Anderson et al 1998

Study details	Population	Intervention/comparison	Results	Notes
Study Anderson et al 1998. **Quality score** - **Length of follow up** N/A **Study type** Quasi-experimental **Aim of the study** To evaluate the impact of AESOP, a multifaceted street outreach intervention for high risk youth (injecting drug users - IDUs) to improve HIV related sexual health behaviours and access to outreach workers. **Location and setting** Five street outreach sites in three cities across the US.	**Number of participants** For each of the five sites the goal was to complete 200 interviews in both the interventions and comparison areas. The actual number completed is not reported. **Participant characteristics** High risk IDUs aged 12 to 23 years. Who had been recurrently without shelter during the past year, without permanent shelter for 2 months, or derived their livelihood from the street economy (drugs, prostitution, panhandling, crime). **Inclusion criteria** Eligible IDU respondents were defined as persons within the geographical bound	**Intervention/:** Five different enhanced street outreach interventions. **Comparison**. Matched non-enhancement locations, or pre-enhancement period. **Children's Hospital of Los Angeles** - Enhanced outreach programme centred on the opening of a shopfront centre ("the Rubber Room") for condom distribution and other services. Other elements of the programme were: • interagency outreach co-ordination • peer outreach team • small print media • referral to NSP **San Francisco City Health Department** - The enhanced intervention was a storefront operation that was developed especially for AESOP. The youth centre fielded a street outreach team that provided (in addition to standard outreach services): referrals for medical, drug treatment, and other services. Activities included: 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** - The project evaluated street outreach to IDUs in inner-city neighbourhoods. The	**Outcomes across all sites** HIV-related risk behaviour Condom behaviours Exposure to street outreach worker The association between interaction with street outreach workers and condom use. **Children's Hospital of Los Angeles** Results indicate that being in the post-enhancement study area (the effect of interest) was not statistically significantly associated with condom use during most recent vaginal sex for main or 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. With respect to using condoms during most recent vaginal sex, at post-enhancement 47.6% of youth reported having used condoms with main partner, and 71.8% reported having used condoms with casual partners. Having a condom at interview was associated with higher odds of having used condoms during most recent vaginal sex with main (OR, 2.3; CI, 1.5–3.6) and casual partners (OR, 2.1; CI, 1.3–3.5). **San Francisco City Health Department** Being in the post-enhancement study area was not significantly associated with *condom use for* main or casual partners. Having a condom at interview, however, was associated with higher likelihood of use during most recent vaginal sex with main partners (OR, 2.4; CI 1.3–4.4). 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 post-enhancement 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). Being in the post-	**Limitations identified by author** Inability to control other factors affecting the behaviour of risk group members, both in the study and comparison areas, and the difficulty of acquiring equivalent samples over time from the shifting street populations. Data collected indicated that other changes were occurring in addition to the AESOP enhancements. These changes included program staffing changes, environmental changes due to weather and other causes, and changes in the location of street populations. The relative lack of findings indicating behaviour change may be due in part to lack of contact with outreach workers who delivered the AESOP enhancement. Although the respondents reported a high level of contact with outreach workers,

Study details	Population	Intervention/comparison	Results	Notes
Source of funding Not reported	aries of the intervention or comparison area who had injected illegal drugs in the past 3 years. **Exclusion criteria** Not reported	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**: This project evaluated 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:** The Philadelphia site evaluated street outreach for IDUs in two North Philadelphia areas. The enhanced street outreach interventions centred on providing specialized 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.	enhancement study area 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 significant effects of being in the post-enhancement 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), indicating a strong indirect relationship between condom use and contact with outreach programs for persons with casual partners. **Aids Programme, Los Angeles County** Analysis indicates that having a condom at the time of interview was associated with more frequent condom use for vaginal sex with main (OR, 2.1; CI, 1.4– 3.2) and casual (OR, 4.1; CI, 2.7–6.1) partners. Having condoms at the time of interview was in turn strongly associated with outreach contact for respondents with main (OR, 2.8; CI, 2.0–3.9) and casual partners (OR, 2.9; CI, 1.9–4.2), indicating consistent indirect effects of outreach programs on use of condoms. **Philadelphia Health Management Corporation** Analysis did not indicate any effects of being in the postenhancement study area on condom use with main partners. For casual partners, being in the postenhancement 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).	many linked their outreach workers to other outreach programs or could not identify the agencies of these workers. Because AESOP interventions were not comparable, data could not be aggregated to examine whether the respondents exposed to the study intervention changed behaviour. **Limitations identified by review team** Study is poorly written up with no participant numbers, no participant characteristics and little detail beyond saying the populations were 'similar'. Lack of detailed data and outcomes limits the strength of this study. The power of the study is not reported **Other comments** N/A

Anonymous 1999

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention/comparison</th><th>Results</th><th>Notes</th></tr>
<tr>
<td>Study
Anonymous 1999

CDC AIDS Community Demonstration Projects Research Group

Quality score
-

Length of follow up
None

Study type
Nested cross sectional study with matched intervention and comparison communities.

Aim of the study
To evaluate a theory based community level intervention to promote consistent condom and bleach use among populations at high risk for HIV</td>
<td>Number of participants
N= 15,205
Intervention group = 8,015
Comparison group = 7,190

Inclusion criteria
(1) at-risk communities: 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) targeted by the local site and
(2) vaginal or anal intercourse in the 30 days before interview or sharing needles for drug injection in the 60 days before interview.

Exclusion criteria
Not reported

Participant characteristics
<table>
<tr><th></th><th>Int, %</th><th>Comp. %</th></tr>
<tr><td>Sex</td><td></td><td></td></tr>
<tr><td>Female</td><td>52.8</td><td>56.3</td></tr>
<tr><td>Male</td><td>47.2</td><td>43.7</td></tr>
<tr><td>Race / ethnicity</td><td></td><td></td></tr>
<tr><td>African American</td><td>55.6</td><td>52.9</td></tr>
<tr><td>White</td><td>22.3</td><td>21.8</td></tr>
<tr><td>Hispanic</td><td>16.8</td><td>20.6</td></tr>
<tr><td>Other</td><td>5.3</td><td>4.8</td></tr>
<tr><td>Age</td><td></td><td></td></tr>
<tr><td>11-29 y</td><td>33.1</td><td>38.0</td></tr>
<tr><td>30-39 y</td><td>40.4</td><td>39.0</td></tr>
<tr><td>40-87y</td><td>26.5</td><td>23.0</td></tr>
</table>
</td>
<td>Intervention: Community level intervention with training, education, small media, and access to condoms and bleach.
Comparison: No intervention

The intervention had 3 key components: (1) mobilization 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.

Targeted at-risk communities, other local residents, and persons from area businesses who had regular contact with the target population were recruited and trained to distribute the intervention materials in their community.
The small-media materials (e.g., community newsletters, pamphlets, baseball cards) contained authentic stories about people from the community that described how they were changing (or preparing to change) their HIV-related risk behaviors. The materials also contained basic AIDS</td>
<td>Outcomes

Positive movement in stages of change towards:

Condom use with main partner
Condom use with non-main partner
Carrying condoms

Interventions aimed to increase stage-of-change scores for condom use during vaginal sex with a main partner in all 10 communities. Across all waves of data collection, 9457 individual responses were obtained on this measure.

Results
At the community level there were statistically significant movements in stages of change towards:
consistent condom use with main partner (effect size 0.19; 95% CI 0.01 to 0.38, p<0.05),
non-main partner (effect size 0.34 : 95% CI 0.04 to 0.63, p<0.05

There was statistically significant movements in the maintenance stage of change towards non-main partner (effect size 9.40: 1.2 to 17.7, p<0.05). There was a non-significant improvement in consistent condom use with main partner ,

There was a statistically significant 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).</td>
<td>Limitations identified by author
With 2 exceptions, the community pairs were not randomly assigned to intervention or comparison status. Data collection methods did not include probability sampling; however, strategies such as the use of random number lists to select potential respondents were used in an attempt to reduce selection bias. The study communities were not assumed, however, to be a representative sample of a larger set of communities or populations at risk for HIV infection. Therefore, these findings should be viewed as an indication of what can occur with this type of community-level intervention and not as an indication of what would necessarily occur in other communities.

Authors report that the bleach analysis was underpowered, which meant that using community as the unit of analysis did not detect a significant intervention effect. A post-hoc estimate of power was</td>
</tr>
</table>

Study details	Population	Intervention/comparison	Results	Notes
infection **Location and setting** 5 US cities **Source of funding** CDC		information, instructions on the use of condoms, and other community-related information. Each story described the role model's progress toward the consistent practice of 1 of 5 risk reduction behaviors: condom use for (1) vaginal or (2) anal sex with a main partner (steady partner or spouse); condom use for (3) vaginal or (4) anal sex with nonmain partners (casual partners, one-time partners, paying partners); or (5) use of bleach to clean needles, syringes, and other equipment used to prepare or inject drugs. Small media were based on the transtheoretical model of behaviour change.		calculated as 0.18. **Limitations identified by review team** **Other comments** The data used for this study was collected from 1991 - 1994, so predates the introduction of ART. Its relevance may therefore be limited.

Bedimo et al 2002

<table>
<tr><th>Study details</th><th>Population</th><th>Economic analysis</th><th>Results</th><th>Notes</th></tr>
<tr>
<td>Study
Bedimo et al 2002
(Additional data from Cohen et al 1999)

Quality score
+

Study type
Cost-utility analysis

Aim of the study
To explore the cost-effectiveness of a large-scale condom distribution programme.

Location and setting
A statewide programme in Louisiana, USA

Length of follow up
N/A

Source of funding
None reported</td>
<td>Participant characteristics
Estimated that the intervention reached 275,000 African Americans.
The distribution scheme was available to the whole population, This study focuses on the African American population of Louisiana.
The scheme was targeted at health clinics and small businesses in neighbourhoods with high rates of STDs.*
<table>
<tr><th>Parameter</th><th colspan="2">Best-case value (range examined) for 3 year intervention period</th></tr>
<tr><th></th><th>Men</th><th>Women</th></tr>
<tr><td>Clients reached by intervention</td><td>192,500 (96,250 - 577,500)</td><td>82,500 (41-247,500)</td></tr>
<tr><td>Acts of intercourse per client</td><td>306 (102-611)</td><td>306 (102-611)</td></tr>
<tr><td>Sex partners (m)</td><td>4 (1-10)</td><td>4 (1-10)</td></tr>
<tr><td>Acts of intercourse per partners (n)</td><td>77 (39-15)</td><td>77 (39-15)</td></tr>
<tr><td>Proportion of condom use, before intervention ($f_{1)}$</td><td>0.40</td><td>0.28</td></tr>
<tr><td>Proportion of condom use, after intervention ($f_{1)}$</td><td>0.52</td><td>0.36</td></tr>
<tr><td>Prevalence of HIV infection in study</td><td>0.016 (0.008-0.032)</td><td>0.006 (0.003 – 0.012)</td></tr>
</table>
</td>
<td>Method of analysis
Cost utility analysis with sensitivity analysis and threshold analysis

Time-line horizon implicitly life time horizon.

Cost of intervention discount at 3% per year.

Implicit that QALY discounted , reviewers assume at 3% per year.

Cost (C) of intervention estimated in 1996 US$. Estimates of lifetime costs of treating HIV-related illness (T) and corresponding QALYs saved (Q) based on research data published in 1997.

T was estimated at $195,188.
Q estimated at 26.4 (based on each averted HIV infection assuming 26 years of age at infection.)

Intervention
During the 3 years from 1994 to 1996, over 33 million condoms were made available in over 1000 public and commercial venues</td>
<td>Outcomes

The programme costs approx $11 per person (high estimate) and approx 55% of the condoms reached the African American population.
Assuming a 50% wastage, the programme can be estimated with preventing 170 HIV infections and saving 1909 QALYS.
An estimated over $33 million in direct costs were averted ,for a programme cost of $3,000,000. Therefore t he programme was cost saving.
<table>
<tr><td>Participants</td><td>275,000</td></tr>
<tr><td>Time frame</td><td>3 years</td></tr>
<tr><td>Programme cost</td><td>$3,000,000</td></tr>
<tr><td>HIV cases averted (CA)</td><td>169.95</td></tr>
<tr><td>Programme cost per CA</td><td>$17,652</td></tr>
</table>
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. Intervention remains cost saving for all plausible values of these parameters.</td>
<td>Limitations identified by author

Assumptions about the number of sex partners and acts of intercourse

Increase in condom use may not be entirely a result of intervention

Number of infections averted was modelled rather than biologically measured.

Limitations identified by review team
Analysis is quite old and based on data from 1994 – 1996.

In 2015 ,with effectiveness of HAART – QALYs saved per person would be much lower.

Other comments
Standards of reporting have improved since the publication of this paper.

