Sexually transmitted infections: condom distribution schemes

Effectiveness and cost-effectiveness evidence review

Chris Carmona, Josephine Kavanagh, Adrienne Cullum, Toni Shaw, Alice Murray

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1. Introduction

During the review of NICE's guideline on "preventing sexually transmitted infections and under-18 conceptions", condom distribution (as a means of preventing Sexually Transmitted Infections [STIs]) was identified as an area where NICE guidance is needed.

This evidence review has been conducted to support the guideline on condom distribution schemes and will focus on the effectiveness of different types of scheme. For the purposes of this review, 'condom' refers to the male condom unless stated otherwise.

2. Methods

This review was conducted according to the methods guidance set out in '<u>Developing NICE</u> guidelines: the manual' (October 2014).

2.1. Review questions

- 1. What multi-component schemes are effective and cost effective in providing condoms to different populations to reduce STIs?
- 2. What single-component schemes are effective and cost effective in providing condoms to different populations to reduce STIs?
- 3. What outlet¹ schemes are effective and cost-effective in providing condoms to different populations to reduce STIs?

The evidence relating to the cost effectiveness of interventions will also be presented in this review. The full economic analysis will be presented separately.

2.2. Searching, screening, quality assessment and data extraction

A single systematic search of relevant databases and websites was conducted from 1996 to September 2015 to identify relevant evidence for this review (see Appendix 1).

The protocol outlines the methods for the review, including the search protocols and methods for data screening, quality assessment and synthesis (see Appendix 2).

¹ Outlet schemes refers to schemes where condoms (and lubricant if appropriate) are sold on at cost price by health or voluntary agencies.

All references from the database searches were screened on title and abstract against the criteria set out in the protocol. A random sample of 10% of titles and abstracts was screened by two reviewers independently, with differences resolved by discussion. Agreement at this stage was 95.2%. Full-text screening was carried out by two reviewers independently on 10% of papers. Agreement at this stage was 100%. Reasons for exclusion at full paper stage were recorded (see below and appendix 5).

Each included study was data extracted by one reviewer, with all data checked in detail by a second reviewer. Any differences were resolved by discussion between the reviewers.

Included studies were rated individually to indicate their quality, based on assessment using a checklist. Each included study was assessed by one reviewer and checked by another. Any differences in quality grading were resolved by discussion. The tool used to assess the quality of studies is included in Appendix 3 and a summary of the QA results of all included studies is included in Appendix 2.4. The quality ratings used were:

- ++ All or most of the checklist criteria have been fulfilled, and where they have not been fulfilled the conclusions are very unlikely to alter.
- + Some of the checklist criteria have been fulfilled, and where they have not been fulfilled, or are not adequately described, the conclusions are unlikely to alter.
- Few or no checklist criteria have been fulfilled and the conclusions are likely or very likely to alter.

3. Results

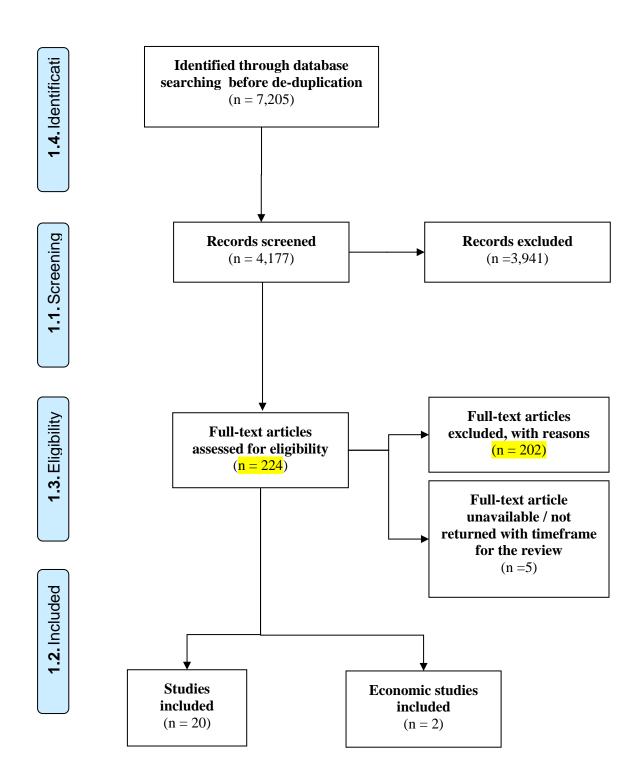
3.1. Flow of literature through the review

22 studies were included in the review. Figure 1 below shows the flow of literature through the review. Full reports of 5 studies could not be found based on the bibliographic information provided. A brief summary of reasons for exclusion at full text is included in the table below.

Reason	Number
Not an intervention study	78
Not primary research	35

pre 1996	36
Not condom distribution scheme	27
Inappropriate methodology	13
Not included country/population	8
Not English Language	2
Duplicate/repeated data	2
Thesis	1
Total:	202

Figure 1. Flow of literature through the review



3.2. Characteristics of the included studies

Full details of the included studies are given in the evidence tables in Appendix 3. Tables 3.2.1 and 3.2.2 below show in which country the studies were conducted, and provide a brief summary of the interventions, populations and settings investigated in these studies.

3.2.1. What schemes are effective in providing condoms to different populations to reduce STIs?

First author,	Design	Country	Setting	Population	Intervention	QA		
year						rating		
<u> </u>	Multicomponent distribution schemes							
High Schools								
Furstenberg (1997)	Before and after	US	High Schools	14 – 18 year olds in school catchment area	'Policy 123' sexual health programme in schools that aimed to maximise access to condoms.	-		
Guttmacher (1997)	Quasi experimental	US	High Schools	High school students who reported sexual activity	Multi component condom project with condom provision, lessons, resource areas and dedicated staff time	-		
Larsson (2006)	Controlled trial	Sweden	High Schools	Swedish high school students.	Multicomponent sex education in schools focussed on condoms and emergency contraception including a condom card for access to free condoms	+		
Outreach and	community							
Anderson (1998)	Quasi experimental	US	Outreach and enhanced outreach	PWID	Condom distribution with co-ordination, small media and referral to NSP	-		
Anonymous (1999)	Nested cross sectional study with matched intervention and comparison communities	US	Areas with high IDU	People at high risk of HIV	Community mobilisation, small media and condom/bleach kit distribution	-		
Rhodes (2009)	Controlled trial	US	City Latino soccer league	Latino men in 89 local amateur soccer	Community lay health advisor delivers HoMBRes	+		

First author, year	Design	Country	Setting	Population	Intervention	QA rating
year				leagues	intervention (a culturally appropriate intervention developed through community-based participatory research methods).	Tating
Rietmeijer (1996)	Quasi experimental	US	Street	PWID	Peer workers distributed small media, condoms and bleach kits.	-
Wendell (2003)	Quasi experimental	US	Community	People in areas with a high risk factors for HIV	Outreach workers were trained to deliver a needs assessment and educational intervention and to hand out leaflets, condoms, beach kits and coupons for needles at local pharmacies.	-
Healthcare se	ettings			•		
Exner (2012)		US	Agencies in receipt of HIV prevention funding	Directors of agencies and HIV sexual risk- reduction coun sellors	Providing free female condoms, support, training and a tool kit including posters, policy guidance etc to clinics	-
Neumann (2011)	Controlled trial	US	STD Clinic	Patients aged 18 and older	VOICES/VOCES video intervention Delivered in small groups at clinic.	-
Oakeshott (2000)	Cluster RCT	UK	GP practices	Women under 35 who attended GP practices for cervical smear tests	10 minutes practice-based teaching on condom promotio n in women. This was backed up with regular supplies of condoms and patient leaflets	++
	onent distribut	tion schem	es			
High Schools		LUC	Hubar Hal	I Black In . I	Ta insurer	
De Rosa (2012)	Cluster controlled trial	US	Urban High Schools with condom	High school students	To improve implementation of structural condom	+

First author, year	Design	Country	Setting	Population	Intervention	QA rating
,			schemes		schemes	J 3
Kirby (1999)	Quasi experimental	US	High Schools	High school students	Free condom distribution via baskets or vending machines	-
Schuster (1998)	Before and after	US	High Schools	Grade 9-12 students	Various modes of condom distribution	+
Wretzel (2011)	Before and after	US	High Schools	15-19 year olds	Condom Availability Programme in High Schools.	-
Commercial a	and other com	munity ve	nues			•
Cohen (1999)	Matched area control	US	Health clinics and small businesses in areas of high HIV prevalence.	Women at family planning or prenatal visits	Condom distribution	-
Ross (2004)	Controlled trial	US	Small businesses in areas of high HIV prevalence	Local communities	Outreach workers recruited small businesses who distributed condoms via a 'bowl on counter' type scheme	-
Weatherburn (1998)	Before and after	UK	Gay venues	MSM	Rubberstuffers condom distribution	+
Schemes to s	sell cost price	condoms				
Dahl (1999)	Comparative observational	CAN	Clubs/ bars and also drugstores	Sexually active young people (18-30)	Discount coupons for buying condoms	-
Studies that of	compare singl	e and mult	i-component scl	hemes		
Senn (2011)	Randomised controlled trial	Switzerla nd	Travel health clinic	18 – 44 travelling without partner	Compared Standard pre- travel consultation; Standard pre- travel consultation plus provision of 3 free condoms; Standard pre- travel consultation, motivational interview and provision of 3 free condoms.	+

