80	70	95	20,333	20,059	274
Genital warts	70	60	90	20,357	20,008	349

TABLE 65 *Sensitivity analyses for changes in STI unit cost*

	Inputs (£)		ICER (£/QALY)		
Variable	**Low**	**High**	**Low**	**High**	**Range**
Chlamydia	538	999	20,906	19,445	1461
HIV	286,058	531,250	20,411	20,035	376
Gonorrhoea	538	999	20,291	20,146	145
Genital warts	394	731	20,247	20,199	48

Note: Input values shown are those for females.

TABLE 66 *Sensitivity analyses for changes in parameter values for QALY gain for STIs*

	Inputs (£)		ICER (£/QALY)		
Variable	**Low**	**High**	**Low**	**High**	**Range**
Chlamydia	0.19	0.35	27,242	16,185	11,057
Gonorrhoea	0.19	0.35	20,755	19,733	1022
Genital warts	0.17	0.31	20,425	20,015	410
HIV	5.9	10.92	20,301	20,145	156

Note: Input values shown are those for females.

TABLE 67 *Sensitivity analyses for the STI complications parameter values*

	ICER range (£/QALY)			
	Prevalence	**Quality of life**	**Duration**	**Unit cost**
Tubal infertility	9354	24,052	8146	1513
Chronic pelvic pain	1217	1767	1208	40
Ectopic pregnancy	62	46	19	43
PID	19	26	8	11

Range of ICER results between low and high parameter values (±30%).

TABLE 68 *Sexual behaviour parameters for the 16- to 19-year-old age group*

Parameter	**Value**	**Reference**
Sexually active	Male 56%, female 66%	ONS Omnibus Survey[130]
Sex episodes per month	6.9	NATSAL[132]
Sex partners per year	Male 2.1, female 2	ONS Omnibus Survey[130]
Condom use	Male 55%, female 47%	ONS Omnibus Survey[130]

NATSAL, National Surveys of Sexual Attitudes and Lifestyles; ONS, UK Office for National Statistics.

TABLE 69 *Results for the teacher-led intervention for the 16- to 19-year-old age group*

Results	Total
Cases control	57.7
Cases intervention	54.2
Cases averted, total	3.5
QALY gained	0.4
Total medical costs averted (£)	3498
Net cost, £	5102
Cost per case averted (all STI) (£)	1448
Cost per QALY gained (£)	11,622

Expected value of perfect information for the prevention of STIs

Decision-makers may be interested in whether it would be worthwhile conducting further research to gain more precise information on uncertain parameters in the model. For example, in our STI model, we may be interested in whether it would be better to derive more precise estimates of the effect of behavioural interventions on condom use or other outcomes (by conducting a further trial), better estimates of sexual activity in younger people, especially those under 16 years of age (using a sexual health survey) and whether either of these would be worthwhile, considering what the likely health gain for the population would be. Value of information analysis attempts to answer these questions by analysing the hypothetical case for which perfect information could be obtained through further research.[114] The EVPI is the price that one would be willing to pay in order to gain access to perfect information through further research, and represents an upper bound on the value of conducting further research. The EVPI varies according to the cost-effectiveness threshold. For interventions in which there is large uncertainty around whether they should be adopted, for example when the ICER is close to the cost-effectiveness threshold, the health-care system may be prepared to pay more for research which informs decisions on these interventions.

For the STI model, the individual EVPI was calculated as the difference between the expected net benefit with perfect and with current information. The total EVPI is estimated for the total current and future population of people who

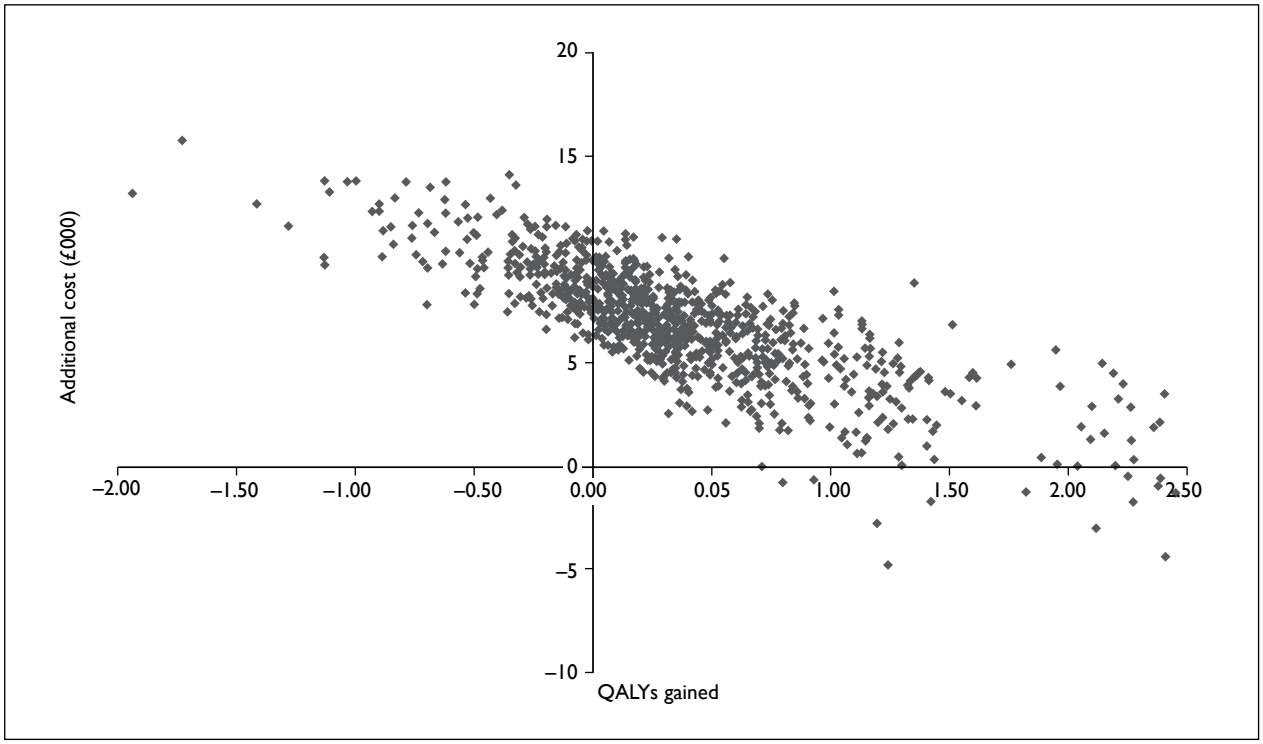

FIGURE 7 *Scatter plot of PSA results for 1000 iterations for the teacher-led intervention.*

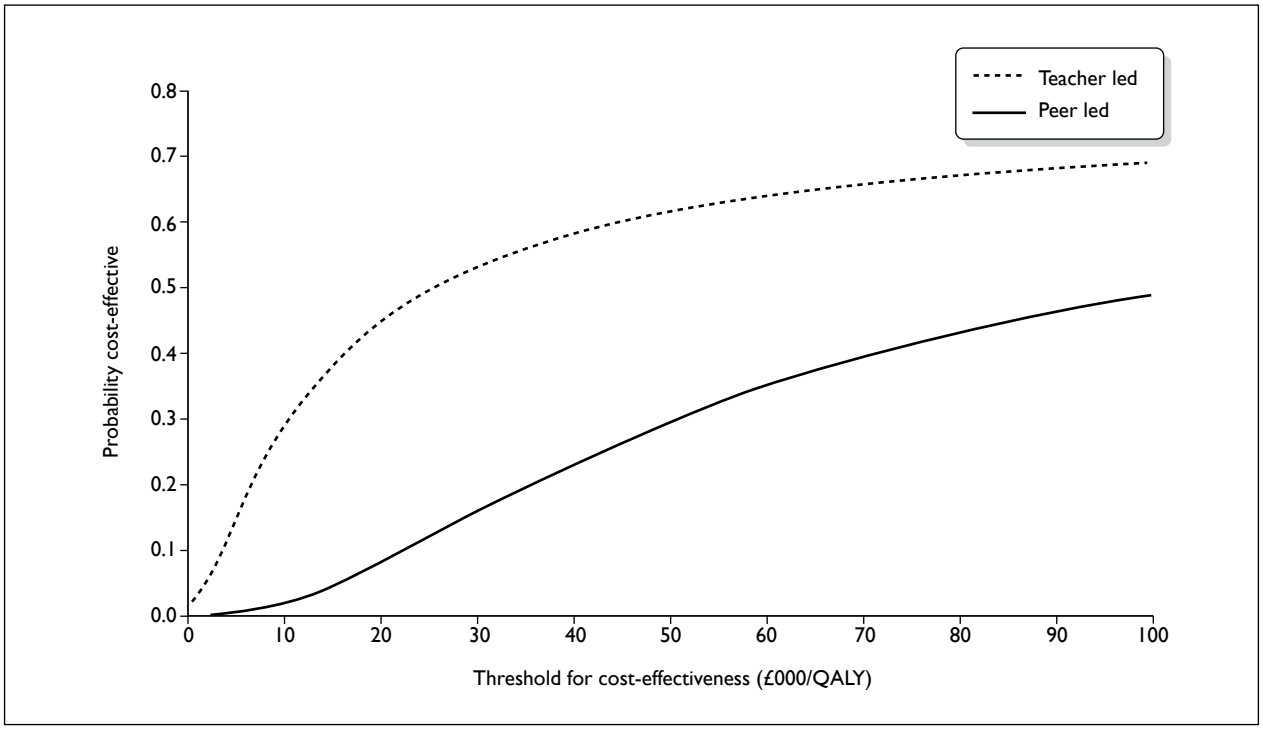

FIGURE 8 *CEAC of results for 1000 iterations for the teacher- and peer-led interventions.*

may benefit from this intervention. We assumed that the effective lifetime of the intervention would be 10 years. The effective lifetime represents the time until a new intervention supersedes or replaces it, rather than the duration of effect. There are 640,000 children of 15 years of age in England and Wales in 2008 (ONS).[157] The effective population over the lifetime of the intervention is 5.2 million (with a discount rate of 3.5%). The population EVPI is shown in *Figure 9*.

At a threshold for cost-effectiveness of £20,000 per QALY, the population EVPI is £12.5M, assuming a 10-year lifetime for the intervention, suggesting a upper limit to expenditure on further research to reduce uncertainty. However this overall EVPI estimate gives no indication which of the uncertain parameters has an impact on the decision whether the new technology is cost effective or not. As a result, the global EVPI does not help to answer the question posed at the beginning of this section – whether it would be better to fund an RCT (to improve the precision of the effect estimate) epidemiological research (on the prevalence of STIs and their complications in this population) or surveys of sexual lifestyles. The following section extends the analysis of EVPI to groups of parameters to identify the priorities for research to reduce decision uncertainty in the model.

Expected value of perfect information for individual parameters

The effect of individual parameters on the population EVPI was investigated by running an EVPPI analysis.[114] This shows the value of reducing the uncertainty surrounding particular input parameters in the decision model, by conducting further research on these parameters in order to obtain perfect information.

The PSA was run for 1000 iterations, whilst keeping the parameter value(s) of interest constant. This process was repeated for 100 different parameter values. The EVPIs associated with the inputs of the model are illustrated in *Figure 10* for a threshold of £20,000 per QALY and a 10-year effective lifetime for the intervention. The value of information associated with the intervention effect for condom use is £10.2M, which is substantially higher than any other model inputs and accounts for over half

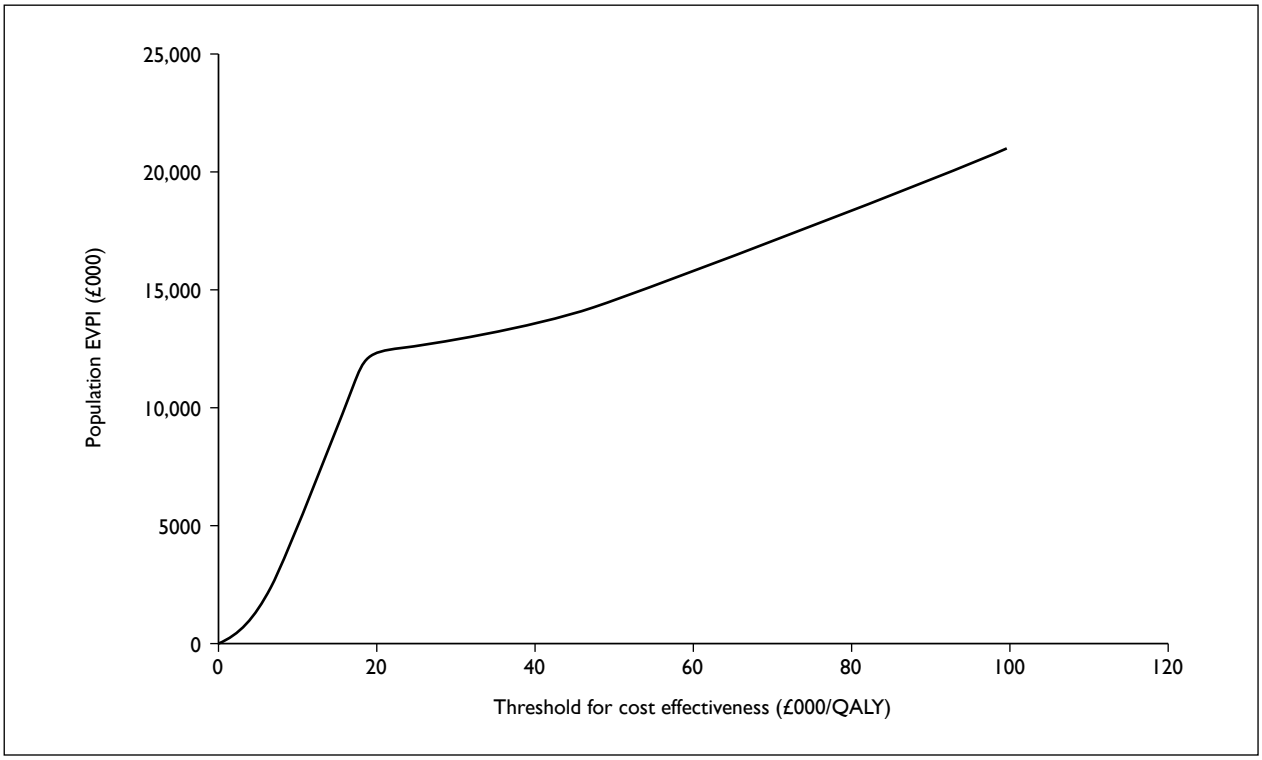

FIGURE 9 Population EVPI curve for the teacher-led intervention.

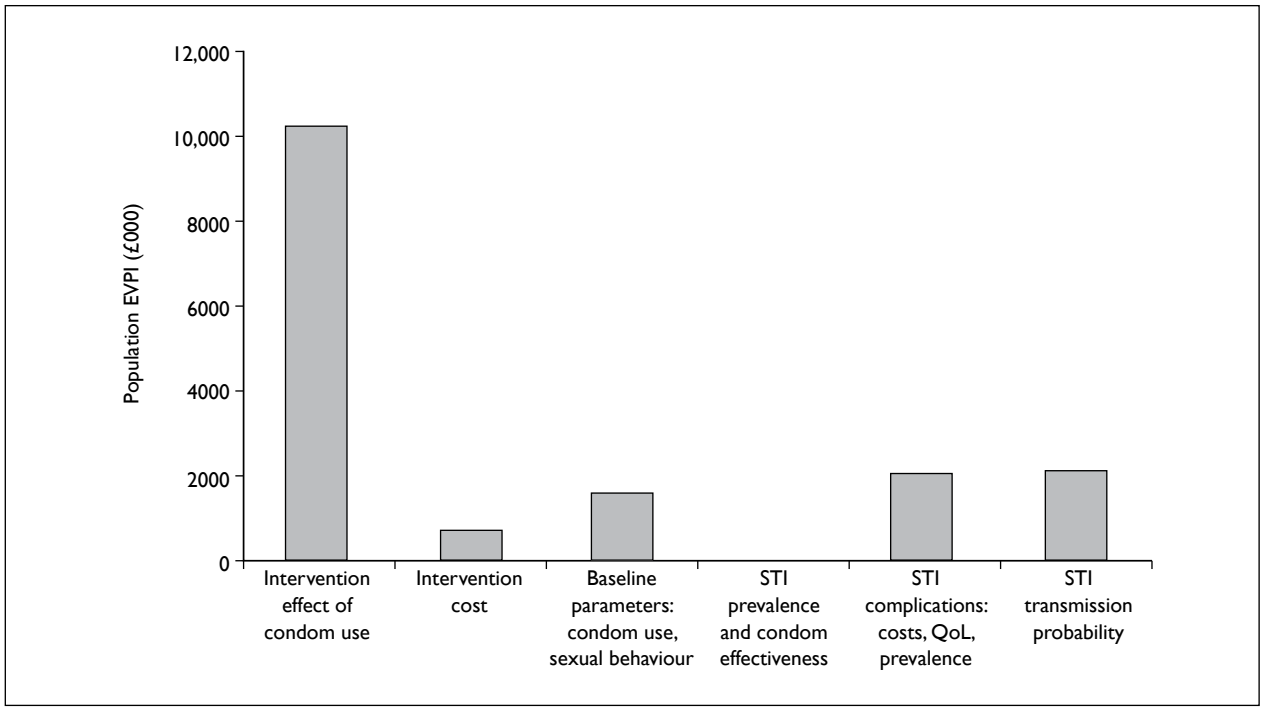

FIGURE 10 EVPI for the individual parameters for teacher-led intervention.

of the decision EVPI. Furthermore, the EVPI for STI prevalence and condom effectiveness is zero and the EVPPI for baseline condom use, sexual behaviour and intervention cost is low, indicating that future research for these parameters would not reduce the decision uncertainty in the model.

Chapter 8
Discussion

Discussion of the systematic review of effectiveness

Principal findings of the systematic review

Effects on sexual behaviour

Although there were statistically significant differences between study groups for outcomes such as improved knowledge and greater self-efficacy, our systematic review showed that, in general, schools-based education and skills development interventions were limited in encouraging safer sexual behaviour amongst young people. Few of the studies reported statistically significant differences between the interventions and their comparators (generally standard sex education or control groups) for outcomes such as condom use, delaying the initiation of sexual activity, frequency of sexual intercourse or number of sexual partners. Similarly, when a subset of the studies were combined statistically in a meta-analysis, the pooled effect estimates were not statistically significant.

Our synthesis of process data revealed several factors that may explain the limited impact of these interventions on safe sexual behaviour. Interventions were not always implemented as intended, with interactive exercises, such as role plays, being more likely to be omitted in comparison with the information giving aspects of the interventions. Barriers to implementation ranged from an unsupportive school culture, which meant that other timetabled activities were given higher priority, to individual provider qualities, such as enthusiasm, credibility and expertise. Furthermore, not all young people found the interventions to be engaging and acceptable. The qualities and skills of the intervention providers, whether or not the intervention content met young peoples' sexual health needs, the operation of gendered norms, and the discomfort felt discussing sexual topic in the school environment all affected young people's engagement. These findings build on those of Payne and colleagues,[158] who found significant relationships between implementation intensity in schools and factors such as integration into school operations and principal support.

Notably both of the UK studies concluded that the interventions had not been wholly successful in encouraging safer sexual behaviour. The authors of both trials discuss the likely reasons for this.

In the SHARE trial there were no statistically significant differences between the intervention and standard sex education in terms of first intercourse without a condom, any evidence of protection against STIs (a composite outcome measure, defined earlier in Chapter 4, Sexual behaviour), frequency of condom use or most recent intercourse without a condom (Wight and colleagues[70]). Long-term follow-up of the young women at age 20, via NHS linkage data, found no statistically significant difference on rates of conception or termination. Although their process evaluation suggested several factors that may account for lack of impact on these outcomes, Wight and colleagues highlight the length of classroom sessions and the age appropriateness of the SHARE programme as key factors. They concluded that the classroom sessions were possibly too short to enable the young people to fully develop sexual negotiation skills. Furthermore, for some young people, the skills would not be put into practice until they had begun sexual relationships, by which time the skills would likely be harder to recall. They noted higher than expected baseline condom use in their sample, and suggest that the potential of school-based sexual health promotion might have already been reached by conventional provision. In terms of recommendations they proposed the need for broader interventions to address socioeconomic determinants of health, as well as strategies involving parents. It is of note that a non-randomised controlled adaptation of SHARE as part of the 'Healthy Respect' intervention in the Lothian and Grampian regions of Scotland (not included in our review) also found a lack of impact on sexual health behaviour outcomes.[159]

In the RIPPLE trial there was no significant reduction in the primary outcome of unprotected first sexual intercourse at age 16 years, and no significant difference in rates of abortion at age 20 years (Stephenson and colleagues[50,89]). There were some positive outcomes, including the finding

that girls in the intervention arm were more confident about using condoms in the future and were significantly less likely to report having had sex by 16 years of age, compared with the control group. The authors discounted the potential for methodological biases to account for the lack of impact on unprotected first sexual intercourse (e.g. diffusion of the intervention to the comparison group). They did, however, point to some of the limitations identified by the process evaluation, namely, pupil dissatisfaction with mixed-sex lessons. One of the recommendations, therefore, was that future interventions should be delivered to single-sex groups, although in the SHARE trial it was found that mixed sex groups might be more beneficial for young men. The authors also concede that the intervention was relatively brief and that a longer or more intense programme might be more successful, although, as discussed above, this was not borne out by the results of the 20-session, 2-year SHARE programme.

Another potential explanation for the general lack of impact of the studies in this systematic review on sexual behavioural outcomes is they did not allow long enough to assess outcomes. As mentioned in Chapter 4, Length of follow-up, 10 of the 15 studies followed up participants for less than 1 year. As not all of the young people were sexually active, and because health-related behaviour is known to take time to adopt and become routine,[160] it is possible that had the young people been followed up for longer, significant differences in outcomes such as condom use may have been observed. However, longer-term follow-up of the RIPPLE trial at age 18 showed that there were no significant differences between study groups in unprotected first sex, regretted or pressured sex (at first and last sex), quality of relationship with current partner and diagnosed STI.

One of the more optimistic studies in terms of impact on safer sexual behaviours was the Safer Choices programme, conducted in urban schools in Texas and California (Coyle and colleagues[58]). There were statistically significant differences between study groups on a number of behavioural outcomes. Unfortunately, a process evaluation of this intervention was not reported, limiting insights into the factors contributing to its success. One potential explanation is that the intervention was more comprehensive than many of the others included in the review. In addition to classroom-based education and skills development activities, a school health promotion council was established, involving all agents within the school to plan activities. Young people themselves were given a leading role as peer educators. And parents were also involved in planning activities and were encouraged to take part in 'homework' with their children to discuss sexual health. Linkages with community health services were also sought. Inclusive, co-ordinated, multicomponent interventions such as this, which seek to influence young people by targeting many of the contexts in which they live (e.g. classroom, wider-school environment, home, community), may be more successful than interventions that primarily focus on the curriculum.

As mentioned earlier in Chapter 4, Origin of the interventions, the results of an evaluation of an adaptation of Safer Choices in an 'alternative' school (for students with behavioural and social problems) are awaited (Tortolero and colleagues[86,87]). It will be interesting to see whether the results are comparable with the original study. Given its promising results, it would be also useful to evaluate an adaptation of Safer Choices in the UK. Some aspects of the intervention may be readily transferable. For example, the National Healthy Schools Programme encourages a 'whole-school' ethos, which appears analogous to the school health promotion council element of Safer Choices. However, qualitative pilot work would be required to assess its social and cultural relevance to the UK. For instance, whether or not parent and teen discussion of sexual health is likely to be an acceptable and effective intervention component.

Effects on other outcomes

It is important to acknowledge that although safer sexual behaviour and absence of infection are important outcomes, positive changes in mediating variables are no less valuable. The improvements in knowledge, behavioural intentions and self-efficacy/confidence around negotiating safer sex reported in the studies included in this review indicate that young people at least have a firm foundation upon which to make decisions. Some stakeholders consider these improvements to be meaningful, and it was on this basis that the then Scottish Executive decided to implement the SHARE curriculum in Scottish schools.[161] The FoK intervention is available for use in the USA,[162] although this has probably been rolled out on the basis of the more successful outcomes achieved in the original evaluation in Baltimore, MD (Stanton and colleagues[88]) (which, as mentioned earlier, did not meet our inclusion criteria as the mean age of the young people was below 13 years).

School-based behavioural interventions are therefore appropriate to improve knowledge, self-efficacy and favourable intended behaviour. The consultation exercise conducted to underpin the UK government's strategy for health promotion, Choosing Health,[21] found that people want to have clear and credible information to enable them to make informed choices. Furthermore, government policies such as 'Every Child Matters' endorse the right for young people to receive high-quality health promotion.[23] Therefore, the limited impact on sexual behaviour of interventions should not hinder the provision of education and support for sexual health.

The results of this systematic review also raise the question of whether the outcomes measured by the studies are sensitive enough to reflect the complex sexual behaviours and lifestyles of young people at the current time. Condom use may not necessarily reflect strategies that some young people use to reduce risks. For example, some couples may 'negotiate safety' through seeking testing for STIs and, following mutual negative results and with effective use of contraception, may then enjoy unprotected intercourse. Uptake of STI testing in this context may therefore be a useful outcome measure for future evaluation studies. This would be a particularly useful marker to evaluate the effectiveness of interventions that not only aim to encourage risk reduction, but also which encourage testing to as a form of secondary prevention. This is all the more appropriate given wider availability in the UK of chlamydia testing.[163] An added benefit would be the identification of long-term viral infections, such as HIV, and timely commencement of antiviral treatment. Media campaigns with MSM have emphasised the long-term advantages of testing and uptake of antiviral treatment, where appropriate.

Effects on inequalities in sexual health

There is growing recognition that sexual health inequalities exist, and that some groups of young people are disproportionately affected by STIs. These groups are often characterised by factors associated with the broader determinants of social and health inequalities, such as gender, ethnicity and sexuality. Exploring the extent to which interventions can reduce, maintain or increase health inequalities requires reporting of data suitable for performing subgroup analyses in systematic reviews. In the studies included in our review, reporting of data useful to assessing differential intervention impact according to population factors was sparse, and varied in detail. Consequently, it was difficult to draw conclusions about the likely effects of the interventions on health inequalities.

For example, a small number of studies reported outcome data according to gender, whereas other studies only reported demographic data on gender across intervention and control groups at baseline. The picture for data on both ethnicity and SES was less encouraging; whilst some demographic data were reported for these factors, they were not presented according to intervention and control group at baseline or follow-up. The fact that more data were presented on gender than other determinants of health may reflect the ease of collecting and analysing these data. However, considering the apparent ease with which these data can be collected, and the valid rationale for doing so, it was disappointing that so little was actually reported. Whilst subgroup analyses that have been not pre-specified should be avoided,[164] and underpowered subgroup analyses in primary reports used only for hypothesis generation, more extensive reporting of outcome data by potential demographic determinants, such as gender, ethnicity and SES, would be of value in assessing the impact of interventions on sexual health inequalities.