Programme costs per HIV case prevented may seem high,</td>
</tr>
</table>

<table>
<tr><th>Study details</th><th>Population</th><th>Economic analysis</th><th>Results</th><th>Notes</th></tr>
<tr>
<td></td>
<td>
<table>
<tr><td>population (n)</td><td></td><td></td></tr>
<tr><td>Prevalence of HIV infection in study partners (n)</td><td>0.006 (0.003-0.012)</td><td>0.016 (0.008 – 0.032)</td></tr>
<tr><td>Condom effectiveness</td><td>90% (80%-95%)</td><td>90% (80%-95%)</td></tr>
<tr><td>Probability of HIV transmission, per act of unprotected intercourse</td><td>0.001 (0.0003-0.0015)</td><td>0.001 (0.0003-0.0015)</td></tr>
<tr><td>Probability of HIV transmission, per act of protected intercourse</td><td>0.0001 (0.0002 – 0.00005)</td><td>0.0001 (0.0002 – 0.00005)</td></tr>
<tr><td>Total condoms distributed</td><td>14,116,667</td><td>4,033,333</td></tr>
<tr><td>Condom wastage</td><td>50% (25%-75%)</td><td>50% (25%-75%)</td></tr>
<tr><td>Total condoms used</td><td>77,058,333</td><td>2,016,66</td></tr>
<tr><td>Discounted medical treatment cost</td><td colspan="2">$195,188</td></tr>
<tr><td>QALYs saved per prevented infection</td><td colspan="2">11.23</td></tr>
</table>
</td>
<td>throughout Louisiana.

Small signs advertising their availability were placed in the sites. 55% were taken by African Americans.</td>
<td></td>
<td>approximately £20,000 at current costs. Nevertheless this remains very cost-effective due to savings on health costs.</td>
</tr>
</table>

Cohen et al 1999

Study details	Population	Intervention/comparison	Results	Notes
Study Cohen et al 1999 **Quality score** - **Length of follow up** Annual surveys 1992-1996. **Study type** Matched area control study **Aim of the study** To evaluate effect of a state-wide large-scale campaign designed to increase accessibility of condoms. **Location and setting** Louisiana, USA, A large-scale campaign targeting health clinics and small businesses in neighbourhoods with high rates of STDs. **Source of funding** Not reported	**Number of participants** *Public clinic survey*: 27 clinics: surveys were distributed to women requesting family planning or prenatal visits, who brought their children for immunizations or well-child visits, or who came for required visits for the Women, Infants, and Children (WIC) Program. Clinics were selected to represent all 9 geographic regions of Louisiana and to include both urban and rural parishes. Respondents in the clinic survey were women who reported having sex in the past 12 months. Although the distribution of respondents race did not differ across each year, marital status and type of clinic visited differed during the study period. *Street survey:* interviewer-assisted street-intercept surveys of African American men, aged 15 through 45 years, in targeted areas of New Orleans. The selected neighbourhoods for these surveys were those with the highest rates of gonorrhoea in New Orleans, including one zip code in which 100 businesses had been recruited to distribute free condoms in	**Intervention:** Provision of free condoms in readily visible and accessible sites through health care facilities and private commercial venues. **Comparison:** No intervention. *Health Clinics.* In May 1993, the Louisiana Department of Health and Hospitals mandated that condoms would be made accessible to all clients of publicly funded health department clinics. Free condoms were made available in all public health clinics (n = 93), community mental health centres (n = 39), and public substance abuse treatment centres (n = 29). 35 private physicians, 105 community health care centres, and at least 27 housing projects made condoms available. Training on condom use, condom efficacy, and increasing condom accessibility was conducted throughout the state. Staff were encouraged to; make condoms freely available; not to limit the number that people could take; to allow clients to take them without asking permission; to take condoms	**Outcomes** Numbers of condoms distributed**.** Condom knowledge Condom behaviours Rate of condom distribution. Prior to intervention in 1992 n=323,000. Post intervention in 1994 n=8,735,000 1995 n= 11,900 000 1996 n=13, 360, 000. *Health clinics* :From 1994 to 1996, self-reported condom use at the last sexual encounter did not change among white women; but increased among African American women (from 28% to 36%) and increased sharply (from 30% to 48%) among those African American women who reported 2 or more partners in the previous year . After logistic regression was used to control for marital status, type of clinic visited, race, and education, there remained a substantial increase in condom use in 1996 compared with 1994 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 the above findings. Between 1994 and 1996 the authors report a statistically significant increase in the percentage of women who used condoms at : the last sexual encounter (P < .04), had condoms (P< .0001), obtained free condoms (P< .0001), knew where to get free condoms (P< .0001), and reported that their friends used condoms (P<.0001).. This final analysis was post-hoc and only included women who used condoms.	**Limitations identified by author** Authors state they were unable to conduct a controlled trial of this intervention, in part because of the popularity of the program as a response to an urgent and critical public health problem. Community-based organizations working to prevent AIDS did not consider it ethical to limit large-scale free condom distribution to only a portion of neighbourhoods. **Limitations identified by review team** Study power calculation not reported. Analysis is old and based on data from 1994 – 1996 when there was no effective treatment for HIV. This study pre-dates the use of HAART. Poor reporting make it difficult to follow and assess.

	1994 (Area A) and matched comparison areas in which businesses had not been recruited during this first year of the program (Area B). Each year, between 500 and 600 men answered the survey in New Orleans. The respondents did not differ across years or between Area A and Area B, 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= .01). The percentage of respondents with less than a high school education and the percentage unmarried did not vary significantly across years or between Areas A and B **.** **Inclusion criteria** Not reported **Exclusion criteria** Not reported.	home and distribute them to anyone they knew who might need them; and to notify any complaints or problems. *Businesses:* In neighbourhoods with the highest rates of STDs businesses were invited to distribute free condoms to their customers. The program was piloted in one area of New Orleans in 1993 and then gradually expanded state-wide in 1994. Approximately 1000 businesses were actively participating in the program at any time. Participating businesses included 324 convenience stores; 388 bars, nightclubs, and liquor stores; 145 beauty salons and barbershops; as well as other businesses such as tattoo parlours, dry cleaners, and low-cost motels. In addition, all community based organizations involved in HIV/STD prevention activities such as street outreach or other types of interventions were supplied with large quantities of condoms for distribution.	*Businesses:* Condom use increased from 40% to 56% in the intervention area between 1994 and 1995 (P< .0001) and decreased slightly to 52% the following year (P= .45). In the comparison area, in which the program was implemented in 1995, condom use increased from 41% to 48% between 1994 and 1995 (P=.06) and increased to 55% in 1996 (P <.003 for 1996 vs 1994). When the authors combined data from the 2 areas, they found other changes over the survey years suggesting that respondents were obtaining and using the program's condoms. From 1994 to 1996, the percentage of respondents who identified the brand of condom being distributed through the health department program as the one they used last increased from 40% to 61% (P <.0001), the percentage who reported they had obtained free condoms increased from 61% to 74% (P < .001), the percentage who knew where to obtain free condoms increased from 63 to 82% (P< .000 1), and the percentage who reported not owning any condoms decreased from 32% to 22% (P< 0.0002).	Contamination between intervention and non-intervention areas was considered likely given that the study was conducted in one city. There are major flaws in outcome reporting. Outcome data appear to be missing. Comparison data often not reported. Within group differences reported when between group data should be available. Conflation of data from intervention and controls groups. **Other comments**

Dahl 1999

Study details	Population	Intervention/comparison	Results	Notes
Study Dahl et al 1999 **Quality score** **-** **Length of follow up** None **Study type** Comparative observational **Aim of the study** To assess the viability of using high-value coupons to induce condom purchases and to identify critical execution factors (i.e., distribution methods, coupon characteristics) that would result in the effectiveness of this type of promotional strategy. **Location and setting** Canada Two settings: (1) widespread local settings including clubs, bars and social settings and (2) drugstores in	**Number of participants** *Intervention* Widespread distribution of two different condom discount vouchers (10% v 7% discount) at a variety of commercial locations. (10% coupons n = 2,300; 75% coupons n = 3,800). *Comparison* Distribution of vouchers at drugstores only. t Wave 1 = 1,080 (10% coupons n= 540; 75% coupons n = 540). Drugstore disbursement Wave 2 = 1,580 (10% coupons n= 819; 75% coupons n = 761). **Participant characteristics** Not reported. **Inclusion criteria** Sexually active young people aged 18-30 years **Exclusion criteria** Not reported.	**Intervention:** distribution of vouchers for discount condoms through a wide variety of local settings **Comparison:** In store distribution of vouchers for through drug stores only Both intervention and comparison provided coupons worth 10% discount or 75% discount on the price of condoms were distributed via 2 schemes targeted at sexually active 18 - 30 year olds. Intervention 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. Comparison Discount coupons were 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 and only at the retail outlet where they were distributed. The in-store disbursement involved 2 separate waves of distribution approximately 2 months apart. 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.	**Outcomes** Rate of condom coupon redemption. **Intervention** 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. Chi-square analysis indicated that this represented a significant difference in redemption for the different coupon value levels (χ^2 = 7.89, P<.01). The higher redemption rate achieved with the 75% coupon, although somewhat greater than the typical coupon redemption rate for condoms (i.e. 0.1%), was still minimal. **Comparison** Coupon promotion was the only significant predictor of number of condoms purchased (t = 10.50, P<.001). The results of the observational measures indicate that among both women and men, the absolute number of condoms purchased during the coupon promotion was significantly greater than the baseline purchase level 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 75% coupon (male purchases: 47.0 vs 5.3 [t = 62.58, P <.001]; female purchases: 18.0 vs 1.3 [t = 45.23, P<.001]). However, the 75% coupon was much more likely to induce purchases among male	**Limitations identified by author** No data reported to support finding on between group comparison. **Limitations identified by review team** Power calculation not conducted. This study is limited by an absence of demographic data about participants and those who purchased or did not purchase condoms.. Limited reporting of between group comparison data . **Other comments**

Vancouver. **Source of funding** Funded in part by grants from the Social Science and Humanities Research Council of Canada.			customers compared to baseline purchase levels (10%voucher redemption: 1.8%; v 75% redemption: 10.8%) as well as female customers (10% redemption: 1.6%; 75% redemption: 5.6%). **Intervention versus comparison** Authors state that instore distribution of coupons resulted in larger redemption rates than the widespread distribution approach. However, no clear data were presented to support this.	

De Rosa et al 2012

Study	Participants	Intervention/Comparison	Results	Comments
Study De Rosa,et al 2012 **Quality score** + **Length of follow up** None **Study type** Quasi experimental/ cluster controlled trial **Aim of the study** To improve implementation of a high school condom availability programme (CAP) and evaluate its effects on student awareness and condom acquisition. **Location and setting** Urban High schools in Los Angeles, CA. USA **Source of funding** Centre for Disease Control, Atlanta, GA, USA.	**Number of participants** Twelve high schools in areas with STI and teen pregnancy rates exceeding the 'Healthy people 2010' goals. Intervention: 6 schools, n=3,295 students. Control: 6 schools, n= 2,635 students **Participant characteristics** High school students. Approximately 45% female. Both intervention and control groups were comparable on sexual behaviour characteristics. Small significant differences in Latino ethnicity (intervention75.8% v Control 76.7%. p= 0.003) and grade were reported (23.6 v 24.6, p > 0.01) were reported, but these were controlled for in the analyses. Pair matching was based on criteria including chlamydia and birth rates, school demographics and number of students. **Inclusion criteria** Nor reported. **Exclusion criteria** Not reported	**Intervention:** Assessment of and Improvement to existing high school condom availability programme (CAP). **Comparison:** No assessment or improvement to existing CAP. Researchers assessed school compliance with the CAP in each of the six intervention schools for the following programme elements: • Oversight committee • Sufficient/appropriate condom distributors • Distributors properly trained • Specific person to order condoms and educational materials • Programme advertised to students • Parental notification of the scheme provided and provisions in place to allow opt-out if needed • Tracking procedures for recording non-consent • School personnel able to tailor distribution according to their school needs. Where these were lacking a tailored action plan was developed and intervention schools were supported in achieving compliance levels.	**Outcomes** Student awareness of scheme Student sexual behaviour and condom use Student acquisition of condoms School condom orders **Results** Of the 68,022 students enrolled in selected classes, 56% (n=37,795) returned consent forms of which 94% (n=35,468) gave consent. Fewer than 3% of those declined participation and 12% were absent on the day of the survey. Overall, 84% of consented students completed the survey (n=29,823) spread over the five years of data collection (years 1 - 5 n = 5,930 (year 1); 5,831 (year 2); 5,878 (year 3); 6,164 (year 4); 6,020 (year 5)respectively). Awareness of the programme was lowest at year 1 and year 2. In the intervention schools, awareness increased by year 3 and continued to do so through to year 5 whereas awareness remained steady or declined in the control schools. At year 4, the increase in awareness from year 1 among intervention participants was twice that of control participants (AOR: 2.17; 95% CI: 1.70, 2.76)* and by year 5 was almost 3 times that of control participants (AOR: 2.78; 95% CI: 2.18, 3.56)*. This pattern remained in separate analyses of sexually active/experienced students. Relative to reports of condom acquisition at year 1, intervention participants had increased odds of condom acquisition compared with control at year 4 (AOR: 1.69; 95% CI: 1.23, 2.32) and year 5 (AOR:1.81; 95% CI: 1.32, 2.49). Compared with condom acquisition at year 1, the odds of sexually experienced students in intervention schools	**Limitations identified by author** Findings are based on self report. No information on programme implementation in control schools Requirement for active parental consent led to a disappointing non-response rate (approx. 52% of potential participants) **Limitations identified by review team** Authors report significant differences across a range of outcomes but do not supply p values. Power calculation not reported. Non-random assignment.

