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Research

HIV prevention in Mexican schools: prospective randomised evaluation of intervention

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Abstract
Objective To assess effects on condom use and other sexual behaviour of an HIV prevention programme at school that promotes the use of condoms with and without emergency contraception.

Design Cluster randomised controlled trial.

Setting 40 public high schools in the state of Morelos, Mexico.

Participants 10 954 first year high school students.

Intervention Schools were randomised to one of three arms: an HIV prevention course that promoted condom use, the same course with emergency contraception as back-up, or the existing sex education course. Self-administered anonymous questionnaires were completed at baseline, four months, and 16 months. Students at intervention schools received a 30 hour course (over 15 weeks) on HIV prevention and life skills, designed in accordance with guidelines of the joint United Nations programme on HIV/AIDS. Two extra hours of education on emergency contraception were given to students in the condom promotion with contraception arm.

Main outcome measures Primary outcome measure was reported condom use. Other outcomes were reported sexual activity; knowledge and attitudes about HIV and emergency contraception; and attitudes and confidence about condom use.

Results Intervention did not affect reported condom use. Knowledge of HIV improved in both intervention arms and knowledge of emergency contraception improved in the condom promotion with contraception arm. Reported sexual behaviour was similar in the intervention arms and the control group.

Conclusion A rigorously designed, implemented, and evaluated HIV education course based in public high schools did not reduce risk behaviour, so such courses need to be redesigned and evaluated. Addition of emergency contraception did not decrease reported condom use or increase risky sexual behaviour but did increase reported use of emergency contraception.

Introduction

Most recent efforts to prevent sexually transmitted infections (including HIV) and pregnancy in adolescents have been school based projects that promoted either condoms or abstinence. Recent meta-analyses show that these strategies have not been evaluated rigorously, especially in developing countries. Of 49 projects to prevent teenage pregnancy in the United States (some were school based HIV prevention programmes), only four programmes reduced age at first intercourse and increased the use of condoms or other contraception at first intercourse (and presumably resulted in decreased rates of pregnancy), and they were based on education to prevent HIV with condom promotion. A recent review of 26 projects to prevent pregnancy (including 10 school based programmes) concluded that these interventions do not delay the onset of sexual activity, increase condom use, or decrease unplanned pregnancy.

The results of a few careful studies of promoting abstinence are mixed. Although abstinence pledges may delay first intercourse, they do not seem to decrease the incidence of sexually transmitted disease or unplanned pregnancy, and they may increase the likelihood of unprotected sex.

Even though these projects have little effect on risky sexual behaviour in adolescents, planners and decision makers still invest large amounts of money and effort in them, without investigating new approaches. It has been estimated that in 2006 more than $100m (£57m; €82m) will be needed globally for school based prevention programmes. Unplanned pregnancy and sexually transmitted infections (including HIV) in adolescents are of major concern in Mexico, as in most of the world. In 2003, 17% of births (>400 000) in Mexico were to women under the age of 20.

According to the 2000 Mexican national health survey, 42% of young men and 26% of young women between 15 and 19 years have had a sexual relationship; only 47% of these young men and 15% of young women had used a condom during their first sexual intercourse.

Use of emergency contraceptive pills might prevent pregnancy without decreasing the use of condoms. We found no published studies comparing the effect of programmes that promote condom use, with and without emergency contraception back-up, on risk behaviour in adolescents. We analysed the effect on sexual behaviour of a high school based programme for preventing HIV and other sexually transmitted diseases by promoting the use of condoms with and without emergency contraception as back-up.

Emergency contraception is available over the counter in Mexico as a morning after pill. Concerns have been expressed that such contraception increases risky behaviour by decreasing the use of condoms, particularly among young people. In a survey of paediatricians in New York, 22% thought that providing emergency contraception encourages adolescents to take sexual
risks and 45% thought that it discourages use of other methods of contraception. These notions have not been confirmed in the few studies that have examined these issues. Studies in the US found that providing emergency contraception in advance to adolescents who attend family planning clinics did not decrease compliance with other methods of birth control. These studies were clinic based; we found no studies that investigated HIV prevention programmes based in school that combine condom promotion with education about and access to emergency contraception. One study of school based education about emergency contraception showed increased knowledge of this form of contraception but no change in use. That study did not evaluate the use of condoms.

Methods

Our cluster randomised trial began in the autumn of 2001. Forty public high schools—about 75% of such schools in the state of Morelos—were randomised to three arms. We estimated sample size according to four factors: expected intra-cluster (school) correlation, expected difference in the outcome variables at follow-up, average of expected observations by school, and feasible number of schools per arm (total). We used an intra-cluster correlation factor of 0.001, based on previous studies. As all outcome variables were proportions, we estimated the sample size by using the difference from the most restrictive proportion (50%), assuming that we wanted to be able to detect an improvement of 10% (five percentage points). From the available data, we knew that the average cluster (school) size was 220 first year students. We estimated the minimum number of schools at 12 per arm. We selected schools and asked them to participate, on the basis of stratified random sampling (stratified by degree of urbanisation), with sampling proportional to school size. All invited schools participated. We used data from the Mexican National Population Council to assign the category of “marginalisation” (see box) and degree of urbanisation for the communities where the schools are located. None of the schools had offered such specific and detailed education about emergency contraception or HIV prevention before. All participating 10th grade students were asked to respond to the questionnaires (in Mexico, high school comprises the 10th to 12th grades, ages 15 to 18). The overall response rate for each round of data collection was more than 95% of students attending school on the day the questionnaire was administered.