The role of theory

The vast majority of the interventions were theory-based, and the theories tended to be drawn from sociopsychological models of health-related behaviour change. At their simplest, these theories propose that interventions which foster favourable attitudes and intentions will, in turn, encourage the adoption and maintenance of health-promoting behaviours. Whilst many texts on the application of theory to explain health-related behaviour acknowledge the role of knowledge, attitudes and behaviours, it is also acknowledged that these cannot necessarily bring about behaviour change without structural and environmental reinforcements (e.g. service provision, policy, legislation, etc.).[165]

The role of peer norms and role models were also considered important. For example, a key tenet of Social Learning Theory[72–74] is that young people will be influenced by the attitudes and behaviour of role models, and will, in turn, copy them. Accordingly, some of the studies included in this review used peers (sometimes chosen for their influence) to deliver interventions. The studies varied in the extent to which they discussed

the conceptual mechanisms through which they expected the interventions to operate. Some made only passing reference to theory (e.g. Coyle and colleagues[58]), whilst others (e.g. Karnell and colleagues[63]) were more explicit about how the theory chosen might encourage favourable sexual behaviour. Of course, no one theoretical model is without limitations, and it was therefore encouraging that many of the interventions were based on a range of complementary models.

Despite the predominance of theory-based interventions, one of the potential explanations for the lack of impact on behaviour in the studies included in this review is that the interventions were poorly conceived. That is, the theories chosen did not adequately guide the intervention in helping young people to develop the knowledge, attitudes and skills necessary to engage in safer sexual behaviour. However, it appears that the theories employed were generally appropriate to the aims of the interventions. For example, the Theory of Planned Behaviour[76] (used in three of the studies) recognises that, despite favourable attitudes and intentions, external factors, such as the influence of sexual partners, can limit the extent to which intentions can be translated into behaviour. To account for this many of the interventions drew on the concept of self-efficacy to underpin the teaching of skills to use condoms correctly and to communicate with partners. The aim was to bridge the gap between intention and behaviour, particularly in situations when sexual partners might favour unprotected sex.

The 'Youth AIDS Prevention Project' evaluated by Levy and Colleagues[65] had a particular focus on teaching young people decision-making and resistance/negotiation skills. They distinguished between 'use self-efficacy' (the perceived ability to obtain and use contraception) and 'refusal self-efficacy' (the perceived ability to refuse to engage in high-risk behaviours). This distinction is reflective of the range of different skills taught by some of the studies.

As reported in Chapter 4, under Skills and self-efficacy, many of the studies demonstrated statistically significant differences between study groups in terms of condom use self-efficacy, suggesting that the theories were only partially successful in achieving behaviour change goals (though the influence of non-theory-related factors, such as the length of follow-up and the appropriateness of specific types of behavioural outcome measures, may have also influenced the results, as mentioned earlier). There were fewer significant differences for other measures such as sex refusal self-efficacy and communication self-efficacy. The reasons for this disparity are not entirely clear, though it is possible that the young people felt more confident about using condoms correctly (e.g. by practising on anatomical models) than they did in terms of communication (e.g. in role play scenarios). This explanation is supported by the results of the synthesis of the process evaluation results (Chapter 5), which found that there were barriers to the teaching of sexual communication skills. This was a particular issue in the SHARE trial,[70] in which, despite the fact that teachers found their training to be beneficial and acceptable, they felt inhibited in facilitating role play and other skills-building exercises in the classroom. It should therefore be acknowledged that whilst an intervention might be well conceived, it may not be delivered as intended, and, consequently, not remain faithful to its theoretical principles.

Another issue to bear in mind is the fact that interventions that foster self-efficacy and teach sexual health negotiation skills may not necessarily be appropriate for all young people. These models assume that young people are committed to protecting themselves from STIs and that, once armed with all the necessary knowledge, skills and confidence, will always choose to have safer sex. However, this is an unrealistic goal as some young people will make a conscious decision to participate in unprotected sex, either episodically or routinely. The theories underpinning the interventions in this systematic review seemed generally more geared to enabling young people to recognise risks and protect themselves, rather than to help those who already have the skills and confidence to negotiate safer sex, but choose not to. It is important that any future interventions with this group should be based on a theoretical perspective that accounts for this.

Finally, this systematic review restricted inclusion to behavioural interventions in which skills were taught within the context of sexual health. It should be acknowledged that there are broader school-based approaches to fostering young people's health (of which sexual health is one outcome), which teach broader everyday life skills that can be applied in a variety of contexts, including personal and sexual relationships.[166] The effectiveness of such interventions might be a suitable topic for future evidence syntheses.

Findings from other systematic reviews

The results of other relatively recent systematic reviews in this area have been mixed, but generally show that behavioural interventions can encourage safer sexual behaviours amongst young people, to varying degrees.

The Cochrane review of 'abstinence plus' interventions (i.e. promotion of abstinence from sexual activity, but also of condom use and other safer sex practices), included 39 randomised or quasi-randomised trials, of which 10 were based in schools (Underhill and colleagues[167]). The mean age of the participants varied between 11 to 19 years, and all were based in the USA, Canada or the Bahamas. A meta-analysis was not performed due to the heterogeneous nature of the interventions, and lack of data. Of the 39 trials, 24 reported a significantly protective intervention effect on any sexual risk behaviour or biological outcomes. The number of trials reporting statistically significant results in favour of the intervention varied according to different behavioural outcomes: self-reported frequency of unprotected vaginal sex (6/12 trials); incidence and frequency of all sex (5/21 trials); number of partners (4/13 trials); condom use (14/26 trials); and sexual initiation (4/19 trials). Statistically significant effects on knowledge in favour of the intervention were reported in many studies. It was concluded that many abstinence-plus programmes reduce short- and long-term HIV risk behaviour.

However, a review of abstinence only interventions in high-income countries by the same authors came to less optimistic conclusions (Underhill and colleagues[168]). Of the 13 randomised or quasi-randomised trials included, seven were school based. There was no consistent effect on unprotected vaginal intercourse, frequency of vaginal sex, number of partners, sexual initiation or condom use.

Robin and colleagues[2] systematically reviewed behavioural interventions to prevent HIV/STIs and pregnancy amongst young people, and published in the 1990s. Of the 20 included studies, nine were based in schools. Nine studies were classified as having a 'positive' effect (defined as a positive effect on at least one behavioural or biological outcome and no negative effects relative to the control group), five studies had 'null' effects (defined as no differences among groups for any of the behavioural or biological outcomes), and three had 'negative' effects (the intervention had any negative impact on one or more of the behavioural or biological outcomes, regardless of any positive findings).

Johnson and colleagues[3] included randomised and quasi-experimental trials of HIV prevention interventions in young people aged 11–18 years. A total of 56 interventions were reviewed, the majority of which were delivered in North America, and in school or community settings. Statistically significant differences in favour of the intervention were found for frequency of sex, condom use, skills for condom use negotiations, and skills for condom use, and communications with a sex partner (based on a meta-analysis of effect sizes). Factors cited as influencing condom use included interventions with condom information and skills training, and studies where the comparison group received less HIV skills training.

Sales and colleagues[169] systematically reviewed STI and HIV interventions published in peer-reviewed journals between 1994 and 2004, delivered in a range of settings for young people aged between 11 and 22 years. Of the 39 interventions included, 13 were conducted in schools. Of these three-quarters reported 'some behaviour change' with reducing the frequency of unprotected sexual intercourse was the most frequent outcome. Several studies reported a delay in initiation of intercourse and/or a delay in frequency of intercourse. Effective interventions were noted to be theory-based, implemented by trained teachers or health educators, and including skills and knowledge-building activities.

In summary, other published systematic reviews of interventions to prevent STIs with young people provide a more optimistic picture of the ability of behavioural interventions to influence sexual behaviour than this systematic review. However, these reviews are not wholly comparable with our review due to differences in scope and inclusion criteria, and, particularly, the fact that they were not restricted to school-based interventions.

Methodological quality of the outcome and process evaluations

The RCTs included in our systematic review were of reasonable methodological quality. However, poor reporting of factors such as randomisation procedure, concealment of allocation and attrition prohibited a thorough assessment of quality.

It is encouraging that a high proportion of the 15 outcome evaluations also conducted a process evaluation. Process evaluation is essential to explain what factors may have contributed to success or failure of the intervention, to assess its acceptability to the stakeholders involved, the determine the fidelity of the intervention delivery, and to establish the generalisability and replicability of an intervention.[170] However, the extensiveness of the process evaluations included in this review varied from cursory monitoring of intervention activities to larger scale, comprehensive quantitative and qualitative evaluation of multiple aspects of the intervention. The two UK-based studies included in the review both conducted comprehensive process evaluations, with extensive data reported in a number of publications[50,70] (see Appendix 7 for a bibliography of these).

Improving the quality and extent of process evaluations would add much value for assessments of the effectiveness of complex interventions, such as the ones under consideration in this review. Process evaluations of experimental interventions should be more than superficial monitoring exercises. Ideally, process evaluations should collect a range of qualitative and quantitative data on intervention fidelity, programme reach, and provider and user perspectives on the intervention. The collection of qualitative data is particularly important for understanding how contextual factors affect implementation and acceptability and for an assessment of the potential generalisability of an intervention.

The wider evidence base

The descriptive map reported in Chapter 3 provides a useful context within which to discuss the results of the systematic review. The majority of studies included in the map, and the systematic review itself, were conducted in the USA. This has been the case in health promotion systematic reviews in other areas, such as healthy eating,[33] and reflects the strong tradition of experimental evaluation of social interventions in the USA over the decades.[171,172]

Many of the interventions mapped were delivered in schools by teachers and/or peers. Although there were some examples of outreach interventions located in community settings, the predominance of school-based activities raises the question of whether the needs of the most vulnerable young people are being met. School activities are not likely to reach those persistently absent from school, young people who have left school early, or young offenders. They may not necessarily appeal to young people who are disaffected by school and the education system in general,[173] although the influence of credible peer educators may help to overcome this. As explained earlier, school-based interventions were prioritised for our systematic review because, in consultation with stakeholders, it was considered that they were likely to reach the greatest number of young people. The systematic review potentially could have focused on a different subset of studies from the map that specifically included young people classified as being 'at risk' (refer back to Chapter 3, *Table 9*). However, this would have resulted in a systematic review of a more diverse set of interventions, in terms of factors such as setting and provider, which would have made comparison between studies more problematic. This does not, though, preclude such a systematic review in the future. One of the advantages of this kind of descriptive map is that it is a resource that can be used to identify and prioritise different topics for future evidence syntheses in accordance with policy needs (see Chapter 9, Recommendations for research).

Discussion of the results of the economic evaluation

Our systematic review of cost-effectiveness studies identified only five economic evaluations of behavioural interventions for the prevention of STIs in young people. These all addressed the prevention of HIV, but only one study evaluated other STIs in addition to HIV. Those studies that did not include other STIs are likely to have underestimated the potential benefits of the interventions. All studies used mathematical models extrapolating the changes in sexual behaviour to number of cases of HIV averted. The evaluations were published between 1998 and 2005 and were conducted in the USA. With the exception of one study for developing countries, all studies evaluated the interventions on a US population. All interventions were effective in improving sexual behaviour in the study groups and thus led to cases of HIV averted. There was a range in assumptions and parameter values used in the mathematical models and this led to substantial differences in the estimated cost-effectiveness of the behavioural interventions.

The model developed in this study allows us to estimate the cost-effectiveness of behavioural interventions for preventing STIs in young people.

However, as the meta-analysis in Chapter 4 (see Sexual behaviour) has not shown a statistically significant intervention effect, the results presented should be treated with caution and only be regarded as illustrative. Based on a pooled RR estimate for condom use of 1.05 (95% CI 0.92 to 1.20) for behavioural interventions, the model estimated that three STI cases would be averted (saving 0.5 QALY) in a cohort of 1000 boys and 1000 girls aged 15 years. The majority of avoided STI cases are for chlamydia. The incremental cost-effectiveness figures of the teacher- and peer-led behavioural interventions were £20,223 and £80,782 per QALY gained, respectively. The relatively high cost for the peer-led intervention arises from the assumption that peer educators are assumed to provide sex education for only 1 year, hence training costs are incurred every year, whereas teachers are assumed to be retrained every 5 years. Sensitivity analyses show the results were most sensitive to the intervention effect, the STI transmission probability and the number of sexual partners in the base-case analysis. The model results were also sensitive to changes to the model parameters for chlamydia, and especially for parameters related to tubal infertility. In a PSA, the probability of the teacher-led intervention being cost-effective was 46% at a willingness-to-pay threshold of £20,000 and 54% at a willingness-to-pay threshold of £30,000.

Few studies that have estimated the cost-effectiveness of interventions to prevent STIs have used estimates of QALYs.[26] Rather, they have used other outcome measures such as cost per major outcome averted or cost per case avoided.[25,59] Adams and colleagues[146] commented that the QALY is the common measure used by decision-makers in the UK and elsewhere, and the use of major outcomes averted implies that all of the major outcomes are equal, which is unlikely to be the case. They recommended that more research is needed to determine QALY values for chlamydia states. We reviewed quality-of-life studies for STIs and a small number of studies that were used to estimate quality of life for individuals who have complications as a result of STIs.

We also conducted a value of information analysis, which found that the upper bound on research expenditure would be £12.5M, for a cost-effectiveness ratio of £20,000 per QALY assuming a 10-year lifetime for the intervention (i.e. the time until a new intervention supersedes or replaces it). An analysis of the individual parameters used in the model, revealed that research would be best funded to establish the intervention effect for condom use from a school-based behavioural STI intervention, as this parameter has a substantially higher EVPPI than any other model inputs, and accounts for more than half of the decision EVPI (£10.2M).

Strengths, limitations and uncertainties of this report

Systematic review of effectiveness

One of the strengths of this review is its adherence to rigorous systematic review methods. We conducted exhaustive searches, applied explicit inclusion criteria to search results, critically appraised included studies and used transparent methods to synthesise study findings. A further strength is our incorporation of two relatively new and innovative review elements. Firstly, we conducted the review in two stages with an initial mapping stage followed by a systematic review of a subset of studies. This process facilitated the involvement of end-users in the design of the review. After our map was completed we consulted with our advisory group to ensure that any subset of studies we focused on was relevant and coherent in terms of policy and practice. Secondly we included, quality assessed and synthesised process evaluations. This enabled us to explore, in a systematic way, factors influencing the implementation of the intervention and to generate an explanation for the outcomes reported.

Despite its strengths the review had limitations. It was preferable for the subset of studies in the systematic review to be homogeneous in terms of intervention characteristics (e.g. provider, setting, materials, length/intensity, etc.) to ensure that their aggregation in a quantitative meta-analysis was meaningful and appropriate (i.e. that 'like was being compared with like'). Whilst prioritising what appears on face value to be a fairly standardised behavioural intervention (i.e. school-based education and skills development sexual health promotion) there was, nonetheless, some degree of variation between the studies. As mentioned above, some interventions were relatively brief whilst others more extensive. Some were curriculum focused, whilst others were delivered in the context of wider school sexual health promotion initiatives, and supplemented by activities in the home and community. Furthermore, although all were included because they included an element of skills

development, the type of skills taught, and the extent to which this was a focus of the intervention, varied. Some were theory-based interventions, designed specifically to improve sexual negotiation skills, whilst others provided relatively little rationale for skills training. This variability should be kept in mind in the interpretation of both the narrative synthesis and the meta-analysis.

The potential to perform meta-analysis was limited primarily by the lack of suitable data from the study publications. Common limitations included failure to report a measure of variance (e.g. SD) to allow continuous outcomes to be combined, or poor reporting of the number of young people with a given outcome (e.g. using a condom) to allow binary outcomes to be pooled. Our attempts to contact the authors to kindly request missing data were generally unsuccessful, as many did not reply to our e-mails. Although some of the studies were carried out some years ago, many of the authors still appear to be actively researching this area. Consequently, only a small proportion of the studies were able to be meta-analysed. Whilst one of the strengths of the meta-analysis was that it was only based on studies judged to be methodologically sound, not all of these studies were able to be included in it due to poor reporting of data.

Another issue to bear in mind is the fact that, despite a relatively narrow age range (13–19 years), it cannot be assumed that teenagers are a homogeneous group. There are likely to be numerous differences between younger and older teenagers in terms of social and sexual development. We have endeavoured, where possible, to take these differences into account in the analysis and interpretation of our results, although data on age subgroups are limited. It is also important to acknowledge that a number of studies that targeted young people aged up to their early to mid-twenties were excluded from our descriptive map (and hence our systematic review). These were not included as the commissioning brief for this project specified inclusion of young people aged 13–19 years. We also noted that much of the epidemiological and sexual lifestyle data relating to young people is for the 16–25 age group. Further evidence synthesis could therefore examine the clinical effectiveness and cost-effectiveness of behavioural interventions in this older group.

Economic evaluation

Our economic evaluation is one of the few published examples of an assessment of the cost-effectiveness of school-based behavioural interventions, particularly in the UK. It was informed by a systematic review of effectiveness and cost-effectiveness studies, and systematic searches for input parameter data.

Despite these strengths it is subject to limitations. As reported in Chapter 4 (see Sexual behaviour), our meta-analysis did not show a statistically significant intervention effect for behavioural outcomes. Absence of a statistically significant difference between behavioural intervention and standard sex education does not necessarily indicate that they are equivalent in terms of effect. However, rather than present a cost-minimisation analysis, which would be commonly be performed in this situation, we chose to report how a simple static model could provide illustrative estimates of the likely cost-effectiveness of two types of school-based behavioural intervention. A quantitative analysis of the impact of uncertainty on these illustrative results was undertaken using probabilistic sensitivity analysis, along with an indication of the likely cost and benefit of future primary research, via expected value of perfect information analysis. The static nature of the model does not take into account the dynamic nature of infectious diseases. However, a more pragmatic approach was considered appropriate, given the absence of key data for parameters needed to develop, calibrate and validate a robust dynamic model.

Chapter 9
Conclusions

There is an extensive evidence base for the prevention of STIs in young people. Much of it focuses on the prevention of HIV through school-based behavioural interventions. The literature is dominated by evaluation studies conducted in North America, although there is a not insignificant volume of evidence from resource-poor countries. Relatively few examples of UK interventions have been published.

This project has focused on one type of behavioural intervention – school-based programmes that provide information and teach young people sexual health negotiation skills. The results show that these programmes can bring about improvements in knowledge and increased self-efficacy. However, there were few significant differences between the intervention and comparator in terms of changes in behavioural outcomes such as condom use. The studies conducted relatively short follow-up assessments at a time when many young people were becoming sexually active. It is possible that favourable behaviour change may have occurred with time, particularly as sexual activity becomes more routine in young people's lives.

School-based skills and information interventions should therefore be used when the objective is to improve knowledge, and to foster favourable attitudes, peer norms and behavioural intentions (particularly for those not yet sexually active). Practitioners and policy-makers should have realistic expectations about the potential for interventions to influence sexual risk behaviour and infection rates until further evaluation evidence is available.

There is uncertainty around the results of our economic evaluation results due to the uncertainty around the effect of intervention on behavioural outcomes. The model results were most sensitive to changes in parameter values for the intervention effect and the transmission probability of STIs. Teacher-led interventions are likely to be cheaper than peer-led interventions.

Recommendations for practice

School-based skills building behavioural interventions should be delivered to improve knowledge, promote favourable attitudes, and increase self-efficacy and the skills necessary to engage in safer sexual behaviour, in accordance with health policy.[21,22] Interventions should be culturally relevant and context specific, taking into account the self-defined needs of subgroups of young people (e.g. young men, young women, levels of sexual experience) and, where possible, be part of a whole-school approach to sexual health promotion. Young people should be involved as equal stakeholders in the design and delivery of interventions.

Careful consideration should be given to the choice of intervention provider. Providers need to be enthusiastic and credible, with considerable expertise in classroom management and the delivery of skill-building activities, such as role plays and group discussions. Providers also need expertise in handling sensitive discussions about sex and relationships, and an appreciation of how wider sociocultural norms can influence sexual health. Teachers and peers alone may not possess all of these skills and qualities.

Attention should be paid to encouraging the full implementation of any skills-based intervention. The interactive learning elements of an intervention have been found to be especially vulnerable to being omitted, but it is these elements that may be the crucial ingredient for empowering young people to practice safe sex behaviours. A supportive school culture, which includes 'buy in' from the senior management team, can facilitate full intervention implementation. This echoes recommendations made by others, including the suggestion that improving pupils' satisfaction with school is a prerequisite to effective sexual health promotion.[173]

Recommendations for research

Primary research

If a further RCT of school-based sexual health education were to be commissioned in the UK it would be useful to evaluate the approach taken in one of the more effective studies included in our review, such as an adaptation of an approach similar to the Safer Choices intervention evaluated in the USA.

The intervention should comprise a range of components, including curriculum activities spread over at least two school years (single-sex lessons where necessary and feasible), accompanied by wider school health promotion activities, plus involvement of parents and, where necessary, health services (e.g. to encourage STI testing) and other relevant stakeholders (e.g. youth workers). A possible approach for evaluation would be for teachers and/or peers to provide factual information about STIs, with specialist trainers brought into schools to teach skills development. A pilot phase using qualitative research should assess the cultural and social relevance to the UK, and adaptations made accordingly.

The effectiveness of 'booster' sessions for young people progressing to further education and for those leaving full-time education should be explored. The aim would be to encourage sexually active young people to maintain protective behaviours, and to support those beginning to have sex in the adoption of safer behaviours.

All future evaluations should be rigorously designed and executed, with long-term follow-up of a range of outcomes, including sexual behaviour (e.g. condom use), conceptions and abortions, use of health services (e.g. STI testing) and rates of infections. Evaluations need to adequately measure the complexity of some young people's risk-reduction strategies, assessing use of negotiated safety strategies with partners.

Outcome evaluations should be accompanied by extensive process evaluation, and have an integral cost-effectiveness evaluation.

Research commissioners, journal editors and other relevant research stakeholders should encourage researchers to undertake analyses to assess the impact of interventions on sexual health inequalities. They should further encourage complete reporting of data and methods of analyses that investigate the impact of an intervention on the health outcomes of different sociodemographic groups.

Journal editors should subscribe to the revised Consolidated Standards of Reporting Trials (CONSORT) statement, which is intended to improve the overall reporting of RCTs,[174] and the Transparent Reporting of Evaluations with Nonrandomised Designs (TREND) statement for improving the reporting of non-randomised evaluations of behavioural and public health interventions.[175] These include guidance on appropriate reporting of outcome data and subgroup analyses.

Evidence synthesis

Further evidence synthesis would be appropriate to identify a subset of studies from our descriptive map with a particular focus on interventions aimed at young people classified as being vulnerable and at risk. It should be acknowledged that this would likely result in a more heterogeneous set of interventions in terms of setting, provider and message.

The effectiveness of skills development interventions in other (non-school) settings is also an important subject for evidence synthesis, complementary to this systematic review.

The effectiveness of broader school-based approaches to fostering young people's health, which teach everyday life skills that can be applied in a variety of contexts, including personal and sexual relationships, might be a suitable topic for future evidence syntheses.

Evidence synthesis could also examine the clinical effectiveness and cost-effectiveness of behavioural interventions in the 16–25 age group.

Cost-effectiveness

As specified above, any future primary research conducted should be accompanied by detailed economic evaluation to assess cost-effectiveness. Detailed data of the costs of mounting the intervention should be collected, and the impact on HRQoL should be assessed to enable cost–utility analysis. The analysis should extend over a time horizon that is long enough to capture all of the intended costs and consequences (e.g. until young people are in their early twenties).

For many of the parameters used to inform our economic model there were few or no available

data for the < 16-year-old age group, necessitating assumptions to be based on extrapolated data from older age groups. For example, there were few data on self-reported sexual behaviour of under-16s (e.g. number of sexual partners or episodes). The third National Survey of Sexual Attitudes and Lifestyles will commence in 2010, although as yet it does not appear that data on under-16s will be collected. There is a need for surveys such as this to collect data on younger teenagers, where possible, to inform research and enable the effective planning of services.

There is also a need for prospective cohort studies to inform the parameters used in economic modelling (e.g. transmission probabilities of STIs).

In order to reduce the uncertainty in the economic evaluation, analyses indicated that it is likely to cost up to £12.5M in order to obtain perfect information and that research would be best funded to establish the effectiveness of the intervention in terms of condom use, as this parameter has the largest effect on the uncertainty of the model results.

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Jonathan Shepherd (Principal Research Fellow), was the Principal Investigator, and chaired the advisory group. He contributed to the writing of the protocol, screened studies for inclusion in the descriptive map, applied keywords, data extracted and quality assessed studies included in the systematic review of effectiveness, conducted the analysis of the descriptive map, conducted the synthesis of outcome data in the systematic review of effectiveness, contributed to the cost-effectiveness analysis, and contributed to the write-up of the final report.

Josephine Kavanagh (Research Officer) was a coapplicant on the research proposal. She contributed to the protocol writing, conducted the literature searches for the systematic review of effectiveness, screened studies for inclusion in the descriptive map, applied keywords, data extracted and quality assessed studies included in the systematic review of effectiveness, contributed to the analysis of the descriptive map, participated in the synthesis of outcome data in the systematic review of effectiveness, and contributed to the write-up of the final report.

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Keith Cooper (Senior Research Fellow, Health Economics) screened studies for inclusion in the systematic review of cost-effectiveness, data extracted and quality assessed studies included in the systematic review of cost-effectiveness, developed the economic model and conducted the cost-effectiveness analysis, and contributed to the write-up of the final report.

Angela Harden (Senior Research Scientist in Evidence Synthesis) was a coapplicant on the research proposal. She contributed to the protocol writing, screened studies for inclusion in the descriptive map, applied keywords, data extracted and quality assessed studies included in the systematic review of effectiveness, participated in the synthesis of outcome evaluations data and led the synthesis of the process evaluation data in the systematic review of effectiveness, and contributed to the write-up of the final report.

Elaine Barnett-Page (Research Officer) conducted the literature searches for the systematic review of effectiveness, screened studies for inclusion in the descriptive map, applied keywords, data extracted and quality assessed studies included in the systematic review of effectiveness, participated in the synthesis of outcome and process evaluation data in the systematic review of effectiveness, and contributed to the write-up of the final report.

Jeremy Jones (Principal Research Fellow, Health Economics) was a coapplicant on the research proposal. He contributed to the protocol writing, screened studies for inclusion in the systematic review of cost-effectiveness, contributed to the development of the economic model and cost-effectiveness analysis, and contributed to the write-up of the final report.

Andy Clegg (Professor of Health Services Research & Director of SHTAC) was a coapplicant on the research proposal. He data extracted and quality assessed studies included in the systematic review of effectiveness, and contributed to the write-up of the final report.

Debbie Hartwell (Research Fellow) screened studies for inclusion in the descriptive map, applied keywords, and contributed to the write-up of the final report.

Geoff Frampton (Research Fellow) screened studies for inclusion in the descriptive map, applied keywords, and contributed to the write-up of the final report.

Alison Price (Information Scientist) was a co-applicant on the research proposal. She conducted the literature searches for systematic reviews of behavioural interventions to prevent STIs, searches for the systematic review of cost-effectiveness, and the searches for input parameter data for the economic model.

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Appendix 1

Research protocol

A systematic review and economic evaluation of behavioural approaches to preventing sexually transmitted infections (STIs) in young people

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Project title

A systematic review and economic evaluation of behavioural approaches to preventing sexually transmitted infections (STIs) in young people. (Funded by the NIHR Health Technology Assessment programme (www.hta.ac.uk). Project reference number 06/72/02.)