		Control schools continued to run their existing project. The intervention period began in 2005 and by autumn 2007, all 6 schools had fully compliant programmes. Results were calculated from student survey data gathered each year from 2005 to 2009 (12 month intervals).	reporting condom acquisition were more than twice control schools (AOR: 2.27; 95% CI 1.47, 3.52); for sexually active students the odds at year 5 were more than 3 times those of control students (AOR: 3.08; 95% CI: 1.77, 5.36). Condom use at last sex remained stable and did not differ significantly between intervention and comparison groups. There was no difference in the number of condoms ordered by intervention and comparison schools at year 1, year 2 and year 3. 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. (Staff interviews revealed that a strong distributor at control school 3 responsible for ordering the bulk of control school condoms, left after year 3.) *Reported as statistically significant though *p* value not reported.	**Other comments**

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Exner et al 2012

Study details	Population	Intervention/comparison	Results	Notes
Study Exner et al 2012 **Quality score** - **Length of follow up** None **Study type** RCT (cross-sectional case study of clients) **Aim of the study** To test the efficacy of an Enhanced Intervention (EI) for female condom (FC) promotion targeting both directors of agencies and HIV sexual risk-reduction counsellors against a Minimal Intervention (MI) that provided agency access to FCs and directors with a rationale for their promotion, but no intervention for counsellors. **Location and setting** USA Agencies in receipt of funding for HIV	**Number of participants** Of the 44 participating agencies, 5% were substance abuse treatment facilities or syringe exchange programs, 7% were family planning clinics, 38% were other medical settings (hospital or STD clinic), and the remainder were community based organisations or outreach organisations. **Participant characteristics** Agencies were pair-matched on four factors: agency size, type of services (medical vs. non-medical), population served (primary ethnic/racial groups; risk profile of patients (injection drug users (IDUs)/partners of IDUs, STI patients, HIV+ persons), high-HIV prevalence census tract clientele),and geographic location (upstate vs. NYC metropolitan area). **Inclusion criteria** To be eligible to participate, agencies had to receive New York State	**Intervention:** Enhanced Intervention (EI) of female condom promotion (FC). **Comparison:** Minimal Interventions (MI) of female condom promotion. **Enhanced Intervention**—Targeted at both the agency- and counsellor-levels. Consisted of the same two components as the MI, but also included (1) at the agency-level, the distribution of a "Female Condom Program and Policy Tool-Kit" to directors and 12 months of technical support; and (2) at the counsellor-level, a one-day FC training workshop, 12 months of technical support, and provision of FC materials for use with clients. The Tool-Kit sent to directors of agencies in the EI contained materials (posters, pamphlets, information sheets) to assist with creation of intra-agency FC promotional policies and practices, as well as pelvic models to be used by sexual risk-reduction counsellors to demonstrate correct FC use with clients. The content and use of these Tool-Kits were reviewed via phone. Further technical support calls were scheduled monthly to check on Action Plans and support continued FC promotional	**Outcomes.** **Client-level, outcomes** Intervention clients counselled had a significant increase in intention to use the FC at follow up compared with the comparison ($P < 0.05$). They also had a significantly higher level of knowledge about the FC than those in MI group ($P < 0.05$). **Agency level FC Policy and Practice Outcomes.** There was no significant change from baseline to follow-up in the comparison (MI) agencies. Although there were increases in the Intervention (EI) agencies in mean change over time in their incorporation of the FC into policies and practices, these changes did not reach statistical significance (β=.77; p=.09), and intervention and comparison agencies did not differ significantly in mean change over time. In analyses stratified by facility type (not shown), there were no significant intervention effects in either type of facility. **Counsellor level outcomes** Intervention (EI) resulted in greater positive change over time in counsellors' knowledge and attitudes about the FC, including attitudes about the effect of the FC on sexual pleasure compared with the comparator (MI). Those assigned to the intervention (EI) but not the comparator (MI) showed significant increases in self-efficacy for FC promotion and more positive attitudes toward the FC's effect on sexual pleasure, with significant group differences in change over time on these two outcomes. Both groups reported significant increases in clients counselled on the FC from baseline to follow-up, for both heterosexually active women and men clients. In exploratory tests of differential intervention effects according to facility type, the proportion of women who have	**Limitations identified by author** Low retention rates of agencies and counsellors. Timing of baseline data collection from agency directors. After they had been exposed to a critical intervention component. Possible failure to understand underlying unevaluated or unanticipated factors that could compromise the quality of matching. Potential volunteer bias in that they may be primed to change Self-reported data **Limitations identified by review team** No allocation concealment. Authors place emphasis on within

prevention and treatment from New York department of health in the NYC metropolitan area and upstate urban areas. **Source of funding** National Institute of Mental Health	Department of Health (NYSDOH) AIDS Institute funding for prevention or treatment initiatives, work with heterosexually-active at-risk populations, and have a client base comprised of at least 60% women. **Exclusion criteria** Not reported.	activities. Counsellors in the EI attended a 6-hour training provided in groups in a local setting, and received their own Tool-Kit with posters, pamphlets and a DVD that promoted the FC to heterosexual couples. Training was conducted in groups of approximately 20. Technical support calls were scheduled monthly. **Minimal Intervention**—The MI, targeted to the agency-level only. Consisted of a regional directors' meeting and provision of free female condoms to the agencies.	sex with men counselled on the FC did not differ by type of facility, although there was a significant interaction between facility type and condition (β=1.62; interaction p=.049), indicating that the intervention effects were greater in medical facilities than the comparator. In the respective analyses for men who have sex with women, stratified analyses revealed a significant intervention effect in both medical (β=1.30; p=.003) and non-medical (β=1.08; p=.06) settings, with the effect being stronger among EI in medical facilities (β=2.68; interaction p=.002). Counsellors in the MI but not the EI reported significant increases in Peer Norms for FC Promotion from baseline to follow-up, there were no significant differences between groups in change over time. Exploratory tests of differential effects according to type of facility showed that intervention effects for the FC pleasure variable were significant in medical (β=.24; p=.01) but not in non-medical facilities, and that this was stronger among EI counsellors in medical facilities (β=.19; interaction p=.07). Likewise, counsellors showed significant knowledge gains in medical (β=2.45; p<.0001) but not non-medical facilities (β=.17; p=.01), with EI intervention effects stronger in medical facilities as well (β=2.29; interaction p=.001). Due both to attrition among counsellors participating in the nested cross-sectional case study and to reassignment of duties, authors stated that they were able to observe only 25 of the 36 counsellors (69% retention) both at baseline and 12 months later. Although the increase in number of FC related discussion points and counselling activities was greater among EI (N=15; mean increase = 3.9) than MI counsellors (N=11; mean increase = 0.90), this difference was not significant,	group analyses rather than between group analyses. Poor reporting of outcome data. Power calculation not reported **Other comments**

Furstenberg et al 1997

Study details	Population	Intervention/Comparison	Results	Comments
Full citation Furstenberg,et al 1997 **Quality score** - **Length of follow up** Unclear, at least one year. **Study type** BA **Aim of the study** To evaluate Policy 123 (a sexual health and condom access project) **Location and setting** High Schools in Philadelphia US **Source of funding** Robert Wood Johnson Foundation grant 2089.	**Number of participants** Numbers interviewed: - Pre-intervention at baseline in 1991: n=1,181. - Post intervention (at least one year follow-up) in1993:n= 2,080 However, analyses only based on public school students - 490 at baseline in 1991 and 945 at follow-up in 1993. The 1993 follow-up taken "after the program had been operating for at least one full year **Participant characteristics** Program and comparison schools differed slightly in their demographic composition. In both years, schools with a Health Resource Centre had a lower proportion of white students (18–19%) than comparison schools (24–28%) and a higher proportion of black students (70–73% vs. 57–65%). The proportion of students who were male was 24–25% in both groups of schools in 1991 and 45–47% in 1993. Students' age varied little by type of school or year. At baseline, condom use at last intercourse was higher in the comparison group (61.9%) compared to the intervention group (52.2). Also, the percentage of students who had sex in the 4 weeks prior to baseline tests was lower in the control group (24%) compared to the intervention group (32%). Authors report that	**Intervention:** A sexual health and condom access programme **Comparison:** No intervention Policy 123 was introduced in 1991. 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 (age 14-18 years).	**Outcomes** Ever had sex After at least one year of the intervention (follow-up in 1993) the proportion of students who had ever had sex was similar in both groups (control 59%, intervention 58%). Yet it did drop slightly in the intervention group, when compared to baseline measurement (64% to 58%). The results are not significant. *Condom use at last intercourse* At follow-up , condom use at last intercourse increased for the entire sample, but the change was greater in the intervention group (from 52% to 58% of sexually active students) than in teh control group (62–65%). The results are not significant. *Had sex in the 4 weeks prior to survey (general measure and specifically without a condom)* For the control group,	**Limitations identified by author** The analysis was based on an aggregation of students from program and comparison schools; however, the sample was still too small to detect significance in differences of modest magnitude. Specific power calculations not reported, but authors state their power analysis revealed that a 25-point increase in condom use at last intercourse (for youths in high-use programs) would have been needed to attain significance. **Limitations identified by review team** The study is poorly reported. The data were collected in 1991-1993 by two different surveys with two different sampling strategies, and no clear indication of length of follow-up. Due to poor reporting it was not possible to assess allocation generation or concealment; or the extent of outcome reporting or potential contamination between intervention and control group. **Other comments** Reporting is poor and very confusing. It is difficult to define the intervention content, the

	these differences were not significant with p values ranging from 0.14-0.72 (individual values not reported). Percentages were adjusted for race, gender, age, previous grade retention, and weighted by proportional representation **Inclusion criteria** 1991: All households in the school catchment area with at least one 14–18-year-old female and one in 10 of those with at least one 14–18-year-old male were eligible. 1993: Eligible youths were randomly drawn from a database of residents of tracts surrounding the program and comparison schools. **Exclusion criteria** More than two interviewees in household.		proportions of students who had sex 4 weeks prior to surveys at both baseline and follow-up was similar (general: 24%-26%; without a condom 5%-5%). For the intervention group, the proportion of students that had sex in 4 weeks prior to surveys dropped slightly at follow-up (general measure: 32%-29%; without a condom: 8%- 6%). The results are not significant.	population, the settings in any detail.