STI: sexually transmitted infection; PWID: people who inject drugs; NSP: needle and syringe programme; IDU: injection drug users; MSM: men who have sex with men

3.2.2. What schemes are cost effective in providing condoms to different populations to reduce STIs?

Study	Design	Setting / Population	Intervention	Perspective	Time horizon	Outcomes	QA
Bedimo et al (2002)	Cost, threshold and cost utility analysis	USA African Americans in area of Louisiana where the distribution scheme was available.	A targeted large-scalecondom distribution programme in commercial and community venues, . Compared to areas with no scheme.	Provider perspective not clearly reported. Reviewers assume societal and provider.	Time-line horizon not clearly reported. Reviewers assume this is implicitly a life time horizon	Programme costs per person. Estimate of HIV infections prevented and QALYS saved. Direct costs averted.	+
Holtgrave et al (2012)	Cost, threshold and cost utility analysis	USA Heterosexual women in areas with disproportion ately high HIV prevalence among women in Washington DC.	Female condom and education scheme. Pre-test, post-test comparison.	Societal and provider perspective.	A 1 year time horizon.	Societal and provider costs and benefits. HIV infections averted. QALYs gained.	++

3.3. Study findings

3.3.1. What schemes are effective in providing condoms to different populations to reduce STIs?

20 studies were included in this part of the review. Overall, the quality of the studies was weak, with only 1 of the studies graded [++] and 6 studies graded [+]. The remaining 13 studies were graded [-] (see Table 3.2.1). Most of the studies (16/20) were from the US with 1 from Canada, 1 from Sweden and 2 from the UK.

Where data are reported we have included effect sizes, means, standard deviations and 95% confidence intervals. However, many of the included studies are poorly reported and sometimes only p values, or simple categorical data are available. In all instances the most complete data available have been presented in the review findings and evidence statements.

Studies were grouped by the type of intervention the study tested and subdivided by setting:

Multi-component condom distribution schemes

- In high schools (3 studies)
- In outreach and community settings (5 studies)
- In healthcare settings (3 studies)

Single component condom distribution schemes

- In high schools (4 studies)
- In commercial venues (3 studies)

Schemes to sell condoms at cost price

• In commercial venues (1 study)

Comparing single and multicomponent distribution schemes

• In a travel health clinic (1 study)

Multi-component condom distribution schemes

High Schools

One quasi-experimental study (Guttmacher 1997 [-]) and one before and after study Furstenberg 1997 [-]) from the US, and one controlled trial (Larsson 2006 [+]) from Sweden reported on multi-component condom distribution schemes in High Schools.

A quasi experimental study by Guttmacher et al (1997 [-]) reports on the impact of a citywide condom distribution project in high schools in New York by comparing rates of sexual activity and condom use with Chicago. Each public high school was mandated to:

- assemble an HIV team, composed of the principal, assistant principal, teachers, parents, students, health resource staff, and other interested personnel, to oversee the program
- 2 teach a minimum of six HIV/AIDS lessons in each grade
- 3 designate and maintain at least one site at the school as a resource room where condoms and AIDS prevention materials were available
- 4 staff this site no less than 10 periods a week and post the hours that the site is open
- 5 identify at least one male and one female staff member as condom resource room volunteers and apprise students of the names of these individuals
- 6 arrange for an HIV/AIDS information session for parents.

The authors surveyed 7,119 students from 12 randomly selected NYC schools and 5738 students from 10 Chicago schools (majority aged 15 – 17, 28% under 14, 10% over 18; limits not given). New York students reported equal rates of sexual activity to Chicago students, but had higher rates of condom use at last intercourse (OR=1.36, p<0.01), whether male (OR=1.29, p<0.01) or female (OR=1.42, p<0.01). For students with 3 or more sexual partners over the previous three months condom use was also greater in NYC than Chicago (OR=1.85; p<0.01). Note that confidence intervals were not reported for these outcomes.

Furstenberg and colleagues (1997 [-]) conducted a before and after study in Philadelphia, US to evaluate the implementation of Project 123 across the city. Project 123 was a sexual health and condom access scheme. The policy had three strategies: It directed schools to develop instruction that promotes "healthy habits and moral values regarding human sexuality" and to convey that "abstinence is the most effective way of preventing pregnancy, sexually transmitted diseases and HIV infection"; it authorized staff education, outreach to parents and partnerships with neighbourhood health care providers; and it recommended the

district's involvement in citywide efforts to maximize access to condoms and to establish a phased-in pilot program of condom availability in schools with classes in grades 9–12. Based on a survey of students (aged 14-18) before and after the implementation of the programme, they report that condom use at last intercourse increased for the entire sample, but the change was greater in schools with health resource centres (from 52% to 58% of sexually active students) than in those without a program (62–65%). The results are not statistically significant and the study is confusing and poorly reported.

Larsson et al (2006 [+]) conducted a controlled trial in high schools in Sweden. They conducted a multicomponent sex education programme named 'The Love Emergency' over 1 year and comprising of 4 strategies:

- A 20 minute lesson on emergency contraception (ECP) from an experienced midwife.
- 2. Three lessons by a male and a female medical student about attitudes and values about contraception, including condom skills.
- 3. A VIP card entitling students to free condoms from the school nurse
- 4. A telephone number for students to access contraceptive counselling from a trained midwife.

A questionnaire was administered before and after the intervention to 18 classes who took the test and to 7 who received no intervention. When compared to the control group, the intervention group had statistically significant improvements over time in relation to:

- Ever having used a condom: % increase over time (intervention 19% v control 0%, p= 0.01)
- Knowledge of effectiveness of emergency contraception: % increase over time (intervention 32% v control 1%, p= < 0.01)
- Could imagine buying condoms: % increase over time (intervention 11% v control 0%, p= 0.03) (There were no statistically significant differences between the two groups on intent to use ECP or recommend ECP, or on attitudes to condoms and ECP. More than one out of four (28%) had opted for free condoms.

Evidence Statement 1: Multicomponent condom distribution programmes in high schools

There was weak evidence from 1 US quasi experimental study [-]¹, 1 Swedish controlled trial [+]1² and US before and after study [-]³ to suggest that multicomponent interventions

that include condom distribution in High Schools increase the number of students (aged 14 – 18) reporting condom use at last intercourse .Where reported, there were no statistically significant difference in levels of sexual activity between intervention and comparison group students.

The studies incorporated condom distribution with lessons on safe sex and having staff available to provide support.

One study¹ reported equal rates of sexual activity to comparison students, but had higher rates of condom use at last intercourse (OR=1.36, p<0.01), whether male (OR=1.29, p<0.01) or female (OR=1.42, p<0.01). For students with 3 or more sexual partners over the previous three months condom use was also greater in the intervention than comparison group (OR=1.85; p<0.01).

One study² found statistically significant improvements over time in relation to ever having used a condom (19% increase, p=0.01), knowledge of effectiveness of emergency contraception (32% increase, p=<0.01), and, pupil could imagine buying condoms (11% increase, p=0.03). There were no significant differences between the two groups on intent to use or recommend emergency contraception, or attitudes to condoms and emergency contraception.

The third study³ was poorly executed and reported, with a high risk of bias, and found no statistically significant changes.

Applicability: The evidence is only partially applicable to the UK because two of the studies were undertaken in the USA and one in Sweden. However, the interventions would be feasible in a UK-based setting.

- 1. Guttmacher et al 1997 [-]
- 2. Larsson et al 2006 [+]
- 3. Furstenberg et al 1997 [-]

Outreach and community

Five US studies reported on multicomponent condom interventions in outreach or community settings. 3 of the studies had a quasi-experimental design (Anderson 1998 [-]; Rietmeijer 1996 [-]; Wendell 2003 [-]), one was a controlled trial (Rhodes 2009 [+]) and one was a nested cross sectional study (Anonymous 1998 [-]).

Two of the studies (Anderson et al, 1998 [-] & Rietmeijer et al, 1996 [-]) targeted people who inject drugs.