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Planned investigation

Background

Epidemiology and policy context

Rates of sexually transmitted infections are continuing to increase in the UK, particularly among young people. Genital chlamydia is currently the most common STI diagnosed in GUM clinics in the UK. The number of cases has risen steadily since the mid-1990s, and rose by 5% (104,733–109,958) between 2004 and 2005.[1] There have also been increases in rates of gonorrhoea, genital herpes and genital warts. Rates of also HIV continue to rise. At the end of 2005, an estimated 63,500 adults aged 15–59 were living with HIV in the UK. Young people aged 16–24 account for about 11% of HIV diagnoses each year.[2]

If undiagnosed and untreated, STIs can lead to serious long-term complications, such as infertility, PID (in women) and epididymitis (in men). Certain types of HPV, for example, are associated with cervical carcinoma.[3] HIV is associated with disease progression to AIDS and related complications, and, if untreated, results in mortality. The impact of increases in the incidence and prevalence of STIs over recent years has placed great demand on health services. Data from the NATSAL show an increase in the number of individuals attending GUM services[4] over a 10-year period. Between 1990 and 2000 there was an increase of 4.3–7.6% in men and 3.3–6.6% among women. This may be explained by increases in rates of STIs, but it is also due to widening access to clinic services and encouraging asymptomatic screening. The average lifetime treatment costs for an HIV-positive individual is estimated to be between £135,000 and £181,000.[5]

Prevention of STIs and teenage pregnancy is currently a high priority for health policy.[6] In 2001, the National Strategy for Sexual Health and HIV was published, demonstrating a commitment to tackling sexual ill-health and unintended pregnancies through improved prevention and treatment.[5] A key aim of the strategy is to address health inequalities and the needs of vulnerable groups, including (amongst others) young people, particularly those in, or leaving, care.

Defining risk

Sexual health is influenced by a complex interplay between a number of factors, including the individual, their sexual partners, and their social and economic environment. In terms of demographic factors, epidemiological data illustrate variability in the incidence and prevalence of STIs according to age, gender and geographical location. Recent routine surveillance data from the HPA show that young women aged 16–19 years have the highest rates of infection of gonorrhoea, chlamydia and genital warts.[1,7,8] The NATSAL (2001)[9] found that early age at first intercourse was significantly associated with pregnancy under 18 years. HPA data also show a marked difference in geographic distribution of gonorrhoea and chlamydia infection in young people, with London having the highest rate of diagnosis, followed by Yorkshire/Humberside and the North West.[1,7]

Lack of knowledge, low self-efficacy and poor condom use/sexual negotiation skills are examples of personal risk factors for STIs. These have been addressed by interventions that provide factual information and skills training. Peer group norms also influence risk taking, and peer-led interventions have been designed to evaluate the effectiveness of harnessing peer influence.[10,11]

Ethnicity is commonly associated with poor health. Data from the NATSAL probability survey show that some ethnic populations are more at risk than others. Black African and black Caribbean respondents were significantly more likely to report early sexual debut (before age 16), previously diagnosed STIs, HIV testing and GUM clinic attendance than Indian and Pakistani respondents.[12] Black Caribbean respondents were significantly more likely to report GUM clinic attendance, STI diagnosis and ever having an HIV test than white men and women. It is suggested that the younger age, single marital status and early age of first intercourse of black Caribbean people relative to other ethnic groups could explain the findings.

Socioeconomic status has long been considered to be a key determinant of health.[13] A number of inter-related factors account for this, including low income, lack of autonomy, social exclusion, poor lifestyles and poor access to health care.[14] Low SES and other factors related to social disadvantage are strongly associated with teenage pregnancy.[15] Research indicates that a combination of access to services and the chance to gain the education and employment needed to succeed reasonably in society is associated with lower rates of teenage pregnancy.[9,16]

Behavioural interventions

There is no precise definition of a behavioural intervention, and concepts and practices vary, but, in general, a behavioural approach might be viewed as an intervention that addresses the health needs of an individual or a population, with the aim of encouraging favourable health-related behaviours. Behaviours are mediated, in part, by improving knowledge, self-confidence, self-efficacy, and encouraging more favourable attitudes and behavioural intentions. Some behavioural interventions are explicitly based on social or psychological theories of behaviour change, for example the Stages of Change ('transtheoretical') model.[17]

The 'message' of the behavioural intervention reflects the particular needs of the recipients, as well as the underlying ideology/policy of the provider. For example, messages could be about maintaining safer sex in those who are sexually active, reducing risks in those who are at increased risk or encouraging abstinence/deferring of sexual activity among those who are not yet sexually active. Intervention activities can vary, from the provision of confidential information and advice around sex and STIs to skills training on how to use condoms and negotiate safer sex with a partner. Sometimes these activities may be integrated within the context of screening, testing and health care.

The classification of behavioural interventions proposed by Darbes and colleagues (2002)[18] will be used as a working definition in this study:

- *Behavioural interventions* These are interventions that aim to change only individual behaviours, without explicit or direct attempts to change the norms of the community or the target population as a whole. Components of such interventions would include counselling, HIV testing and counselling, peer education, referrals, skills training, and the provision of risk-reduction materials.
- *Social interventions* These are interventions that aim to change not only individual behaviours, but also social norms or peer norms. Strategies, such as community mobilisation, diffusion, building networks, and structural and resource support, are often used to bring about changes in social norms and/or peer norms.
- *Policy interventions* These are interventions that aim to change individual behaviour or peer/social norms or structures through administrative or legal decisions. Examples include needle-exchange programmes, condom availability in public settings, and mandated HIV education in all schools of a district.

Current UK practice

In current UK practice, behavioural interventions to prevent STIs are provided by services such as primary care, community family planning, GUM, primary care trust health promotion services and the voluntary sector (e.g. Brook Advisory Centres). Sexual health promotion is also provided in schools and colleges as part of the curriculum, as well as being a component of school-based health services. A variety of people are involved, including health professionals, teachers, social workers, youth offending teams, prison and probation services, and parents and young people themselves. In some cases they collaborate to provide multicomponent interventions. Behavioural approaches, therefore, may potentially encapsulate a wide variety of interventions with diversity in terms of provider, setting and message.

Cost-effectiveness of behavioural interventions

Searches of electronic bibliographic databases conducted for this protocol yielded a variety of published cost-effectiveness analyses of STI prevention interventions. However, not all of these featured young people,[19] or could be classed as behavioural interventions,[20] and many were based on evaluations of interventions conducted in the USA, dating back to the late 1980s/early 1990s.[21] These are of questionable relevance to the UK at the current time, where service provision and the epidemiology of STIs may be quite different.

For example, Pinkerton and colleagues[22]reported the cost-effectiveness of a RCT of an intensive 1-day cognitive–behavioural HIV-risk-reduction intervention for African-American young men in Philadelphia. The intervention, originally conducted in 1988, aimed to increase knowledge of HIV/AIDS and to weaken problematic attitudes towards risky sexual practices. Control group participants attended a similarly designed workshop, with a focus on career opportunities instead of sexual health. The intervention was associated with favourable changes in number of partners, and use of condoms. A mathematical model was used to translate changes in sexual behaviour into the probability of HIV transmission for intervention and control groups. For each infection averted, the savings in future HIV-related medical care costs and QALYs was estimated. The intervention averted 0.8% of an infection,

corresponding to savings of around US$1500 in future HIV/AIDS-related medical care costs, and one-tenth of a QALY over an assumed 1-year duration of effectiveness. The cost per QALY saved was around US$57,000, which fell to US$28,000 in the subset of participants who reported sexual activity in the 3 months preceding the intervention. Results were sensitive to assumed duration of intervention effectiveness, discount rates, staff training costs, and baseline HIV prevalence in the population. The authors debate a key issue, namely how relevant the risk-reduction messages and skills-building techniques used in the 1988 intervention are to young people today.

In terms of UK-based cost effectiveness assessments, NICE have published public health guidance on sexual health.[23] The guidance covers one type of behavioural approach, that is, one-to-one interventions. Effectiveness data are derived from an accompanying rapid review of international RCTs, evaluating counselling interventions. Cost–utility estimates are reported for each of the included RCTs, based on a hypothetical cohort of 1000 people receiving the intervention and the comparator, respectively. There was wide variation in estimates, with costs per QALY ranging from £3200 to £96,000. Variation in the intensity of the intervention, and, consequently, the costs for staff time was a key driver of cost-effectiveness. The authors noted that effect estimates (i.e. rates of STIs) reported in the RCTs were higher than would be expected in England, suggesting uncertainty in the findings.

In summary, that there is a paucity of published cost-effectiveness studies of behavioural approaches to STI prevention that are relevant to the UK, underscoring the need for up-to-date policy-relevant cost-effectiveness analysis. It will be important for such analysis to carefully assess the applicability of data from interventions originally designed for specific cultural groups and populations in other countries to young people in the UK at the current time.

Rationale for the study

There is a large body of published primary research on the effectiveness of interventions to prevent STIs (and unintended pregnancy) amongst young people, much of it non-UK literature. Several systematic reviews have been published over the years summarising this research.[24–26] In 2004, the former Health Development Agency (now the Centre for Public Health Excellence at NICE) assessed these systematic reviews in its series of Evidence Briefings.[27-29] The briefings suggested that we do not yet have a clear picture of the effectiveness of behavioural interventions for the prevention of STIs amongst young people. There was only 'tentative' evidence from systematic reviews that specific behavioural approaches, such as individual risk counselling can be effective, and that interventions that promote risk reduction, rather than abstinence alone, are more likely to be effective. There was 'insufficient' evidence from systematic reviews to support or discount the effectiveness of detached education or outreach interventions, or that school-based abstinence only approaches are effective. Many of the systematic reviews and economic evaluations included in the Evidence Briefings are now out of date. A thorough assessment of the effectiveness and cost-effectiveness of behavioural approaches to STI prevention in young people, particularly those at higher risk, is therefore important to meet the needs of policy and practice.

Research aim

Research question: What is the effectiveness and cost-effectiveness of different behavioural approaches in preventing STIs among young people aged 13–19 years?

Objectives

The main objectives will be as follows:

- to conduct a systematic review of the effectiveness of different behavioural approaches to the prevention of STIs
- to assess the cost-effectiveness of different behavioural approaches through economic modelling, where appropriate.

Research methods

Systematic review of effectiveness

A two-stage systematic review will be conducted.

Stage one – descriptive mapping exercise

The first stage will be a descriptive mapping of studies meeting a set of inclusion criteria (*Table 70*). Relevant studies will be classified on the basis of their key characteristics according to a standardised classification system for public health and health promotion research,[30] using the web-based systematic review software EPPI-REVIEWER.[31] For more information on EPPI-REVIEWER visit http://eppi.ioe.ac.uk/cms/Default.aspx?tabid=184)

It will prove difficult to search for evaluations of behavioural interventions to prevent STIs in young people who are considered to be high risk, as few relevant index terms exist in electronic bibliographic databases to enable more specific

searches. The purpose of this exercise, therefore, is to facilitate a more detailed description of the evidence base so that a subset of policy-relevant studies may be subjected to detailed systematic review. The completed descriptive map will be presented to the project's advisory group, who will be asked to help prioritise a subset of studies that most closely resemble current UK practice, which are most likely to address current policy and practice needs (for more information on the Advisory Group, see section Advisory group).

Studies will be classified according to:

- subgroups of young people, based on markers of their 'risk' of acquiring an STI (e.g. SES, ethnicity, educational status, geographical location, STI history, HIV status, self-reported risk behaviour)
- STI(s) under focus (e.g. HIV/chlamydia/gonorrhoea/genital warts/non-specific urethritis)
- intervention evaluated (e.g. education/skills training/counselling/provision of resources and services)
- intervention provider (e.g. teacher/youth worker/peer/health professional/social worker)
- intervention setting (e.g. school/community/youth group/health care/outreach/home)
- country and location (e.g. UK/rural/urban/coastal)
- outcome (e.g. different sexual behavioural outcomes/STI infection rates).

Stage two – in-depth systematic review

The second stage will be a detailed systematic review in which a prioritised subset of studies from the descriptive map will undergo detailed data extraction, critical appraisal and synthesis, as described below. The inclusion criteria for this second stage will be further defined following presentation of the completed descriptive map to the project's advisory group.

Literature search

Study reports will be identified from the following sources:

- bibliographic databases (commercial and specialist); hand searching of key journals (where necessary); citation searches of key authors; reference lists of key papers; references on key websites; personal contacts/advisory group; direct requests to key informants
- six published EPPI-Centre reviews, which cover, amongst other topics, sexual health.[10,32–36]

The following electronic bibliographic databases will be searched:

- MEDLINE (via Ovid)
- MEDLINE In-Process & Other Non-Indexed Citations (via Ovid)
- EMBASE (via Ovid)
- PsycINFO (via Ovid)
- Educational Resources Information Centre (ERIC) (via CSA)
- CINAHL (via Ovid)
- Trials Register of Promoting Health Interventions (TRoPHI – the EPPI-Centre register of RCTs and non-randomised controlled trials)
- The Cochrane Central Register of Controlled Trials (CCRCT)
- Applied Social Sciences Index and Abstracts (ASSIA) (via CSA)
- POPLINE
- Sociological Abstracts (SOCABS) (via CSA).

The following websites will also be searched to identify relevant studies:

- The UK National Library for Health (NLH) – www.library.nhs.uk/Default.aspx
- UNAIDS –www.unaids.org/en/
- Google Scholar – http://scholar.google.co.uk

Searches will take place for the period 1985 to the present. Non-English language articles will not be included.

Highly sensitive search strategies will be developed in order to retrieve a high volume of references using combinations of controlled vocabulary and free-text terms (the latter restricted to the title or abstract fields). There will be four sets of search terms: young people *and* STIs *and* prevention *and* outcome evaluations.

Personal contact will be made with key researchers and other systematic reviewers in the fields of STI prevention. Requests for further relevant studies will be made to the authors of relevant outcome evaluations, and to members of the advisory group. The reference lists of studies already identified will be scanned for potentially relevant reports.

References will be uploaded to EPPI-REVIEWER, where they will be stored ready for screening.

TABLE 1 *Stage one – inclusion criteria for descriptive mapping exercise*

Population	**Young people aged 13–19 years (as specified in the HTA commissioning brief)**
Design	Outcome evaluations (RCT or non-randomised controlled trial)
	'Outcome evaluations', defined as studies designed to establish whether the intervention changes the outcomes specified in the aims of the study. We will only include studies that have used a control or comparison group(s) (whether randomised or not). Outcome evaluations that include an integral cost-effectiveness analysis will also be included and results reported.
	We will also consider any process data collected within the outcome evaluations to explore issues of acceptability, feasibility and generalisability. Process data will also be used to identify factors associated with intervention effectiveness (see section Data Synthesis)
	Studies reported in abstract form only (e.g. conference proceedings) will only be included if they are published on or after 2005
Intervention	We propose an inclusive strategy and define behavioural interventions as 'any activity to encourage young people to adopt behaviours that will protect them from acquiring STIs'
Comparator	The commissioning brief states that the comparator should be 'standard practice'. Current service provision in the UK is variable and it is difficult to define standard practice. Potentially eligible studies are likely to have included a range of comparators. In some studies the intervention will have been given in addition to standard practice (e.g. behavioural skills training in addition to information provision plus vs information provision only). We will not exclude studies on the basis of comparator, but will be guided by our expert advisory group on which comparators most closely resemble UK practice
Outcomes	Studies that report the impact of the intervention on a sexual behavioural outcome will be included. For example:
	Self-reported condom use (e.g. frequency of use)
	Numbers of sexual partners (including abstinence)
	Studies reporting incidence/prevalence of STIs are to be included, provided that they have also reported a behavioural outcome
	Studies reporting pregnancy-related outcomes (e.g. rate of conceptions) can be included, provided that they have included a sexual behaviour outcome
	In addition to the above, data on other outcomes that mediate behaviour change may be extracted where available (e.g. changes in knowledge; attitudes, intentions, skills, self-efficacy)

De-duplication will take place to remove duplicate references found within, and between, bibliographic databases.

A separate search will be conducted to identify systematic reviews of the effectiveness of behavioural interventions to prevent STIs. The primary purpose will be to check the bibliographies of relevant systematic reviews to identify any relevant outcome evaluations. The search for systematic reviews will be based on those conducted for the Evidence Briefings on STIs and HIV.[27,28] As these briefings searched up to 2003, our search will commence from 2003 to the present. Databases to be searched will include: Cochrane Database of Systematic Reviews (CDSR); Database of Abstracts of Reviews of Effectiveness (DARE); MEDLINE (Ovid); MEDLINE In-Process & Other Non-Indexed Citations (Ovid); EMBASE (Ovid); CINAHL (Ovid); British Nursing Index; PsycINFO; Educational Resources Information Centre (ERIC); and Sociological Abstracts.

Study inclusion

The planned inclusion criteria for the descriptive mapping exercise are shown in *Table 70*. Inclusion and exclusion criteria will be applied successively to titles and abstracts by one reviewer. Full reports will be obtained for those studies that appear to meet the criteria or where there is insufficient information from the title and abstract. Full reports will be assessed by two reviewers independently. Disagreements will be resolved through discussion and recourse to a third reviewer if necessary. A QUOROM-style flow chart will be used to document the numbers of studies included and excluded at each stage of the review.

Data extraction

A standardised framework will be used to collect data from outcome evaluations and entered into EPPI-REVIEWER. This framework was developed specifically for studies in health promotion and public health and has been successfully

used in over 20 published systematic reviews. The guidelines enable reviewers to extract data on: the development and content of the intervention evaluated; the design and results of the outcome evaluation; details of any integral process evaluation; and data to assess the methodological quality of the outcome and process evaluation. The guidelines pay particular attention to generalisability and applicability of the intervention, which will be important in order to interpret the transferability of international literature to the UK context.

As mentioned earlier (Literature search), some of the relevant studies are likely to have been included in previous EPPI-Centre systematic reviews, and therefore will have already undergone data extraction and quality assessment. Data on these studies will be retrieved from EPPI-REVIEWER for analysis and any further data extraction specific to the proposed systematic review. This will potentially reduce the workload and is an effective use of an existing resource.

Quality assessment

The quality of outcome evaluations will be appraised using criteria described in previous published EPPI-Centre reviews.[10,26,37] This will be conducted by two researchers independently. Any disagreements will be resolved through discussion and recourse to a third team member if necessary. Quality criteria include factors such as blinding, attrition and loss to follow-up; data analysis methods (e.g. intention to intervene, unit of analysis); method of allocation to study groups; and reliability and validity of data collection and analysis methods. Outcome evaluations will be categorised into two groups: 'sound' and 'not sound'.

'Sound' outcome evaluations will be those deemed to meet the following four criteria:

1. employing a control/comparison group equivalent to the intervention group on sociodemographic and outcome variables
2. providing pre-intervention data for all individuals/groups as recruited into the evaluation
3. providing post-intervention data for all individuals/groups, and
4. reporting on all outcomes – only the results of 'sound' outcome evaluations will be analysed in detail.

These criteria, however, only capture some of the known sources of bias in outcome evaluations. They do not distinguish between RCTs and non-randomised trials, or between quality of method and quality of reporting. We will include, therefore, a further category of studies as 'sound despite discrepancies with the four core criteria'. This category includes, for example, studies in which full pre-intervention data were not presented but authors stated that there were no significant differences between the groups or differences had been accounted for in data analysis.

Data synthesis

Two types of data will be available: numerical data in the form of effect sizes from trials, and textual data describing interventions, populations, outcomes and the results of any process evaluations. Statistical methods will be used to synthesise effect sizes, where possible, using the EPPI-REVIEWER software, and following standard methods for statistical meta-analysis.[38] Methods for the synthesis of process evaluations and textual data will be based on methodology from our previous work on the synthesis of 'qualitative' research[39,40] and from other groups.[41] There will be five stages:

1. Evidence tables will be prepared to describe variation in intervention type, content, setting, provider, sample characteristics and type of outcome. When available, process data will be described on acceptability, barriers and facilitators to implementation and delivery, coverage/intervention reach, and generalisability.
2. Process data will be synthesised thematically using inductive methods that we have developed in previous reviews.[42] Two reviewers will (1) read and re-read these data; (2) apply codes to capture the content of these data; and (3) group and organise codes into higher-order themes. These themes will be used to illuminate issues of acceptability, barriers and facilitators to implementation and delivery, coverage/intervention reach, and generalisability, and to generate hypotheses about factors related to intervention effectiveness.
3. Checks for statistical heterogeneity will be made and, if appropriate and feasible, effect sizes on priority outcomes from individual trials will be pooled using statistical meta-analysis.
4. Variation in effect sizes will be explored according to hypotheses developed in Stage

Two on factors that may influence intervention effectiveness (e.g. do interventions with characteristics associated with the acceptability of interventions have greater effects than those that do not?). Sensitivity analyses will be conducted to explore heterogeneity due to differences in study quality (e.g. sound/sound despite discrepancies).

5. On the basis of the findings of the above four stages, conclusions will be drawn on: which interventions are effective for encouraging sexual risk reduction and reducing STIs; which interventions are appropriate and acceptable to young people; the barriers and facilitators to intervention implementation and how these vary according to different types of interventions or settings; and which risk groups of young people the interventions reach/do not reach.

Economic evaluation

A review of economic evaluations of interventions to prevent STIs will be conducted. It is not intended that the results be reported as a systematic review. Rather, the purpose is to identify recent relevant evaluations, in order to analyse the methodological approaches undertaken, and to discern whether and how existing models can be adapted for use in the current project.

Where necessary a decision-analytic model will be devised to assess the cost-effectiveness of behavioural approaches to STI prevention. The exact structure of the model will be designed to reflect the natural history of STIs, and will be validated through discussion with expert advisors. Modelling will be conducted according to accepted methodology for economic evaluations.[43,44] The perspective will be the NHS and PSS.

Model structure

The structure and parameters of the model will be informed primarily by the systematic review of effectiveness studies. Additional targeted searches will be undertaken to identify specific data to populate the model. These will include searches for data on STI epidemiology and natural history; the health-related quality-of-life impacts of STIs and their complications; and the cost of behavioural interventions and health-care costs. Where these data cannot be identified through searches, estimates will be based on information supplied by our expert advisory group and others.

The model will contain a hypothetical cohort of individuals and will estimate changes in STI incidence and prevalence following introduction of a behavioural intervention. Given that there is likely to be substantial variation in the types of intervention identified in the systematic review of effectiveness, the subset of intervention(s) that most closely resemble those used in current UK practice will be modelled in the cost-effectiveness analysis. The advisory group and other experts will help to assess the relevance of the published interventions to current practice. Where possible examples of different 'types' of behavioural intervention will be modelled (e.g. interventions to provide basic factual information provision; interventions to teach behavioural skills; and counselling/cognitive behavioural therapy interventions).

The model will provide a cost-consequence analysis, reporting the costs of interventions included in the systematic review and their consequences in terms of STIs prevented. The model will also estimate the longer term consequences of preventing infections (e.g. HIV), in terms of benefits (infections averted, improvements in health-related quality of life, and life years saved) and costs (e.g. assessing and treating the infection and its complications). Cost-effectiveness will be estimated for subgroups where the data allow (e.g. those with a previous history of STIs; younger teenagers).

Input data

Changes to the incidence of STIs, where reported by studies included in the systematic review of effectiveness, will be entered into the model. Where data on STIs are not reported by effectiveness studies, the impact of changes in self-reported sexual behaviour on the incidence of STIs will be estimated, where possible. For example, Wang and colleagues[45] adapted the Bernoulli model of HIV transmission to estimate the reduction in primary and secondary transmission of HIV and other STIs associated with a school-based prevention programme. The probability of becoming infected was estimated by applying the probability of adopting risk reducing behaviour (in this case, condom use by students in the intervention and control groups) to the per-act transmission probability for a given disease and a given sexual activity. This model could also be used to estimate the impact, in terms of avoided infections, of programmes aiming to reduce numbers of sexual partners, numbers of sexual acts with each partner or reduction in high-risk sexual activity.

Costs and resource estimation

The resources necessary for providing the intervention will be estimated from the systematic review of effectiveness, and from discussion with expert advisers. This will be supplemented by data sought from primary care trusts on the resources used and costs of interventions run by health service professionals (e.g. costs for condoms distributed, costs for human resources to provide the intervention). Unit costs for these resources will be developed based on data in published sources, such as the Unit Costs of Health and Social Care, PSSRU.[46] Data on the cost of assessing and treating HIV and other STIs will be sought from Southampton University Hospitals Trust (SUHT), who routinely supply the Southampton Health Technology Assessments Centre (SHTAC) with cost data and clinical expertise.

Costs and benefits will be discounted using standard rates (3.5%).[47] Uncertainty relating to input parameters and assumptions will be explored using sensitivity analyses (deterministic and, where appropriate and feasible, probabilistic). The key variables to be explored will include: intervention effect estimates (e.g. self-report behaviour, STI incidence); baseline STI prevalence estimates, baseline risk (e.g. self-reported behaviour, STI history); intervention costs; health-related quality of life; and STI treatment costs.

Outcomes

Results will be expressed in terms of incremental cost-effectiveness ratios (e.g. incremental costs per infection averted). For infections associated with long-term morbidity and mortality (e.g. HIV), results will be expressed in terms of life-years saved and incremental cost per QOLY saved). CEACs will be generated in any probabilistic sensitivity analysis to illustrate the probability of the intervention being cost-effective over a range of willingness-to-pay values. The model will be developed using standard software, such as Microsoft Excel and Tree-Age Pro. Although de novo modelling is planned, the possibility of adapting an existing published model along the lines of the proposed model will be explored through contact with experts in the field.

Ethical arrangements

No specific ethical arrangements necessary.

Outputs of the review

The results will be reported in a final report to the HTA programme, for publication as a monograph in the Health Technology Assessment series. A series of publications describing different aspects of the project (e.g. effectiveness results from outcome and process evaluations, cost-effectiveness results) will be written and submitted to high-impact academic and practice journals. Abstracts will be submitted to relevant major national and international conferences.

Competing interests

No member of the team has registered any competing interests.

Project management and milestones

Milestones	Month
Project initiation	
Development of protocol	1–2: Feb–Mar (2008)
Systematic review	
Literature searches	1–2: Feb–Mar
Study selection	2–4: Mar–May
Study retrieval	2–4: Mar–May
Production of descriptive map	4–5: May–Jun
Data extraction	5–7: Jun–Aug
Data analysis	6–8: July–Sept
Economic evaluation	
Review of economic evaluations	1–3: Feb–Apr
Model conceptualisation	3–4: Apr–May
Input data collection	4–6: May–Jun
Model construction and validation	5–7: Jun–Aug
Run model	8–9: Sep–Oct
Sensitivity analysis	9–10: Oct–Nov
Final report	
Drafting of final report	6–10: Jul–Nov
Advisory group review/peer review of draft report	11: Dec
Submission and dissemination of report	12: Jan (2009)

Advisory group

User involvement in the review will be sought via a multidisciplinary advisory group. We plan to invite the following representatives:

- clinicians specialising in GUM
- health promotion practitioners specialising in sexual health
- youth workers/practitioners working with vulnerable young people
- voluntary sector representatives
- policy specialists (e.g. from Department of Health/NICE Centre for Public Health Excellence)
- academics (e.g. including health economists and experts in the field of sexual health research).

Up to three meetings will be held, corresponding with the key stages of the project. The first meeting will be held around months 4–5 (May–Jun) to prioritise a subset of studies from the descriptive map and to present an outline conceptualisation of the economic model. The second meeting will be held around months 8–9 (Sep–Oct). The group will also be asked to read and comment on the draft report in month 11 (Dec).