Guttmacher 1997

Study details	Participants	Intervention / Comparison	Results	Commentary
Study Guttmacher et al 1997 (Additional data from Guttmacher et al 1998; Guttmacher et al 1995) **Quality score** - **Length of follow up** Unclear, but approximately 3 years after start of intervention. **Study type** Quasi-experimental **Aim of the study** To examine the impact of a condom availability programme in NYC public high schools by comparing rates of sexual activity and condom use for New York students and similar students in Chicago. **Location and setting** New York High Schools, USA **Source of funding** A grant from The Robert Wood Johnson Foundation,	**Number of participants** **Intervention:** 7,119 students from 12 randomly selected NYC schools. **Comparison:** 5,738 students from 10 Chicago schools. **Participant characteristics** The majority of the students were between 15 and 17 years old. Slightly more females. 28% Hispanic/Latino, 47% African-American / Black Caribbean. The intervention and comparison groups were comparable across all demographic and sexual behavioural characteristics. Significantly more NYC students that Chicago students knew someone with HIV infection or AIDS (p<0.01). **Inclusion criteria** Not reported **Exclusion criteria** Not reported	**Intervention:** High school based condom availability programme **Comparison:** Schools with no condom distribution scheme, but with HIV/AIDS education *Intervention* In 1991 the New York City (NYC) Board of Education implemented a non-clinic-based, system wide school condom availability programs. Each public high school was mandated to do the following: (1) assemble an HIV/AIDS team, composed of the principal, assistant principal, teachers, parents, students, health resource staff, and other interested personnel, to oversee the CAP; (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 are 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; and (6) arrange for an HIV/AIDS information session for parents. Condoms were not supposed to be given to students whose parents actively refused consent. 12 high schools were randomly selected after all 120 NYC schools had been comprehensively stratified by type and socio-economic status of	**Outcomes** (Note: All outcomes measured via a survey undertaken approx. 3 years after start of the intervention, but not clearly stated). Sexual activity (all students). Condom use (by students who reported having sex in the 6 months prior to survey). **Results** Intervention students reported equal rates of sexual activity to comparison students, but had significantly 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 in the months prior to survey, condom use was also greater in the intervention than the comparison group (OR=1.85; p<0.01)	**Limitations identified by author** No baseline measurement of condom use in NYC prior to implementation of CAP. No random assignment. **Limitations identified by review team** No power calculation reported. The intervention was introduced in 1991 and the survey was carried out in “early fall 1994”. It is not clear when in the year the intervention was implemented or whether it was rolled out in schools straight away. Therefore it is not clear how long the follow-up period is. We have interpreted this as follow up survey approx. 3 years post start of intervention. Comparison of two cross-sectional surveys in intervention and non-

with additional funding from the Aaron Diamond Foundation, the New York Community Trust, and the William T. Grant Foundation.		school. This sample was shown to be representative of the student population in the NYC school system. *Comparison* Ten Chicago public high schools were chosen to match the NYC sample of students on relevant demographic characteristics. In both intervention and comparison, students completed self-administered surveys approx. 3 years after start of intervention. The surveys were designed to measure students' knowledge, attitudes, and self-reported behaviour related to sexual activity, condom use, and HIV risk reduction.		intervention cities. Data for intervention city (NYC) are collected during intervention period with no baseline data. Authors use data from "new' students" (students who have been in an NYC or Chicago high school for less than 1 year) as a 'proxy baseline' measure. Confidence intervals not reported with effect sizes. **Other comments**

Holtgrave et al 2014

<table>
<tr><th>Study details</th><th>Population</th><th>Economic analysis</th><th>Results</th><th>Notes</th></tr>
<tr>
<td>Study
Holtgrave et al 2012

Quality score
++

Study type
Threshold and cost–utility analysis.

Aim of the study
To examine the affordability, performance standards, and relative cost-effectiveness of female condom product (FC2) provision and educational services.

Location and setting
Areas with disproportionately high HIV prevalence among women in Washington DC. USA.

Length of follow up
N/A</td>
<td>Participant characteristics
The project targeted heterosexual women in Areas with disproportionately high HIV prevalence among women in Washington DC. It provided brief educational interventions (less than 15 min) to 38,000 women and men, extended education sessions (more than 15 min) to 8,000, conducted more than 300 group education sessions, trained nearly 500 peers at health and non-health locations and distributed more than 300,000 FC2s.

.</td>
<td>Method of analysis
Standard methods of cost, threshold and cost–utility analysis were employed.
A 1 year time horizon was used to capture both costs and benefits. Both societal and provider perspectives were employed.
Intervention cost divided by the net present value (discounted at 3 %) of the lifetime medical care costs of a case of HIV. Analysis employed $100,000 per QALY saved.

Cost Analysis: A standard micro-costing approach was used to account for resources consumed by the female condom (FC) provision and education intervention regardless of whether that amount was above or below the grant support provided. These costs are reported in the table 1below. The approach of the programme was to build competency and capacity in organizations working in the field of women’s health and HIV and/or STI prevention (e.g providing outreach and education in community settings such as beauty salons and health centres). The purpose was not to establish brand new, stand alone service delivery programmes. It was assumed that the FC2 programme delivered on the margin of existing service delivery programmes.
1. Input parameter values for cost, threshold and cost–utility analyses

<table>
<tr><th>Parameter</th><th>Parameter value</th><th>Source</th></tr>
<tr><td>Education costs</td><td>$152,100</td><td>1</td></tr>
<tr><td>Staff costs</td><td>$42,875</td><td>1</td></tr>
<tr><td>Distribution costs</td><td>$16,900</td><td>1</td></tr>
<tr><td>Marketing costs</td><td>$73,766</td><td>1</td></tr>
<tr><td>Procurement costs</td><td>$128,535</td><td>1</td></tr>
<tr><td>Condoms procured</td><td>200,000</td><td>1</td></tr>
<tr><td>% condoms used during sex</td><td>65 %</td><td>1</td></tr>
<tr><td>% condoms used for other</td><td>17%</td><td>1</td></tr>
</table>
</td>
<td>Outcomes
The basic investment in the delivery of the intervention was $414,186. Expressed as a cost per product used during sex this is $3.19.

The societal perspective cost-saving threshold analysis result was 1.13 infections that would have to be averted to be cost-saving. The public sector provider perspective cost-saving threshold result 1.50. (Both threshold results are low due to the high cost of HIV care over the lifespan, and both thresholds would appear to be readily achievable). The cost-effective threshold result (from the societal perspective only) is 0.46, 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. Intervention remains cost saving for all plausible values of these parameters.

The base case estimate for the number of HIV infections averted by the intervention is approximately 23.35 infections averted. The base case CUA ratio indicates cost savings.

Allowing for crowd out of male condom use by female condom use at the specified level, the overall CUA result still indicates cost-saving.

Further, even allowing crowd out if FC2 effectiveness were to drop as low as 7.04 % the result will still indicate cost-savings. The results are highly robust to uncertainty in the input parameters.

“Overall, mathematical modeling analyses estimated that the intervention averted</td>
<td>Limitations identified by author
Retrospective analysis - does not benefit from prospective cost analysis. However, given the robustness of the findings, any marginal uncertainty in cost estimates would appear to have little impact on the major conclusions.

It would be ideal to measure directly the impact of the intervention on observed HIV incidence; however, the cluster RCT that would be necessary to field such a study would be extremely expensive and likely prohibitively large in size. Therefore, we needed to rely on mathematical modeling techniques.

Further information about sexual networks in the targeted area would have been useful for building a more complex</td>
</tr>
</table>

<table>
<tr><th>Study details</th><th>Population</th><th>Economic analysis</th><th>Results</th><th>Notes</th></tr>
<tr>
<td>Source of funding
Johns Hopkins University received support for this economic evaluation from the Female Health Company, the producer of the female condom product, FC2. The Washington DC Department of Health received support for the FC2 dissemination and education project from the Female Health Company; the educational project was also supported by the MAC AIDS Fund. Final control of the analysis and publication rested with the authors.</td>
<td></td>
<td>
<table>
<tr><td>purposes</td><td></td><td></td></tr>
<tr><td>% of condoms not used</td><td>18%</td><td>1</td></tr>
<tr><td>Lifetime HIV medical care costs</td><td>$367,134</td><td>2</td></tr>
<tr><td>No. QALYs saved per infection averted</td><td>5.3</td><td>3</td></tr>
<tr><td>% HIV medical care costs in public sector</td><td>75%</td><td>4</td></tr>
<tr><td>Female HIV prevalence</td><td>8.8%</td><td>4</td></tr>
<tr><td>Male HIV prevalence</td><td>6.6%</td><td>4</td></tr>
<tr><td>HIV- women with non-ulcerative STI</td><td>8.8%</td><td>4</td></tr>
<tr><td>HIV- Women with ulcerative STI</td><td>2.3%</td><td>4</td></tr>
<tr><td>Female condom effectiveness</td><td>95%</td><td>5</td></tr>
<tr><td colspan="3">Per act HIV transmission probabilities</td></tr>
<tr><td>No STI, female to male</td><td>0.0005</td><td>5,6</td></tr>
<tr><td>No STI, male to female</td><td>0.001</td><td>5,6</td></tr>
<tr><td>Non-ulcerative STI, male to female</td><td>0.01</td><td>5,6</td></tr>
<tr><td>Ulcerative STI, male to female</td><td>0.03</td><td>5,6</td></tr>
<tr><td>Crowd out of male condom use</td><td>0–13 %</td><td>5,7</td></tr>
</table>

Cost–utility analysis (CUA): To calculate the number of HIV infections averted by the intervention they: estimated the HIV infections that would have occurred with and without FC2 products and education; took into account area male and female HIV prevalence; STI rates among sexually active heterosexual women, per sexual act transmission probabilities, and overall effectiveness of the female condom. Lacking sexual network information on all FC2 users, assumption made that all sex acts were randomly distributed among women and their sexual partners. Conservatively only modelled ‘‘first generation ’’infections and transmissions.
</td>
<td>
approximately 23 HIV infections (even with the uncertainty inherent in this estimate, this value appears to well exceed the necessary thresholds), and the intervention resulted in a substantial net cost savings.”
.
Table 2 Results of cost, threshold and cost–utility analyses
<table>
<tr><td colspan="2">CAU results</td></tr>
<tr><td>Total overall program cost</td><td>$414,186.00</td></tr>
<tr><td>Cost per FC2 used during sex</td><td>$3.19</td></tr>
<tr><td colspan="2">Threshold analysis results (necessary infections averted)</td></tr>
<tr><td>Societal perspective cost-saving threshold</td><td>1.13</td></tr>
<tr><td>Payor perspective cost-saving threshold</td><td>1.50</td></tr>
<tr><td>Societal perspective cost-effective threshold</td><td>0.46</td></tr>
<tr><td colspan="2">Estimated HIV infections averted</td></tr>
<tr><td>Female to male transmission</td><td>5.08</td></tr>
<tr><td>No STI, male to female</td><td>6.61</td></tr>
<tr><td>Non-ulcerative STI, male to female</td><td>6.54</td></tr>
<tr><td>Ulcerative STI, male to female</td><td>5.13</td></tr>
<tr><td>Total HIV infections averted</td><td>23.35</td></tr>
<tr><td colspan="2">Overall CAU result</td></tr>
<tr><td>Societal perspective</td><td>Net savings $8.160 M</td></tr>
<tr><td>Payor perspective</td><td>Net savings $6.017 M</td></tr>
<tr><td colspan="2">Impact of allowance for male condom crowd-out</td></tr>
<tr><td>Total HIV infections averted</td><td>20.32</td></tr>
<tr><td>Societal perspective cost–utility analysis</td><td>Net savings $7.046 M</td></tr>
<tr><td>Payor perspective cost–utility analysis</td><td>Net savings $5.181 M</td></tr>
</table>
</td>
<td>
mathematical model.

Modelling of only first generation transmissions builds in an inherent conservativeness to the analyses.

Analysis only considers the female condom provision and education program relative to the absence of the program. It cannot answer questions of whether female condoms are the most cost-effective possible intervention.

Limitations identified by review team
N/A

Other comments

N/A
</td>
</tr>
</table>

Kirby et al 1999

Study	Participants	Intervention / Comparison	Results	Comments
Full citation Kirby,et al 1999 **Quality score** - **Length of follow up** 24 months **Study type** Before and after study **Aim of the study** To measure the number of condoms taken and subsequent changes in knowledge behaviour and condom use following implementation of condom availability schemes in Seattle High Schools. **Location and setting** High Schools in Seattle, USA. **Source of funding** Centre for Disease Control and Prevention and the Robert Wood	**Number of participants** 1991 survey: 7,179 1993 survey: 7,893 **Inclusion criteria** All 10 high schools in Seattle. **Exclusion criteria** Not reported. **Participant characteristics** For the intervention group, participants were in grades 9-12 (aged 14-18). There was no difference in age, gender, or ethnicity between baseline and follow-up two years later. For the comparison group, data was used from nationally a representative survey that was administered at the same time. After standardisation, participants who took part in the national survey were comparable to the intervention group on age, grade level, gender, and ethnicity as well as most of the sexual and contraceptive behavioural measures. The only significant differences were that a slightly smaller proportion of the intervention group had more than 4 sexual partners in their lifetime, compared to the national sample (15% compared to 18%, *P*= 0.001) and that intervention group participants were	**Intervention:** Freely available condoms in schools via health centres and reduced cost via vending machines. **Comparison:** Pre and post intervention in Seattle, and comparison with national data sources. Intervention Condoms were made available in Seattle schools through (1)baskets of condoms located in health centres and (2) 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. These vending machines were placed in public locations-in halls outside gymnasiums and auditoriums and in lobbies, career centres, and student activity rooms. All vending	**Outcomes** Number of condoms obtained. Use of school obtained condom during sex **Results** **Number of condoms obtained:** During the first 2 years following intervention students obtained more than 50 times as many condoms from baskets as they did from vending machines (131 185 vs 2526). In the 2 schools that had both baskets of condoms and vending machines during the two year intervention period, students obtained 63 times more condoms from baskets as from vending machines at follow-up compared to baseline (17 599 vs 279). Among the schools with health centres and baskets of condoms, the number of condoms obtained during the two year intervention period varied from 6.2 condoms per student at baseline to 12.8 condoms per student by follow-up and from 16.1 condoms per sexually experienced student to 23.4 condoms per sexually experienced student at follow-up. The 2 schools with the largest mean numbers of condoms per student were also the 2 schools with the largest numbers of baskets of condoms and the only 2 schools that made condoms available in the clinic bathrooms. In contrast students in the schools that made condoms available only through vending machines obtained fewer than 0.2 condoms per student and 0.5 condoms per sexually experienced student. **School obtained condom use**	**Limitations identified by author** The primary limitation of this study is that it did not include random assignment, which might have determined whether schools made condoms available at all and whether they made them available through baskets or vending machines. **Limitations identified by review team** No power calculation reported Non randomised allocation, and