Anderson et al (1998 [-]) conducted a quasi-experimental study to measure changes in HIV-related risk behaviour, to measure changes in exposure to street outreach workers, and to measure the association between interaction with street outreach workers and condom use as part of a 5-year, multifaceted evaluation of street outreach interventions to injection drug users (IDUs) and high-risk youth. They evaluated five different enhanced street outreach interventions:

- Childrens Hospital of Los Angeles Enhanced outreach programme centred on the opening of a shopfront centre ("the Rubber Room") for
 - condom distribution
 - interagency outreach co-ordination
 - peer outreach team
 - small print media
 - referral to NSP
- San Francisco City Health Department A storefront operation and a street
 outreach team that provided (in addition to standard outreach services): referrals for
 medical, drug treatment, and other services. Community activities were sponsored at
 a youth centre: discussion groups, women's shower times, community-designed HIV
 prevention posters, a Grateful Dead prevention message video and Grateful Dead
 logo condoms, and outpatient drug treatment services.
- University of Illinois at Chicago street outreach to IDUs in innercity neighbourhoods. The enhanced intervention centred on services delivered from a mobile van that provided on-site HIV counselling and testing, and condom distribution. Additional enhancements included increasing the number of outreach

workers, escorting clients to referral services, improving client follow-up, and making community presentations.

- Aids Programme Los Angeles County: street outreach interventions for IDUs. The
 enhanced intervention centred on additional services provided by the outreach
 workers, including the provision of on-the-street HIV counselling and testing, a
 referral tracking system, and the use of HIV prevention narratives based on
 indigenous artwork on a series of cards. There is no reference to condom distribution
 in the description of this particular project.
- Philadelphia Health Management Corporation: interventions centred on
 providing specialised training to outreach workers related to (a) staging clients into
 stage-of-change categories, (b) improved client follow-up, (c) escorting clients to
 referral services, (d) use of improved reporting forms, and (e) community
 presentations. Outreach workers were added.

Children's Hospital of Los Angeles - Results indicate that the intervention was not statistically significantly associated with condom use during most recent vaginal sex for main or casual partners. 47.6% of youth reported having used condoms with main partner, and 71.8% reported having used condoms with casual partners. Getting condoms from outreach workers was a strong predictor of having condoms for youth who reported main (odds ratio [OR], 2.5; confidence interval [CI], 1.5–4.2) and casual (OR, 2.4; CI, 1.5–4.0) partners.

San Francisco City Health Department - The intervention was not significantly associated with condom use for main or casual partners. For respondents with main partners, having a condom at interview was, in turn, strongly associated with having received condoms from outreach workers (OR, 3.4; CI, 1.8–6.4).

University of Illinois at Chicago - Being in the study area was associated with higher use of condoms during most recent vaginal sex with main partner (OR, 1.9; CI, 1.3–2.7). It was also associated with a higher odds of getting condoms from outreach workers (OR, 3.1; CI, 1.3–7.6) and having condoms at interview (OR, 2.0; CI, 1.0–4.0). For condom use with casual partners, there were no statistically significant effects of being in the study area. Similar to condom use for main partners, having condoms is a strong predictor of condom use (OR, 3.0; CI, 1.9–5.0) and is in turn strongly related to outreach contact (OR, 2.3; CI, 1.3–4.1).

Philadelphia Health Management Corporation - Analysis did not indicate any effects of being in the study area on condom use with main partners. For casual partners, being in the study area had a statistically significant effect on condom use (OR, 3.7; CI, 1.4–9.6). However, condom use with casual partners decreased in the comparison area (from 81.3% to 60.0%), and condom use remained the same in the study area (68.0% to 64.5%). This decrease suggests that the enhancement was effective in maintaining condom use with casual partners. As was true at other sites, having a condom at interview was a strong predictor of condom use with main (OR, 1.8; CI, 1.2–2.6) and casual (OR, 2.2; CI, 1.3–3.6) partners. Contact with street outreach programs was a consistent predictor of having condoms at interview for respondents who had main (OR, 3.0; CI, 2.0 –4.6) and casual partners (OR, 2.0; CI, 1.3 – 3.4).

The paper was poorly written and the authors do not summarise their findings or draw any overall conclusions beyond saying that the quasi experimental design did not identify many areas in which there was a change in condom use behaviours associated with enhanced programs and statistically significant effects were only seen in Chicago and Los Angeles.

A quasi experimental study by Rietmeijer and colleagues (1996 [-]) examined the effectiveness of small media materials that included role model stories developed based on behavioural models. These were distributed by trained peer volunteers or 'interactor' volunteers (business people or community leaders for example) along with bleach kits (for cleaning drug related equipment) and condoms in areas with a high number of people who inject drugs. When compared with the comparison site, subjects (who had injected drugs or had vaginal sex within the previous 30 days) from the intervention site reported significant increases in consistent use of condoms with occasional partners (OR 13.6; 95%CI 3.2 - 58.0; p<0.001). No effects were seen for steady partners. Use of bleach also increased statistically significantly (OR 2.6, 95% CI 1.3 -5.1, p<0.001).

Anonymous (1999 [-]) used a cross sectional design to test an intervention to improve movement along the stages of change towards consistent condom and bleach use for people at increased risk of HIV2 with 3 key components: (1) mobilisation of community members to distribute and verbally reinforce prevention messages and materials among their peers, (2) creation of small-media materials featuring theory-based prevention messages in the form of role-model stories, and (3) increased availability of condoms and bleach kits. People living in the study area were surveyed and compared to a similar area

² active injection drug users, female sex partners of male injection drug users, female commercial sex workers and other women who trade sex for money or drugs, youth in high-risk situations, non-gay-identified men who have sex with men, and residents of census tracts where rates of sexually transmitted diseases are high.

with no intervention. At the community level movement towards consistent condom use with main partner (effect size 0.19; 95% CI 0.01 to 0.38, p<0.05),) and non-main partner (effect size 0.34 : 95% CI 0.04 to 0.63, p<0.05) was greater in intervention than comparison communities. The intervention group experienced a statistically significant movement in the maintenance stage of change towards consistent use of condoms with non-main partner (effect size 9.40: 95% CI 1.2 to 17.7, p<0.05), when compared to control. There was no statistically significant impact on this outcome for main partners. There was 12.4% increase in the proportion of respondents carrying condoms in the intervention communities when compared to the control communities (95% CI 6.8% to 18.0, P< .0001).

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Rhodes et al (2009 [+]) conducted a controlled trial among Latino soccer players in a Latino men's league. Community lay health advisors delivered a culturally appropriate intervention (developed through community-based participatory research methods). The community lay health advisors trained as: 1) health advisors able to make referrals to increase knowledge about HIV and STDs and testing and increase condom use skills; 2) opinion leaders to bolster positive and reframe negative socio-cultural expectations about what it means to be a man; 3) community advocates to work towards environmental change. Participation in the intervention was associated with statistically significant improvements in consistent condom use (65.6& vs 41.3%; OR 2.3, 95% CI 1.2 – 4.3; p=0.01), HIV testing (64.4% vs 41.8%; OR 2.5, 95%CI 1.5 – 4.3; p=0.001), knowledge of HIV (74.1% vs 43.5%; OR 1.7 95%CI 1.4 – 2.1; p= 0.001), and self-efficacy to use condoms (55.6% vs 38.2%; OR 1.6, 95% CI 1.1 – 2.6; p= 0.01).

In a quasi-experimental study by Wendell et al (2003 [-]), trained outreach workers delivered a needs assessment and educational intervention, handed out bleach kits (to clean drug taking equipment) and condoms, and gave out vouchers for clean injecting equipment from a local pharmacy in areas with high risk factors for HIV. After controlling for demographic characteristics and sexual risk factors people in the intervention sites were more likely to use condoms than people in comparison sites (OR 1.37, 95% CI 1.20, 1.56; p<0.001). In addition, people in intervention sites had statistically significantly better scores than comparison sites on contact with outreach worker (OR 6.74, 95% CI 5.94,7.66); knowing where to get free condoms (OR 3.2, 95% CI 2.75,3.73); last condom free (OR 1.73, 95% CI 1.61,1.89); has condom with them or at home (OR 2.29, 95% CI 1.89,2.76); used condom at last encounter (OR 1.4, 95% CI 1.58,2.08).

Evidence Statement 2: Multicomponent condom distribution programmes delivered through outreach or in community settings

There was weak evidence from 2 quasi experimental studies (both [-])^{1,2} with drug users in a broad range of community and outreach settings in the US that multicomponent condom distribution programmes can increase levels of consistent condom use with occasional partners² (OR 1.36, 95% CI 3.2 – 58.0), though not with steady partners.