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Appendix 2

MEDLINE (via Ovid) search strategy for systematic review of effectiveness

1. exp Health Promotion/
2. exp Health Education/
3. exp Preventive Health Services/
4. exp Preventive Medicine/
5. exp Primary Prevention/
6. Public Health/
7. exp Social Medicine/
8. exp Behavior Therapy/
9. exp behavior control/
10. attitude to health/or health knowledge, attitudes, practice/
11. exp Health Behavior/
12. exp Sexual Behavior/
13. exp risk reduction behavior/or exp risk-taking/ or exp condoms/
14. exp unsafe sex/
15. exp safe sex/
16. exp sexual abstinence/
17. exp Sex Education/or exp sexology/
18. ((prevent$or reduc$or educat$or promot$or increas$or decreas$or facilitat$or barrier$or encourag$) adj2 (sex$or HIV or STI or STIs or STD$)).ab,kw,ti.
19. or/1–18
20. exp Sexually Transmitted Diseases/
21. exp Sexually Transmitted Diseases, Bacterial/
22. exp chancroid/or exp chlamydia infections/ or exp lymphogranuloma venereum/or exp gonorrhea/or exp granuloma inguinale/or exp syphilis/
23. exp HIV Infections/
24. exp Acquired Immunodeficiency Syndrome/
25. Herpes Genitalis/
26. Condylomata Acuminata/
27. (HPV or human papilloma$).ab,kw,ti.
28. ((genital or venereal) adj2 wart$).ab,kw,ti.
29. (STI or STIs or STD or STDs).ab,kw,ti.
30. (Sexual$transmit$adj3 (infect$or disease$)).ab,kw,ti.
31. 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
32. exp Adolescent/
33. (young$adj2 (men or man or woman or women or female$or male$or people or person)).ab,kw,ti.
34. (teenage$or adolescen$or youth or youths).ab,kw,ti.
35. 32 or 33 or 34
36. 19 and 31 and 35
37. randomized controlled trial.pt.
38. controlled clinical trial.pt.
39. clinical trial.pt.
40. random$.ti,ab.
41. control$.ti,ab.
42. (effectiveness or trial).ti.
43. placebo.ti,ab.
44. intervention$.tw.
45. ((control$or experimental or compar$) adj2 (Group$or trial$or study or studies or evaluat$or condition)).ti,ab.
46. 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45
47. 36 and 46
48. limit 47 to yr='1985 – 2008'
49. exp pharmacology, clinical/or exp pharmacology/
50. exp surgical procedures, operative/
51. exp Therapeutics/
52. exp HIV infections/dt
53. exp Sexually Transmitted Diseases/dt
54. 49 or 50 or 51 or 52 or 53
55. 48 not 54
56. from 55 keep 1–1000
57. from 55 keep 1001–2000
58. from 55 keep 2001–3000
59. from 55 keep 3001–3668

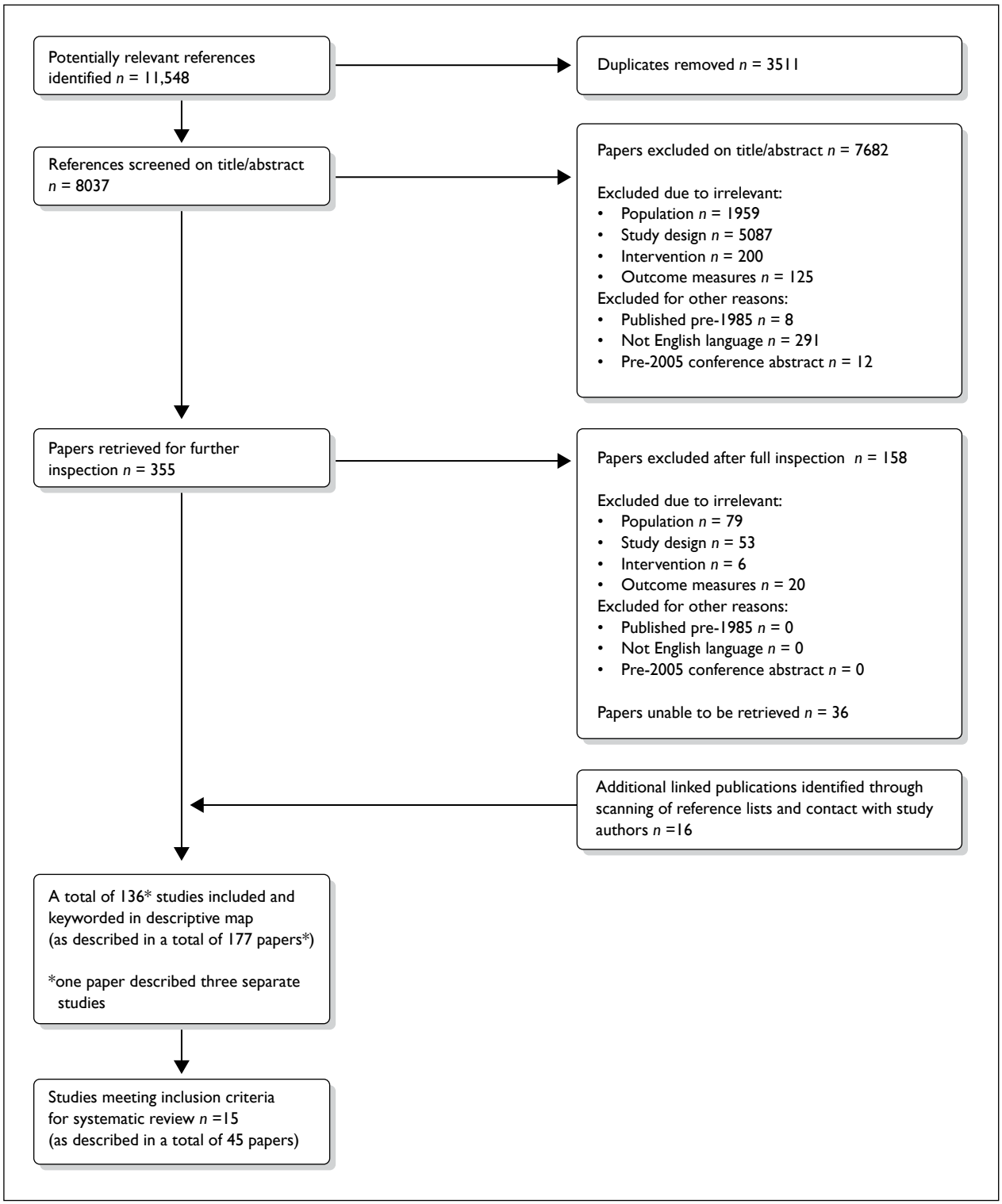
Appendix 3

Inclusion worksheet for systematic review of effectiveness

Trial name or number				
Population: Young people aged 13–19 years	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	Type: EXCLUDE1 (irrelevant population)
Design: Outcome evaluation (RCT or non-randomised controlled trial)	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	EXCLUDE2 (irrelevant study design)
Intervention: Behavioural interventions that aim to prevent STIs Currently defined as: 'any activity to encourage young people to adopt sexual behaviours that will protect them from acquiring STIs' Any STI is eligible, including HIV	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	EXCLUDE3 (irrelevant intervention)
Outcomes: Reports impact of the intervention on a sexual behavioural outcome. For example: • self-reported condom use (e.g. frequency of use) • numbers of sexual partners (including abstinence) • studies reporting incidence/prevalence of STIs to be included, provided that they have also reported a behavioural outcome • studies reporting pregnancy-related outcomes (e.g. rate of conceptions) can be included, provided that they have included a sexual behaviour outcome.	Yes ↓ Next question	Unclear ↓ Next question	No → EXCLUDE	EXCLUDE4 (irrelevant outcome measures)
Final decision	**INCLUDE**	**UNCLEAR (Discuss)**	**EXCLUDE**	**Results of discussion**

Appendix 4

QUOROM flow chart for systematic review of effectiveness



Appendix 5

Data extraction and quality assessment instrument

Section A: Support for the study	
A.1 Source of funding	A.1.1 Not stated A.1.2 Stated (write in)
A.1 Source of funding	A.1.1 Not stated A.1.2 Stated (write in)
Section B: Study design	
B.1 What type of study is described?	B.1.1 RCT B.1.2 Cluster RCT B.1.3 Non-randomised controlled study B.1.4 Cluster non-randomised controlled study B.1.5 Process evaluation B.1.6 Other (describe)
B.2 Country in which intervention was implemented *Note: This is not necessarily the same as the country of the research institutions. If the study is conducted in more than one country, indicate them all*	B.2.1 Germany B.2.2 The Netherlands B.2.3 Tanzania B.2.4 Kenya B.2.5 USA B.2.6 UK B.2.7 Finland B.2.8 Israel B.2.9 Norway B.2.10 Rwanda B.2.11 Sweden B.2.12 South Africa B.2.13 France B.2.14 Thailand B.2.15 Iceland B.2.16 Belgium B.2.17 Peru B.2.18 Switzerland B.2.19 China B.2.20 The Philippines B.2.21 Italy B.2.22 Honduras B.2.23 Canada B.2.24 Australia B.2.25 Holland B.2.26 New Zealand B.2.27 Japan B.2.28 Poland B.2.29 Singapore

	B.2.30 Nicaragua B.2.31 India B.2.32 Ghana B.2.33 Indonesia B.2.34 Greece B.2.35 Ireland B.2.36 Nigeria B.2.37 Other
Section C: Description of intervention	
C.1 What is the name of the programme?	C.1.1 No name C.1.2 Named (describe)
C.2 Content of the intervention package *Describe the intervention in detail, whenever possible copying the authors' description from the report word for word. Descriptions should cover type, provider and medium. If specified in the report, also describe in details what the control/ comparison group(s) were exposed to*	C.2.1 Details
C.3 Aim(s) of the intervention	C.3.1 Not stated C.3.2 Not explicitly stated *Write in, as worded by the reviewer* C.3.3 Stated (write in) *Write in, as stated by the authors*
C.4 Theoretical model (as stated by the authors) *Indicate ALL of the models which authors state they have used in the design of the intervention*	C.4.1 Not stated C.4.2 Unclear C.4.3 Community-orientated Model *Models which attempt to change attitudes or norms of a distinct group (e.g. prostitutes), by targeting a large proportion of the group. The intervention may involve self-efficacy or traditional education presentations, but also involves changing the context in which individuals operate by instilling new norms in all or most of the community members, relying on peer support and not on self-efficacy* C.4.4 Cognitive Theory *These emphasise the causal role of cognition in the development of behaviour, including problem behaviours. Interventions derived from these theories (rational–emotive therapy, cognitive therapy, stress inoculation therapy, anger control) focus therapeutic effort of effecting changes in the way people think (e.g. selective perception, misattribution, faulty information processing)* C.4.5 Eco-behavioural/Ecological Action Model *These focus attention on the influence of social factors, such as external stressors (e.g. poverty, serious life events), societal values, and developmental factors, and examine these within the framework of theories of learning.* C.4.6 Health Belief Model *This states that the likelihood of an individual adopting preventative behaviour(s) is dependent on four personal perceptions: their SUSCEPTIBILITY to the condition; the SERIOUSNESS of the condition; the BENEFITS and the efficacy of the preventative behaviour(s), and the extent of the BARRIERS to the behaviour(s)*

	C.4.7 Learning Theory *Two paradigms of learning are included under this heading: (1) respondent (or classical) conditioning, thought to account for the acquisition of a range of emotional and affective behaviour (such as phobias, anxiety, sexual dysfunction); key therapeutic interventions include graded in vivo exposure and systemic desensitisation; and (2) operant (or instrumental) conditioning, which highlights the impact of environmental stimuli on behaviour; key therapeutic interventions include differential reinforcement, extinction, time-out, and punishment* C.4.8 Psychodynamic Theory *This derives from the work of Freud, and stresses the importance of early life experiences on the development of personality, particularly the psychosocial dramas and conflicts of key stages such as Oedipal phase.* C.4.9 Social Learning Theory *Social learning theory (sociopsychological/social cognitive/ empowerment/self-esteem/self-efficacy, etc.). This adds cognitive and observational learning to the respondent and operant paradigms (see above) and essentially says that human beings do not respond to stimuli, but interpret them. The key intervention derived from this theory is modelling (e.g. skills training)* C.4.10 Systems Theory *This emphasises the interconnectedness of different parts of a whole, functioning entity such as the family, and conceptualises the problems experienced by individual family members as symptomatic of system 'malfunctioning'. Often problems are thought to arise because the family system has failed to re-establish an equilibrium following a system-disrupting crisis. Therapeutic strategies are aimed at assisting the family's return to a state of equilibrium and include: joining, reframing, and prescribing tasks.* C.4.11 Traditional Education/Reasoned Action Model *Models which assume that information presented to individuals will be absorbed directly, improving knowledge, or affecting their attitudes or behaviour. The objective is to alter knowledge only, although assumptions may be made about knowledge affecting behaviour. Models assume that individuals always act in a rational, logical way. Progressive media (e.g. video, theatre) may be used but information is still given in a didactic way.* C.4.12 Other (specify)
C.5 What year did the intervention start?	C.5.1 Stated (describe) C.5.2 Not stated C.5.3 Unclear (describe)
C.6 What is the length of the intervention?	C.6.1 Stated (describe) C.6.2 Not stated C.6.3 Unclear (describe)
C.7 Number of people recruited to provide the intervention (or comparison condition)	C.7.1 Reported (write in) C.7.2 Unclear C.7.3 Not stated
C.8 How were the people providing the intervention recruited?	C.8.1 Stated (write in) C.8.2 Not stated

C.9 Was special training given to people providing the intervention? *Provide as much detail as possible*	C.9.1 Yes (specify) C.9.2 No C.9.3 Unclear C.9.4 Not stated
C.10 Did the authors indicate any costs related to the intervention? *Provide as much detail as possible*	C.10.1 Yes (write in) C.10.2 No
Section D: Description of the study sample	
D.1 Socioeconomic position *Record numbers/proportion where specified. This relates to socioeconomic position in keywording stage: young people specified with differential risk because of their socioeconomic position* *This might include:* • *direct or indirect income measures (e.g. parental income or access to free school meals/Medicaid)* • *various established neighbourhood deprivation scores* • *various established social class classification systems* • *authors description, e.g. ' residents of a deprived inner-city neighbourhood', 'young people from a largely middle-class background', etc*	D.1.1 Details D.1.2 Not reported
D.2 Age group *Record age range and numbers/proportion of the population in each age group, if specified. We would like to know more about whether studies address 'younger' or 'older' young people*	D.2.1 Details D.2.2 Not reported
D.3 Ethnicity *Write in authors' quantitative and qualitative description*	D.3.1 Details D.3.2 Not reported
D.4 Region/place of residence *Young people considered at risk in terms of their location (e.g. rural, urban, seaside)* *Record numbers/proportion of population in each type of region if specified*	D.4.1 Rural D.4.2 Urban D.4.3 Other D.4.4 Not stated
D.5 Sex *Record numbers/proportion of population in each sex if specified*	D.5.1 Female D.5.2 Male D.5.3 Mixed sex D.5.4 Not stated
D.6 Information about the family *This might include family size, structure, etc*	D.6.1 Details D.6.2 Not reported
D.7 Information about participants' religion reported	D.7.1 Details D.7.2 Not reported
D.8 Sexual orientation *Record numbers/proportion of population of each orientation if specified*	D.8.1 Heterosexual D.8.2 Gay D.8.3 Lesbian D.8.4 Not stated D.8.5 Other (details) *e.g. young people explicitly experiencing confusion about their sexual orientation (details)*

D.9 Information about participants' occupation reported *Given the age range of our review population, it is likely that occupation will relate to parental occupation. Please state if this is the case*	D.9.1 Details D.9.2 Not reported
D.10 Information about participants' education reported *Young people specified as being at risk because of their educational status (e.g. low educational achiever/absent from school)* *If parental education status reported please provide details – this may be a proxy measure of SEP*	D.10.1 Details (young people) D.10.2 Not reported (young people) D.10.3 Details (parents) D.10.4 Not reported (parents)
D.11 Social capital *Young people specified as being at risk because they lack social capital* *'Social capital' describes support available through informal social networks of neighbourhoods, communities and families – in relation to young people, social capital might be related to: family structure, and the form and quality of family relationships*	D.11.1 Details D.11.2 Not reported
D.12 Disability *Young people specified as being at risk because they have a disability* *(e.g. existence of physical or mental illness or disability, learning disability)*	D.12.1 Details D.12.2 Not reported
D.13 Information about previous STI reported *Young people at risk because of a previous history of STI*	D.13.1 Details D.13.2 Not reported
D.14 Existing STI (other than HIV) *Young people at risk because of they currently have an STI (not including HIV)*	D.14.1 Details D.14.2 Not reported
D.15 HIV positive *Young people at risk because they are diagnosed with, or suspected to have, HIV infection*	D.15.1 Details D.15.2 Not reported
D.16 Drug user *Young people at risk because they use, or have used, illicit drugs*	D.16.1 Details D.16.2 Not reported
D.17 Alcohol user *Young people at risk because of their level of alcohol consumption*	D.17.1 Details D.17.2 Not reported
D.18 Commercial sex worker *Young people at risk because they sell sex*	D.18.1 Details D.18.2 Not reported
D.19 Sexual behaviour *Young people at risk because of high-risk sexual behaviour or potential high-risk sexual behaviour*	D.19.1 Details D.19.2 Not reported
D.20 Looked after young people *Young people at risk because they are looked after (i.e. in care)*	D.20.1 Details D.20.2 Not reported
D.21 Offenders *Young people at risk because they are in the criminal justice system (e.g. in prison/detention/correctional programme)*	D.21.1 Details D.21.2 Not reported

D.22 Other factor – please specify	D.22.1 Details
D.23 Sampling and recruitment procedures	D.23.1 Details D.23.2 Not reported
D.24 Were any incentives provided to recruit people into the study?	D.24.1 Yes (specify) D.24.2 Not stated
D.25 Were participants asked for their consent before entering the study? *This refers to the eligible sample*	D.25.1 Requested from participants D.25.2 Requested from others (specify) D.25.3 Not relevant (e.g. mass media) D.25.4 Unclear D.25.5 No/not stated
Section E: Planning and process measures	
Questions E.1–11 relate to the planning and development of the intervention and study in general	
Questions E.12–19 relate specifically to the process evaluation	
E.1 Was the intervention based on a needs assessment?	E.1.1 Not stated E.1.2 Yes, no further information provided/information unclear E.1.3 Yes, based on 'comparative need' *'Comparative need' is derived from examining, for example, the services provided in one area to one population, and using this as the basis to determine the sort of services needed in another area with a similar population* E.1.4 Yes, based on 'felt need' *'Felt need' is what people say they want or what they think are the problems that need addressing* E.1.5 Yes, other (specify) E.1.6 No, but another rationale for delivering the intervention/ undertaking the study E.1.7 Yes, based on 'normative need' *'Normative needs' refers to what expert opinion defines as need* E.1.8 Yes, based on 'expressed need' *'Expressed need' refers to what one can infer about the need of a community by observing their use of services* E.1.9 Yes, reference to source of further information given (write in)
E.2 Who identified the aim(s) of the intervention?	E.2.1 Other (specify) E.2.2 Not stated E.2.3 Evaluator E.2.4 Health promotion practitioner E.2.5 (A sample of the) study population (specify) E.2.6 (A sample of the) target population (specify) E.2.7 Intervention provider E.2.8 Funder E.2.9 Unclear

E.3 Who was involved in the development of the intervention?	E.3.1 Not stated E.3.2 Unclear E.3.3 Evaluator E.3.4 Funder E.3.5 Health promotion fractioned E.3.6 Intervention provider E.3.7 (A sample of the) study population (specify) E.3.8 (A sample of the) target population (specify) E.3.9 Other (specify)
E.4 Was the intervention piloted? *A pilot study involves preliminary use of some or all of the elements of the intervention in order to refine the intervention or its delivery. This does not include similar interventions tested by others*	E.4.1 Not stated E.4.2 Unclear E.4.3 The authors consider this study to be a pilot E.4.4 Yes, previously piloted with the study population E.4.5 Yes, previously piloted with a sample of the target population (specify) E.4.6 Yes, previously piloted with others (specify) E.4.7 No
E.5 Do the authors indicate any specific barriers to developing/delivering the intervention?	E.5.1 Yes (specify) E.5.2 No
E.6 Do the authors indicate any factors favourable to developing/delivering the intervention?	E.6.1 Yes (specify) E.6.2 No
E.7 Were views on the evaluation design sought?	E.7.1 Not stated E.7.2 Unclear E.7.3 Yes, from funders E.7.4 Yes, from health promotion practitioners E.7.5 Yes, from intervention providers E.7.6 Yes, from the study population E.7.7 Yes, from a sample of the target population (specify) E.7.8 Yes, from others (specify) E.7.9 No
E.8 Who identified the range of processes/outcomes to be addressed?	E.8.1 Not stated E.8.2 Unclear E.8.3 Evaluator E.8.4 Funder E.8.5 Health promotion practitioner E.8.6 Intervention provider E.8.7 (A sample of the) study population (specify) E.8.8 (A sample of the) target population (specify) E.8.9 Other (specify)
E.9 Who carried out the evaluation?	E.9.1 Not stated E.9.2 Unclear E.9.3 Health promotion practitioner E.9.4 Researcher (specify) E.9.5 (Individuals from the) target population (specify) E.9.6 Other (specify)
E.10 Does the report describe how the evaluators were selected?	E.10.1 No E.10.2 Unclear E.10.3 Yes (specify)

E.11 Was special training provided for the evaluators?	E.11.1 Not stated E.11.2 Unclear E.11.3 Yes (specify) E.11.4 No
E.12 Which processes were evaluated? *Tick as many as appropriate. Specify further where possible*	E.12.1 Perceptions, understanding or acceptability of the intervention E.12.2 Accessibility of the intervention/programme reach E.12.3 Consultation/collaboration/partnerships (specify) E.12.4 Content of the intervention E.12.5 Implementation/delivery of the intervention E.12.6 Costs associated with the intervention E.12.7 Management and responsibility E.12.8 Quality of the programme materials E.12.9 Skills and training of the intervention providers E.12.10 Other (specify)
E.13 What methods were used to collect data on the processes involved? *Tick as many as appropriate. Specify further where possible*	E.13.1 Not stated E.13.2 Unclear E.13.3 Documentation E.13.4 Focus group E.13.5 Interview E.13.6 Observation E.13.7 Self-completion report or diary/questionnaire E.13.8 Other (specify)
E.14 Who were the data collected from?	E.14.1 Not stated E.14.2 Unclear E.14.3 Intervention provider (write in numbers) E.14.4 (A sample of the) study population (write in numbers) E.14.5 Other (specify)
E.15 When did the evaluation take place in relation to the intervention? *Tick as many as appropriate. Specify further where possible*	E.15.1 Not stated E.15.2 Unclear E.15.3 Afterwards (please specify) E.15.4 Concurrently E.15.5 For a limited period during the intervention (please specify) E.15.6 Other (please specify)
E.16 About which processes do the authors offer conclusions? *Tick as many as appropriate. Write in ALL conclusions*	E.16.1 None E.16.2 Unclear E.16.3 Acceptability of the intervention E.16.4 Accessibility of the intervention/programme reach E.16.5 Consultation/collaboration/partnerships E.16.6 Content of the intervention E.16.7 Implementation of the intervention E.16.8 Costs associated with the intervention E.16.9 Management and responsibility E.16.10 Quality of the programme materials E.16.11 Skills and training of the intervention providers E.16.12 Other (specify)

E.17 Were steps taken to increase rigour/minimise bias and error in the sampling for the process evaluation? *Consider whether:* • *the sampling strategy was appropriate to the questions posed in the process evaluation (e.g. was the strategy well reasoned and justified?)* • *attempts were made to include all relevant stakeholders and/or obtain a diverse sample (think about who might have been excluded who may have had a different perspective to offer)* • *characteristics of the sample critical to the understanding of the study context and findings were presented (i.e. do we know who the participants are in terms of, for example, role in the intervention/evaluation, basic sociodemographics, etc.)*	E.17.1 Yes, a fairly thorough attempt was made (please specify) E.17.2 Yes, several steps were taken (please specify) E.17.3 Yes, a few steps were taken (please specify) E.17.4 Unclear (please specify) E.17.5 No, not at all/not stated/can't tell(please specify)
E.18 Were steps taken to increase rigour/minimise bias and error in the data collected for the process evaluation? *Consider whether:* • *data collection tools were piloted/validated (if quantitative)* • *data collection was comprehensive, flexible and/or sensitive enough to provide a complete and/or vivid and rich description/evaluation of the processes involved in the intervention [e.g. did the researcher's spend sufficient time at the site/with participants? Did they keep 'following up'? Were steps taken to ensure that all participants were able and willing to contribute? (e.g. confidentiality, language barriers, power relations between adults and young people) Was more than one method of data collection used? Was there a balance between closed and open-ended data collection methods?*]	E.18.1 Yes, a fairly thorough attempt was made (please specify) E.18.2 Yes, several steps were taken (please specify) E.18.3 Yes, a few steps were taken (please specify) E.18.4 Unclear (please specify) E.18.5 No, not at all/not stated/can't tell (please specify)
E.19 Were steps taken to increase rigour/minimise bias and error in the analysis of the process data? *Consider whether:* • *data analysis methods were systematic (e.g. was a method described/can a method be discerned?*) • *diversity in perspective was explored* • *the analysis was balanced in the extent to which it was guided by preconceptions or by the data (i.e. participants views, researcher observations, etc.*) • *the analysis sought to rule out alternative explanations for findings (in qualitative research this could be done by, for example, searching for negative cases/exceptions, feeding back preliminary results to participants, asking a colleague to review the data, or reflexivity; in quantitative research this may be done by, for example, significance testing*)	E.19.1 Yes, a fairly thorough attempt was made (please specify) E.19.2 Yes, several steps were taken (please specify) E.19.3 Yes, some steps were taken (please specify) E.19.4 Unclear (please specify) E.19.5 No, not at all/not stated/can't tell(please specify)
E.20 Were the findings of the process evaluation grounded in/supported by the data? *Consider whether:* • *enough data are presented to show how the author's arrived at their findings* • *the data presented fit the interpretation/support claims about patterns in data* • *the data presented illuminate/illustrate the findings* • *(for qualitative studies) quotes are numbered or otherwise identified so that the reader can see that they don't just come from one or two people*	E.20.1 Reasonably well grounded/supported (please specify) E.20.2 Fairly well grounded/supported (please specify) E.20.3 Limited grounding/support (please specify)