Johnson Foundation.	slightly less likely than those in the national sample to have used withdrawal during their last act of intercourse (11% vs 15%, P=.010).	machines dispensed condoms for a reduced cost of $0.25 each. Aside from cost, there were no restrictions placed on students' purchasing these condoms. Comparison Surveys were conducted at baseline and two years after the start of the intervention in all 10 Seattle high schools and compared with surveys of nationally representative samples of schools participating in the national Youth Risk Behaviour surveillance System (National results weighted to match local population).	Two years after the start of the intervention, survey results from the intervention group show that 29% of students obtained at least 1 condom at school, but only 13% of all students actually used a school-obtained condom during sex. These percentages were higher for sexually experienced students (47% and 30%, respectively). Among students who had ever used a condom from school, 62% had used 1 to 5 condoms, 18% had used 6 to 10 condoms, 8% had used 11 to 20 condoms, and 12% had used 21 or more condoms. Sexually experienced students in schools with health centres were more than twice as likely to have obtained and used a condom from school as were sexually experienced students in schools with only vending machines (42% vs 18%). Students who were more sexually active were significantly more likely than their less active counterparts to have used a condom obtained from school: Students who had begun having sex at a younger age (P = .001); who had had sex more frequently in the previous 3 months (P = .000);and who had had more sexual partners (P = .000) were all more likely to have used a school-supplied condom. Among students who had engaged in sex during the preceding 3 months, the percentage who used a condom the last time they had sex decreased from 57% to 51% among the Seattle students, while it increased from 53% to 56% among students in the national samples. These relative changes were significantly different (P=.04). Analyses by gender, age, ethnicity, or risk group revealed that compared with the changes over time in the national survey, use of condoms during the last act of sex did not increase significantly among any of these groups.	no allocation concealment. Poor reporting of outcomes. Old study. Intervention conducted prior to existence of HAART. **Other comments**

Larsson et al 2006

Study details	Population	Intervention/comparison	Results	Notes
Study Larsson et al 2006 'The Love Emergency' **Quality score** + **Length of follow up** One year **Study type** Controlled before and after study **Aim of the study** To evaluate an intervention aimed at improving knowledge of, attitudes to, and practices regarding condoms and emergency contraception among Swedish high school students. **Location and setting** Sweden High school classes in two vocational schools. **Source of funding** Uppsala County Council, the Family Planning Fund of Uppsala and the Swedish National Institute of Public Health	**Number of participants** Intervention group: 18 classes with 282 students Comparison group: 7 classes with 179 students (Sample size calculated to reflect a 10% difference between the groups at significance level $p < 0.05$ regarding knowledge of timeframes for use of emergency contraception.) **Participant characteristics** Mean age = 17.25 years, range 16-20. There was an equal gender difference, between the groups. Intervention and comparison group comparable in all demographic characteristics apart from study program with a significant majority of intervention students studying media, and comparison students study hotel & catering. Interventions and comparison groups were also comparable across all measures of relationship status, sexual experience and contraceptive experience. Three out of four 77% reported experience of sexual intercourse with over one third reporting first experience prior to age 15. The majority (76%) had used contraception, mostly condoms at first intercourse (60%). **Inclusion criteria** A strategic sample of classes of 17 year olds from two vocational high school programs was divided into an intervention group and a comparison group.	**Intervention:** Multicomponent sex education in schools, named 'The Love Emergency' **Comparison:** No intervention. Intervention delivered over 1 year and comprising of 4 strategies: 1. A face-to-face 20 minute group lesson on emergency contraception from an experienced midwife (details of experience or relevant training not reported). Size of group also not reported. 2. Three lessons (face-to-face) by a male and a female medical student (who had completed a national training program on the intervention) 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, consisting of 50 multiple choice questions based on previous studies. The content of the questionnaire was a mixture of demographic info, sexual behaviour, condom use and emergency contraceptive	**Outcomes** Condom use, Intent to use emergency contraception (ECP). Knowledge of ECP. Attitudes to condoms and ECP. Intentions to use, discuss or buy condoms. Use of ECP, and recommend ECP. Of the 461 eligible students, mean age 17 years, 390 (85%) completed the pre-test and 326 (71%) the post-test. **Results** Measurements taken directly before and after 1 year-long intervention. When compared to the control group, the intervention group had significant improvements over time in relation to: Ever used a condom: % increase over time (IG 19% v CG 0%, *P*= 0.01) Knowledge of effectiveness of ECP day 3: % increase over time (IG 32% v CG 1%, *P*= < 0.01) Could imagine buying condoms : % increase over time (IG 11% v CG 0%, p= 0.03). There were no significant	**Limitations identified by author** Of the 461 eligible students 390 (85%) completed the pre-test and 326 (71%) the post-test Lack of randomisation. **Limitations identified by review team** Schools were not randomly selected, authors identified sites based on logistical reasons **Other comments**

	Exclusion criteria Not reported	pill. Also within the questionnaire was a validated instrument to measure sense of coherence (Anonovsky Orientation to Life Questionnaire, short form (SOC-13)).	differences between the two groups on any other measures. More than one out of four studies (28%) had opted for free condoms during intervention.	

Neumann et al 2011

Study details	Population	Intervention/comparison	Results	Notes
Full citation Neumann et al 2011 VOICES/VOCES study **Quality score** **-** **Length of follow up** Average of 17 months **Study type** Non-randomised controlled trial **Aim of the study** To assess the effectiveness of the VOCES/VOICES video intervention when compared with usual care (regular clinic services). **Location and setting** Two STD clinic settings in New York, USA and San Juan, Puerto Rico **Source of funding**	**Number of participants** N=3365 (New York n = 1771; Puerto Rico n = 1594) Intervention, n =1685; Comparison, n =1680; (99.7% acceptance rate). (Basing calculations on a previous trial, authors estimated needing 4000 participants to detect study-related differences in incident STDs in either condition. This sample size assumed a relative risk of 0.88 (5% of comparison and 22% of intervention participants developing incident STDs during follow-up), with power of 0.8 to detect differences at significance level of 0.05.) **Inclusion criteria** STD clinic patients aged 18 and older were recruited to either the intervention or control group , whilst in the waiting area in both sites. **Exclusion criteria** Not reported. **Participant characteristics** The sample was almost evenly split between groups (intervention, n =1771, 52.0%; comparison, n = 1594, 48.0%), and by gender (female, 51.5%; male, 48.5%). There is a significant site-by gender difference; 52.6% of participants in intervention were	**Intervention:** VOICES/VOCES video intervention **Comparison:** Usual care (regular clinic services). Intervention The study examined the "Video Opportunities for Innovative Condom Education and Safer Sex" (VOICES/ VOCES) intervention. VOICES/VOCES is a 45-minute intervention intended to increase STD knowledge, proper condom use, and condom negotiation skills. A facilitator delivers the intervention in a private room to 4 to 8 participants, who, preferably, are of the same sex and same race or ethnicity. Information on STD/HIV risk behaviours and condom use is delivered by culturally specific videos, group discussion, and a poster of various condom brands' features. Participants' roleplay condom negotiation modelled in the videos and choose free sample condoms. At each of the two intervention sites, health department staff and health educators attended 2-days training conducted by the intervention developers that followed CDC's training protocol. Alternating 4-week blocks were systematically assigned to intervention) and comparison conditions for approximately 22 months at each site. STD clinic patients aged 18 and older were recruited individually in the waiting area. After providing written consent, they went to a private room to complete a patient profile,	**Outcomes** Incident STDs (clinic staff maintained an onsite tracking database) Knowledge and attitudes about HIV/STD and condom use (questionnaire) Condom acquisition.(Researchers collected coupons from redemption sites) **Results** A total of 3365 patients were recruited, completed the protocol, and followed through STD surveillance systems for an average of 17 months. Of 397 with an incident infection, 226 (13.4%) were among those enrolled during comparison blocks; 171 were among those in the intervention condition (10.2%). Intervention group participants had significantly fewer incident STIs at follow-up than the comparison group (HR, 0.63; 95% CI, 0.49–0.81; P = 0.001). When compared to the comparison group - intervention participants had significantly improved scores on : STD 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). In an analysis of variance controlling for site and gender, females receiving the intervention	**Limitations identified by author** Fidelity of intervention may have increased the positive impact of the intervention in NY as opposed to PR.(e.g. Intervention providers in PR appeared to deviate from the CDC protocol). **Limitations identified by review team** Sample not randomised and therefore open to bias. Allocation not adequately concealed. High likelihood of contamination between intervention and control groups. **Other comments**

Centers for Disease Control and Prevention	male, compared to 43.9% in comparison (2 analysis, P <0.001). Across sites, participants' mean age was 29.3 years (range, 18–71), 22.2% had an STD diagnosed during the enrolment visit, 49.6% reported a prior STD, and 7.9% reported same sex behaviour. Study conditions at each site were similar, but combining them shows a few differences: participants' mean age (intervention, 29.5 years; comparison, 29.1, P <0.21), married or main partner status (intervention, 33.8%; comparison, 37.6%, P 0.001), STD at enrolment (intervention, 19.6%; comparison, 24.8%, P <0.001), reported prior STD (intervention, 55.1%; comparison, 44.1%, P <0.001), and reported same gender sex (intervention, 8.7%; comparison, 7.1%, P <0.05). Because there were significant differences in participant characteristics by condition, separate Cox regression analyses were conducted by site for intervention and control groups controlling simultaneously for reported prior STD, STD at enrolment, marital status, and same sex behaviour in the previous year.	and intervention block patients participated in a VOICES/VOCES session. While still in the room, all participants completed a survey assessing STD/HIV-related knowledge and attitudes; chose sample condoms; and received a coupon for 3 condoms redeemable at a local business. Participants received an incentive worth about $7. Participation required 20 to 70 minutes, depending on condition, after which patients returned to the waiting area for their clinic appointment.	scored significantly higher on the STD knowledge scale (4.54 vs. 4.18, P<0.001) and the knowledge, attitude, and self-efficacy scale (10.60 vs. 9.56, P<0.001). Positive effects were more consistent in New York compared to Puerto Rico, which may be related to fidelity of implementation.	

Oakeshott et al 2000

<table>
<tr><th>Study details</th><th>Participants</th><th>Intervention/Comparison</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Full citation
Oakeshott,et al 2000

Quality score
++

Length of follow up
1-3 months

Study type
cluster RCT

Aim of the study
To see if a practice-based sexual health education intervention increases the number of women having smears who are given condoms and advice on avoiding STDs. To see if this low cost intervention affects subsequent condom use.

Location and setting
GP practices in South London, UK

Source of funding
This study was funded by the South Thames Project Grant Scheme with</td>
<td>Number of participants
A total of 1382 women aged 16–34 years (mean age 27 years) were recruited between May 1994 and October 1995. Of these, 1056 women (76%) returned postal questionnaires (intervention n = 490; control n = 566)

Participant characteristics
80% of responders were white, 8% Afro-Caribbean, 5% Black African, 3% Indian subcontinent and 4% other ethnic groups. This is similar to the local ethnic profile in the 1991 census. Response rates, ages, prior condom use (16% always, 11% usually, 29% sometimes, 44% never) and numbers of sexual partners in the previous year (6% none, 73% one, 14% two, 7% more than two) were similar in intervention and control groups.

However, fewer women in intervention than control practices considered themselves to be of Afro-Caribbean or black African ethnic origin: 10%</td>
<td>Intervention:
GP based sexual health education intervention
Comparison:
No intervention

One practice from each matched pair was randomly allocated to receive the intervention.

All practices were asked to recruit 50 consecutive women aged <35 years attending for a cervical smear, test them for chlamydia and take consent to complete a postal questionnaire on sexual health. The questionnaire was sent to all participants 1–3 months after their smear test (whether they received the intervention or not). .