Moderate evidence from 3 studies in the US (1 cross sectional [-]³; 1 controlled trial [+]⁴ and 1 quasi experimental [-]⁵) suggests that participatory and theory based multicomponent educational/condom distribution interventions (including health advice, advocacy and health education, for example) can have a statistically significant impact on: movement along the stages of change towards consistent condom consistent use with main and non-main partner3; consistent condom use (OR 2.3, 95% CI 1.2 – 4.3; p=0.01), HIV testing (OR 2.5, 95%CI 1.5 – 4.3; p=0.001), knowledge of HIV (OR 1.7 95%CI 1.4 – 2.1; p= 0.001), and self-efficacy to use condoms (OR 1.6, 95% CI 1.1 – 2.6; p= 0.01)4; and, likelihood of using a condom (OR1.37, 95% CI 1.20, 1.56; p<0.001), used condom at last encounter (OR 1.4, 95% CI 1.25,1.27), knowing where to get free condoms (OR 3.2, 95% CI 2.75,3.73)5.

Applicability: The evidence is only partially applicable to the UK because all of the studies were undertaken in the USA. However, the interventions would be feasible in a UK-based setting.

- 1. Anderson et al, 1998 [-]
- 2. Rietmeijer et al, 1996 [-]
- 3. Anonymous 1998 [-]
- 4. Rhodes 2009 [+]
- 5. Wendell 2003 [-]

Healthcare settings

Two studies from the US (Exner et al, 2012 [RCT -] and Neumann et al, 2011 [CT-]) and 1 from the UK (Oakeshott et al, 2000 [cRCT ++]) examined the effectiveness of multicomponent interventions in healthcare settings.

Exner et al (2012 [-]) conducted an RCT in agencies that were receiving state money for HIV prevention. They compared a minimal intervention, which consisted of providing free female condoms to the agencies along with a regional level directors meeting to an enhanced intervention which included the meeting and free female condoms, but added at the agency-level, the distribution of a "Female Condom Program and Policy Tool-Kit" to directors and 12 months of technical support; and at the counsellor-level, a one-day female condom training workshop for staff, 12 months of technical support, and provision of female condom materials for use with clients. The Tool-Kit sent to directors of agencies in the enhanced intervention contained materials (posters, pamphlets, information sheets) to assist with creation of intra-agency female condom promotional policies and practices, as well as pelvic models to be used by sexual risk-reduction counsellors to demonstrate correct female condom use with clients. When compared with minimal intervention, enhanced intervention clients counselled had a statistically significant increase in intention to use the female condom at follow up (p< 0.05). They also had a statistically significantly higher level of knowledge about the female condom than those in minimal intervention group (p< 0.05).

Neumann et al (2011 [-]) used a controlled trial in sexual health clinics in the US and Puerto Rico to assess the effectiveness of the "Video Opportunities for Innovative Condom Education and Safer Sex" (VOICES/ VOCES) intervention. VOICES/VOCES is a 45-minute video intervention intended to increase STI knowledge, proper condom use, and condom negotiation skills in men and women. When compared to the comparison group intervention participants had statistically significantly fewer incident STIs at follow-up than the comparison group (HR, 0.63; 95% CI, 0.49–0.81; P = 0.001). They also had statistically significantly improved scores on STI knowledge (4.89 vs. 3.87, p = 0.001); condom knowledge, attitude, and efficacy (10.98 vs. 9.16, p = 0.001), and were more likely to redeem condom coupons (27.6% vs. 24.3%, p = 0.05).

Oakeshott et al (2000 [++]) conducted a cluster RCT (cRCT) in London, UK. They recruited GP practices for a sexual health intervention aimed at women attending for cervical smear tests. Practice nurses and GPs in 28 intervention practices were given 10 minutes practice-based teaching on condom promotion in women. This was backed up with regular supplies of condoms and patient leaflets for the duration of the study. When appropriate, practices

were asked to advise women having smears about safer sex and to offer them free condoms and the leaflet "Wise up to condoms" (this describes how to negotiate condom use and where to obtain further supplies of condoms). More women in intervention than control practices reported receiving advice on avoiding sexually transmitted infections (27% versus 10%, 95% CI 3-29) and being given condoms (28% versus 1%,95% CI 8-40, p < 0.05,). However, there was no difference in subsequent condom use, even in the 22% of women reporting \geq 2 sexual partners in the previous year.

Evidence Statement 3: Multicomponent condom distribution programmes delivered in healthcare settings

There was weak evidence from 1 RCT[-]¹ that providing female condoms and supporting frontline staff can increase client's knowledge of the female condom and intention to use them.

Weak evidence from 1 CT [-] 2 supports the use of a video intervention in sexual health settings to reduce STIs (HR, 0.63; 95% CI, 0.49–0.81; P = 0.001), and improve STI knowledge (4.89 vs. 3.87, p =0.001); condom knowledge, attitude, and efficacy (10.98 vs. 9.16, p = 0.001), and were more likely to redeem condom coupons (27.6% vs. 24.3%, p = 0.05).

Strong evidence from 1 UK RCT [++]³ indicates that a condom education and distribution programme in general practice increased the number of women receiving advice on STIs (27% versus 10%, CI 3-29) and condom distribution (28% versus 1%, p < 0.05, CI 8-40), but did not have an effect on subsequent condom use.

Applicability: The evidence is only partially applicable to the UK because 2 of the studies were undertaken in the USA. However, the interventions would be feasible in a UK-based setting. 1 study was undertaken in the UK so its findings are directly relevant.

- 1. Exner et al, 2012 [-]
- 2. Neumann et al, 2011 [-]
- 3. Oakeshott et al 2000 [++]

Single-component condom distribution schemes

High Schools

One cluster controlled trial (De Rosa 2012 [+]),one quasi-experimental study (Kirby 1999 [-]) and two before and after (BA) studies (Schuster 1998 [+], Wretzel 2011 [-]) evaluated single-component condom distribution schemes in high schools. All four studies were conducted in high schools in the USA amongst students aged approximately 14-17.

A cluster controlled trial by De Rosa et al (2012 [+]) aimed to evaluate the impact of improving the implementation of an existing school district high school condom distribution scheme by measuring its impact on student awareness and condom acquisition. The study was set in 12 urban high schools in areas with high STI and teen pregnancy rates in Los Angeles, USA.

Following researcher assessment of the schools' compliance with elements of the condom distribution scheme, a tailored action plan was developed and intervention schools were supported in achieving compliance levels. Control schools continued to run their existing project. Compliance with the following elements of the scheme were assessed: oversight committee; sufficient numbers of trained and appropriate condom distributors; named person to order condoms and educational materials; advertising; methods of parental notification and consent; and, the ability of the school to tailor distribution according to their needs.

There were six schools each in the intervention and control groups. The intervention period began in 2005 and by autumn 2007, all 6 intervention schools had fully compliant programmes. Results were calculated from student survey data gathered each year from 2005 to 2009 (12 month intervals). At baseline both the intervention and control groups were comparable on most demographic and sexual behaviour characteristics. Small statistically significant differences in Latino ethnicity and grade existed, however these differences were controlled for in the analyses. The authors measured changes to the following outcomes: student awareness of the scheme; student sexual behaviour and condom use; student acquisition of condoms; and, school condom orders.

Relative to reports of *condom acquisition* at year 1, intervention participants had increased odds of condom acquisition compared with the control group at year 4 (OR: 1.69; 95% CI: 1.23, 2.32) and year 5 (OR:1.81; 95% CI: 1.32, 2.49). This pattern remained in separate analysis of sexually active/ experienced students: the odds of sexually experienced students

in intervention schools reporting condom acquisition were more than twice control schools at year 4 (OR: 2.27; 95% CI 1.47, 3.52);and at year 5 were more than 3 times those of control students (OR: 3.08; 95% CI: 1.77, 5.36). Four years after the start of the intervention, the increase in awareness of the intervention from year 1 among intervention participants was twice that of control participants (OR: 2.17; 95% CI: 1.70, 2.76) and by year 5 was almost 3 times that of control participants (OR: 2.78; 95% CI: 2.18, 3.56). This pattern remained in separate analyses of sexually active/experienced students. (Whilst the authors state that findings were statistically significant they did not report *p* values in this paper.) There was no statistically significant difference between the intervention and control groups on *condom use at last sex*. The *number of condoms ordered* at year 4 and year 5 differed greatly with the intervention schools ordering 7,200 and control schools ordering 500. However, this may be explained by staff interviews which revealed that a strong condom distributor at control school 3 responsible for ordering the bulk of control school condoms, left after year 3.)

Kirby et al (1999 [-]) conducted a quasi-experimental study to evaluate the impact of a condom distribution scheme on the number of condoms taken and subsequent changes in knowledge, behaviour and condom use in 10 Seattle High Schools (population aged approx. 14-18 years).