E.21 Please rate the findings of the process evaluation in terms of their breadth and depth *Consider whether:* *(NB: it may be helpful to consider 'breadth' as the extent of description and 'depth' as the extent to which data has been transformed/analysed)* • *a range of processes/issues were covered in the evaluation* • *the perspectives of participants are fully explored in terms of breadth (contrast of two or more perspectives) and depth (insight into a single perspective)* • *both the strengths and weaknesses of the intervention are described/explored* • *the context of the intervention has been fully described/ explored* • *richness and complexity has been portrayed (e.g. variation explained, meanings illuminated)* • *there has been theoretical/conceptual development*	E.21.1 Limited breadth or depth E.21.2 Good/fair breadth but very little depth E.21.3 Good/fair depth but very little breadth E.21.4 Good/fair breadth and depth
E.22 To what extent does the process evaluation privilege the perspectives and experiences of young people? *Consider whether:* • *Young people are included in the process evaluation* • *There was a balance between open-ended and fixed response options* • *Whether young people were involved in designing the research* • *There was a balance between the use of an a priori coding framework and induction in the analysis* • *The position of the researchers (did they consider it important to listen to the perspectives of young people?)* • *Steps were taken to assure confidentiality and put young people at their ease*	E.22.1 Not at all E.22.2 A little (please specify) E.22.3 Somewhat (please specify) E.22.4 A lot (please specify)
E.23 Overall, what weight would you assign to this process evaluation in terms of the reliability of its findings? *Guidance:* *Think (mainly) about the answers you have given to questions E17–20 above.*	E.23.1 Low E.23.2 Medium E.23.3 High
E.24 What weight would you assign to this process evaluation in terms of the usefulness of its findings? *Guidance:* *Think (mainly) about the answers you have given to questions E20–22 above and consider:* • *how well intervention processes are described (e.g. does it provide useful information on barriers and facilitators to implementation – factors that others implementing the intervention would need to consider?)* • *whether the findings can help us to explain the relationship between intervention process and outcome (e.g. why the intervention worked or did not work; factors influencing effectiveness; how the intervention achieved its effects)*	E.24.1 Low E.24.2 Medium E.24.3 High

Section F: Methodological characteristics of the study	
F.1 Number of participants recruited to intervention and control/comparison groups if applicable *On the basis of those from whom baseline data were collected. Or number in study population as a whole, if only one group*	F.1.1 Not stated F.1.2 Unclear (please specify) F.1.3 Reported (please write in)
F.2 What was the unit of allocation into each intervention and control/comparison group?	F.2.1 Not relevant (study not a trial) F.2.2 Not stated F.2.3 Unclear F.2.4 Community F.2.5 Family F.2.6 Group/class, e.g. tutor group F.2.7 Individuals F.2.8 Institution F.2.9 Region F.2.10 Other (please specify)
F.3 Was the allocation to intervention and control/comparison groups done blind?	F.3.1 Not relevant (study not a trial) F.3.2 Not stated F.3.3 Unclear (please specify) F.3.4 Yes F.3.5 No
F.4 Were participants aware which group they were in for the evaluation?	F.4.1 Not relevant (study not a trial) F.4.2 Not stated F.4.3 Unclear F.4.4 Yes F.4.5 No
F.5 Was outcome measurement done blind? *i.e. Were those assessing the outcomes aware whether the participant had been in a control/comparison group or intervention group?*	F.5.1 Not relevant (study not a trial) F.5.2 Not stated F.5.3 Unclear F.5.4 Yes F.5.5 No
F.6 What sort of measurement tool(s) is/are used to collect outcome data?	F.6.1 Interview F.6.2 Observation F.6.3 Practical test F.6.4 Psychological test F.6.5 Self-completion report or diary/questionnaire F.6.6 Clinical test F.6.7 Other (specify) F.6.8 Unclear F.6.9 Not stated
F.7 Number of outcome assessment periods *i.e. How many times were data on outcome variables collected after the intervention?*	F.7.1 Not stated F.7.2 Unclear F.7.3 One F.7.4 Two F.7.5 Three F.7.6 Four or more (specify)

F.8 Timing(s) of pre-intervention measurements	F.8.1 Not stated F.8.2 Unclear (please specify) F.8.3 Stated (please write in) F.8.4 Not relevant
F.9 Timing(s) of post-intervention measurements *Choose one of the categories and indicate the exact timings if specified.* *Note: 'Immediately after the intervention' is at the bottom of the list!*	F.9.1 Not stated F.9.2 Unclear F.9.3 Up to 1 month F.9.4 Up to 3 months F.9.5 3–6 months F.9.6 6–12 months F.9.7 1–2 years F.9.8 2–3 years F.9.9 3–5 years F.9.10 More than 5 years F.9.11 None F.9.12 Immediately after intervention
F.10 Data analysis method	F.10.1 Not relevant (study not a trial) F.10.2 Not stated F.10.3 Unclear F.10.4 'Intention to intervene' *'Intention to intervene' means that data were analysed on the basis of the original number of participants recruited into the different groups* F.10.5 'Intervention received' *'Intervention received' means the data were analysed on the basis of the number of participants remaining in the groups at the time of measurement*
F.11 Unit of data analysis *Were the results reported according to the unit of allocation? For example, if individuals were allocated to different groups, results from individuals should be analysed and reported, whereas if schools were allocated to different groups then results from each school should be analysed and reported*	F.11.1 Not relevant (study not a trial) F.11.2 Not stated F.11.3 Unclear (please specify) F.11.4 Same as unit of allocation F.11.5 Different from unit of allocation (please specify)
F.12 If a cluster trial do the authors report an intraclass correlation	F.12.1 Yes (specify) F.12.2 No
F.13 Was the instrument used to assess outcomes piloted/validated?	F.13.1 Reported (specify) *Add in details of any pilot study; validation exercises; references to other publications which describe the instrument (or studies in which it has been employed)* F.13.2 Unclear F.13.3 Not reported

Section G: Avoiding selection bias	
G.1 How were subjects allocated to control and intervention groups? *Study can 'pass' if participants were allocated using an acceptable method of randomisation* *Note: If method of randomisation is not stated, tick 'yes' but indicate this in your comments. If you have suspicions about whether methods of allocation were randomised by an acceptable method, please also indicate these here*	G.1.1 Random *e.g. Table of random numbers, computer-generated random sequences* G.1.2 Non-random *e.g. Date of birth, day of week, month of year, medical record number, order in which participants included in the study, such as alternation* G.1.3 No allocation *e.g. Study not a trial* G.1.4 Not clear/not stated
G.2 Which major prognostic factors are baseline values reported for? *Note: Major prognostic factors will often be the baseline value of all outcomes and at least one socioeconomic variable*	G.2.1 Ethnicity G.2.2 Sex G.2.3 Marital status G.2.4 Age G.2.5 SES (income or class) G.2.6 Education G.2.7 Health status G.2.8 All pre-intervention outcome scores G.2.9 Some pre-intervention outcome scores
G.3 Were baseline values of major prognostic factors reported for each group as allocated (e.g. intervention and control group)?	G.3.1 Yes for all individuals in study at baseline measurement G.3.2 Yes for all individuals remaining in study for follow-up G.3.3 Yes for some other subgroup of individuals G.3.4 No G.3.5 Not applicable (one group in study only)
G.4 Are baseline values of major prognostic factors balanced between the groups in the trial? *Note: Major prognostic factors are balanced between groups if the groups are drawn from similar populations and have similar sociodemographic variables and baseline values of all outcome measures. Record the extent to which your decision is supported by presented data on outcomes and/or by other information in the report (e.g. statements in text)*	G.4.1 Not applicable (one group in study only) G.4.2 Unclear G.4.3 Balanced G.4.4 Not balanced G.4.5 Other (specify)
G.5 Did the analysis adjust for baseline imbalances in major prognostic factors between groups?	G.5.1 Not applicable (one group in study only) G.5.2 Not relevant (groups were equivalent) G.5.3 Yes G.5.4 No
Section H: Avoiding attrition bias	
H.1 Is the attrition rate reported separately according to allocation group?	H.1.1 Yes H.1.2 No H.1.3 Not applicable (one group in study only)
H.2 What is the attrition rate?	H.2.1 For the intervention group(s) H.2.2 For the control/comparison group(s) H.2.3 Overall H.2.4 Unclear (please specify) H.2.5 Not relevant (no details on attrition reported)

Section I: Avoiding selective reporting bias	
I.1 What outcomes did the authors say they were intending to measure (i.e. as described in the aims of the evaluation)? *Select as many as possible and specify data collection instrument used where possible*	I.1.1 Not stated I.1.2 Unclear I.1.3 Access to/availability of resources I.1.4 Attitudes I.1.5 Awareness/beliefs I.1.6 Behaviour (observed) I.1.7 Behaviour (reported) I.1.8 Clinical risk factor(s) as determined by a clinical test, e.g. blood pressure, cholesterol level I.1.9 Health problem or state (prevalence and/or incidence) *Including anxiety, depression, other mental health state; other examples – pregnancy, coronary heart disease* I.1.10 Intentions I.1.11 Knowledge I.1.12 Legislation/regulation I.1.13 Practical skill I.1.14 Self-efficacy/self-esteem/self-confidence I.1.15 Service use I.1.16 Other
I.2 For whom were outcomes given?	I.2.1 Unclear (specify) I.2.2 Information for some individuals/groups only (specify) I.2.3 Information for all individuals/groups I.2.4 Info for study population as a whole
I.3 For which outcomes were data collected at follow-up presented? *Compare the outcomes reported with your answers above*	I.3.1 Unclear I.3.2 Information for some outcomes only I.3.3 Information for all outcomes I.3.4 No final data reported, only change reported (specify) I.3.5 Other (specify)
Section J: Decision on soundness of study	
J.1 Was selection bias avoided? *1. Study can 'pass' if participants were allocated using an acceptable method of randomisation (i.e answer at G1.1) OR:* *2. Studies can 'pass' if (1) baseline values of major prognostic factors are reported for each group for virtually all participants as allocated (i.e. answer at G.3.1) AND if baseline values of major prognostic factors are balanced between groups in the trial (i.e. answer at G.4.3) OR imbalances were adjusted for in analysis (i.e. answer at G.5.3)*	J.1.1 Yes J.1.2 No
J.2 Was bias due to loss to follow-up avoided? *Study can pass this component if:* *1. The attrition rate is reported separately according to allocation group (i.e. answer at H.1.1), AND if* *2. The attrition rate differs across groups by less than 10% and is less than 30% overall (i.e. answer at H.2) OR baseline values of major prognostic factors were balanced between groups for all those remaining in the study for analysis (i.e. answer at G.5)* *Note: For studies which are not trials, this question should simply read 'Is the attrition rate less than 30% of the original participants?'*	J.2.1 Yes J.2.2 No

J.3 Was selective reporting bias avoided? *Studies can pass this component if authors report on all outcomes they intended to measure as described in the aims of the study*	J.3.1 Yes J.3.2 No
J.4 Is the study sound? *To be sound a study has to avoid all three of the specified types of bias*	J.4.1 Not sound J.4.2 Sound J.4.3 Reviewers judge study sound despite discrepancy with quality criteria (clarify)
Section K: Outcomes *DO NOT COMPLETE THIS SECTION UNLESS THE STUDY HAS BEEN JUDGED BY BOTH REVIEWERS TO BE SOUND* Where available, please include ALL analyses relevant to any of the PROGRESS-Plus risk factors. These may take the form of well-reported subgroup analyses, or the authors may simply state that there was no difference in outcomes between males and females, for example	
K.1 What was the impact of the intervention on sexual behaviour? • *Please add in results for this outcome measure. Use tables where necessary* • *Please report for all time periods at which the outcome was measured (e.g. immediately post intervention; 3 months' follow-up, 6 months' follow-up, etc.)* • *Please also report the time period over which the behaviour took place (e.g. use of condoms at most recent intercourse; use of condoms during past 6 weeks, etc.)* • *Please specify which kind of sexual activity, if reported (e.g. vaginal, anal, oral)* *Note: To insert tables check the 'HTML editor' box in the dialogue window. This only works with Internet Explorer (not Firefox*)	K.1.1 Frequency of sex *Please add in results for this outcome measure. Use tables where necessary* *Please specify which kind of sexual activity, if reported (e.g. vaginal, anal, oral*) K.1.2 Number of sexual partners *Please add in results for this outcome measure. Use tables where necessary* *Please record whether casual or regular partner (or other classification of partners*) K.1.3 Delaying onset of sexual activity *Please add in results for this outcome measure. Use tables where necessary* K.1.4 Abstinence from sexual activity *Please add in results for this outcome measure. Use tables where necessary* K.1.5 Condom use for vaginal intercourse *Please add in results for this outcome measure. Use tables where necessary* *Results might be expressed as the proportion of young people using condoms, and/or proportion of episodes in which a condom was/was not used* *Please record if data are reported for different types of partner (e.g. casual partner, regular partner*) K.1.6 Condom use for anal intercourse *Please add in results for this outcome measure. Use tables where necessary* *Results might be expressed as the proportion of young people using condoms, and/or proportion of episodes in which a condom was/was not used* *Please record if data are reported for different types of partner (e.g. casual partner, regular partner*) K.1.7 Number of young people reporting having sex *Please add in results for this outcome measure. Use tables where necessary* *Can include number becoming sexually active during the study*

	K.1.8 Use of other (non-condom) contraception method *Please add in results for this outcome measure. Use tables where necessary* K.1.9 Age at first sexual intercourse *Please add in results for this outcome measure. Use tables where necessary* K.1.10 Use of drugs/alcohol during sex *Please add in results for this outcome measure. Use tables where necessary* K.1.11 Refusal of sex/unprotected sex K.1.12 Other (please define) *Please add in results for this outcome measure. Use tables where necessary* K.1.13 Not applicable – outcome not measured
K.2 What was the impact of the intervention on biological outcomes? *Please add in results for this outcome measure. Use tables where necessary*	K.2.1 Incidence of sexually transmitted infection (STI) *Please add in results for this outcome measure. Use tables where necessary* *Please specify which STI, if reported* K.2.2 Pregnancy *Please add in results for this outcome measure. Use tables where necessary* K.2.3 Other (please define) *Please add in results for this outcome measure. Use tables where necessary* K.2.4 Not applicable – outcome not measured
K.3 What was the impact of the intervention on knowledge of STIs? *Please add in results for this outcome measure. Use tables where necessary*	K.3.1 Specify *Please add in results for this outcome measure. Use tables where necessary* K.3.2 Not applicable – outcome not measured
K.4 What was the impact of the intervention on attitudes towards STIs? *Please add in results for this outcome measure. Use tables where necessary*	K.4.1 Specify *Please add in results for this outcome measure. Use tables where necessary* K.4.2 Not applicable – outcome not measured
K.5 What was the impact of the intervention on behavioural intentions? *Please add in results for this outcome measure. Use tables where necessary*	K.5.1 Specify *Please add in results for this outcome measure. Use tables where necessary* K.5.2 Not applicable – outcome not measured
K.6 What was the impact of the intervention on self-efficacy? *Please add in results for this outcome measure. Use tables where necessary*	K.6.1 Specify *Please add in results for this outcome measure. Use tables where necessary* K.6.2 Not applicable – outcome not measured
K.7 What was the impact of the intervention on skills? *Please add in results for this outcome measure. Use tables where necessary*	K.7.1 Specify *Please add in results for this outcome measure. Use tables where necessary* K.7.2 Not applicable – outcome not measured

K.8 What was the impact of the intervention on beliefs? *Please add in results for this outcome measure. Use tables where necessary*	K.8.1 Specify *Please add in results for this outcome measure. Use tables where necessary* K.8.2 Not applicable – outcome not measured
K.9 What was the impact of the intervention on other outcomes? (specify) *Please add in results for this outcome measure. Use tables where necessary*	K.9.1 Specify *Please add in results for this outcome measure. Use tables where necessary*
Section L: ...And finally	
L.1 Please check the keywords applied in the mapping stage for accuracy *In the light of the data extracted, please check whether any of the existing keywords are superfluous, or whether any additional keywords should be added*	L.1.1 Changes to be made to the keywording *Please record any changes to be made to the keywording*
L.2 Reviewer's comments *Add in here any comments you may have on issues not covered by the preceding questions, as well as your general impressions of the study*	L.2.1 Specify
L.2 Reviewer's comments *Add in here any comments you may have on issues not covered by the preceding questions, as well as your general impressions of the study*	L.2.1 Specify

Appendix 6

Evidence tables for the RCTs with integral process evaluations included in the systematic review

Authors/date; country/area	Population details	Details of intervention	Processes evaluated
Borgia *et al.* 2005;[51] Rome, Italy	Mean age 18.3 years; 50.8% male, 49.2% female	**Aims:** To evaluate the effectiveness of peer education when compared to teacher-led curricula in AIDS prevention programmes conducted in schools in Rome, Italy. Because teacher-led interventions represent the usual practice in AIDS prevention within our school contexts, they have been taken into account as a reference, in order to assess the eventual advantages produced by the implementation of a peer-led educational programme The specific objectives, shared by both intervention groups, were as follows: (1) to increase knowledge of the transmission and prevention of HIV; (2) to address social influences and group norms with respect to sexual behaviour; (3) to improve decision-making, communication and negotiation skills and related self-efficacy; (4) to place the risks related to specific contexts and behaviour in their proper dimension; and (5) to abolish prejudice and stigmatisation towards persons with AIDS **Provider(s):** Peers **Training:** 5-day residential training led by a psychologist **Setting:** School **Content:** Interactive methods used **Length/Intensity:** 10 hours conducted over 5 sessions **Comparator:** Teacher-led health education	*Content of the intervention* *Implementation of the intervention* *Costs associated with the intervention* *Quality of materials* *Other* *Duration of the interventions* *Involvement of students in the classes* *Perception of student assimilation of the intervention*
Jemmott *et al.* 1999;[62] New Jersey, USA	African-American adolescents, mean age 13.2 years; 53.8% female, 46.2% male	**Aims:** The authors examined whether the intervention reduced HIV risk-associated sexual behaviour at 3- and 6-month follow-ups and whether it caused positive changes on behavioural beliefs, self-efficacy, and intentions – the conceptual mediators of behaviour change suggested by the theories on which the intervention was based 'The goal was to increase knowledge about the risks of various behaviours and the specific belief that condoms can reduce the risk of STD, including HIV' (p. 168) In addition the authors aimed to test the 'matching hypothesis' in a systematic way. They randomly assigned young inner-city African-American male and female adolescents to the conditions of a 4-way factorial design, crossing intervention (HIV, health education control) with facilitator gender (male, female), facilitator race (African-American, white), and gender composition of the small group (single gender, mixed gender) **Providers:** 'Adult facilitators' **Training:** The facilitators were 'specially trained' **Setting:** School/community **Content:** Designed to be culturally appropriate for young inner-city African-Americans. Covered transmission of STIs (including HIV), abstinence, unprotected sexual intercourse, multiple partners, and vaginal and anal intercourse, and promoted the use of condoms. Included many interactive sessions and modelled correct use of condoms. **Length/intensity:** 5-hour small group interventions **Comparator:** A general health promotion intervention	*Implementation* *Content* *Skills and training of the providers*

Authors/date; country/area	Population details	Details of intervention	Processes evaluated
Jemmott *et al.* 1992;[43] Philadelphia, USA	Black males, mean age 14.64 years	**Aims:** The AIDS risk reduction condition was 'designed to increase their knowledge of AIDS and STDs and to weaken problematic attitudes towards risky sexual behaviours' (p. 373) **Providers:** Facilitators **Training:** Facilitators received 6 hours of training **Setting:** School **Content:** 'Participants in the AIDS risk-reduction condition received a 5-hour intervention designed to increase their knowledge of AIDS and STDs and to weaken problematic attitudes towards risky sexual behaviours. The intervention included information about risks associated with intravenous drug use and specific sexual activities. Videotapes, games, exercises, and other culturally and developmentally appropriate materials were used to reinforce learning and to encourage active participation. All materials had been extensively pilot tested and were selected not only to provide accurate information, but also to do so in ways that would be interesting to inner-city black male adolescents.' (p. 373) **Length/intensity:** 1 5-hour intervention **Comparator:** An intervention concerning career planning and opportunities	*Perceptions, understanding or acceptability of the intervention* *Accessibility of the intervention/ programme reach* *Implementation/delivery of the intervention* *Other*
Karnell *et al.* 2006;[63] Pietermaritzburg Kwa-Zulu-Natal, South Africa	Students of median age 16, predominantly (94%) Zulu ethnic group	**Aims:** The objectives of the programme were to impart key HIV and alcohol related facts, enhance students' understanding of the consequences of drinking alcohol and having unprotected sex, aid students' identification of positive alternatives to drinking alcohol or having sex, expose students to specific techniques for resisting pressure to drink or have sex, give students the opportunity to practice such techniques through role play exercises, and enhance students' ability to plan ahead to avoid situations in which they would be likely to engage in risk behaviours **Provider(s):** Teachers and peers **Training:** Peers received 2 days' training **Setting:** School **Content:** Primarily focused on skills development; specific techniques, practised through role play exercises, to resist pressure to have unsafe sex and use alcohol. The centrepiece was four monologues by fictional teenage characters describing their dilemmas regarding having sex and using alcohol. These formed the basis for class discussion – led by peer leaders – and group assignments **Length/intensity:** 10 units of 30 minutes each delivered over 8 weeks **Comparator:** 'Life Orientation' instruction	*Perceptions, understanding or acceptability of the intervention* *Implementation/delivery of the intervention* *Skills and training of the intervention provider* *Other*

Authors/date; country/area	Population details	Details of intervention	Processes evaluated
Levy *et al.* 1995;[65] Chicago, USA	12- to 14-year-olds, majority African-American (64.3% in control group, 47.8% in the intervention group)	**Aims:** To assess the impact of a school-based AIDS prevention programme on student participation in sexual risk and protective behaviours such as use of condoms and use of condoms with foam and intention to participate in such behaviours **Providers:** 'Trained' health educators **Training:** No further details given **Setting:** School **Content:** Used an integrated approach to multiple risk reduction and prevention using knowledge transfer, active learning and skills-building techniques to influence student knowledge, attitudes, intentions and behaviour and to affect peer norms. Topics included HIV/AIDS, pregnancy and STD prevention, and enhancement of decision-making and resistance/negotiation skills. Specific activities consisted of lectures, class discussions, video presentations, small group exercises, role plays, brainstorming, educational competitions and discussion of anonymous questions from students Students in both experimental conditions were required to complete homework assignments and all parents were invited to attend a Youth AIDS Prevention Project (YAPP) orientation meeting In the parent-interactive condition, students were required to complete additional homework assignments (two extra in 7th grade, one extra in 8th grade) with a parent or guardian, who also was encouraged to attend more intensive parent meetings about the programme, to become involved with the school programme, and to discuss HIV/AIDS with their children **Length/intensity:** 15-lesson curriculum; lessons lasted between 38 and 50 minutes **Comparator:** The control group received the intervention the following year; in the year of the intervention, they received 'basic minimal' AIDS education	*Perceptions, understanding or acceptability of the intervention* *Implementation/delivery of the intervention*
Roberto *et al.* 2007;[66] 'a rural Appalachian county', USA	Experimental school, students with a mean age of 15.50 years; control school, students with a mean age of 15.68 years; majority of both groups European-American	**Aims:** The authors talk of the importance of increasing perceptions of 'personally relevant (susceptibility) and serious (severity) threat' and of 'an effective means of reducing the threat (response efficacy) that they are capable of performing (self-efficacy). Thus, the intervention was created to increase perceptions of these four variables' (p. 56). Ultimately, the intervention was to encourage students to engage in the recommended behaviours: 'to delay initiation of sexual activity and to increase use of condoms for those who were sexually active' (p. 56). **Provider(s):** Computer **Training:** N/A **Setting:** School **Content:** Computer-based activities, including a 'truth or myth' session, an exercise on risky behaviour and a refusal skill activity **Length/Intensity:** 7 weeks, 6 activities (all six repeated in week 7), each of 15 minutes' duration **Comparator:** Received nothing	*Perceptions, understanding or acceptability of the intervention* *Accessibility of the intervention/ programme reach* *Implementation/delivery of the intervention*

Authors/date; country/area	Population details	Details of intervention	Processes evaluated
Stephenson *et al.* 2004;[50] Central and Southern England, UK	Participants 13–14 years, peer leaders 16–17 years	**Aims:** Researchers aimed to investigate the effectiveness of peer-led vs teacher-led SRE at reducing termination of pregnancy and unprotected sexual intercourse, and at improving the quality of sexual relationships **Provider(s):** Peers **Training:** 2 days' intensive training **Setting:** School **Content:** Interactive sessions on relationships, STIs, condoms and contraception. Teachers were not in attendance during the session. Sessions involved games and small group work, discussions, brainstorms, role playing and demonstrating how to use condoms. 'The approach emphasizes development of skills for sexual negotiation as well as knowledge about pregnancy, contraception, STIs, and the use of sexual health and contraceptive services' **Length/intensity:** Delivered during the summer term in 3 1-hour sessions **Comparator:** Usual teacher-led sex education	*Acceptability of the intervention* *Accessibility of the intervention/ programme reach* *Consultation/collaboration/ partnerships* *Implementation of the intervention* *Skills and training of the providers* *Other*
Wight *et al.* 2002;[70] Scotland, UK	Pupils aged between 13–14 years	**Aims:** The aims were to reduce unsafe sexual behaviours, reduce unintended pregnancies and improve the quality of sexual relationships **Provider(s):** Teachers **Training:** 5 days' teacher training **Setting:** School **Content:** The SHARE programme advises teenagers to delay sexual intercourse until they are sure they are ready and to always use a condom until they plan to have children. It combines active learning (small group work and games), information leaflets on sexual health, and development of skills, primarily through the use of interactive video but also through role playing. It included sessions on relationships, talking about sex, sexual risk-taking, refusal skills practice, resisting pressure, planning to keep safe and where to go for help **Length/intensity:** 20 sessions, 10 at 13–14 years, 10 at 14–15 years **Comparator:** Control schools received 7–10 lessons in total and these were primarily devoted to provision of information and discussion	*Content of the intervention* *Consultation/collaboration/ partnerships* *Implementation of the intervention* *Acceptability of the intervention* *Skills and training of the intervention providers*

Authors/date; country/area	Population details	Details of intervention	Processes evaluated
Zimmerman *et al.* 2008;[71] Cleveland, OH and Louisville, KY, USA	Urban 14- to 15-year-olds; about half of the participants were white, one-third black	**Aims:** To assess whether adapting a successful school-based curriculum to meet the needs of high sensation-seeking individuals improves its effectiveness in promoting safer behaviours **Provider(s):** Teachers, peers **Training:** Teachers received 2.5 days of training; peer leaders attended a 2-day out-of-school course facilitated by the trainers who trained the teachers **Setting:** School **Content:** There were two interventions, both designed to enhance students' skills to resist unprotected sex by modelling those skills and then providing students opportunities for practice. The curriculum emphasises that youth should avoid unprotected intercourse; that the best way to do this is to abstain from sex; and that if they do not abstain from sex, they should use contraceptives (especially condoms) to guard against pregnancy and STDs, especially HIV. One of the interventions was modified to make it more successful at changing the behaviour of high sensation-seeking and impulsive youth. This was done by adding short 'trigger' videos, use of peer facilitators, creating more realistic role plays, classroom games and prizes, and providing students with video cameras to record role plays **Length/intensity:** 16–17 class sessions **Comparator:** The standard, non-skills-based HIV prevention curriculum for that school, with some schools not offering any HIV prevention education	*Acceptability of the intervention* *Content of the intervention* *Implementation of the intervention*

Appendix 7

Bibliography of studies included in systematic review

Below is the primary reference to each of the 15 RCTs included in the systematic review, with references to secondary publications (where applicable) in bullet points.