Intervention

Practice nurses and GPs in 28 intervention 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.) Regular supplies of leaflets</td>
<td>Outcomes
Given condom and STI advice
Condom use

At 1-3 month follow-up, more women in intervention than control practices reported receiving advice on avoiding sexually transmitted infections in their postal questionnaires (27% versus 10%) and being given condoms (28% versus 1%, P < 0.05). However, there was no difference in subsequent condom use, even in the 22% of women reporting >=2 sexual partners in the previous year
<table>
<tr><th></th><th>Intervention practices n=14 (% of women)</th><th>Control practices n=14 (% of women)</th><th>Difference in % ages[a] (95% CI)</th></tr>
<tr><td colspan="4">Advised about avoiding STDs</td></tr>
<tr><td>All women n = 1056</td><td>27</td><td>10</td><td>16* (3 to 29)</td></tr>
<tr><td>Women with >2 partners n = 227</td><td>34</td><td>18</td><td>16 (–1 to 34)</td></tr>
<tr><td colspan="4">Given condoms</td></tr>
<tr><td>All women n = 1050</td><td>28</td><td>1</td><td>24** (8 to 40)</td></tr>
<tr><td>Women with >2 partners n = 225</td><td>39</td><td>5</td><td>28* (6 to 48)</td></tr>
<tr><td colspan="4">Used condoms more since smear test</td></tr>
<tr><td>All women n = 873</td><td>8</td><td>6</td><td>2 (–1 to 6)</td></tr>
<tr><td>Women with >2 partners n = 191</td><td>15</td><td>14</td><td>–1 (–10 to 8)</td></tr>
<tr><td colspan="4">Used condoms at last sexual intercourse</td></tr>
<tr><td>All women n = 988</td><td>27</td><td>18</td><td>–2 (–8 to 5)</td></tr>
<tr><td>Women with >2 partners n = 221</td><td>37</td><td>37</td><td>–2 (–21 to 18)</td></tr>
</table>
* P , 0.05; **P , 0.01. a Figures are estimated differences in percentages from analysis of variance to allow for paired analysis where percentage per practice</td>
<td>Limitations identified by author

Self-reported data may mean problems of reliability and recall.

Small sample size.

The study only included women attending for cervical smears.

Limitations identified by review team
Cluster randomisation may cause a systematic bias by practice.

Allocation was not adequately concealed.

Other comments

Women in the UK start having smears at age 25. Study population age</td>
</tr>
</table>

additional support from the South London Faculty of the RCGP.	(49/491) versus 15% (85/561) P < 0.01. 28 out of 33 practices agreed to participate. Practices were put into matched pairs on the basis of number of principals (<=2/>2), Jarman underprivileged area rating (>=25/>25) and cervical smear target reached (<80%/>=80%). **Inclusion criteria** Women under 35 who attended 28 south London GP practices for cervical smear tests. **Exclusion criteria** Not reported	and condoms were provided for the duration of the study. The authors do not give specific details on the advice component of the intervention, such as timing and opportunities for questions. The practice nurses and GPs received 10 minutes practice-based teaching on condom promotion in women. Comparison Postal questionnaire only with no leaflet or GP/practice nurse education.	is weighted for number of patients sampled. Observed intra-cluster correlation coefficient for condom use at last sexual intercourse = 0.0002. The sample size of 1056 subjects (equivalent sample 1037) would have allowed us to detect an increase of 8% in the percentage of patients whose partner used a condom at the last sexual intercourse (i.e. from 28% in the control group to 36% in the intervention group) with power 80% and 5% significance level.	ranged between 16-34. The authors do not discuss this further. It is possible that few participants were aged below 25 , and it could be that this age group are at a higher risk of STDs.

Rietmeijer et al 1996

Study	Participants	Intervention/Comparison	Results	Comments
Full citation Rietmeijer et al 1996 **Quality score** - **Length of follow up** Unclear – approximately 30 months **Study type** Quasi experimental **Aim of the study** To evaluate the impact of an HIV risk reduction programme among injecting drug users (IDU) **Location and setting** Denver, Colorado (CO), USA **Source of funding** Centres for Disease Control and Prevention Cooperative Agreement	**Number of participants** A total of 13,145 individuals were approached in neighbourhoods with high injecting drug user (IDU) prevalence in Denver . 2,599 met the eligibility criteria and consented to the full interview. After removal of duplicates and sex-workers 1,997 interviews were analysed. Intervention: N=809 Comparison: N=1107 The comparison group were from Long Beach. This group had acted as an intervention control in a previous evaluation of a similar intervention. This was a post-hoc choice of comparison groups due to contamination of original comparison group. Condom use was evaluated separately and limited to the 978 respondents who reported vaginal sex with occasional partners and the 1,120 respondents who reported vaginal sex with regular partners. **Inclusion criteria** IDUs who had injected drugs in the previous 30 days who had injected drugs in the previous 30 days (to evaluate bleach use) or had sex in the previous 30 days (to evaluate condom use) **Exclusion criteria** Sex workers	**Intervention:** Peer delivered deliver education, condoms and bleach bottles. **Comparison:** No intervention Intervention Small media materials that included role model stories were 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 and condoms. Interactions between peer volunteers involved using small media to model behaviours appropriate to the stage of change of the participant. However the details of the intervention were not reported in details. Questionnaires were administered in both the intervention and comparison site in 10 3-month waves (3 pre intervention, 7 post intervention. The first wave was a pilot and not included in the analysis). Ii is not reported whether the questionnaire was validated. Comparison A non-intervention area in Long Beach.	**Outcomes** Use of condoms for vaginal intercourse with occasional partners. Use of condoms for intercourse with regular partners. **Results** The follow-up period is not clearly reported but may have been approximately 30 months. When compared with the comparison site, subjects 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 difference in effect was seen for steady partners.	**Limitations identified by author** External factors, demographic changes, transient populations, sampling bias, social desirability bias. **Limitations identified by review team** No power calculation reported. Non-matched comparison group. Comparison group from Long Beach chosen by authors when it became apparent that original comparison group had been contaminated. Unclear follow up. Old study with data collection preceding introduction of HAART. **Other comments** Another outcome

	Participant characteristics Significant differences existed in demographic composition between intervention and comparison sites for sex, ethnicity, age and self-reported HIV status. Additionally, significant changes occurred over time in the intervention area for sex and ethnicity.			measured in the survey was whether participants cleaned needles with bleach before sharing.

Rhodes et al 2009

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention/comparison</th><th>Results</th><th>Notes</th></tr>
<tr>
<td>Full citation
Rhodes et al 2009

(*Additional data from process evaluation. Rhodes et al 2012)

Quality score
+

Length of follow up
18 months

Study type
Controlled before and after

Aim of the study
To increase condom use and HIV testing among Latino men.

Location and setting
USA
North Carolina soccer league teams.

Source of funding
This study was supported under a cooperative agreement from the CDC through the Association for Prevention Teaching and Research.</td>
<td>Number of participants
30 local soccer teams in North Carolina were selected for intervention teams (n=15) and control teams (n=15). Total number of participants was 222.

Teammates nominated and elected one member to be trained as a lay health advisor (LHA) per intervention team..

Details of training provided and by whom are not reported.

Inclusion criteria
Membership of a rural Latino soccer league.

Exclusion criteria
Not reported

Participant characteristics
There were no significant statistical differences between the groups on sociodemographic characteristics (p>0.05 for each).

Of the 222 participants, mean age was 29.8 (±8.3; range 18–71) years.
Men reported being originally from:
Mexico 60.8% (n=135)
El Salvador 14.0% (n=31)
Guatemala 6.8% (n=15)
Honduras 5.9% (n=13)
Colombia 1.8% (n=4)</td>
<td>Intervention:
Identified individuals were trained as lay health advisor and tasked with delivering intervention

During a four-session, 16-hour LHA training, the 15 LHA were trained to:

1) act as health advisors for team mates and make referrals to increase knowledge about HIV and STDs and testing and increase condom use skills; 2) act as opinion leaders to bolster positive and reframe negative socio-cultural expectations about what it means to be a man ; 3) act as community advocates to work towards environmental change.

LHA's reported that the most common activity they undertook was condom distribution (Rhodes et al 2012).

The 15 LHA worked with their teammates for 18 months. Data were collected at baseline and 18-month post-LHA training from a random sample of teammates</td>
<td>Outcomes:
Consistent condom use in past 30 days
HIV testing
High knowledge of HIV transmission and prevention
High self-efficacy for condom use
High adherence to traditional masculine norms
High sense of mastery over circumstances

The follow up assessment contained 192 items with predefined response categories. The assessment administered by a male native Spanish-speaking staff member, who was involved in the training of the LHA but not in intervention delivery. The assessment took 45 to 120 minutes to complete.

Participation in the intervention was associated with statistically significant improvements on condom used, HIV testing, knowledge of HIV, and self-efficacy to use condoms at 18 months. There was no difference between groups on adherence to traditional masculine norms, or sense of mastery over circumstances at 18 months.
<table>
<tr><th>Outcome</th><th>Intervention</th><th>Control</th><th>OR (95% CI)</th><th>P</th></tr>
<tr><td>Consistent condom use, past 30 days</td><td>65.6%</td><td>41.3%</td><td>2.3 (1.2–4.3)</td><td>0.01</td></tr>
<tr><td>HIV testing</td><td>64.4%</td><td>41.8%</td><td>2.5 (1.5–4.3)</td><td>0.001</td></tr>
<tr><td>High knowledge of HIV transmission and prevention</td><td>74.1%</td><td>43.5%</td><td>1.7 (1.4–2.1)</td><td>0.001</td></tr>
</table>
</td>
<td>Limitations identified by author
None reported

Limitations identified by review team
No randomisation.

No power calculation reported

No details given of who provided the training of LHAs and no assessment of how adequately they were trained. Fidelity of intervention therefore unclear.

No data given on questionnaire completion or drop out rates.

Possibility of contamination between intervention and control groups as LHAs provided intervention beyond football teams which could included members of comparison teams</td>
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<td></td>
<td>Other areas 6.4% (n=14).

Over half of all participants (n=117) reported educational attainment of 8 years or fewer; and over half reported being accompanied (n=118). Mean length of time in the US was 8.8 (±7.6) years; 70.4% (n=150) reported year-round employment; and 69.1% (n=143) reported estimated annual salaries $21,999 or below. All self-identified as heterosexual; six reported having had sex with men within past year.</td>
<td>from the intervention and control teams.

Comparison:
Waiting list control. Comparison group offered intervention post collection of follow-up data.</td>
<td>
<table>
<tr><td>High self-efficacy to use condoms</td><td>55.6%</td><td>38.2%</td><td>1.6 (1.1–2.6)</td><td>.01</td></tr>
<tr><td>High adherence to masculine norms</td><td>45.9%</td><td>41.6%</td><td>1.2 (0.6–2.0) .6</td><td>0 .6</td></tr>
<tr><td>High sense of mastery over circumstances</td><td>67.4%</td><td>61.1%</td><td>1.3 (0.8–1.9)</td><td>0.7</td></tr>
</table>

The process evaluation (Rhodes et al 2101) reported that:

The LHA reported conducting 2,364 activities, for a mean of 8.8 activities per LHA per month(half were conducted with soccer teammates and half with non-teammates within their social circle).

The most common activity was condom distribution comprising almost half of all activities (n=52% of activities with teammates).

Most activities were conducted with men; about 2% were conducted with women.
</td>
<td>Other comments

Specific to a USA migrant group that may not be culturally applicable to the UK.</td>
</tr>
</table>

Ross et al 2004

<table>
<tr><th>Study details</th><th>Participants</th><th>Intervention/Comparison</th><th>Results</th><th></th></tr>
<tr>
<td>Study
Ross et al 2004

Quality score
-

Length of follow up
2 years

Study type
Controlled trial

Aim of the study
To investigate the impact of a small media campaign to reduce syphilis through testing, treatment, and condom use in two urban predominantly African-American communities with high syphilis rates.

Location and setting
Communities with high rates of syphilis in</td>
<td>Number of participants
In early 1998 (pre-intervention), 808 street intercept interviews were conducted in each of the two areas. Intervention n=419, Control n= 38.
In 2000 (post intervention), 822 interviews were conducted. Intervention n=422, Control n=400.

The interview instrument was developed from the initial interviews and piloted on a sample of 10 in the intervention community. Interviews were conducted by an outreach worker from the community based partner located in the intervention community. Respondents who were >18 years old were approached in a variety of locations, including parking lots or sidewalks outside local businesses, bus stops, drug corners, and front yards. A seven page semistructured survey instrument was used to elicit information about sociodemographic characteristics, knowledge of syphilis, perceptions of disease severity, exposure to messages about syphilis, awareness of local screening and treatment services, sexual behaviour (including last sexual encounter), and drug use.

Participant characteristics
<table>
<tr><th>Sociodemographic and sexual variables</th><th colspan="2">Baseline (n = 808)</th><th colspan="2">Post-intervention (n = 822)</th></tr>
<tr><td></td><td>Intervention (n = 419)</td><td>Control (n = 389)</td><td>Intervention (n = 422)</td><td>Control (n = 400)</td></tr>
<tr><td>Male</td><td>239 (57%)</td><td>219 (56%)</td><td>286 (68%)</td><td>242 (61%)</td></tr>
<tr><td>African-American</td><td>357 (85%)</td><td>355 (91%)</td><td>408 (97%)</td><td>373 (93%)</td></tr>
<tr><td>White</td><td>32 (8%)</td><td>15 (4%)</td><td>2 (0.5%)</td><td>2 (0.5%)</td></tr>
<tr><td>Employed</td><td>244 (58%)</td><td>233 (60%)</td><td>224 (53%)</td><td>230 (58%)</td></tr>
<tr><td>Full time jobs</td><td>181 (75%)</td><td>163</td><td>168 (75%)</td><td>186</td></tr>
</table>
</td>
<td>Intervention: Small media campaign and condom distribution through community businesses.