The condom distribution scheme consisted of making condoms available in Seattle schools through: baskets of condoms located in health centres and vending machines. Initially 5 high schools that had health centres began making free condoms available in 2 to 6 baskets located in: clinic reception areas (all centres); examination areas (most centres); and clinic bathrooms (2 centres). No restrictions were placed on the students obtaining condoms. A year later 1 or 2 condom vending machines were placed in each of the 5 schools without health centres and in 2 of the schools with health centres. Vending machines were placed in public locations-in halls outside gymnasiums and auditoriums and in lobbies, career centres, and student activity rooms. All vending machines dispensed condoms at a reduced cost, again there were no restrictions placed on students' purchasing these condoms.

A baseline survey and follow up survey two years after the start of the intervention were conducted in all 10 Seattle high schools and compared with surveys of nationally representative samples of schools participating in the national Youth Risk Behavior Surveillance System (National results weighted to match local population).

Seattle students obtained an average of 4.6 condoms per year, the vast majority of these came from baskets rather than vending machines. After two years of the intervention, students had obtained more than 50 times as many condoms from baskets as they did from vending machines (131,185 vs 2526). Post-intervention and compared to national data the percentage of Seattle students who had ever had sex remained stable, as did the mean age at first intercourse; the percentage of students who had sex in the previous three months decreased statistically significantly (p =0.024); as did the percentage of students who reported having sex with 4 or more partners in the last 3 months (p= 0.015) and the percentage of sexually experienced students who used a condom the last time they had sex decreased statistically significantly (p= 0.042).

Schuster et al (1998 [+]) conducted a before and after study to evaluate the impact of a condom distribution scheme on student sexual behaviours in one Los Angeles high school. The scheme consisted of making condoms available to students in plastic packets containing two male condoms, an instruction sheet and a card warning that "Condoms are not 100% effective in preventing AIDS/HIV, sexually transmitted diseases or pregnancy during sexual intercourse. Abstinence is! Not all teenagers are sexually active.

THINK BEFORE YOU ACT! The consequences may be for a lifetime." Condom packs were made available in baskets placed in four classrooms and outside of the nurse's office; some of these sites were accessible at times when students could obtain condoms unnoticed by others. An honesty box was placed close by requesting that students 25c (approx. 28p value in 1998) for each packet they took (the authors do not report whether this was a reduced cost price).

Prior to implementation of the 1,945 students in grades 9–12 (aged approx. 14-17 years) (98% of eligible students) completed a self-administered anonymous survey on their sexual behaviour and on related knowledge and attitudes. At follow up one year later, 1,110 students (59% of eligible students) completed the same survey. Baseline and follow-up samples were comparable on gender and grade. However compared with the baseline the follow-up sample had fewer black and Hispanic students and they were more likely to have parents who were college graduates and were more likely to expect to attend graduate or professional school.

At one year follow-up there was no statistically significant change in the percentage of males or females who had ever had vaginal intercourse or who had had vaginal intercourse during the year prior to the survey. The percentage of males who reported *using condoms* every time they engaged in vaginal intercourse increased statistically significantly, from 37% at

baseline to 50% (p=0.005) at follow up, and the percentage of males who reported condom use at recently initiated first vaginal intercourse increased from 65% to 80% (p=0.038). However, female respondents showed no statistically significant change in their condom use. Intention to use a condom or vaginal intercourse did not change statistically significantly for students who had had vaginal intercourse, but it increased dramatically for those who had never had vaginal intercourse from 62% at baseline to 90% at follow-up among males (p<0.001), and from 73% to 94% among females (p<0.001).

Wretzel at al (2011 [-]) conducted a comparative observational study to evaluate the impact of a city wide high school condom distribution scheme on STI rates in 15-19 year olds attending high schools in Holyoke, Massachusetts (MA). The authors do not describe the content of the scheme further.

The authors compared the reported rates of STI's in 15-19 year olds collected by the Massachusetts Department of Public Health for three years before and three years after the introduction of the condom distribution scheme. These were compared with similar data from Springfields MA which did not have a condom distribution scheme. The population of intervention city was 36,765, and the population of comparator city was 151,176. Participants were comparable on most demographic characteristics. However, the comparator area had a substantially higher number of African American participants, and the intervention a substantially higher number of Hispanic participants. No calculation of significance in these differences was reported.

There was no statistically significant difference between the intervention and comparison cities in the decline of male or females cases of gonorrhoea, or chlamydia per year after the introduction of the intervention. However when rates of gonorrhoea and chlamydia infection were combined over the 3 years after the start of the intervention, males in the comparator city had a 23% increase in combined STI rates whilst males in the intervention city showed a 47% decrease. The difference over this period was statistically significant (p < 0.01). However, there was no statistically significant difference on combined STI rates between intervention and comparator cities for females.

Evidence Statement 4: Interventions to improve existing area wide high school single component condom distribution schemes

There was moderate evidence from 1 US cRCT [+]¹ that an intervention to improve compliance with elements of an existing area wide high school condom distribution scheme

amongst 14-17 year olds can: increase acquisition of condoms amongst students (both sexually inexperienced and sexually experienced/active students): at 4 year follow-up (OR: 1.69; 95% CI: 1.23, 2.32) and 5 year follow-up (OR:1.81; 95% CI: 1.32, 2.49); improve awareness of the scheme: 4 year follow-up (OR: 2.17; 95% CI: 1.70, 2.76) and 5 year follow-up (OR: 2.78; 95% CI: 2.18, 3.56). The intervention does not increase condom use at last sex amongst students (both sexually inexperienced and sexually experienced/active high school students).

Applicability: The evidence is only partially applicable to the UK because the intervention was conducted in the USA. It is unclear to what extent this intervention to improve delivery of a condom distribution scheme would be feasible in a UK-based setting, given that area wide school based schemes are not common.

1.De Rosa 2012 [+]

Evidence Statement 5: Single component condom distribution programmes in high schools.

There was conflicting evidence from 1 US quasi experimental study [-]¹, and two US BA studies [+]² [-]³ about the effects of single component condom distribution schemes in US high schools.

One study of a city wide free or reduced price condom distribution scheme [-] 1 in high school students aged 14-18, reported that the percentage of sexually experienced students who used a condom the last time they had sex decreased statistically significantly (p= 0.042) when compared to a matched area with no scheme two years after the scheme was introduced. There was no difference in onset of sexual activity or age at first intercourse. The intervention area had lower rates of: students who had sex in the previous three months (p=0.024), and students who reported having sex with 4 or more partners in the last 3 months (p= 0.015).

A study of a condom distribution scheme where condom packs (with an honesty payment box) were made available in a single high school to students aged 14-17 years [+] ² found that one year after the introduction of the scheme males reported a statistically significant 13% increase in using condoms every time they had vaginal intercourse (from 37% to 50%, p=0.005), and a 15 % increase at recent first vaginal intercourse (from 65% to 80% p=0.038). There was no statistically significant change for females (from 27 to 32%). There was no difference in intention to use a condom amongst, sexually experienced students, but

a statistically significant increase in intention to use a condom amongst non-sexually experienced females (21% increase, 73% to 94%, p<0.001) and males (28% increase, 62% to 90%, p=0.001). There was no difference in onset of, or increase in sexual activity A study of a city-wide high school condom distribution scheme to prevent STIs (not further described) ([-])³ reported no difference in annual male or female cases of gonorrhoea, or chlamydia in any of the three years of follow-up after the introduction of the scheme. However there was a statistically significant decline in combined STI rates for males (p < .01), but not for females.

Applicability: The evidence is only partially applicable to the UK because the schemes were conducted in high schools in the USA.

1.Kirby et al 1999 [-], 2. Schuster et al 1998 [+], 3. Wretzel et al 2011 [-]

Commercial and other community venues

Three studies evaluated condom distribution schemes in a variety of commercial and other community venues including UK gay bars and cafes, and public sector venues. All were targeted either towards high risk groups, or groups living in areas of high STI prevalence. One UK before and after study (Weatherburn et al 1998 [+]) evaluated a free condom distribution scheme in commercial gay venues in 1996. A matched area control study (Cohen 1999 [-]) conducted in the USA evaluated a free condom distribution scheme in a combination of public health and commercial venues. Ross et al (2004 [-]) conducted a controlled trial (CT) in the USA to evaluate a dual component small media and condom distribution campaign.

All three studies evaluated interventions that were introduced before the widespread uptake of highly active anti-retroviral therapy (HAART) in Europe and the USA.

In a before and after study Weatherburn et al (1998 [+]) evaluated the 'Rubberstuffers' intervention: a free condom distribution scheme in 8 central London commercial gay venues (bars/cafes). The intervention consisted of condoms being made freely available in 4 different locations within the bars: 1) From behind the bar on request from staff; 2) Open access on the bar but within sight of bar staff; 3) Open access from the area of magazine and leaflet racks, within sight of other patrons; 4) Open access via dispensers in the toilet

areas (not necessarily in sight of anyone else). Gay men were surveyed over 5 consecutive days prior to the roll out of the scheme and over 10 consecutive days one year later.