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Appendix 8

Tabulated results of systematic review

TABLE 70 *Behavioural outcomes – initiation of sex*

	Sexual initiation[a]				Statistical significance
Intervention vs standard sex education					
Coyle *et al.*[58]	***n***	**Estimated effect size**	**Standard error**	**95% CI**	No statistically significant differences between students in the Safer Choices and comparison schools at follow-up
	2565	1.13	0.24	(0.71 to 1.82)	
Wight *et al.*[70]	**Intervention**		**Control**		Difference (95% CI)
Young men	23.6%		23.9%		–0.4 (–5.7 to 4.9) *p*-value 0.89
Young women	31.8%		33.0%		–1.2 (–5.3 to 3.0) *p*-value 0.59
Zimmerman *et al.*[71]	Outcome reported for only the difference between baseline and Time 3 and not data extracted due to unacceptably high attrition at Time 3 (Time 3 did not pass as sound)				
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)					
Klepp *et al.*[64]	**Intervention schools**		**Comparison schools**		
	6.6%		16.5%		Net effect 9.9, $p = 0.19$ (sexual initiation baseline to follow-up)
Roberto *et al.*[66]	**Experimental group**		**Control group**		
	8% ($n = 10$)		18% ($n = 33$)		$p < 0.01$, OR 2.93; control group adolescents nearly three times more likely to initiate sexual activity between pre-test and post-test
Stanton *et al.*[69]	Outcome data only reported at 9 months and not data extracted as this time point did not pass as sound				
Peer-led vs teacher-led interventions					
Stephenson *et al.*[50]	**Intervention**		**Control**		
6 month – boys	242/1980		196/1660		UEI: 1.07 (0.76 to 1.50) AEI: 1.06 (0.74 to 1.52)
6 month – girls	230/1895		221/1588		UEI: 0.86 (0.69 to 1.07) AEI: 0.92 (0.75 to 1.11)
18-month – boys	543/1700		444/1300		UEI: 0.90 (0.65 to 1.23) AEI: 0.92 (0.65 to 1.28)
18-month – girls	610/1615		562/1297		UEI: 0.80 (0.66 to 0.97) AEI: 0.82 (0.68 to 0.98)

AEI, adjusted effect for intervention; UEI, unadjusted effect for intervention.

a A sexual initiation outcome was not reported by: Levy and colleagues[65] and Karnell and colleagues[63] (intervention vs standard sex education); Jemmott and colleagues[62] (intervention vs control); and Borgia and colleagues[51] (peer-led vs teacher-led intervention).

TABLE 71 *Behavioural outcomes – condom use*

Behavioural outcome	Results				Statistical significance
Intervention vs standard sex education					
Coyle *et al.*[58]					
	n	**Estimated effect size**	**Standard error**	**95% CI**	
Use of condoms at first intercourse[a]	285	0.68	0.48	0.26 to 1.75	$p = 0.42$
Use of condoms at last intercourse	1018	1.91	0.27	1.13 to 3.21	At follow-up, sexually experienced students in intervention schools were significantly more likely to have used condoms ($p = 0.02$) than students in comparison schools
Frequency of sexual intercourse without a condom in the last 3 months	963	0.50	0.31	**Ratio**[b] –2.24	Sexually experienced students in intervention schools reported fewer acts of intercourse without a condom in the 3 months preceding the follow-up survey than did sexually experienced students in comparison schools ($p = 0.03$); the group by location interaction was significant for this variable ($p = 0.05$) and indicated the effects were greater in Texas than in California
Karnell *et al.*[63]					
Used a condom during last sex	**Intervention (% change)**	**Comparison (% change)**	**Intervention effect**		
Overall	4.2	2.2	2.0		No statistically significant differences were reported
Male	3.5	–0.5	4.0		
Female	2.5	2.5	0.0		
Had had sex at pre-test	–2.1	–5.5	3.4		
Had not had sex at pre-test	5.7	6.4	–0.7		
Levy *et al.*[65] (for those initiating sex, termed 'changers', since baseline only)					
	Parent and non-parent combined	**Control**			
Ever used condoms	($n = 186$) 81.1%	($n = 124$) 87.3%			No significant difference between groups reported
Ever used condoms with foam	($n = 186$) 24.3%	($n = 124$) 14.5%			$p < 0.01$
Used condoms (those sexually active in last 30 days)	($n = 49$) 87.8%	($n = 43$) 76.7%			No significant difference between groups reported
Used condoms with foam (changers sexually active in last 30 days)	($n = 49$) 40.8%	($n = 43$) 25.6%			No significant difference between groups reported

Behavioural outcome	Results			Statistical significance
Wight *et al.*[70]				
First intercourse without condom (virgin before first year programme)	**Intervention**	**Control**		**Difference (95% CI)**
Young men	5.2%	5.7%		–0.5 (–2.5 to 1.5) $p = 0.63$
Young women	9.7%	9.1%		0.6 (–1.9 to 3.1) $p = 0.66$
Most recent sexual intercourse without condom[c]				
Young men	33.6%	34.9%		–1.3 (–5.9 to 3.3) $p = 0.60$
Young women	44.9%	44.0%		0.9 (–5.7 to 7.4) $p = 0.81$
Condom use	**Mean score for condom use (1 = never, 5=always)**	**Mean score for condom use (1 = never, 5 = always)**		
Young men	3.80 ($n = 421$)	3.79 ($n = 451$)		0.0 (–0.2 to 0.2) $p = 0.93$
Young women	3.51 ($n = 639$)	3.58 ($n = 623$)		–0.1 (–0.3 to 0.1) $p = 0.55$
Zimmerman *et al.*[71]				
	Modified intervention	**Original intervention**	**Standard**	No significant differences among the curriculum groups at any time
Used a condom at last sex				
Time 1	73.0%	77.7%	73.3%	
Time 2	70.2%	73.8%	69.9%	
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)				
Jemmott *et al.*[62]				
Frequency of unprotected coitus (without a condom)	**HIV prevention** (adjusted mean ± SE)	**Control** (adjusted mean ± SE)		
Pre-intervention	0.806 ± 0.221	0.593 ± 0.234		Adolescents in the intervention group reported less unprotected coitus, $F(1, 399) = 4.66$, $p = 0.031$ than those in the control group
3-month follow-up	0.387 ± 0.070	0.370 ± 0.076		
6-month follow-up	0.474 ± 0.148	0.704 ± 0.157		

continued

TABLE 71 *Behavioural outcomes – condom use (continued)*

Behavioural outcome	Results						Statistical significance
Jemmott *et al.*[43]							
	AIDS prevention		**Control**	**Difference (95% CI)**			
Rated frequency of condom use	4.35		3.50	0.85 (0.14 to 1.56)			No statistical between group comparisons reported
No. of days respondent did not use a condom during coitus	0.64		2.38	–1.73 (–2.86 to 0.60)			
Klepp *et al.*[64]: outcome not reported							
Stanton *et al.*[69]							
Used a condom in last episode	**'Focus on Kids'**		**Control**				
Baseline	0.80		0.80				Condom-use rates declined over time in both groups; use rates did not differ based on intervention assignment at any follow-up period overall or among youth who initiated sex or had been sexually experienced at baseline
3-month adjusted mean against baseline	0.73		0.77				
6-month adjusted mean against baseline	0.69		0.75				
Frequency of condom use (1- to 5-point scale)							
Baseline	2.37		2.09				No significant difference reported
3-month adjusted mean against baseline	2.46		2.47				
6-month adjusted mean against baseline	2.71		2.33				
Roberto *et al.*[66]	**Condom use at last intercourse** (individuals sexually active in the last 4 months): there was no significant difference between the experimental and control schools on this variable. No numeric data were reported						
Peer-led vs teacher-led interventions							
Borgia *et al.*[51]							
Frequency of condom use (%) during the previous 3 months	**Teacher led**			**Peer led**			
	Never	Often or Sometimes	Always	Never	Often or Sometimes	Always	
Pre	39.1	31.9	29.0	31.9	31.3	36.8	There was an increase in the percentage of students using condoms often or sometimes, and a decrease in the percentage of those always using condoms. In the peer-led group, the percentage of students never using condoms slightly increased. Pre-post-intervention changes were significant ($p < 0.05$ in both groups)
Post	39.5	38.2	22.3	34.4	38.0	27.6	

Behavioural outcome	Results		Statistical significance
Stephenson *et al.*[50]			
Unprotected (without condom) first heterosexual intercourse by age 16	**Intervention** (estimated cumulative proportion)	**Control** (estimated cumulative proportion)	
Boys	6.2% (4.2–8.2)	4.7% (2.6–6.8)	–1.4% (–4.4 to 1.6, $p = 0.36$)
Girls	8.4% (6.3–10.4)	8.3% (6.1–10.5)	–0.4% (–3.7 to 2.8, $p = 0.79$)
Boys and girls	7.6% (5.9–9.4)	6.8% (5.0–8.7)	–0.8% (–3.5 to 1.8, $p = 0.53$)
Used condom at first sex	**Intervention**	**Control**	
6-month – boys	198/238 (83.19%)	152/193 (78.76%)	UEI, 1.33 (0.80 to 2.21); AEI, 1.42 (0.80 to 2.53)
6-month – girls	168/230 (73.04%)	159/215 (73.95%)	UEI, 0.96 (0.63 to 1.45); AEI, 0.89 (0.58 to 1.34)
18-month – boys	420/528 (79.55%)	352/432 (81.48%)	UEI, 0.88 (0.59 to 1.31); AEI, 0.95 (0.62 to 1.43)
18-month – girls	454/602 (75.42%)	420/550 (76.36%)	UEI, 0.95 (0.71 to 1.26); AEI, 0.86 (0.67 to 1.12)
Used condom at last sex[d]	**Intervention**	**Control**	
18-month – boys	251/352 (71.31%)	203/264 (76.89%)	UEI, 0.75 (0.50 to 1.13); AEI, 0.69 (0.47 to 1.01)
18-month – girls	318/509 (62.48%)	255/409 (62.35%)	UEI, 1.01 (0.77 to 1.32); AEI, 0.96 (0.74 to 1.25)

AEI, adjusted effect for intervention; UEI, unadjusted effect for intervention.
a Among those initiating sex since baseline only.
b Ratio of group estimate to group standard error.
c Sexually experienced students.
d For pupils who had sex again since first occasion.

TABLE 72 *Behavioural outcomes – sexual intercourse*

	Sexual intercourse[a]	Results						Statistical significance
Intervention vs standard sex education								
Coyle *et al.*[58]		***n***	**Estimated effect size**		**Standard error**	**Ratio[b]**		
	Number of times had sexual intercourse in last 3 months	965	1.16		0.16	0.94		No significant difference, $p = 0.35$
	Use of alcohol and other drugs before sex in last 3 months	973	0.06		0.07	0.86		No significant difference, $p = 0.39$
Karnell *et al.*[63]	**Self or partner drinking last sex (% change scores)**	**Intervention**		**Comparison**		**Intervention effect**		
	Overall	–0.9		4.5		–4.4		
	Male	–2.7		11.1		–13.8		
	Female	2.6		–1.3		3.9		
	Had had sex at pre-test	–0.6		0.7		–1.3		
	Had not had sex at pre-test	–0.1		14.9		–15.0		$p < 0.05$
Levy *et al.*[65]	**Frequency of sex in the past 30 days**	**Parent**		**Non-parent**		**Control**		
		7th grade pre-test	8th grade post-test	7th grade pre-test	8th grade post-test	7th grade pre-test	8th grade post-test	Control vs treatment groups combined: seventh to eighth grade differences not significant
	Not at all	85.7	78.5	83.5	79.5	85.5	77.7	
	Less than once a week	7.8	12.5	7.0	8.5	7.0	10.1	Non-parent vs parent: seventh to eighth grade differences not significant
	Once a week or more	6.5	9.0	9.5	12.0	7.5	12.2	
	Frequency of sex in the past 30 days 'changers' subgroup	**Parent and non-parent groups combined**				**Control**		
		8th grade post-test				8th grade post-test		Students in the intervention group had been sexually active marginally less often in the past 30 days than control students ($p < 0.10$)
	Not at all	73.7				65.3		
	Less than once a week	16.7				17.7		
	About once a week	7.0				8.1		
	Several times a week/every day	2.7				8.9		

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	Sexual intercourse[a]	Results			Statistical significance
Zimmerman *et al.*[71]	**Ever had sex**	**Modified intervention**	**Original intervention**	**Standard**	No significant differences between the groups
	Baseline (start of 9th grade)	42.9	43.2	47.4	
	Time 2 (end of 9th grade)	42.4	45.2	50.1	
	Used alcohol at last sex				
	Baseline (start of 9th grade)	10.2	14.5	12.2	No significant differences among the curriculum groups at any time
	Time 2 (end of 9th grade)	9.6	14.7	7.7	
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)					
Jemmott *et al.*[62]	**Coitus (practising abstinence)**	**Results of ANCOVA**			
	6-month follow-up	$F(1, 380) = 0.55$, $p = 0.45$; intervention group were not more likely to practise abstinence			
	Anal intercourse	**Results of ANCOVA**			
	Six-month follow-up	$F(1, 403) = 11.70$, $p = 0.0007$; a significantly lower percentage of adolescents in the intervention group reported engaging in anal intercourse in the previous 3 months than in the control group			
	Frequency of anal intercourse	**Results of ANCOVA**			
	Six-month follow-up	$F(1, 409) = 8.29$, $p = 0.004$; intervention participants reported having anal intercourse statistically significantly less frequently than control group participants			
Jemmott *et al.*[43]		**AIDS prevention**	**Control**	**Difference (95% CI)**	
	Coitus	0.48	0.60	–0.12 (–0.27 to 0.3)	No statistical between group comparisons reported
	Number of days respondent had coitus	2.15	5.48	–3.32 (–5.78 to –0.89)	
	Heterosexual anal sex	0.07	0.27	–0.19 (–0.32 to –0.06)	
	No. days respondent had heterosexual anal sex	0.36	0.92	–0.55 (–1.17 to 0.07)	
Stanton *et al.*[69]	**Had sex in the last 6 months**	**Focus on Kids (mean frequency)**	**Control (mean frequency)**		
	Baseline	0.19	0.27		Rates of sexual intercourse during the past 6 months increased over time, but did not differ by intervention status
	Three-month adjusted mean against baseline	0.25	0.28		
	Six-month adjusted mean against baseline	0.27	0.28		

continued

TABLE 72 *Behavioural outcomes – sexual intercourse (continued)*

	Sexual intercourse[a]	Results		Statistical significance
Peer-led vs teacher-led interventions				
Stephenson *et al.*[50]	**Had sex since first sex[c]**	**Intervention**	**Control**	
	Boys (18-month follow-up)	361/1587 (22.75%)	275/1209 (22.75%)	UEI: 1.01 (0.75 to 1.37) AEI: 1.08 (0.77 to 1.49)
	Girls (18-month follow-up)	521/1561 (33.38%)	429/1200 (35.75%)	UEI: 0.92 (0.73 to 1.15) AEI: 0.93 (0.74 to 1.16)

AEI, adjusted effect for intervention; ANCOVA, analysis of covariance; UEI, unadjusted effect for intervention.

a A sexual initiation outcome was not reported by: Wight and colleagues[70] (intervention vs standard sex education); Klepp and colleagues[64] and Roberto and colleagues[66] (intervention vs control), and Borgia and colleagues[51] (peer-led vs teacher-led intervention).

b Ratio of group estimate to group standard error.

c Also reported as 'had sex more than once'.

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TABLE 73 *Behavioural outcomes – contraception*

	Contraception[a]	Results				Statistical significance
Intervention vs standard sex education						
Coyle *et al.*[58]		***n***	**Estimated effect size**	**Standard error**	**95% CI**	
	Protection against pregnancy at last intercourse[b]	998	1.62	0.22	1.05 to 2.50	0.03
Wight *et al.*[70]	**Most recent intercourse with oral contraception, with or without condom**	**Intervention**		**Control**		**Difference (95% CI)**
	Young men (sexually experienced)	18.7		21.2		–2.5 (–8.0 to 2.9) $p = 0.38$
	Young women (sexually experienced)	30.4		28.0		2.4 (–4.1 to 8.9) $p = 0.48$
	Unintended pregnancies					
	Young women	(48/1201) 4.0		(35/916) 3.8		1.0 (0.6 to 1.8), $p = 0.91$
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)						
Stanton *et al.*[69]	**Birth control pill and condom used at last sexual intercourse**	**Focus on Kids**		**Control**		Does not report a statistical comparison
	Baseline	0.28		0.26		
	Three-month adjusted mean against baseline	0.23		0.33		
	Six-month adjusted mean against baseline	0.30		0.30		

continued

TABLE 73 *Behavioural outcomes – contraception (continued)*

	Contraception[a]	Results		Statistical significance
Peer-led vs teacher-led interventions				
Stephenson *et al.*[50]	**Used contraception at first sex**	**Intervention**	**Control**	
	Six-month follow-up – boys	204/238 (85.71%)	156/193 (80.83%)	UEI: 1.48 (0.99 to 2.22); AEI: 1.63 (0.99 to 2.67)
	Six-month follow-up – girls	182/230 (79.13%)	164/215 (76.28%)	UEI: 1.21 (0.83 to 1.77); AEI: 1.14 (0.81 to 1.62)
	18-month follow-up – boys	443/528 (83.90%)	367/432 (84.95%)	UEI: 0.92 (0.64 to 1.33); AEI: 1.01 (0.68 to 1.49)
	18-month follow-up – girls	496/602 (82.39%)	450/550 (81.82%)	UEI: 1.03 (0.81 to 1.31); AEI: 0.90 (0.73 to 1.11)
	Used contraception at last sex	**Intervention**	**Control**	
	18-month follow-up – boys	301/352 (85.51%)	229/264 (86.74%)	UEI: 0.91 (0.52 to 1.59); AEI: 1.06 (0.70 to 1.63)
	18-month follow-up – girls	431/509 (84.68%)	341/409 (83.37%)	UEI: 1.09 (0.74 to 1.63); AEI: 1.06 (0.70 to 1.63)
	No unintended pregnancy	**Intervention**	**Control**	
	Girls by 18-month follow-up	1221/1263 (96.67%)	1584/1621 (97.72%)	UEI: 1.51 (1.05 to 2.18); AEI: 1.40 (0.97 to 2.02) Compared with the control arm, girls in the peer-led arm reported somewhat fewer unintended pregnancies [37 (2.3%) vs 42 (3.3%)] ($p = 0.07$)
	Abortions by age 20	**Intervention**	**Control**	**Adjusted OR (95% CI)**
	From matching to routine data[c]	119/2380 (5.0%, 95% CI 4.0 to 6.3)	113/2260 (5.0%, CI 4.0 to 6.4)	1.07 (0.80 to 1.42)
	Live births by age 20.5	**Intervention**	**Control**	
	From matching to routine data [c]	178/2373 (7.5%, 95% CI 5.9 to 9.6)	237/2236 (10.6 95% CI 6.8 to16.1)	0.77 (0.51 to 1.15)

AEI, adjusted effect for intervention; UEI, unadjusted effect for intervention.

a A contraception outcome was not reported by: Levy and colleagues,[65] Karnell and colleagues[63] and Zimmerman and colleagues[71] (intervention vs standard sex education); Jemmott and colleagues,[62] Klepp and colleagues,[64] and Roberto and colleagues,[66] (intervention vs control); and Borgia and colleagues[51] (peer-led vs teacher-led intervention).

b Condom alone, condom and contraceptive pills, or contraceptive pills alone.

c Denominators calculated by reviewer and rounded.

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TABLE 74 *Behavioural outcomes – sexual partners*

	Sexual partners[a]	Results				Statistical significance
Intervention vs standard sex education						
Coyle *et al.*[58]		***n***	**Estimated effect size**	**Standard error**	**Ratio[b]**	
	Number of sexual partners without a condom in last 3 months	1002	0.68	0.21	–1.81	0.07
	Number of sex partners in last 3 months	998	0.91	0.16	0.57	0.57
Levy *et al.*[65]		**Intervention** (changers subgroup, $n = 186$)		**Control** (changers subgroup, $n = 124$)		No significance between groups reported
	Number of partners in the past 12 months	1.35 (SD = 1.35)		1.40 (SD = 1.50)		
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)						
Jemmott *et al.*[62]	**Number of coital partners**	**HIV prevention** (adjusted mean ± standard errors)		**Control** (adjusted mean ± standard errors)		
	Pre-intervention	0.555 ± 0.130		0.935 ± 0.139		
	3-month follow-up	0.642 ± 0.266		0.844 ± 0.287		
	6-month follow-up	0.378 ± 0.096		0.611 ± 0.103		
	Number of anal sex partners					
	Pre-intervention	0.201 ± 0.060		0.194 ± 0.066		
	3-month follow-up	0.139 ± 0.066		0.241 ± 0.073		
	6-month follow-up	0.073 ± 0.043		0.226 ± 0.048		Intervention group: anal intercourse with fewer partners [$F(1, 409) = 8.29$, $p = 0.004$] than control group

continued

TABLE 74 *Behavioural outcomes – sexual partners (continued)*

	Sexual partners[a]	Results						Statistical significance
Jemmott et al.[43]		**AIDS prevention**		**Control**		**Difference (95% CI)**		
	Number of coital partners	0.85		1.79		–0.93 (–1.53 to –0.33)		No statistical significance among group comparisons reported
	Number of coital partners involved with other men	0.19		1.75		–1.55 (–2.67 to –0.43)		
	Number of female anal sex partners	0.13		0.61		–0.47 (–0.86 to 0.08)		
Roberto et al.[66]	**Number of partners in the last 4 months**	**Experimental group**			**Control group**			
	Pre-test	1.03			1.08			ANOVA $F(1, 90) = 2.57$, eta-squared = 0.03. $p = 0.055$; experimental group outperformed control group
	Post-test	1.07			1.64			
Peer-led vs teacher-led interventions								
Borgia et al.[51]		**Teacher led [mean (SD)]**			**Peer led [mean (SD)]**			Post-intervention there were significant changes ($p < 0.01$) in the teacher-led arm: there was an increase in the percentage of students with more than one partner and a decrease in the percentage of abstinent students; in the peer-led arm, both of these percentages increased
	Number of sexual partners in the previous 3 months	**Number of partners**	**One partner**	**More than one partner**	**Number of partners**	**One partner**	**More than one partner**	
	Pre-test	30.3	64.5	5.2	28.1	65.1	6.8	
	Post-test	25.7	64.8	9.5	32.7	54.7	12.6	

a A sexual partners outcome was not reported by: Karnell and colleagues,[63] Wight and colleagues[70] and Zimmerman and colleagues[71] (intervention vs standard sex education); Klepp and colleagues[64] and Stanton and colleagues[69] (intervention vs control); and Stephenson and colleagues[50] (peer-led vs teacher-led intervention).

b Ratio of group estimate to group standard error.

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TABLE 75 *Behavioural outcomes – other outcomes*

	Other behavioural outcomes	Results				
Intervention vs standard sex education						
Coyle *et al.*[58]		***n***	**Estimated effect size**	**Standard error**	**95% CI**	***p*-value**
	Tested for HIV	1039	0.78	0.37	(0.38 to 1.59)	0.49
	Tested for other STDs	1038	1.05	0.34	(0.54 to 2.04)	0.088
Wight *et al.*[70]	**Any evidence of sex unprotected against STDs ever (whole follow-up sample)**	**Intervention**	**Control**		**Difference (95% CI)**	***p*-value for difference**
	Young men	14.0	13.9		0.1 (–2.1 to 2.3)	0.93
	Young women	23.7	22.2		1.6 (–2.4 to 2.9)	0.45
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)						
Jemmott *et al.*[62]	Risky sexual behaviour index data could not be extracted because labels on the *y*-axis of figure 2 in the publication[62] contain duplicate values and the text does not clarify what the scale should be				Less HIV risk-associated sexual behaviour in the intervention group than the control group [$F(1, 445) = 7.36$, $p = 0.007$]	
Jemmott *et al.*[43]		**AIDS prevention**	**Control**		**Difference (95% CI)**	
	Risky behaviour (summary measure)	0.13	0.61		–0.47 (–0.86 to 0.08) No statistical significance between group comparisons reported	

TABLE 76 *Knowledge outcomes*

	Knowledge outcomes	Results				Statistical significance
Intervention vs standard sex education						
Coyle *et al.*[58] Output from multilevel model (multilevel model, scale range 0–1)		***n***	**Estimated Effect size**	**Standard error**	**Ratio of group estimate to group standard error**	
5 items: possible answers = true; false; or not sure	Knowledge of HIV	3494	0.13	0.03	5.30	$p = 0.00$
5 items: possible answers = yes; no; or not sure	Knowledge of other STDs	3207	0.11	0.002	5.36	$p = 0.00$
Karnell *et al.*[63] 10 true/false items; number of correct responses summed to create an index with a maximum value of 10	General knowledge regarding prevention of HIV and other STDs	No numerical data reported				Text reports no intervention effect
Levy *et al.*[65] 26 items: range of scores not stated, but presumed to be 0–26	**Knowledge of AIDS facts**	**Parent: mean score**	**Non-parent: mean score**	**Control: mean score**		The control vs combined treatment groups differences between 7th and 8th grade were significant ($p < 0.001$) The non-parent vs parent differences between 7th and 8th grade were not significant
	7th grade pre-test	17.98	17.59	17.98		
	8th grade	23.44	22.95	23.44		
Wight *et al.* (SHARE)[70] 8 questions on practical knowledge about sexual health led to calculation of a mean score range of –8 to +8	**Practical knowledge about sexual health**	**Intervention: mean score**		**Control: mean score**		
	Young men	4.35		3.66		Difference (95% CI): 0.7 (0.2 to 1.2), $p = 0.003$
	Young women	5.11		4.66		Difference (95% CI): 0.5 (0.1 to 0.9), $p = 0.008$
Zimmerman *et al.*[71] 10 true/false items; correct responses summed to create an index with a maximum value of 10	**Knowledge of prevention of pregnancy and STDs including HIV**	**Modified intervention: mean score**	**Original intervention: mean score**	**Standard: mean score**		'Knowledge gains were significantly greater for both intervention groups than for the comparison group' 'Overall group differences between Time 1 and Time 2 significant at $p < 0.001$'
	Time 1	4.03	3.80	3.61		
	Time 2	5.35	5.22	4.28		

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	Knowledge outcomes	Results			Statistical significance
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)					
Jemmott *et al.*[62] 56-item inventory regarding the transmission and consequences of AIDS and STDs; a single summary score reflects the number of true/false items correctly answered; higher scores indicate greater knowledge	**HIV risk-reduction knowledge**[a]	**HIV prevention**	**Control**		Adolescents who had received the HIV risk-reduction intervention scored higher in HIV risk-reduction knowledge
	Pre-intervention	39/56	38.3/56		
	Post-intervention	40.2/56 ± 0.5	36.8/56 ± 0.5		$F(1, 493) = 24.17$, $p = 0.0001$
	3-month follow-up	40.5/56 ± 0.5	38/56 ± 0.5		$F(1, 477) = 20.50$, $p = 0.0001$
	6-month follow-up	40.4/56 ± 0.5	38.7/56 ± 0.5		$F(1, 457) = 6.02$, $p = 0.014$
Jemmott *et al.*[43] 57 true/false questions about AIDS and STDs; the number correct out of 57 was calculated	**AIDS and STD knowledge**	**AIDS prevention**	**Control**	**Difference (95% CI of difference)**	Participants in the AIDS condition had greater knowledge
	Post-intervention	46.22	40.37	5.85 (3.23 to 8.48)	$F(1, 151) = 19.58$, $p < 0.0001$.
	3-month follow-up	47.20	44.40	2.8 (0.72 to 4.88)	$F(1, 147) = 9.46$, $p < 0.003$
Klepp *et al.*[64] 18 statements regarding HIV transmission routes and AIDS. Possible answers 'correct,' 'incorrect,' or 'do not know' recoded to 0 (wrong answer or 'do not know') vs 1 (correct answer) and summed to form a knowledge score	**HIV transmission routes and AIDS**	**Intervention schools: mean score**	**Comparison schools: mean score**		
	Baseline	11.5	11.2		
	Follow-up	13.8	11.1		Net effect 2.4, $p = 0.0004$
Stanton *et al.*[69] 30 knowledge (true/false) questions	**HIV/AIDS knowledge**	**Focus on Kids**	**Control**		
	Baseline % correct	76.18 $p < 0.05$ for difference at baseline, controlled for in analysis	73.97		
	3-month adjusted mean against baseline (%)	78.52	78.11		
	6-month adjusted mean against baseline (%)	77.22	77.61		

continued

TABLE 76 *Knowledge outcomes (continued)*

	Knowledge outcomes	Results		Statistical significance
Roberto *et al.*[66]	**Knowledge**	**Experimental group**	**Control group**	
12 statements regarding knowledge (not defined, but pregnancy, STD and HIV were the focus of the paper; response categories of 'true', 'false' and 'don't know', with 'don't know' responses scored as incorrect	Pre-test	6.60	6.85	
	Post-test	7.96	6.60	ANOVA: $F(1, 323) = 29.69$, $p < 0.001$; experimental group outperformed the control group Eta-squared = 0.09
Peer-led vs teacher-led interventions				
Borgia *et al.*[51]	**Knowledge of HIV transmission and prevention**	**Teacher led: [mean (SD)]**	**Peer led: [mean (SD)]**	Significant increase in both arms pre-test to post-test $p < 0.05$
7 questions, each with five possible answers, scored 1 = 'correct answer', 0 = 'wrong answer'; total scale score was computed as a sum of each item score and then standardised to 0–100 range	Pre-test	40.6/100 (21.1)	43.0/100 (20.6)	'In the peer-led arm, improvement in the knowledge score was significantly greater compared to that in the teacher-led arm'
	Post-test	55.2/100 (24.1)	63.7/100 (25.6)	
Stephenson *et al.*[50]	**STI acquisition prevention knowledge**	**Intervention**	**Control**	
STI acquisition prevention knowledge: number correct of 3 binary questions[b]	6-month follow-up – boys	1098 (52.7%)	838 (47.8%)	UEI[c] 1.24 (0.96 to 1.60) AEI[c] 1.24 (0.96 to 1.59)
	6-month follow-up – girls	1337 (67.0%)	1018 (61.8%)	UEI 1.27 (1.01 to 1.60) AEI 1.27 (1.01 to 1.59) 'Knowledge of methods to prevent STIs was significantly better after peer-led SRE at first follow-up for girls ($p = 0.0002$)'
	18-month follow-up – boys	1265 (68.7%)	909 (64.1%)	UEI 1.33 (1.03 to 1.73) AEI 1.31 (1.02 to 1.68) 'Knowledge of methods to prevent STIs was significantly better after peer-led SRE at second follow-up for boys $p = 0.001$'
	18-month follow-up – girls	1447 (82.3%)	1068 (77.8%)	UEI 1.35 (1.00 to 1.82) AEI 1.34 (0.97 to 1.84)

AEI, adjusted effect for intervention; UEI, unadjusted effect for intervention.
a Adjusted means and SEM (all estimated by the reviewer, with difficulty, from very small figure).
b Stephenson and colleagues also report on the outcome of STIs knowledge (number correct of 4 binary questions), which is not shown here.
c All of the STI acquisition prevention knowledge intervention effects are reported as ORs.