Comparison: Provision of condoms only to businesses, using a different project name and logo.

Extensive formative research involving communities to develop intervention. The Intervention included dual components:

1) Role model stories in small media (brochures, posters, coasters, matchbooks, t-shirts, videos and billboards) were made available through community businesses.

2) Condom distribution

Initially, 30 Community businesses were recruited. 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</td>
<td>Outcomes:
Condom use
Knowledge of syphilis
Sexual behaviours

Results
The authors report that when comparing interventions and comparison areas, the interventions areas had significant increases in condom use in last sexual act, and some aspects of knowledge of syphilis. No data are reported to support these findings.

There was a significantly high level of cross contamination between the intervention and control areas. In the intervention area, an average of 2.99 (SD 3.74) products were seen by 70.8% of the sample, while in the comparison area 2.04 (3.00) products were seen by 64.5% of the sample (both p=0.05).

The authors conducted a post-hoc analysis which combined data from intervention and comparison areas. This was then analysed</td>
<td>Limitations identified by authors
There was significant cross contamination of media impact, with respondents in the comparison area seeing an average of two media items compared with three in the intervention area.

Limitations identified by review team
No power calculation reported

Significant contamination.

No randomisation and no allocation concealment..

Due to a high level of contamination. Authors presented majority of results as a comparison of those people who saw small media and those who did not, as opposed to intervention v comparison areas..</td>
</tr>
</table>

<table>
<tr>
<td>Houston/Harris County, US.

Source of funding
Centers for Disease Control and Prevention</td>
<td>
<table>
<tr><td></td><td></td><td>(71%)</td><td></td><td>(81%)</td></tr>
<tr><td>Lives with sex partner</td><td>123 (29%)</td><td>138 (36%)</td><td>130 (31%)</td><td>160 (40%)</td></tr>
<tr><td>Marital status– single</td><td>255 (61%)</td><td>215 (56%)</td><td>245 (58%)</td><td>214 (54%)</td></tr>
<tr><td>Number of sex partners in last 4 weeks</td><td>2.67</td><td>2.39</td><td>0.79</td><td>0.91</td></tr>
<tr><td>Times had sex in last 4 weeks</td><td>15.84</td><td>13.83</td><td>8.12</td><td>9.22</td></tr>
<tr><td>Number of those times used condoms</td><td>5.76</td><td>5.15</td><td>3.18</td><td>2.67</td></tr>
<tr><td>Proportion of times used condoms</td><td>0.42</td><td>0.40</td><td>0.44</td><td>0.38</td></tr>
</table>
Inclusion criteria
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).
Individual participants were street intercepts.

Exclusion criteria
Under 18 years old.
</td>
<td>them. Most residents of the community were no more than four blocks from a community business partner.

After 6 months, an additional 20 businesses approached the project staff and requested to be part of the project, and by the end of the intervention, there were 50 community business partners in the intervention area. (Ten businesses dropped out or were removed from the partners list for various reason) .
.
Comparison:
Matched areas without small media campaign or associated condom distribution.</td>
<td>according to media exposure (those who did and did not report seeing any media products as a measure of exposure response).

Media exposure was associated with significant increases in knowledge of syphilis, testing, and condom use.</td>
<td>The study began in in 1998 prior to the wide spread introduction of HAART.

Other comments</td>
</tr>
</table>

Schuster et al 1998

<table>
<tr><th>Study details</th><th>Participants</th><th>Intervention/Comparison</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Study
Schuster,et al1998

Quality score
+

Length of follow up
One year.

Study type
Single group before and after study

Aim of the study
To examine the effectiveness of a school based condom distribution scheme and its effects on student sexual behaviour.

Location and setting
A high school in Los Angeles county, USA

Source of funding
Agency for Health Care Policy and Research, Rockville, MD the American Foundation for AIDS Research, Los Angeles; the Brotman Foundation of California, Encino, CA; the California Wellness Foundation, Woodland Hills, CA; and the Robert Wood Johnson Clinical Scholars Program, Los</td>
<td>Number of participants
Prior to intervention n = 1,946 (98% of eligible students)
Post intervention n = 1,100 (59% of eligible students)

Participant characteristics
<table>
<tr><th>Characteristic</th><th>Baseline</th><th colspan="2">Follow-up</th></tr>
<tr><td></td><td>(N=1,945)</td><td>Unweighted (N=1,112)</td><td>Weighted (N=1,112)</td></tr>
<tr><td>Sex</td><td></td><td></td><td></td></tr>
<tr><td>Male</td><td>52</td><td>50</td><td>52</td></tr>
<tr><td>Female</td><td>48</td><td>50</td><td>48</td></tr>
<tr><td>Grade</td><td></td><td></td><td></td></tr>
<tr><td>9</td><td>25</td><td>24</td><td>25</td></tr>
<tr><td>10</td><td>27</td><td>28</td><td>27</td></tr>
<tr><td>11</td><td>26</td><td>28 2</td><td>5</td></tr>
<tr><td>12</td><td>22</td><td>21</td><td>23</td></tr>
<tr><td>Race/ethnicity</td><td></td><td></td><td></td></tr>
<tr><td>White</td><td>48</td><td>55</td><td>48</td></tr>
<tr><td>Black</td><td>9</td><td>6</td><td>8</td></tr>
<tr><td>Hispanic</td><td>27</td><td>22</td><td>27</td></tr>
<tr><td>Asian/Pacific islander</td><td>10</td><td>13</td><td>10</td></tr>
<tr><td>Other</td><td>6</td><td>4</td><td>7</td></tr>
<tr><td>No. of parents who completed college</td><td></td><td></td><td></td></tr>
<tr><td>Neither</td><td>44</td><td>39</td><td>45</td></tr>
<tr><td>≥1</td><td>56</td><td>61</td><td>55</td></tr>
<tr><td>Educational expectations</td><td></td><td></td><td></td></tr>
<tr><td>No college</td><td>18</td><td>13</td><td>18</td></tr>
<tr><td>College</td><td>33</td><td>32</td><td>31</td></tr>
<tr><td>Graduate/prof. school</td><td>49</td><td>55</td><td>51</td></tr>
<tr><td>Primary language spoken at home</td><td></td><td></td><td></td></tr>
<tr><td>English</td><td>71</td><td>74</td><td>71</td></tr>
<tr><td>Other</td><td>29</td><td>26</td><td>29</td></tr>
<tr><td>Household composition</td><td></td><td></td><td></td></tr>
<tr><td>Two parents</td><td>47</td><td>49</td><td>47</td></tr>
</table>
</td>
<td>Intervention: Condom availability and message

Comparison: Same group are assessed before and after the intervention..

Intervention
The program consisted of making available to students 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.”

Packets were 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. A can was placed next to each basket with a sign requesting that students leave 25 cents for each packet they took. Implementation of the program was publicized within</td>
<td>Outcomes:
At 12 months post intervention
N of students having intercourse
Condom use every intercourse
Intention to use condoms

Prior to implementation of the intervention 1,945 students in grades 9–12 (98% of eligible students) completed a self-administered anonymous survey on their sexual behavior and on related knowledge and attitudes; one year later, 1,110 students (59% of eligible students) completed a follow-up survey.
Results
One year after the start of the intervention compared to baseline, there was no significant change in the percentage of males or females who had ever had vaginal intercourse (baseline vs follow-up: male 56% vs55%; female 45% vs 46%) or who had had vaginal intercourse during that year (baseline vs follow-up: male 51% vs 52%; female 42% vs 44%) . Individual p values not reported.

The percentage of males who reported using condoms every time they engaged in</td>
<td>Limitations identified by author
No randomisation.
No control group.
Self-report data.

Limitations identified by review team
The authors report a controversy regarding consent and parents at the time of the second data collection and speculate that this may be the cause of the sudden decline in respondents compared to the first (high response) data collection phase.

No power calculation reported

Dropout rates not reported.

Other comments</td>
</tr>
</table>

Angeles.	<table><tr><td>Other</td><td>53</td><td>51</td><td>53</td></tr><tr><td>Total</td><td>100</td><td>100</td><td>100</td></tr></table> **Inclusion criteria** Students in Grades 9 - 12 (UK school years 9-13, ages 14-18) **Exclusion criteria** Students enrolled in English-as-a-second-language classes (about 16% of the school population) and students in intensive special education classes were excluded from the study, at the request of the principal.	the school. Comparison Data were collected from the same group after the intervention. The interview instrument was developed from the initial interviews and piloted on a sample of 10 in the intervention community. Interviews were conducted by an outreach worker from the community based partner located in the intervention community. Respondents who were >18 years old were approached in a variety of locations, including parking lots or sidewalks outside local businesses, bus stops, drug corners, and front yards. We used a seven page semistructured survey instrument to elicit information about sociodemographic characteristics, knowledge of syphilis, perceptions of disease severity, exposure to messages about syphilis, awareness of local screening and treatment services, sexual behaviour (including last sexual encounter), and drug use. The authors do not report whether this was a validated survey tool.	vaginal intercourse during the past year increased 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). On the other hand, female respondents showed no significant change in their condom use, from 27% at baseline to 32% at one year follow-up (p value not reported). The self-reported likelihood of using a condom for vaginal intercourse during the following year did not change significantly for students who had had vaginal intercourse, but it increased dramatically for those who had never had vaginal intercourse. There was a dramatic increase in anticipated condom use among students of both sexes who had never had vaginal intercourse—from 62% at baseline to 90% at follow-up among males, and from 73% to 94% among females (p<.001 for both). At both baseline and one year follow-up survey points, 10–13% of students responded that they definitely would not have vaginal intercourse during the following year.	

Senn 2011

Study details	Participants	Intervention/Comparison	Results	Comments
Study Senn et al 2011 **Quality score** + **Length of follow up** Not reported **Study type** RCT **Aim of the study** To investigate the potential benefits of a motivational brief intervention (BI) and the provision of condoms on the engagement in unprotected casual sex by people who are travelling. **Location and setting** Travel clinic, Lausanne, Switzerland **Source of funding** Loterie Romande, Switzerland	**Number of participants** 5148 eligible travellers were attending a hospital travel clinic from 2006 to 2008. 1681 agreed to participate and were randomly assigned to one of 3 arms of the trial. 1115 subjects (66%) completed the study. Intervention 1 - brief intervention group: n=596 Intervention 2 – condom provision group: n= 359 Control group: n=729 **Participant characteristics** Travellers aged 18-44 years without their regular sexual partner. . The mean age was 29. Baseline characteristics reported as similar across the 3 groups.	**Intervention 1**: Standard pre-travel consultation plus provision of free condoms. **Intervention 2:** Standard pre-travel consultation, plus motivational brief intervention (BI) and provision of free condoms. **Comparison:** Standard pre-travel consultation Eligible visitors to the clinic were asked if they were willing to participate in a study investigating the risk of STIs abroad. If they agreed, they had to fill a pre-travel questionnaire on their life habits at home and previous trips abroad. They were informed that they would receive a post-travel postal questionnaire. Then, they were randomly assigned to one of the 3 arms of the study: 1. Standard pre-travel consultation plus provision of 3 free condoms 2. Standard pre-travel consultation, motivational interview and provision of 3 free condoms. 3. Standard pre-travel consultation Two weeks following their return from travel, the post-travel questionnaire was sent to them.	**Outcomes:** Consistent condom use There was no significant difference in the prevalence of subjects using condoms inconsistently when the 3 groups were compared. 28% (95%CI=16-40) in the motivational BI group 24% (95%CI=10-37) in the condoms group 24% (95%CI=14-33) in the control group (p = 0.42).	**Limitations identified by author** Small sample size Significant refusal rate of MI. **Limitations identified by review team** Number randomised to condoms group only 50% size of other groups. Non- random allocation and allocation not concealed. Sample size calculations imply that the sample is too small to detect significance (authors abandoned recruitment following an ad hoc futility analysis). **Other comments**

Weatherburn et al 1998

<table>
<tr><th>Study details</th><th>Participants</th><th>Intervention/Comparison</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Study
Weatherburn,et al 1998

'Rubberstuffers'
Quality score
+

Length of follow up
One year

Study type
Before and after

Aim of the study
To evaluate the impact of the Rubberstuffers pilot free condom distribution scheme in commercial gay venues.

Location and setting
Commercial gay venues, Central London, UK

Source of funding
SIGMA Research were commissioned by ILHHCG (Inner London HIV Health Commissioners Group) to evaluate the Pan London</td>
<td>Number of participants:

8 central London commercial gay venues (bars/cafes). One venue withdrew so data were only included for 7 venues.
N=1,055 completed and usable questionnaires.
Before: 431 questionnaires from 18 different gay venues.
After: 624 questionnaires from 16 gay venues.