One year after the intervention the largest number of condoms distributed was from those made available via dispensers in the toilet areas. Survey respondents were statistically significantly more likely to have condoms at home post-intervention (83% vs 72.9%, χ^2 = 15.78, p<0.0001). The proportion that had Rubberstuffers packs rose from 41.3% to 61.9% (χ^2 = 43.31, p<0.001) There was a statistically significant increase in the number of men carrying condoms whilst out in gay venues (from 21.6% to 2.7%). The number of condoms purchased decreased statistically significantly following intervention: the average number purchased pre-intervention was 20 (mean 31.4, SD 37.4) post-intervention this had reduced to 12 (mean 23.6, SD 34.8). The proportion of participants obtaining free condoms rose statistically significantly (χ^2 = 7.622, p< 0.01) from pre-intervention (76.4%) to post-intervention (83.1%), and statistically significantly more men (χ^2 = 15.049, p<0.0001) had received condoms from a gay venue in the previous 6 months - from 54.5% to 66.3%. No statistically significant change was noted on the frequency of unprotected anal intercourse: 9.5% (pre-intervention) and 9.9% (post-intervention). The authors did not report p values for all outcome measures.

Cohen et al (1999 [-]) conducted a comparative observational study, with a partial control in a matched area, to evaluate the impact of what they describe as a state-wide 'social marketing' intervention that made condoms freely available within public and private sector venues in areas of high STI prevalence in Louisiana, USA. This large-scale targeted condom distribution scheme started in 1994 is not what would be considered a social marketing intervention 20 years later. This study does not provide evidence of the impact of social marketing in this field.

In May 1993, the Louisiana Department of Health and Hospitals made free condoms available in the following public sector venues: public health clinics (n = 93), community mental health centres (n = 39), public substance abuse treatment centres (n = 29), 35 private physicians, 105 community health care centres, and at least 27 housing projects. Trained staff were encouraged to: make condoms freely available without limits or clients having to request them; to take condoms home and distribute them; and to notify any complaints or problems. Within the private sector, approximately 1000 businesses in neighbourhoods with the highest rates of STDs businesses were invited to distribute free condoms to their customers. Participating businesses included: convenience stores (n-324); ;bars nightclubs, and liquor stores (n=388); beauty salons and barbershops (n=145); as well

as other businesses such as tattoo parlours, dry cleaners, and low-cost motels. All community based organizations involved in HIV/STD prevention activities were included.

Annual surveys of self-reported sexual behaviour were completed over the course of the intervention, from baseline in 1992 to 1994. Respondents of the anonymised clinic surveys were women of child bearing age who reported having sex in the past 12 months. The women were similar in terms of race across each year, but differed in marital status and type of clinic visited. The results from this survey were assessed based on differences over time, with no matched control group. Respondents of the interviewer-assisted street surveys were African American men aged 15 -45 years, in targeted areas of New Orleans. The surveys were undertaken in two areas with the highest rates of gonorrhoea in New Orleans, one where businesses had been recruited for the intervention from 1994 (Area A)and one as a matched comparison area where businesses had not been recruited during this first year of the program (Area B). Respondents did not differ demographically, except in year 1 when the median age in Area B was slightly older than that in the intervention group (29.3 vs 28.7,p=0.01).

Comparison of data collected from clinic surveys in 1994 and 1996 showed no difference in self-reported condom use at the last sexual encounter among white women, and increased condom use among African American women (from 28% to 36%). Further analysis revealed an increase in condom use among all women with 2 or more sex partners (OR = 1.36; 95% CI = 1.10, 1.67) and among African American women with 2 or more sex partners (OR= 1.42; 95% CI= 1.13, 1.91). The number of sex partners over the 3 years did not change among respondents (OR = 1.1; 95% CI = 0.98, 1.22). No p values were presented for any of these outcomes.

Outcomes for condom distribution via businesses in matched controlled areas appear to be equivocal but are uncertain as the authors report within area, rather than between area differences over time.

Ross et al (2004 [-]) conducted a quasi-experimental study to evaluate the impact of a targeted small media campaign to reduce syphilis through testing, treatment, and condom use in two urban predominantly African-American communities with high syphilis rates. The intervention was introduced in 1998, in Houston/Harris County, USA.

There was extensive formative research involving communities to develop the intervention which is a dual- rather than single-component intervention. The intervention consisted of: a

small media campaign (role model stories in small media: e.g. brochures, posters, coasters, matchbooks, t-shirts, videos and billboards); and, free condom distribution via community businesses (the type of community businesses were not further described). Outreach workers supplied samples of all the materials, and shopkeepers or service providers could choose those they wished to stock. Bowls of condom/ lubricant packages were placed on counters or similar places accessible to the public without need to request them. By the end of the intervention, there were 50 community business partners in the intervention area. Most residents of the community were no more than four blocks from a community business partner.

Intervention and comparison communities were selected from the 12 zip codes in Houston/Harris County with the highest syphilis rates (>300/100 000 in 1994). Participants were similar on demographic and behavioural characteristics at baseline. The authors did not report p values for differences, but data were controlled for age, years of schooling, marital status, condom use, and number of sexual partners during data analysis. The authors state that when comparing intervention with comparison areas two years after the scheme was introduced, there were statistically significant increases in condom use in last sexual act, and some aspects of knowledge of syphilis in the intervention areas. However, they do not present clear data to support these findings.

There was a statistically significant high level of cross contamination between the intervention and control areas. The authors conducted a post-hoc analysis which combined data from intervention and comparison areas. This was then analysed according to media exposure (those who did and did not report seeing any media products as a measure of exposure response). The authors state that media exposure was associated with statistically significant increases in knowledge of syphilis, testing, and condom use. However, both of these post-hoc findings combine data from a range of knowledge and behavioural outcomes without reporting combined data and p values. As such these findings should be treated with caution.

Evidence Statement 6: Single component condom distribution programmes in commercial and other community venues.

There was weak evidence from one UK BA study [+]^{1,} and two US controlled studies [-]^{2,3}, about targeted single component condom distribution programmes impact on: condom availability, acquisition, or use; STI knowledge; and rates of STI cases. A diverse range of commercial and other community venues were involved in these three schemes.

One UK study¹ of a free condom distribution scheme in London commercial gay venues (cafes and bars) found that one year post-intervention: condoms were most frequently obtained from those made available in the bathrooms; respondents were statistically significantly more likely to have condoms at home (p<0.0001); be carrying condoms whilst out in gay venues (from 21.6% to .7%); statistically significantly fewer condoms were being purchased; the proportion of participants obtaining free condoms rose statistically significantly (p< 0.01); statistically significantly more men (p<0.0001) had received condoms from a gay venue. There was no statistically significant change in frequency of unprotected anal intercourse: 9.5% (pre-intervention) and 9.9% (post-intervention).

One US study ² of a state-wide targeted large-scale condom distribution campaign to increase accessibility of condoms through health care facilities (public health clinics, community mental health centres, substance abuse treatment centres, private physicians community health care centres, and housing projects); private commercial venues (convenience stores, bars nightclubs, and liquor stores, beauty salons and barbershops, tattoo parlours, dry cleaners, and low-cost motels); and community based organizations involved in HIV/STD prevention activities found: no difference in self-reported condom use at the last sexual encounter among white women, and increased condom use among African American women (from 28% to 36%); and, an increase in condom use among all women with 2 or more sex partners (OR = 1.36; 95% CI = 1.10, 1.67).

One US study³ of a dual-component small media and condom distribution campaign to reduce syphilis presented limited evidence of the impact of the intervention two years after the scheme was introduced. The authors note statistically significant increases in both condom use in last sexual act, and some aspects of knowledge of syphilis but do not present clear data to support these findings. The impact of the intervention is uncertain due to the high number of comparison group participants that also received the intervention.

Applicability: The evidence is limited in its current applicability to the UK because two studies were conducted in the US, and two were conducted at a time when HAART was not widely available.

1. Weatherburn et al 1998 [+] 2. Cohen et al 1999 [-] 3. Ross et al 2004 [-]

Schemes to sell cost price condoms

Dahl et al (1999 [-]) conducted a comparative observational study to evaluate the viability and effectiveness of using high-value discount coupons to induce condom purchases, and to identify intervention factors (i.e., distribution methods, coupon characteristics) that would aid effectiveness. The study was conducted in Vancouver, Canada. Whilst the scheme was said to be targeted towards sexually active 18 - 30 year olds, no participant characteristics were reported. Widespread distribution was compared with distribution at drugstores alone.