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TABLE 77 *Skills and self-efficacy outcomes*

	Outcome	Results				Statistical significance
Intervention vs standard sex education						
Coyle *et al.*[58]	**Self-efficacy**	***n***	**Estimated effect size**	**Standard error**	**Ratio[a]**	
Output from multilevel model (multilevel model, scale range 0–1)	Refusing sex	3335	0.03	0.03	0.99	$p = 0.3$; no significant differences between groups
	Condom use	3528	0.13	0.02	5.26	$p = 0.00$; students in intervention schools had significantly higher scores on the condom use self-efficacy scale than students in comparison schools
	Communication	3328	0.01	0.002	0.20	$p = 0.84$; no significant differences between groups
Karnell *et al.*[63]	***Sex refusal self-efficacy***	**Intervention change**	**Comparison change**		**Intervention effect**	Results showed an intervention effect among female students on sex refusal self-efficacy; female students in the intervention group became more confident about their ability to refuse sex than female students in the comparison group ($p < 0.5$)
Sex refusal self-efficacy: assessed using a 5-point (categories of confidence) Likert-type scale with 6 items measuring individuals' ability to refuse sex in various situations	Overall	0.08	–0.16		0.24	
	Male	–0.16	–0.05		–0.11	
	Female	0.27	–0.26		0.53 ($p < 0.05$)	
	Had had sex at pre-test	0.02	0.05		–0.03	
Condom use self-efficacy: assessed using a 5-point (categories of confidence) Likert-type scale with 5 items	Had not had sex at pre-test	0.14	–0.26		0.40	
	Condom use self-efficacy	**Intervention change**	**Comparison change**		**Intervention effect**	No intervention effect was reported for condom use self-efficacy
	Overall	–0.08	–0.06		–0.2	
	Male	–0.10	–0.30		0.20	
	Female	–0.03	0.12		–0.15	
	Had had sex at pre-test	–0.21	–0.17		–0.04	
	Had not had sex at pre-test	0.01	0.00		0.01	
Levy *et al.*[65]	No self-efficacy outcome measured					

continued

TABLE 77 *Skills and self-efficacy outcomes (continued)*

	Outcome	Results			Statistical significance
Wight *et al.*[70]	No self-efficacy outcome measured				
Zimmerman *et al.*[71b] Refusal self-efficacy – 6-item scale measuring ability to refuse sex in various situations: 1 = 'definitely can't say no' to 5 = 'definitely can say no' Condom self-efficacy – 5 items: 1 = 'disagree a lot' to 5 = 'agree a lot' Situation self-efficacy (negotiate potentially risky situations) – 4 items: 1 = 'I definitely can't do this' to 5 = 'I definitely can do this'	***Refusal self-efficacy*** *(mean scores)*	**Modified intervention**	**Original intervention**	**Standard**	Changes in mediating variables did not differ among groups at either follow-up
	Time 1	3.78	3.71	3.75	
	Time 2	3.86	3.73	3.74	
	Condom self-efficacy *(mean scores)*	**Modified intervention**	**Original intervention**	**Standard**	
	Time 1	4.28	4.14	4.21	
	Time 2	4.25	4.17	4.24	
	Situational self-efficacy *(mean scores)*	**Modified intervention**	**Original intervention**	**Standard**	
	Time 1	3.77	3.65	3.73	
	Time 2	3.93	3.82	3.79	
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)					
Jemmott *et al.*[62] All ratings were made on 7-point scales	**Condom use self-efficacy[c] (mean ± SEM)**	**HIV prevention**	**Control**		Immediately post intervention the adolescents who had received the HIV prevention intervention had greater self-efficacy to use condoms [$F(1, 488) = 4.08$, $p = 0.044$]; the same was true at 3 months [$F(1, 472) = 3.88$, $p = 0.05$], and 6 months [$F(1, 452) = 5.00$, $p = 0.026$]
	Pre-intervention	4.72 (not possible to read SEMs)	4.65 (not possible to read SEMs)		
	Post-intervention	5.11 ± 0.07	4.85 ± 0.1		
	3-month follow-up	5.25 ± 0.07	5.05 ± 0.1		
	6-month follow-up	5.4 ± 0.07	5.1 ± 0.1		
Jemmott *et al.*[43]	No self-efficacy outcome measured				
Klepp *et al.*[64]	No self-efficacy outcome measured				

	Outcome	Results		Statistical significance
Stanton *et al.*[69] Abstinence self-efficacy: 5 statements, each with a 5-point Likert scale (1 = 'Strongly agree' to 5 = 'Strongly disagree', or vice versa, depending on the question) Condom use self-efficacy: 7 statements, each with a 5-point Likert scale (1 = 'Strongly agree' to 5 = 'Strongly disagree', or vice versa, depending on the question)	**Abstinence self-efficacy**	**FoK**	**Control**	At 6 months post intervention, FoK youth demonstrated significantly higher perceptions of self-efficacy regarding abstinence (3.60 vs 3.74, $p < 0.01$), compared with Control youth
	Baseline: mean Likert scale score	3.73	3.76	
	3-month adjusted mean against baseline	3.770	3.719	For the youth who completed their assigned intervention, FoK again conferred significant protection at 6 months; FoK had higher perceptions of self-efficacy than Control youth (3.72 vs 3.60, $p < 0.05$)
	6-month adjusted mean against baseline	3.737 ($p < 0.01$)	3.597	Youth who were virgins at baseline: FoK youth again demonstrated significantly higher perceptions of self-efficacy to refuse sex than Control youth (3.78 vs 3.63, $p < 0.01$) at 6 months post intervention
				Youth sexually experienced at baseline: no significant differences between control and FoK youth were reported
	Condom use self-efficacy	**Focus on Kids**	**Control**	Six months post intervention, FoK youth demonstrated significantly higher perceptions of self-efficacy to use condoms than Control youth (4.36 vs 4.17, $p < 0.05$)
	Baseline: mean Likert scale score	4.21 ($p < 0.05$ for difference with control)	4.38	
	3-month adjusted mean against baseline	4.407	4.29	Among youth who had completed their assigned intervention, at 6 months, perceived self-efficacy was marginally higher for FoK than Control youth (4.32 vs 4.16, $p < 0.10$).
	6-month adjusted mean against baseline	4.357 ($p < 0.05$)	4.171	Youth who were virgins at baseline: data not presented
				Youth sexually experienced at baseline: a significant difference in favour of FoK at the 6-month follow-up only (FoK 4.357 vs Control 4.171, $p < 0.05$)

continued

TABLE 77 *Skills and self-efficacy outcomes (continued)*

	Outcome		Results		Statistical significance
Roberto *et al.*[66]			**Experimental group**	**Control group**	
Condom negotiation: measured using 4 5-point Likert-type items Condom use self-efficacy: measured using 4 5-point Likert-type items Situational self-efficacy: measured using 3 5-point Likert-type items Refusal self-efficacy: measured using 5 5-point Likert-type items	Condom negotiation	Pre-test	4.40	4.22	$F(1, 321) = 4.53$ ($p < 0.05$; *experimental group outperformed control group*), eta-squared = 0.02
		Post-test	4.44	3.98	
	Condom self-efficacy	Pre-test	4.04	4.15	$F(1, 322) = 2.13$, eta-squared = 0.01
		Post-test	4.18	4.11	
	Situational self-efficacy	Pre-test	3.89	3.74	$F(1, 322) = 4.08$ ($p < 0.05$; *experimental group outperformed control group*), eta-squared = 0.01
		Post-test	4.05	3.64	
	Refusal self-efficacy	Pre-test	4.12	3.85	$F(1, 322) = 0.62$, eta-squared = 0.02
		Post-test	4.24	3.86	
Peer-led vs teacher-led interventions					
Borgia *et al.*[51]	***Prevention skills***		**Teacher led [mean (SD)]**	**Peer led [mean (SD)]**	The total scores for prevention skills increased significantly ($p < 0.05$) from pre-test to post-test within both arms The changes in prevention skills did not differ between the trial arms; however, regardless of the arm, all improvements were greater for females, and sexual activity at baseline was associated with greater improvement in prevention skills (regression coefficient in sexually active vs not active = 1.5 (95% CI 0.1 to 2.9)
Skills in prevention, communication and negotiation (11 items, each with ordinal response measuring self-perceived ability: 'much' = score 4, 'sufficiently' = 3, 'little' = 2, 'not at all' = 1); total scale score was computed as a sum of each item score and then standardised to 0–100 range	Pre-test		69.1 (14.4)	68.3 (15.0)	
	Post-test		70.6 (15.3)	69.9 (15.3)	

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	Outcome	Results		Statistical significance
Stephenson *et al.*[50] *Numbers are those who answered 'easy' or 'very easy'*	***Saying no to unsafe sex (6 month follow-up)***	**Intervention**	**Control**	
Confidence about saying no to unwanted sexual activity: 5-point ordinal scale (as below)[d]	6-month follow-up – boys	1206 (59.5%)	977 (59.6%)	UEI 0.98 (0.87 to 1.09) AEI 0.99 (0.87 to 1.11)
	6-month follow-up – girls	1388 (70.6%)	1198 (75.3%)	UEI 0.86 (0.71 to 1.04) AEI 0.86 (0.71 to 1.04)
	18-month follow-up – boys	1183 (67.3%)	872 (68.6%)	UEI 1.00 (0.83 to 1.21) AEI 1.01 (0.84 to 1.21)
	18-month follow-up – girls	1367 (79.7%)	1082 (83.7%)	UEI 0.86 (0.75 to 0.99) AEI 0.86 (0.74 to 1.00) Compared with the control group, girls in the peer-led arm were less confident about refusing to do something they did not want to do sexually ($p = 0.04$)
Confidence about using condoms: average of 2 5-point scales (1 = 'very difficult', 2 = 'difficult', 3 = 'unsure', 4 = 'easy', 5 = 'very easy')	***Confidence about using condoms***	**Intervention (mean score ± SD)**	**Control (mean score ± SD)**	
	6-month follow-up – boys	4.18 ± 0.74, $n = 2038$	4.15 ± 0.75, $n = 1660$	UEI 0.06 (–0.01 to 0.14) AEI 0.07 (–0.01 to 0.05)
	6-month follow-up – girls	3.81 ± 0.75, $n = 1965$	3.78 ± 0.79, $n = 1600$	UEI 0.09 (0.01 to 0.16) AEI 0.09 (0.02 to 0.12)
	18-month follow-up – boys	4.38 ± 0.67, $n = 1760$	4.36 ± 0.67, $n = 1278$	UEI 0.02 (–0.05 to 0.09) AEI 0.03 (–0.04 to 0.06)
	18-month follow-up – girls	4.14 ± 0.70, $n = 1715$	4.14 ± 0.71, $n = 1292$	UEI 0.04 (0.003 to 0.09) AEI 0.05 (0.01 to 0.09) Compared with the control group, girls in the peer-led arm became more confident about using condoms [mean score 3.36 out of 5 (0.80) vs 3.49 (0.79) respectively at baseline, and 4.14 (0.70) vs 4.14 (0.71) at second follow-up, $p = 0.009$]

continued

TABLE 77 *Skills and self-efficacy outcomes (continued)*

	Outcome	Results		Statistical significance
Confidence about discussing sex and contraception with a partner: average of 2 5-point scales (as above)	**Confidence about discussing sex and contraception with a partner**	**Intervention**	**Control**	The arms did not differ for girls or boys at either follow-up for confidence about discussing contraception or sex with a partner
	6-month follow-up – boys	3.83 ± 0.84, *n* = 2030	3.79 ± 0.86, *n* = 1643	UEI 0.05 (–0.03 to 0.13) AEI 0.05 (–0.03 to 0.13)
	6-month follow-up – girls	3.75 ± 0.84, *n* = 1595	3.74 ± 0.84, *n* = 1967	UEI 0.02 (–0.03 to 0.07) AEI 0.02 (–0.03 to 0.08)
	18-month follow-up – boys	4.07 ± 0.81, *n* = 1760	4.06 ± 0.76, *n* = 1278	UEI 0.003 (–0.06 to 0.06) AEI 0.001 (–0.05 to 0.06)
	18-month follow-up – girls	4.06 ± 0.77, *n* = 1713	4.10 ± 0.78, *n* = 1293	UEI –0.01 (–0.07 to 0.06) AEI –0.01 (–0.07 to 0.05)

AEI, adjusted effect for intervention; UEI, unadjusted effect for intervention.

a Ratio of group estimate to group standard error. The ratio of the group coefficient estimate to its standard error reflects the impact of the intervention: when the ratio exceeds 1.96 in absolute value, the result is significant at $p < 0.05$.

b Data for Time 1 vs Time 3 comparison not data extracted due to the high attrition at Time 3. Followed up at Time 2, *n* = 1811.

c Adjusted means and SEM (all estimated by the reviewer, with difficulty, from very small figure).

d For these outcomes the effects are all ORs.

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TABLE 78 *Attitude outcomes*

		Results				Statistical significance
Intervention vs standard sex education						
Coyle *et al.*[58]		***n***	**Estimated effect size**	**Standard error**	**Ratio of group estimate to group standard error**	
	Attitude towards sexual intercourse	Numerical data not reported				No significant difference existed between students in the two programmes in their attitude towards sexual intercourse ($p = 0.25$)
	Attitudes towards condom use	Numerical data not reported				Students in intervention schools expressed significantly more positive attitudes towards condom use at follow-up than students in comparison schools ($p = 0.00$)
Karnell *et al.*[63]	**Positive attitudes towards condom use**	**Intervention change**	**Comparison change**	**Intervention effect**		
	Overall	0.17	0.08	0.09		No report of any significant differences
	Had sex at pre-test	0.17	0.01	0.16		
	Had not had sex at pre-test	0.17	0.13	0.04		
	Positive attitudes about alcohol					
	Overall	–0.01	0.16	–0.17		No report of any significant differences
	Male	0.09	0.03	0.06		
	Female	–0.13	0.22	–0.35		
	Negative attitudes about alcohol					
	Overall	–0.15	–0.08	–0.07		No report of any significant differences
	Male	–0.05	–0.16	0.11		
	Female	–0.22	–0.06	–0.16		
Levy *et al.*[65]	Outcome not reported					

continued

TABLE 78 *Attitude outcomes (continued)*

		Results			Statistical significance
Wight *et al.*[70]	Attitudes not measured				
Zimmerman *et al.*[71]	**Attitude about waiting to have sex (range 1–4)**	**Modified intervention (mean score)**	**Original intervention (mean score)**	**Standard (mean score)**	No significant difference between the groups
	Time 1	2.75	2.84	2.81	
	Time 2	2.69	2.71	2.66	
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)					
Jemmott *et al.*[62]	Attitudes not measured				
Jemmott *et al.*[43]	**Attitude towards risky sexual behaviours**	**AIDS prevention**	**Control**	**Difference (95% CI of difference)**	
	Post-intervention	3.02	3.48	–0.46 (–0.77 to –0.15)	Participants in the AIDS condition expressed less favourable attitudes towards risky sexual behaviours [$F(1, 150) = 8.42$, $p < 0.004$) than participants in the control group
	3-month follow-up	3.13	3.38	–0.54 (0.04)	Difference in the groups was no longer statistically significant [$F(1, 144) = 2.82$, $p < 0.10$
Klepp *et al.*[64]	**Attitudes towards people with AIDS**	**Intervention schools (mean score)**	**Comparison schools (mean score)**		
	Baseline	6.4	6.9		
	Follow-up	8.8	6.5		Net effect 2.8, $p = 0.0015$
	Attitudes towards engaging in sexual intercourse	**Intervention schools (mean score)**	**Comparison schools (mean score)**		
	Baseline	40.7	741.5		
	Follow-up	50.0	47.0		Net effect 3.8, $p = 0.27$
Roberto *et al.*[66]	**Attitude towards waiting to have sex**	**Experimental group**	**Control group**		
	Pre-test	3.77	3.68		ANOVA: $F(1, 318) = 2.92$, eta-squared = 0.1, $p < 0.05$, experimental group outperformed control group
	Post-test	3.71	3.44		
Stanton *et al.*[69]	Attitudes not measured				

		Results		Statistical significance
Peer-led vs teacher-led interventions				
Borgia et *al.*[51]	**Attitudes towards persons with AIDS**	**Teacher led [mean (SD)]**	**Peer led [mean (SD)]**	The total scores for attitudes increased significantly (Wilcoxon test $p < 0.05$) from pre-test to post-test within both arms
	Pre-test	42.0 (26.0)	45.6 (24.9)	
	Post-test	48.3 (26.7)	49.2 (25.6)	
Stephenson et *al.*[50]	**Positive attitude towards using condoms**	**Intervention (peer led, %)**	**Control (teacher-led, %)**	
	6-month follow-up – boys	Score 1 = 1.37	Score 1 = 1.83	UEI 1.14 (0.94 to 1.37)
		Score 2 = 1.43	Score 2 = 1.45	AEI 1.15 (0.95 to 1.39)
		Score 3 = 7.13	Score 3 = 7.99	
		Score 4 = 34.01	Score 4 = 36.56	
		Score 5 = 56.06	Score 5 = 52.17	
	6-month follow-up – girls	Score 1 = 0.78	Score 1 = 0.77	UEI 1.18 (0.94 to 1.48)
		Score 2 = 0.89	Score 2 = 0.96	AEI 1.15 (0.92 to 1.44)
		Score 3 = 3.86	Score 3 = 3.93	
		Score 4 = 22.04	Score 4 = 25.16	
		Score 5 = 72.43	Score 5 = 69.18	
	18-month follow-up – boys	Score 1 = 1.39	Score 1 = 1.46	UEI 1.09 (0.93 to 1.29)
		Score 2 = 1.05	Score 2 = 0.73	AEI 1.09 (0.92 to 1.29)
		Score 3 = 5.87	Score 3 = 7.20	
		Score 4 = 32.79	Score 4 = 32.47	
		Score 5 = 58.90	Score 5 = 58.14	
	18-month follow-up – girls	Score 1 = 0.59	Score 1 = 1.03	UEI 1.20 (0.98 to 1.48)
		Score 2 = 0.47	Score 2 = 0.95	AEI 1.19 (0.98 to 1.45)
		Score 3 = 2.47	Score 3 = 3.32	
		Score 4 = 21.59	Score 4 = 23.18	
		Score 5 = 74.88	Score 5 = 71.52	

continued

TABLE 78 *Attitude outcomes (continued)*

	Results		Statistical significance
Positive attitudes to sex	**Intervention**	**Control**	
6-month follow-up – boys	3.79 (0.58)	3.79 (0.58)	UEI 0.003 (–0.03 to 0.04) AEI 0.002 (–0.04 to 0.04)
6-month follow-up – girls	3.70 (0.54)	3.70 (0.56)	UEI 0.02 (–0.03 to 0.07) AEI 0.01 (–0.04 to 0.06)
18-month follow-up – boys	3.84 (0.56)	3.82 (0.56)	UEI 0.04 (–0.01 to 0.09) AEI 0.04 (–0.01 to 0.10)
18-month follow-up – girls	3.80 (0.56)	3.78 (0.57)	UEI 0.04 (–0.01 to 0.09) AEI 0.04 (–0.01 to 0.09)

AEI, adjusted effect for intervention; UEI, unadjusted effect for intervention.

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TABLE 79 *Behavioural intention outcomes*

	Intentions outcome	Results			Statistical significance
Intervention vs standard sex education					
Coyle *et al.*[58]	Outcome not measured				
Karnell *et al.*[63]	**Intention to have sexual intercourse in the next 3 months**	**Intervention change**	**Comparison change**	**Intervention effect**	
	Overall	0.00	0.06	–0.06	
	Had sex at pre-test	–0.06	–0.24	0.18	
	Had not had sex at pre-test	–0.06	0.25	–0.31	
	Intention to use a condom consistently during sexual intercourse over the next 3 months				
	Overall	0.18	–0.01	0.19	
	Had sex at pre-test	0.45	–0.32	0.77	Intervention effect statistically significant $p < 0.01$
	Had not had sex at pretest	0.17	0.12	0.05	
Levy *et al.*[65]	**All for subgroup of changers**	**Treatment**		**Control (mean score)**	
	Intend on possibly having sex	84.8		88.7	
	For those who plan on having sex, they intend on possibly using condoms	98.7		97.2	
	For those who plan on having sex, they intend on possibly using condoms with foam	84.6		62.9	$p < 0.001$
Wight *et al.*[70]	Outcome not measured				
Zimmerman *et al.*[71]	**Intention to have sexual intercourse (score range 1–5)**	**Modified intervention (mean score)**	**Original intervention (mean score)**	**Standard (mean score)**	No significant differences between the groups
	Time 1	2.48	2.36	2.60	
	Time 2	2.65	2.59	2.68	
	Intention to use condoms consistently	Data not reported for this outcome			

continued

TABLE 79 *Behavioural intention outcomes (continued)„*

	Intentions outcome	Results			Statistical significance
Intervention vs control (no intervention, delayed intervention, non-sex education intervention)					
Jemmott *et al.*[62]	**Condom use intentions** [a]	**HIV prevention**	**Control**		
	Pre-intervention	5.5 (not possible to data extract SEM)	5.35 (not possible to data extract SEM)		
	Post intervention	5.5 ± 0.1	5.1 ± 0.1		Intervention group had firmer condom use intention than those in the control group [$F(1, 488) = 5.42$, $p = 0.02$]
	3-month follow-up	5.85 ± 0.1	5.45 ± 0.1		Condom use intentions maintained [$F(1, 472) = 5.89$, $p = 0.016$]
	6-month follow-up	5.8 ± 0.1	5.5 ± 0.1		Condom use intentions maintained [$F(1, 452) = 3.89$, $p = 0.049$]
Jemmott *et al.*[43]	**Intention to engage in risky sexual behaviour**	**AIDS prevention**	**Control**	**Difference (95% CI of difference)**	
	Post intervention	2.83	3.40	–0.57 (–0.84 to 0.30)	AIDS prevention participants had weaker intentions to engage in risky sexual behaviors than participants in the control group [$F(1, 150) = 17.45$, $p < 0.0001$]
	3-month follow-up	2.87	3.30	–0.43 (–0.74 to 0.12)	AIDS prevention participants had weaker intentions to engage in risky sexual behaviors than participants in the control group [$F(1, 144) = 7.58$, $p < 0.007$]
Klepp *et al.*[64]	**Intention to engage in sexual intercourse in the next 3 months**	**Intervention schools (%)**	**Comparison schools (%)**		
	Baseline	28.3	31.1		
	Follow-up	10.0	24.1		Net effect 11.3, $p = 0.006$
Roberto *et al.*[66]	Outcome not measured				
Stanton *et al.*[69]	Outcome not measured				
Peer-led vs teacher-led interventions					
Borgia *et al.*[51]	Outcome not measured				
Stephenson *et al.*[50]	Outcome not measured				

a Adjusted means and SEM (all estimated by the reviewer, with difficulty, from very small figure).

Appendix 9

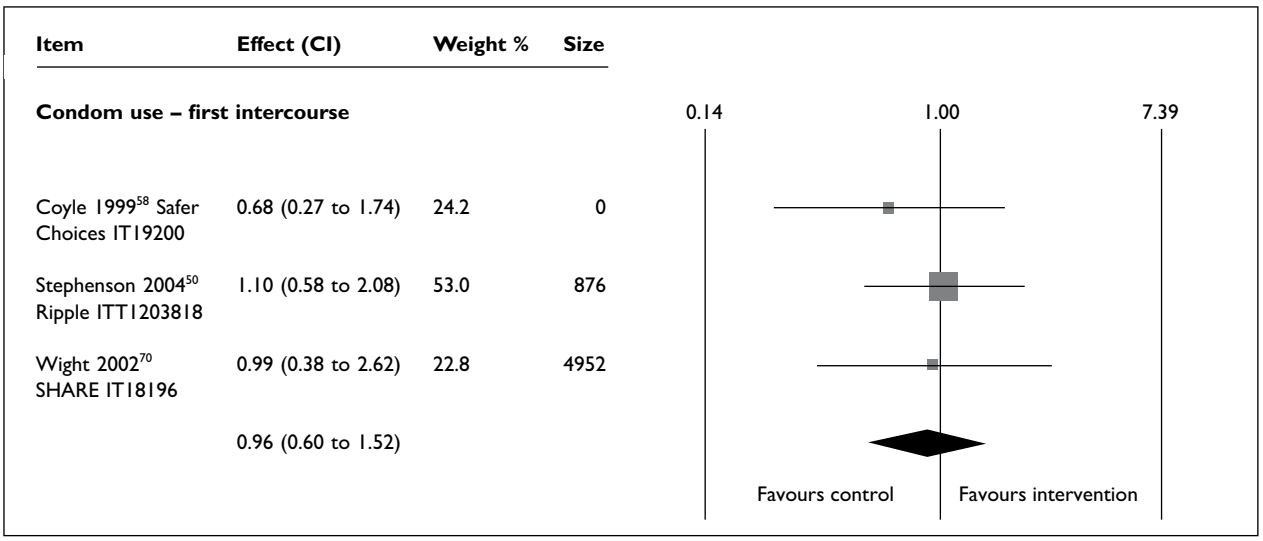
Additional meta-analysis

This appendix presents additional results from the meta-analysis (Chapter 4, Synthesis of results of sound outcome evaluations), for the outcomes of condom use at first and last intercourse, with subgroup analyses for boys and girls where reported by the trials.