These venues were already distributing paid for condoms supplied by Rubberstuffers on request from behind the bar.

Participant characteristics
Impact on gay mens access to and use of condoms
Interviewees were comparable between the two different waves of condom distribution

<table>
<tr><th></th><th>Before</th><th>After</th></tr>
<tr><td>Age</td><td></td><td></td></tr>
<tr><td>Median</td><td>30</td><td>30</td></tr>
<tr><td>IQR</td><td>27-36</td><td>25-35</td></tr>
<tr><td>Mean</td><td>31.9</td><td>31.1</td></tr>
<tr><td>Range</td><td>17-63</td><td>17-88</td></tr>
<tr><td>Ethnicity/nationality</td><td></td><td></td></tr>
<tr><td>White</td><td>90.2%</td><td>94%</td></tr>
<tr><td>Black</td><td>2.1%</td><td>1.6%</td></tr>
<tr><td>Black British</td><td>2.1%</td><td>0.8%</td></tr>
<tr><td>Jewish</td><td>1.5%</td><td>0%</td></tr>
</table>
</td>
<td>Intervention: Various approaches to making free condoms available in gay venues.
Control: Pre-intervention when condoms were available from behind the bar on request and were charged for.

Prior to introduction of the free condom intervention, baseline figures were collected over a series of 4 week periods, from the 8 venues.
After implementation of the intervention, bars freely distributed condoms in 4 ways over different periods of time: 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</td>
<td>Outcomes :
Condom distribution by method.
Access to and use of condoms.

Monitoring condom distribution by method
Numbers of condoms taken were monitored by venue staff at each venue and each method of distribution.
Week averages and percentage change from the 'Behind the Bar' baseline.
<table>
<tr><th></th><th>Behind bar</th><th>On bar</th><th>%</th><th>Rack</th><th>%</th><th>Toilet</th><th>%</th></tr>
<tr><td>Total packs</td><td>4200</td><td>6760</td><td>+78</td><td>6500</td><td>+81</td><td>8680</td><td>+171</td></tr>
</table>
Most venues reported a preference for offering a mixture of these methods. The largest number of condoms distributed was from those made available via dispensers in the toilet areas (not necessarily in sight of anyone else) .

Impact on gay mens access to and use of condoms
Possession of condoms at time of interview: Post-intervention respondents were significantly more likely to have condoms at home (83% vs 72.9%, $\chi^2 = 15.78$, $p<0.0001$. This significant rise is attributable to the intervention. The proportion that had Rubberstuffers packs rose from 41.3% to 61.9% ($\chi^2 = 43.31$, $p<0.0001$) while the proportion with condoms from other sources had fallen slightly (not significant). Men were also more likely to be carrying condoms at the time they completed the questionnaire. There was a significant increase in the number of men carrying condoms whilst out tin gay venues (from 21.6% to 2.7%).*
Purchase of condoms: There was no significant difference in the overall proportion of men purchasing condoms from shops and gay venues. However the number of condoms purchased decreased 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).
Free condoms: Pre- and post-intervention more than 3/4 of respondents had received free condoms in the previous 6 months, however the proportion rose significantly ($\chi^2 = 7.622$, $p< 0.01$) from</td>
<td>Limitations identified by author
None reported

Limitations identified by review team

No power calculation conducted.

Questionnaire data collected very intensively so may represent a 'snapshot' .

Central London has a very specific gay subculture and may not be comparable to other areas of the UK.

Other comments
This was a multi-component evaluation of the rubberstuffers scheme.

Two components are reported in this evidence</td>
</tr>
</table>

<table>
<tr>
<td>Free Condom Distribution Scheme. RS Health (a non-profit making HIV prevention charity also known as Rubberstuffers) were contracted by ILHHCG to provide and implement the scheme.</td>
<td>
<table>
<tr><td>Mixed race</td><td>4.1%</td><td>3.6%</td></tr>
<tr><td>British</td><td>58.2%</td><td>57.1 %</td></tr>
<tr><td>European</td><td>20.7%</td><td>22.1 %</td></tr>
<tr><td colspan="3">Employment</td></tr>
<tr><td>Employed</td><td>78.2%</td><td>80.5 %</td></tr>
</table>
Inclusion criteria
Monitoring condom distribution by method
8 venues were selected in central London. Selection was purposive to ensure adequate numbers of condoms would be distributed.

Impact on gay mens access to and use of condoms
Gay men using central London gay venues who consented to fill in a questionnaire.

Exclusion criteria
Spoilt/incomplete/unusable questionnaires
</td>
<td>consecutive days one year later when the scheme had been running for 11 months. Teams visited gay venues at night and distributed and collected questionnaires.
The questionnaire was developed and pre-tested . It was designed to be quick to fill in (2-3 mins) and therefore was one side of A4 .</td>
<td>pre-intervention (76.4%) to post-intervention (83.1%), and 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%.
Use of condoms: Not all condoms were used for anal intercourse (or any form of sexual activity). No significant change was noted on the frequency of unprotected anal intercourse - 9.5% (pre-intervention and 9.9% i(post-intervention).
<table>
<tr><th></th><th>% 1995</th><th>%1996</th><th>P</th></tr>
<tr><td>FREE: used for anal intercourse</td><td>66.8</td><td>68.5</td><td>NS</td></tr>
<tr><td>Bought: used for anal intercourse</td><td>68.6</td><td>61.4</td><td>NS</td></tr>
<tr><td>FREE: Still got some</td><td>72.2</td><td>79.2</td><td><0.02</td></tr>
<tr><td>Bought: Still got some</td><td>54.5</td><td>53.5</td><td>NS</td></tr>
<tr><td>FREE: Given away/passed on</td><td>25.8</td><td>27.5</td><td>NS</td></tr>
<tr><td>BOUGHT: Given away/passed on</td><td>25.6</td><td>19.5</td><td>NS</td></tr>
<tr><td>FREE: used for another purpose</td><td>27.5</td><td>25.8</td><td>NS</td></tr>
<tr><td>BOUGHT: used for another purpose</td><td>21.8</td><td>24.2</td><td>NS</td></tr>
<tr><td>FREE: Disposed of otherwise</td><td>13.3</td><td>13.5</td><td>NS</td></tr>
<tr><td>BOUGHT: Disposed of otherwise</td><td>3.8</td><td>9.8</td><td><0.04</td></tr>
</table>
*P value not reported.
</td>
<td>table.</td>
</tr>
</table>

Wendell et al 2003

<table>
<tr><th>Study</th><th>Participants</th><th>Intervention/Comparison</th><th>Results</th><th>Comments</th></tr>
<tr>
<td>Full citation
Wendell et al 2003

Quality score
-
Length of follow up
Unclear – though appears to be 2 years.

Study type
Quasi experimental

Aim of the study
To determine whether street based outreach by community-based organisations (CBOs) for HIV prevention is effective at increasing condom use.

Location and setting Streets in neighbourhoods with high HIV risk factors in.Louisiana, USA
Source of funding
None reported</td>
<td>Number of participants
Intervention in 66 areas = 4950 questionnaires
Comparator in 13 areas = 1597 questionnaires

Participant characteristics
Comparison group significantly more likely to be male (60% vs 52%) and slightly older (p<0.001). Race was similar between groups.

Inclusion criteria

Aged 18 - 65

Had sex in previous 12 months

Exclusion criteria
Women who only reported sex with other women in the previous 12 months</td>
<td>Intervention:
Street outreach to prevent HIV infection

Comparison:
No intervention

Outreach workers were trained to deliver a needs assessment and educational intervention and to hand out leaflets, condoms, bleach kits and coupons for needles at local pharmacies.</td>
<td>Outcomes
Contact with outreach worker; know where to get free condoms; last condom free; has condom with them or at home; use condom at last encounter; used the street outreach brand condom at last encounter.
Results

People in intervention sites had significantly better scores across all the outcomes listed above when compared to the comparison sites (P<0.001).

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 (OR1.37, 95% CI 1.20, 1.56; P<0.001).

Contact with an outreach worker mediated condom use.
<table>
<tr><th>Survey question</th><th>OR (95%CI)</th></tr>
<tr><td>Had contact with outreach worker</td><td>6.74 (5.94,7.66)*</td></tr>
<tr><td>Know where to get free condoms</td><td>3.2 (2.75,3.73)*</td></tr>
<tr><td>Got last condom free vs purchased</td><td>1.73 (1.61,1.89)*</td></tr>
<tr><td>Has condom with them or at home</td><td>2.29 (1.89,2.76)*</td></tr>
<tr><td>Used a condom at last sex</td><td>1.4 (1.25,1.27)*</td></tr>
<tr><td>Used the street outreach brand condom at last encounter</td><td>1.81 (1.58,2.08)*</td></tr>
</table>
*P < 0.001</td>
<td>Limitations identified by author
Post-test design cannot account for pre - xisting differences.

Outreach workers who delivered intervention also administered questionnaires.

Study protocol not always followed.

No power calculation.

Unclear follow-up length.

Limitations identified by review team
Error in results table with CIs for condom use at last intercourse

Other comments</td>
</tr>
</table>

Wretzel et al 2011

<table>
<tr><th>Study details</th><th>Population</th><th>Intervention/comparison</th><th>Results</th><th>Notes</th></tr>
<tr>
<td>Full citation
Wretzel et al 2011

Quality score
-

Length of follow up
3 years.

Study type
Before and after

Aim of the study
To determine the effects of a school based condom scheme on STI rates in 15-19 year olds.

Location and setting
US A.
High Schools in Holyoke, Massachusetts (MA)

Source of funding
Not reported</td>
<td>Number of participants
Population of intervention city = 36,765
Population of comparator city = 151,176

Inclusion criteria
All population aged 15 -19 in intervention and comparator cities

Exclusion criteria
Not reported

Participant characteristics
<table>
<tr><th></th><th>Intervention N=39,765</th><th>Control N=151,176</th></tr>
<tr><td>Female</td><td>53.2 %</td><td>52.8%</td></tr>
<tr><td>Age <18 years</td><td>29.5%</td><td>28.9%</td></tr>
<tr><td>Black persons</td><td>3.7%</td><td>21.0%</td></tr>
<tr><td>Latino origins</td><td>41.4%</td><td>27.2%</td></tr>
<tr><td>Below poverty line</td><td>26.4%</td><td>23.1%</td></tr>
<tr><td>Dropout rate</td><td>11.3%</td><td>10.9%</td></tr>
</table>
Participants were comparable on most demographic characteristics. However, Springfield had a substantially higher number of African American participants, and Holyoke a substantially higher number of Hispanic participants. No calculation of significance in difference was reported.</td>
<td>Intervention: Condom availability scheme in Holyoke, MA.

Comparison: School population in Springfield, MA where no condom availability scheme available.

In 2005, the intervention city implemented a Condom Availability Programme in High Schools.

The researchers examined Public Health data for incidence of chlamydia and gonorrhoea in the two populations for three years before and three years after the introduction of the scheme.</td>
<td>Outcomes
Rates of gonorrhoea and chlamydia (data gathered from Massachusetts Department of Public Health - both STIs are reportable infecrtions).

Gonorrhoea:
Intervention males averaged a 43% decline of cases per year after the introduction of the intervention. Males in the control city averaged a 3% decline. This difference was not significant (P <0.07).

Intervention females averaged a 14% decline of cases per year after the introduction of the intervention. Females in the control city averaged a 6% decline. This difference was not significant (P =0.58).

Chlamydia:
Intervention males experienced an average 14% decline in cases in the post-intervention period. Males in the control city experienced a 9% increase. This difference was not significant (P <0.07).

Intervention females showed no decline in cases per year after the introduction of the intervention. Females in the control city averaged a46% decline. This difference was not significant (P =0.62).

Combined STI:
Males in the intervention city showed a 47% decrease in the rates of gonorrhoea and chlamydia infection combined over the 3 years after intervention period. Males in the comparator city had a 23% increase in the rates of gonorrhoea and chlamydia infection. The difference in regression slopes in this period was significant (p < .01).

Females in the intervention city showed a 2.5% decrease</td>
<td>Limitations identified by author
Data not reported by ethnicity only gender.

Observational study.

There were less than an average of 7 cases of gonorrhoea per year in Holyoke Therefore small changes in number of cases produced large changes on rates per 100,000, and potentially reduced significance levels.

Limitations identified by review team
Large inconsistencies between two populations.

No description of intervention delivery, provider, or organisational aspects of this city-wide intervention.

Sample and comparator cities are very different in terms of size and ethnicity..</td>
</tr>
</table>

Study details	Population	Intervention/comparison	Results	Notes
			in the rates of STIs combined over 3 years post-intervention. Females in the comparator city had a 4% decrease in rates of STIs combined. This difference in was not significant (p = 0.73).	**Other comments**