Both intervention and comparison sites were provided with coupons worth 10% discount or 75% discount on the price of condoms. Discount coupons were distributed at a variety of locations frequented by the target population (e.g., bars, nightclubs, sports and special events, fitness clubs, shopping centres, and recreation parks). The coupons were redeemable (within 6 months) at any retail outlet that carried the corresponding brand. Redemption was tracked with the cooperation of a coupon clearinghouse. In the comparison group discount coupons were only distributed to members of the target population as they entered a particular drugstore where the couponed brand was sold. These coupons were usable only on the day of distribution at the particular drugstore. Two separate waves of distribution approximately 2 months apart were conducted. On both occasions, the coupons were distributed between 3:00 PM and 7:00 PM on a Friday and Saturday. The face value of the coupon was alternated each hour. Coupons were distributed to all identifiable members of the target population as they entered the store.

The redemption rates for the widespread distribution were 0.0% (0/2300) for the 10% coupons and 0.3% (13/3800) for the 75% coupons. Whilst this was a minimal redemption rate, there was a statistically significant difference in redemption for the different coupon value levels ($\chi 2 = 7.89$, P<.01). In the drugstore distribution only comparison group, the absolute number of condoms purchased during the coupon promotion whilst low was statistically significantly greater than the baseline purchase level at wave 1 with both the 10% coupon (male purchases: 8.0 vs 5.3 [t = 4.07, p<.01]; female purchases: 6.0 vs 1.3 [t= 12.76, p<.001]) and the 10% coupon (male purchases: 10% coupon (male purchases: 10% redemption: 10

Evidence Statement 7: Single component reduced price condom distribution programmes in commercial and other venues.

There was weak evidence from a Canadian comparative observational study [-]¹ to evaluate the viability and effectiveness of using high-value discount coupons targeted towards sexually active 18 - 30 year olds, to induce condom purchases.

There was minimal redemption of either the 10% or 75% redemption coupons whether distributed widely or in drugstores only. In the drugstore distribution group, the number of condoms purchased during the coupon promotion was statistically significantly greater than the baseline purchase level 2 months earlier:

- 10% coupon (male purchases: 8.0 vs 5.3, p<.01; female purchases: 6.0 vs 1.3, p<.001)
- 75% coupon (male purchases: 47.0 vs 5.3, p <.001; female purchases: 18.0 vs 1.3, p<.001).

The 75% coupon was more likely to induce purchases.

Applicability: The evidence is limited in its current applicability to the UK because the study was conducted in the Canada.

1. Dahl et al 1999

Comparing single versus multi- component schemes

Senn et al (2011 [+]) conducted a three-armed RCT at a travel clinic in Switzerland, to evaluate the effectiveness of an intervention that consisted of standard pre-travel consultation plus motivational brief intervention (BI) and the provision of condoms on the engagement in unprotected casual sex by people who are travelling. The intervention focussed on travellers aged 18-44 years travelling without their regular sexual partner.

The intervention was conducted at the Department of Ambulatory Care and Community Medicine, University Hospital Lausanne. 5148 eligible travellers were seen in the travel clinic from 2006 to 2008; of these 1681 people consented to participate in the study and were randomly assigned to one of 3 arms of the trial. 1115 subjects (66%) completed the study. The intervention (BI) was compared to groups who received a standard pre-travel

consultation plus free condoms (condom group), or a standard pre-travel consultation only (control group). Baseline questionnaires were completed by participants prior to their consultation. Follow-up questionnaires were completed by respondents on their return from traveling and posted back to the research team. The average age of participants was 29. The allocation groups were comparable at baseline as were those who completed the post-travel questionnaire.

The motivational BI was semi-structured the main focus was to explore the ambivalence of the traveller to change their sexual behaviour and to adopt a safer attitude in the event of a casual sexual relationship while travelling. It was designed to fit in a pre-travel consultation, and lasted about 5 minutes. Information on STIs delivered during the motivational BI was summarized on an information sheet delivered to the traveller. It covered three topics: 1) prevalence of sexual intercourse and rate of condom use while traveling, 2) general information on different STIs and their prevalence rates around the world, 3) different means of protection against STIs. Travelers were offered a free box of 3 condoms for their trip at the end of the motivational BI.

The results of the evaluation showed no statistically significant difference in the numbers of participants who reported inconsistent condom use between the three groups: BI group 28% (95% CI 16-40.); condom group 24% (95% CI 10-37); and control group 24% (95% CI14-33) (p = 0.42)

Stratification of the results by previous STI and gender also showed no statistically significant difference in consistent condom use.

Evidence Statement 8: Single versus multi-component condom distribution schemes

There was moderate evidence from 1 Swedish three-armed RCT [+]¹ that a motivational brief intervention and/or the provision of free condoms in a hospital-based travel clinic did not modify risky sexual behaviours of young people travelling abroad without their usual sexual partner .There was no statistically significant difference in the numbers of participants who reported inconsistent condom use between the three groups: BI group 28% (95% CI 16-40); condom group 24% (95% CI 10-37); and control group 24% (95% CI14- 33) (p = 0.42)

Applicability: The evidence is only partially applicable to the UK because the intervention was conducted in Switzerland. However, it is possible that this could feasibly be delivered in

a similar setting where they exist.

Senn et al 2011 [+]

3.3.2 What schemes are cost effective in providing condoms to different populations to reduce STIs?

Two studies were included in the cost effectiveness review. Both studies were conducted in the USA in areas of high HIV prevalence. Bedimo et al (2002 [+]) conducted a cost-utility analysis of a large-scale condom distribution programme in Louisiana. Holtgrave et al (2012 [++]) conducted a cost-utility analysis of a female condom distribution and education scheme in Washington DC.

Social marketing condom distribution scheme

Bedimo et al 2002 [+], conducted a cost utility analysis and threshold analysis to calculate the cost-effectiveness of large-scale targeted condom distribution scheme evaluated from 1994 to 1996. Condoms were made freely available in over 1000 public and commercial venues in Louisiana. The scheme was compared to similar areas without a condom distribution scheme. The results of the original evaluation of effectiveness are reported in Cohen et al 1999 [-], and are discussed elsewhere in this report (see section 3.3.1 above). The analysis was only conducted on African-American participants. There were 275,000 participants, with programme costs at \$3,000,000, the time frame was 3 years, and an estimated 169.95 HIV cases were averted. Programme costs per case averted were estimated at \$17,652.

The results of the analysis are presented in the table below:

Parameter	Best-case value (range examined) for 3 year intervention period			
	Men	Women		
Clients reached by intervention	192,500 (96,250 - 577,500)	82,500 (41-247,500)		
Acts of intercourse per client	306 (102-611)	306 (102-611)		
Sex partners (m)	4 (1-10)	4 (1-10)		
Acts of intercourse per partners (n)	77 (39-15)	77 (39-15)		

Proportion of condom use, before intervention (f_{1})	0.40	0.28	
Proportion of condom use, after intervention (f_{1})	0.52	0.36	
Prevalence of HIV infection in study population (n)	0.016 (0.008-0.032)	0.006 (0.003 – 0.012)	
Prevalence of HIV infection in study partners (n)	0.006 (0.003-0.012)	0.016 (0.008 – 0.032)	
Condom effectiveness	90% (80%-95%)	90% (80%-95%)	
Probability of HIV transmission, per act of unprotected intercourse	0.001 (0.0003-0.0015)	0.001 (0.0003-0.0015)	
Probability of HIV transmission, per act of protected intercourse	0.0001 (0.0002 – 0.00005)	0.0001 (0.0002 – 0.00005)	
Total condoms distributed	14,116,667	4,033,333	
Condom wastage	50% (25%-75%)	50% (25%-75%)	
Total condoms used	77,058,333	2,016,66	
Discounted medical treatment cost	\$195,188		
QALYs saved per prevented infection	\$11.23		

The programme cost approximately \$11 per person and approximately 55% of the condoms reached the African American population. Assuming a 50% wastage, the authors estimated that the scheme prevented 170 HIV infections and savings of 1909 QALYS. An estimated \$33 million in direct costs were averted, for a programme cost of \$3 million. Therefore the programme was cost saving. The results are stable with little variation in cost-utility ratios due to changes in number of clients, number of sex partners, prevalence of HIV infection, condom wastage or probability of HIV transmission. The intervention remained cost saving for all plausible values of these parameters.

It should be noted that this study is based on data from 1994 – 1996, and prior to the widespread availability of highly active anti-retroviral treatment (HAART).

Evidence statement 9: cost-effectiveness of a large-scale targeted condom distribution scheme in areas of high HIV prevalence.

There is moderate evidence from 1 US study (a cost utility analysis [+])¹ which showed that a large-scale targeted condom distribution scheme was cost-effective in an African-American

population. 170 HIV infections were averted resulting in savings of 1909 QALYS, with an estimated \$33 million in direct costs being averted.