Condom use at first intercourse

Subgroup	Study	Outcome	Group 1	Group 2	Odds ratio	CI lower | upper
Condom use: first intercourse	Coyle *et al.*[58] – Safer Choices	Condom use at first intercourse (initiators only, 7-month follow-up)	0.000 | 0.000	0.000 | 0.000	0.680	0.265 | 1.742
Condom use: first intercourse	Stephenson *et al.*[50] – RIPPLE	Combined: used condom at first sex 6 months	0.000 | 0.000	0.000 | 0.000	1.103	0.584 | 2.083
Condom use: first intercourse	Wight *et al.*[70] – SHARE	Combined: condom use (at first intercourse) after first year	0.000 | 0.000	0.000 | 0.000	0.994	0.377 | 2.617
		Total			0.958	0.603 | 1.522

Heterogeneity statistic $Q = 0.704$, df = 2, $p = 0.703$, $I^2 = 0\%$.
File draw N = 2.
Test statistic (combined effect) $z = 0.181$, $p = 0.856$.
Meta-analysis method: inverse variance (fixed effects model).

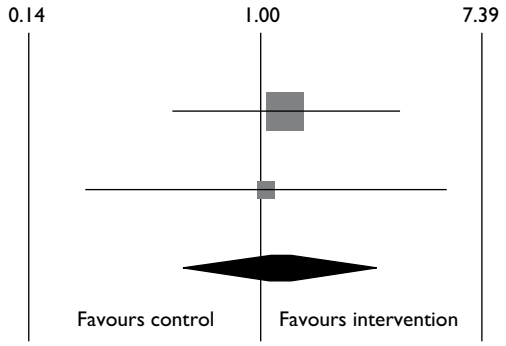


Condom use at first intercourse – boys only

Subgroup	Study	Outcome	Group 1	Group 2	Odds ratio	CI lower | upper
Condom use: boys, first sex	Stephenson *et al.*[50] – RIPPLE	Used condom at first sex, BOYS 6 months	198.000 | 40.000	152.000 | 41.000	1.335	0.507 | 3.516
Condom use: boys, first sex	Wight *et al.*[70] – SHARE	Condom use BOYS (at first intercourse) after first year	1042.000 | 57.000	1154.000 | 70.000	1.109	0.228 | 5.404
		Total			1.269	0.556 | 2.900

Heterogeneity statistic $Q = 0.0385$, df = 1, $p = 0.845$, $I^2 = 0\%$.
File draw N = 1.
Test statistic (combined effect) $z = 0.566$, $p = 0.571$.
Meta-analysis method: inverse variance (fixed effects model).

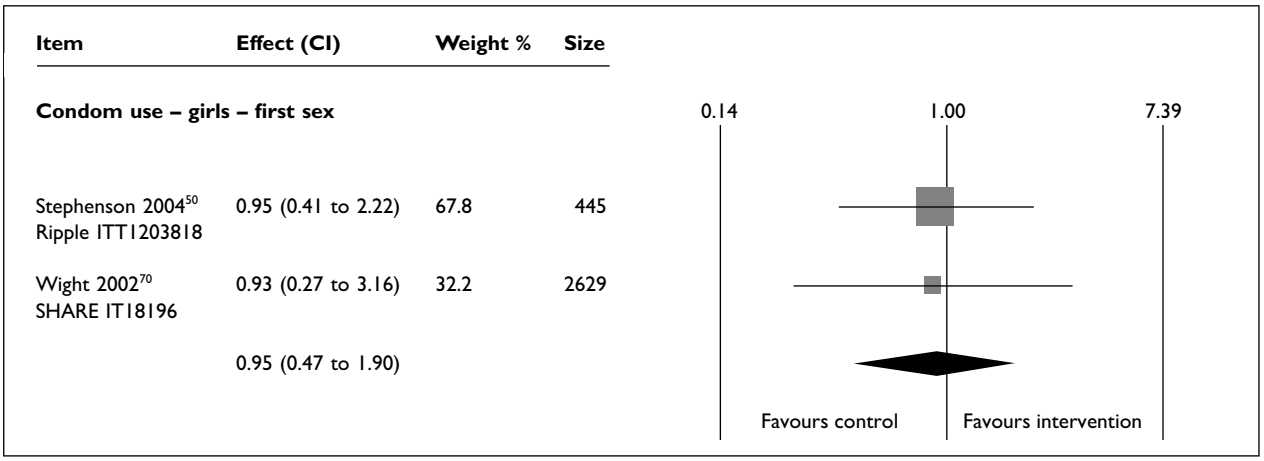
Item	Effect (CI)	Weight %	Size
Condom use – boys – first sex			
Stephenson 2004[50] Ripple ITT1203818	1.34 (0.51 to 3.52)	72.8	431
Wight 2002[70] SHARE IT18196	1.11 (0.23 to 5.40)	27.2	2323
	1.27 (0.56 to 2.90)		



Condom use at first intercourse – girls only

Subgroup	Study	Outcome	Group 1	Group 2	Odds ratio	CI lower | upper
Condom use: girls, first sex	Stephenson *et al.*[50] – RIPPLE	Used condom at first sex, GIRLS 6 months	168.000 | 62.000	159.000 | 56.000	0.954	0.411 | 2.217
Condom use: girls, first sex	Wight *et al.*[70] – SHARE	Condom use GIRLS (at first intercourse) after first year	1182.000 | 127.000	1200.000 | 120.000	0.931	0.274 | 3.165
		Total			0.947	0.473 | 1.895

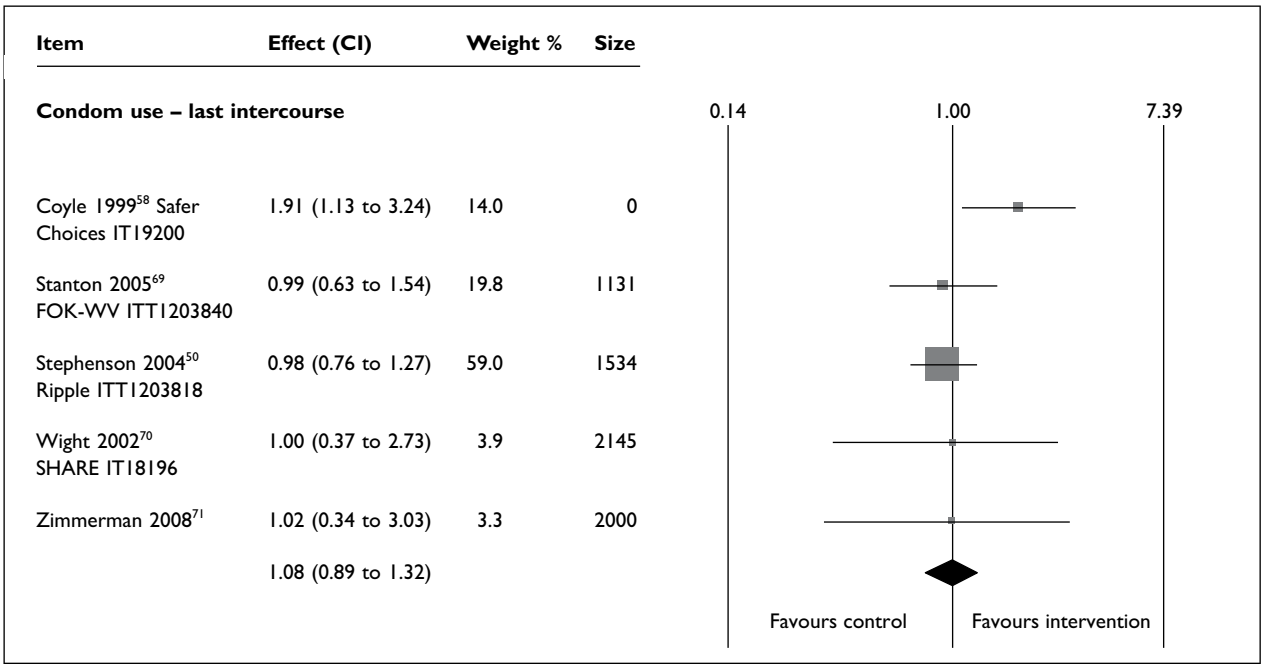
Heterogeneity statistic $Q = 0.00109$, df = 1, $p = 0.974$, $I^2 = 0\%$.
File draw N = 1.
Test statistic (combined effect) $z = 0.155$ $p = 0.877$.
Meta-analysis method: inverse variance (fixed effects model).



Condom use at last intercourse

Subgroup	Study	Outcome	Group 1	Group 2	Odds ratio	CI lower | upper
Condom use: last intercourse	Coyle *et al.*[58] – Safer Choices	Condom use last intercourse (7-month follow-up)	0.000 | 0.000	0.000 | 0.000	1.910	1.125 | 3.242
Condom use: last intercourse	Stanton *et al.*[69] – FoK-WV	Used a condom in last episode at 3 months	635.000 | 235.000	191.000 | 70.000	0.990	0.635 | 1.545
Condom use: last intercourse	Stephenson *et al.*[50] – RIPPLE	Combined: used condom at last sex 18 months	0.000 | 0.000	0.000 | 0.000	0.982	0.759 | 1.271
Condom use: last intercourse	Wight *et al.*[70] – SHARE	Combined outcome: condom use (last intercourse) 3–6 months	0.000 | 0.000	0.000 | 0.000	1.001	0.367 | 2.726
Condom use: last intercourse	Zimmerman *et al.*[71]	Condom use at last sex (one academic year)	807.000 | 342.000	595.000 | 256.000	1.015	0.340 | 3.034
		Total			1.082	0.887 | 1.319

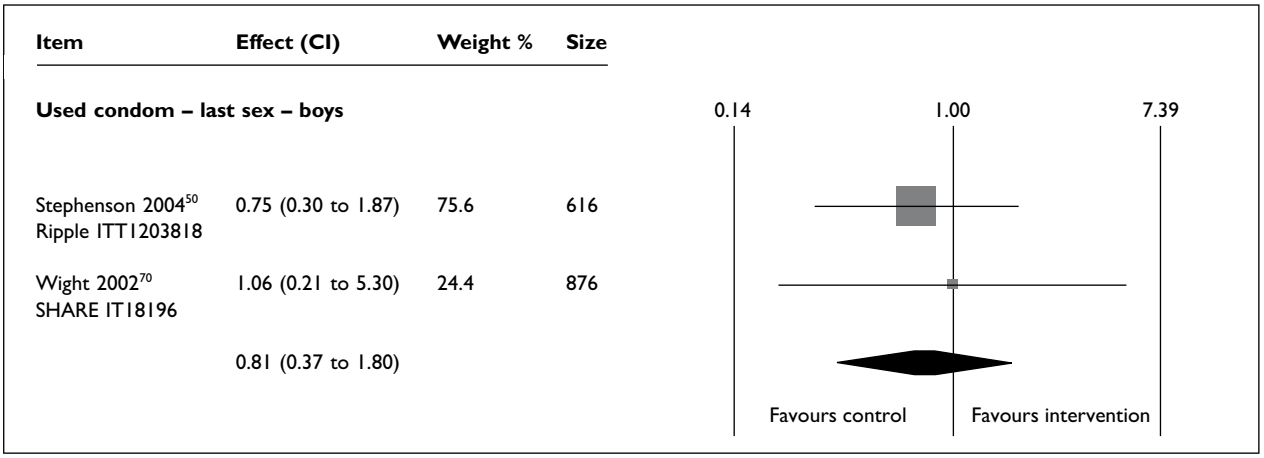
Heterogeneity statistic $Q = 5.16$, df = 4, $p = 0.271$, $I^2 = 22.5\%$.
File draw N = 4.
Test statistic (combined effect) $z = 0.777$, $p = 0.437$.
Meta-analysis method: inverse variance (fixed effects model).



Condom use at last intercourse – boys only

Subgroup	Study	Outcome	Group 1	Group 2	Odds ratio	CI lower | upper
Used condom: last sex, boys	Stephenson *et al.*[50] – RIPPLE	Used condom at last sex: boys, 18 months	251.000 | 101.000	203.000 | 61.000	0.747	0.299 | 1.866
Used condom: last sex, boys	Wight *et al.*[70] – SHARE	Condom use (last intercourse), boys, 3–6 months	281.000 | 142.000	295.000 | 158.000	1.060	0.212 | 5.302
		Total			0.814	0.367 | 1.803

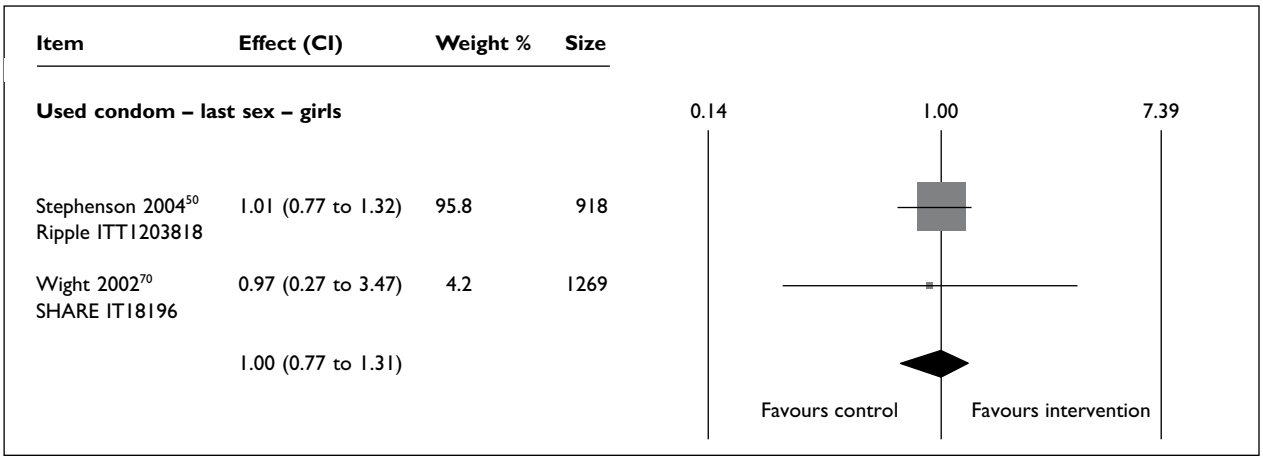
Heterogeneity statistic $Q = 0.137$, df = 1, $p = 0.711$, $I^2 = 0\%$.
File draw N = 1.
Test statistic (combined effect) $z = 0.508$ $p = 0.611$.
Meta-analysis method: inverse variance (fixed effects model).



Condom use at last intercourse – girls only

Subgroup	Item	Outcome	Group 1	Group 2	Odds ratio	CI lower | upper
Used a condom: last sex, girls	Stephenson *et al.*[50] – RIPPLE	Used condom at last sex, girls, 18 months	318.000 | 191.000	255.000 | 154.000	1.005	0.769 | 1.315
Used a condom: last sex, girls	Wight *et al.*[70] – SHARE	Condom use (last intercourse), girls, 3–6 months	355.000 | 289.000	350.000 | 275.000	0.965	0.268 | 3.472
		Total			1.004	0.772 | 1.306

Heterogeneity statistic $Q = 0.00376$, df = 1, $p = 0.951$, $I^2 = 0\%$.
File draw N = 1.
Test statistic (combined effect) $z = 0.0279$, $p = 0.978$.
Meta-analysis method: inverse variance (fixed effects model).



Appendix 10

MEDLINE (Ovid) search strategy for review of cost-effectiveness studies

1. exp Sexually Transmitted Diseases/(206406)
2. 'Chlamydia Infections'/(10291)
3. 'Gonorrhea'/(10081)
4. 'Pelvic Inflammatory Disease'/(4138)
5. exp HIV Infections/(169184)
6. 'Acquired Immunodeficiency Syndrome'/(66750)
7. Herpes Genitalis/(3235)
8. Condylomata Acuminata/(3667)
9. Syphilis/(13099)
10. 'Papillomavirus Infections'/(7419)
11. (sexual$transmit$adj3 infection$).ti,ab. (3419)
12. (sexual$transmit$adj3 disease$).ti,ab. (9770)
13. (STIs or STI or STDs or STD).ti,ab. (9292)
14. Unsafe Sex/(734)
15. sexually transmitted infection$.mp. (2819)
16. Risk Reduction Behavior/(1911)
17. 'Condoms'/(4967)
18. contracept$.ti. (22186)
19. Safe Sex/(1228)
20. sexual health.mp. (1980)
21. sexual abstinence/(893)
22. safe$sex.ti,ab. (1284)
23. or/1–22 (255030)
24. exp preventive health services/(305696)
25. 'Patient Education'/(50147)
26. exp Behavior Therapy/(35650)
27. Sex Education/(6714)
28. exp Health Promotion/(31991)
29. 'Counseling'/(21084)
30. exp School Health Services/(15174)
31. adolescent health services/(3156)
32. ((behavio?r$or conduct or attitude$or intent$or knowledge or self-confidence or information or skill$or risk or health) adj5 (train$or chang$or alter$or prevent$or reduc$or promot$or increas$or decreas$or improv$or program$or curricul$or educat$or project$or campaign$or approach$or facilitat$or advice or counsel$or provi$)).ti,ab. (538730)
33. (cognitive adj3 therap$).ti,ab. (4901)
34. (behavio$adj3 therap$).ti,ab. (8106)
35. or/24–34 (832512)
36. 23 and 35 (38822)
37. exp ECONOMICS/(383052)
38. exp 'Costs and Cost Analysis'/(133267)
39. 'Cost-Benefit Analysis'/(41727)
40. Quality-Adjusted Life Years/(3230)
41. exp MODELS, ECONOMIC/(5632)
42. exp FEES/and CHARGES/(7184)
43. exp BUDGETS/(9655)
44. ((cost$or economic) adj2 (benefit$or utilit$or minim$or effective$or evaluat$)).ti,ab. (55745)
45. (value adj2 (money or monetary)).tw. (648)
46. (economic adj2 burden).tw. (1591)
47. or/37–46 (412594)
48. letter.pt. (607009)
49. editorial.pt. (212191)
50. comment.pt. (343880)
51. or/48–50 (869840)
52. 47 not 51 (379235)
53. 36 and 52 (2718)
54. (teenage$or adolescent$).ti,ab. (96096)
55. (young adj3 (people or person$or adult$)).ti,ab. (48296)
56. 'Adolescent'/(1211252)
57. 54 or 55 or 56 (1249068)
58. 53 and 57 (580)
59. limit 58 to yr = '1990 – 2007' (535)
60. limit 59 to english language (511)

Appendix 11

Distributions used for the probabilistic sensitivity analyses

Table 80 shows the distributions used for parameters in the economic model. The main parameters were varied according to the ranges shown in the one way sensitivity analyses in the main report (*Table 62*). These ranges were used as the 95% CIs to estimate parameters for the normal distribution. In the case of the parameters which used the triangular distribution, the ranges shown are the outer bounds of the distribution.

Some of the parameters varied according to a proportional increase or decrease from the baseline value. These are shown in the table as those values with a mean of 1. For these parameters the new value used in the PSA is the baseline multiplied by the proportional change.

TABLE 80 *Parameters used for the probabilistic sensitivity analysis*

Parameter name	Base-case mean	Lower 95% CI	Upper 95% CI	Distribution	Parameters
Intervention					
Cost of programme (£/individual)	4.3	3	5.6	Gamma	$\alpha = 42$ $\beta = 0.103$
Sexually active	1	0.7	1.3	Log normal	$\mu = 0.000$ $\sigma = 0.158$
Intervention effect, condom use	1.07	1.01	1.13	Log normal	$\mu = 0.049$ $\sigma = 0.068$
Baseline					
Condom use	1	0.85	1.15	Log normal	$\mu = 0.000$ $\sigma = 0.077$
Sexual episodes per partner	10	6	14	Log normal	$\mu = 2.303$ $\sigma = 0.216$
Number of sexual partners per year	1	0.75	1.25	Log normal	$\mu = 0.000$ $\sigma = 0.130$
Model parameters					
Single sex act transmission probability	1	0.3	1.8	Log normal	$\mu = 0.000$ $\sigma = 0.457$
STI prevalence rate	1	0.7	1.3	Log normal	$\mu = 0.000$ $\sigma = 0.158$
Condom effectiveness in preventing HIV	1	0.85[a]	1.05[a]	Triangle	Min. = 0.85, max. = 1.05 Mode = 1
STI complications, all STIs					
Prevalence	1	0.7	1.3	Log normal	$\mu = 0.000$ $\sigma = 0.158$
Quality of life	1	0.8[a]	1.2[a]	Triangle	Min. = 0.8, max. = 1.2 Mode = 1
Unit costs (£)	1	0.7	1.3	Log normal	$\mu = 0.000$ $\sigma = 0.158$

All parameters shown as log-normal are sampled from normal distributions – the sampled value is exponentiated for use in the model. The normal distributions have a mean (μ) equal to the natural logarithm of the base-case mean (column 2) and standard deviation (σ) calculated from the natural logarithm of the upper and lower 95% confidence limits using the following formula:

$$\frac{\ln(\text{UCI}) - \ln(\text{LCI})}{2 * 1.96}$$

See Briggs and colleagues[114] for details and explanation of this approach.
a These values are used for the outer bounds of the distribution.

Appendix 12

Generation of pooled risk ratio effect estimate for condom use required for the economic model

For the purposes of economic modelling, a pooled RR for the general outcome of condom use was required. In our synthesis of the results of sound outcome evaluations for sexual behaviour we report a pooled OR for the outcome 'All condom use' of 1.07 (95% CI 0.88 to 1.30) (see *Figure 3* in Chapter 4, Condom use). The pooled OR therefore had to be converted into a pooled RR.

However, for one of the studies in the meta-analysis, the results of the Safer Choices intervention by Coyle and colleagues,[58] the trial publication reported only the following data from the output of a multilevel model:

Outcome	*n*	Effect size (OR)	SE	95% CI	*p*-value
Use of condoms at last intercourse	1018	1.91	0.27	1.13 to 3.21	0.02

The numbers of young people in the intervention and comparison groups, and the numbers of young people reporting condom use in these two study groups, were not reported. For the OR meta-analysis, we were able to enter the reported Coyle effect size directly into our meta-analysis software. Conversion of the results of the Coyle study in a RR meta-analysis, however, required imputation of the number of young people reporting condom use, i.e. completing a 2×2 data table for the Coyle and colleagues study. (Note: We wrote to the study author to request the relevant data but did not receive a reply.)

We imputed values for group size, number of young people reporting condom use and number not reporting condom use, such that an OR as close as possible to the reported OR of 1.91 was generated:

	Intervention group	Comparison group
Group size	571	447
Event	370	219
No event	201	228

The imputed values above generate an OR of 1.916 for the Coyle and colleagues study, with a 95% CI for the OR of 1.49 to 2.47. These imputed values were then used to include the Coyle study in a RR meta-analysis of all condom use (*Figure 11*). The pooled random effect RR estimate for condom use used in the economic model was therefore 1.05 (95% CI 0.92 to 1.20) (test for heterogeneity $p = 0.00141$, $I^2 = 74.7\%$).

The pooled RR and the pooled OR presented in *Figure 3* in Chapter 4 (under Condom use) are consistent in that they both show a non-statistically significant intervention effect.

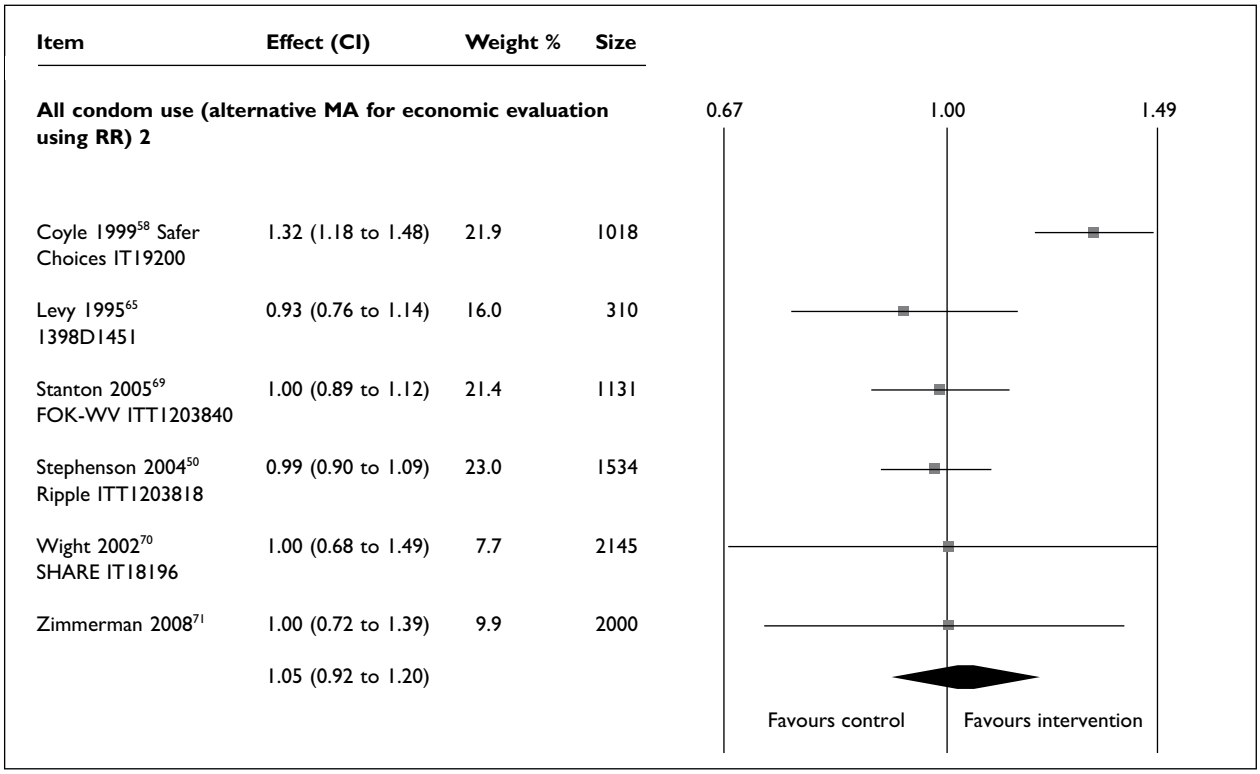


FIGURE 11 *Meta-analysis plot for the outcome 'All condom use' (relative risk).*

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We look forward to hearing from you.

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