Applicability: The evidence is only partially applicable to condom distribution schemes in the UK because the study was undertaken in the USA. Furthermore it was conducted prior to the widespread availability of HAART.

1. Bedimo et al. 2002 [+]

Female condom, education and distribution schemes

Holtgrave et al 2012 [++] conducted a cost utility analysis with sensitivity and threshold analysis to calculate the cost-effectiveness of a female condom distribution scheme with an educational component. The intervention was targeted towards heterosexual women living in areas with disproportionately high female HIV prevalence in Washington DC. The analysis was conducted retrospectively on data collected for a single group pre- and post-test evaluation. The scheme provided brief educational interventions to 38,000 women and men, and extended education to 8,000. More than 300 group education sessions were conducted, approximately 500 peers at health and non-health locations were trained, and more than 300,000 female condoms were distributed.

A 1 year time horizon was used to capture both costs and benefits. Both societal and provider perspectives were employed. Intervention costs were divided by the net present value (discounted at 3 %) of the lifetime medical care costs of a case of HIV. The analysis employed \$100,000 per QALY saved.

The results of the analysis are presented in the tables below:

Input parameter values for cost, threshold and cost-utility analyses

Parameter	Parameter value
Education costs	\$152,100
Staff costs	\$42,875
Distribution costs	\$16,900
Marketing costs	\$73,766
Procurement costs	\$128,535

Condoms procured	200,000
% condoms used during sex	65 %
% condoms used for other purposes	17%
% of condoms not used	18%
Lifetime HIV medical care costs	\$367,134
No. QALYs saved per infection averted	5.3
% HIV medical care costs in public sector	75%
Female HIV prevalence	8.8%
Male HIV prevalence	6.6%
HIV- women with non-ulcerative STI	8.8%
HIV- women with ulcerative STI	2.3%
Female condom effectiveness	95%
No STI, female to male	0.0005
No STI, male to female	0.001
Non-ulcerative STI, male to female	0.01
Ulcerative STI, male to female	0.03
Crowd out of male condom use	0–13 %

Results of cost, threshold and cost-utility analyses

Cost –utility analysis results						
Total overall program cost	\$414,186.00					
Cost per female condom used during sex	\$3.19					
Threshold analysis results (necessary infections averted)						
Societal perspective cost-saving threshold	1.13					
Provider perspective cost-saving threshold	1.50					
Societal perspective cost-effective threshold	0.46					
Estimated HIV infections averted						
Female to male transmission	5.08					

No STI, male to female	6.61
Non-ulcerative STI, male to female	6.54
Ulcerative STI, male to female	5.13
Total HIV infections averted	23.35
Overall CAU result	
Societal perspective	Net savings \$8.160M
Provider perspective	Net savings \$6.017M
Impact of allowance for male condom crowd-out	
Total HIV infections averted	20.32
Societal perspective cost–utility analysis	Net savings
	\$7.046M
Provider perspective cost–utility analysis	Net savings
	\$5.181M

The societal perspective cost-saving threshold analysis result was 1.13 infections that would have to be averted to be cost-saving. The provider perspective cost-saving threshold result was 1.50 HIV infections averted. The cost-effective threshold result (from the societal perspective only) is 0.46 HIV infections averted, and was considered achievable. The results are stable with little variation in cost-utility ratios due to changes in number of clients, number of sex partners, prevalence of HIV infection, condom wastage or probability of HIV transmission. The intervention remained cost saving for all plausible values of these parameters.

The base case estimate for the number of HIV infections averted by the intervention was approximately 23 infections averted, and approximately 124 QALYs saved. The base case cost-utility analysis ratio indicated cost savings. Further analysis allowing for crowd out of male condom use by female condom use still indicated cost-savings. Furthermore, even allowing crowd out if female condom effectiveness were to drop as low as 7.04 % the results still indicated cost-savings. The results are highly robust to uncertainty in the input parameters.

Evidence statement 10: cost-effectiveness of a targeted female condom education and distribution scheme in areas of high female HIV prevalence.

There is good evidence from 1 US study (a cost utility analysis [++])¹ which showed that a targeted female condom education and distribution scheme was cost-effective in an area of high female HIV prevalence. 23 HIV infections were averted resulting in savings of 124 QALYs, and an estimated \$7 million net savings from a societal perspective, and \$5 million net savings from the provider perspective.

Applicability: The evidence is only partially applicable to females condom distribution schemes in the UK because the study was undertaken in the USA.

1. Holtgrave et al 2012 [++]

4. Discussion

a. Strengths and limitations of the review

Overall, the quality of the studies was weak. As noted in section 3.3, there were

- 13 [-] quality studies,
- 6 [+] quality studies
- 1 [++] quality study.

The two cost-effectiveness studies were rated [+] and [++].

Several limitations are seen across many of the studies, relating to the age of the studies (50% were published between 1996 and 1999); outcome measures; weak reporting and study design issues. Studies relied on subjective measures for use of, or intention to use condoms, as well as other sexual behaviours, and few studies collected outcome data on STIs. Poor reporting included a lack of reporting on participant characteristics, supporting statistical data, p values and within rather than between group comparisons. Design issues included a lack of blinding, and power analyses. Further detail of the strengths and weaknesses of individual studies can be found in the evidence tables (Appendix 4).

b. Applicability

16 of the studies are from the US, 1 from Canada, 1 from Sweden and 2 from the UK. Both of the economic studies were conducted in the USA. The preponderance of studies from the US may limit the applicability of some findings to the context of condom distribution schemes in the UK due to differences in healthcare policy, funding and service delivery.

The age of some of the studies also limits their applicability to the current context. Whilst the focus of this review is not on condom distribution schemes for the prevention of HIV infection alone, it is an important consideration. The management of HIV/AIDS has since 1996 normally included the use of multiple drugs that act on different viral targets and is known as highly active antiretroviral therapy (HAART). HAART has been so successful that in many parts of the world, HIV has become a chronic condition in which progression to AIDS is increasingly rare. Whilst studies published prior to 1996 were excluded from this evidence review, a number of included studies report evaluations of interventions conducted prior to 1996 and the introduction of HAART into clinical practice. One economic study was based on data collected in the USA from 1994 – 1996, since the advent of HAART the number of QALYs saved per HIV infection avoided today would be much lower.

c. Gaps in the evidence

The <u>Scope</u> identified the following key issues, and key questions related to them:

1. What multi-component schemes are effective and cost effective in providing condoms to different populations to reduce STIs?

Whilst we identified three schemes based in high schools, we found no studies evaluating multi-component schemes targeted towards young people in other settings young people frequent, including health care settings, youth clubs or other youth services. This represents a clear gap in the current evidence base, especially given the existence of the C-Card Scheme in the UK.

Four of the five outreach and/or community based schemes focused on high-risk individuals or areas including injecting drug-users and other people at increased risk of injecting drug use. However, we found no studies evaluating condom distribution schemes focussed on sex workers or other high risk populations. Whilst one of these studies was community

based and provided in local amateur football clubs there we did not identify any other studies which evaluated community-based interventions.

Only three studies evaluated schemes conducted in healthcare settings including a sexual health clinic, and a UK GPs surgery. There is a clear gap in the evidence base on multi-component interventions in health care settings such as sexual and reproductive health clinics and GP surgeries.

2. What single-component schemes are effective and cost effective in providing condoms to different populations to reduce STIs?

We identified a similar gap in the evidence base to that reported above in the multicomponent intervention section of this discussion. Whilst we identified four schemes based in High Schools, we found no studies evaluating single-component schemes targeted towards teenagers and young people in other settings young people frequent, including health care settings, youth clubs, or other youth services. This represents a clear gap in the current evidence base.

There was an absence of studies evaluating single component condom distribution schemes targeting high-risk population groups, apart from one study conducted in gay venues, and schemes set in areas considered to be high-risk. This may reflect the view that high-risk individuals and groups require more complex holistic interventions to change sexual behaviours. However, there is a lack of evidence to support this view.

Whilst one scheme was delivered in health clinics and small businesses, only one scheme was delivered in a health setting alone, and this was evaluated in a travel clinic. There is a clear gap in the evidence base in relation to health settings, especially the more obvious ones such as sexual and reproductive health clinics, and GP surgeries.

3. What outlet schemes are effective and cost-effective in providing condoms to different populations to reduce STIs?

Only one study, (Dahl, 1999) evaluated the viability and effectiveness of an outlet scheme, using high-value discount coupons targeted towards sexually active 18 - 30 year olds, to induce condom purchases.

Whilst not 'outlet schemes' all the 3 schemes that provided access to reduced cost condoms were conducted in the USA are old studies and of overall weak quality.

5. Included studies

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