Ten of the 40 schools were randomised as control schools and continued with the biology based sex education course implemented by the Ministry of Education. We randomised 15 schools to receive the HIV education course with condom promotion and 15 schools to the same course plus a module on emergency contraception and improved access to such contraception. Two of these 30 schools initially randomised as intervention schools did not teach the intervention course, even though their teachers had been trained successfully. The primary analysis was an intention to treat analysis. We also report an actually treated analysis, in which these two schools that did not receive the intervention were included as control schools (see tables on bmj.com).

Participating schools chose 106 teachers to take part in a week long (40 hour) training session between November 2001 and January 2002. Teachers from the 15 schools randomised to teach emergency contraception had an extra two hour training module. Training covered the content and goals of each class. Teachers participated directly in the activities they would teach. Questionnaires given before and after training showed improved basic knowledge of HIV and AIDS, attitudes towards people with HIV, perception of ability to teach the material, and confidence in dealing with sensitive subjects in class.

The curriculum was based on teaching life skills and followed the guidelines of the UN programme on HIV/AIDS for effective school based programmes. Almost half of the time in class was focused on the consequences of unprotected sex and how to avoid it. Other classes dealt with the social pressures that influence sexual behaviour (peer pressure, cultural values) and provided practice in communication, negotiation, and refusal skills.

In February 2002, the teachers began to teach the 15 week, 30 hour course (16 weeks, 32 hours for the promotion with contraception arm). Students completed a 93 item anonymous questionnaire during class on three occasions: baseline in February 2002, immediately after intervention in June 2002, and one year later in June 2003. The questionnaires covered knowledge and attitudes about HIV, AIDS, and emergency contraception; sexual experience; and the use of condoms at first and most recent intercourse. We also asked about tobacco, alcohol, and drug use, compensated sex (exchange of sex for money, goods, or favours), social networks, socioeconomic status, and intention to continue in school. Data were entered twice to minimise errors in data entry.

The research team monitored the progress of the intervention in each school throughout the programme. Monitoring consisted of 424 telephone calls to teachers, 212 visits to schools to speak with teachers and head teachers, and 25 direct class observations.

Consent

We obtained informed signed consent from each student before each questionnaire was completed. All questionnaires were anonymous.

Data analysis

All analyses took the cluster sample design into account (fixed effects were used for regression and standard errors were adjusted for number of primary sampling units for the descriptive statistics). We used Stata 8.0 for all analyses.

We used nine questions on biology, transmission, and prevention to assess knowledge of HIV. Responses were graded on a five point scale from certain that the statement is true to certain that it is false. We summed the points for each question (0 for completely incorrect, 4 for completely correct) to produce a single score for each student. The resulting score varied from 0 to 36.

We considered students to be knowledgeable about emergency contraception if they identified such contraception as pills, taken orally, that prevent pregnancy if taken after sexual intercourse. To investigate attitudes about condoms, we asked
about the acceptability of condoms; we assessed whether the student would use a condom, and whether they would prefer sex with a condom at their next sexual intercourse. We also asked whether they would interrupt sex to ask their partner to use a condom, and whether they would tell their partner that they would only have sex with a condom (sex was conditional on condom use).

Because the questionnaire was self-administered and anonymous, we could not ensure that all questions were answered or that answers were consistent. Thus, sample size is not homogeneous across different variables or analyses.

For the behavioural variables included in the baseline questionnaire, we estimated the difference in differences at school level by using fixed effects logistic regression models to correct for intra-school correlation and to take potential trends into account.

We included a dichotomous variable for each intervention and another to distinguish the baseline survey from the follow-up survey, we used the age the respondent would have been at baseline to avoid confusion with the time trend. For the follow-up survey, we used the age the respondent would have been at the time of the survey, to make the variables comparable.

We used age at baseline instead of age at the time of the survey to capture the impact of each intervention on the outcome variable. We included a dichotomous variable for each intervention and another to distinguish the baseline survey from the follow-up survey, we used the age the respondent would have been at baseline to avoid confusion with the time trend. For the follow-up survey, we used the age the respondent would have been at the time of the survey, to make the variables comparable.

Results

Our sample comprised 10,954 students at baseline (February 2002), 9,572 students immediately after the intervention (June 2002), and 7,908 students at one year follow-up (June 2003). Between baseline and first follow-up, 14.4% (1,582/10,954) of students dropped out, and 22% (2,064/9,572) dropped out between the second and third follow-up. This is mainly because of the high dropout rates in Mexican schools. The dropout rate from the first to second year of high school in Morelos was about 37% for students who entered school in 2000 (higher than the estimated national dropout of 30%).

Mean age was 16.7 at follow-up, and 44% of the students were male compared with 48% at baseline (see table 1). Overall 17% (692/4,031) of young women and 27% (814/3,015) of young men reported sexual activity, with no significant differences between the three arms. At baseline 10% (511/4,942) of young women and 27% (841/3,105) of young men reported sexual activity. We found no significant differences between intervention groups at baseline, but significant differences were seen in follow-up. In the condom promotion group, young women were slightly older (about 0.1 years) and were at least 10 percentage points more likely to report having a boyfriend than women in other groups. Knowledge of HIV (biology, transmission, prevention) and knowledge of emergency contraception was greater for the condom promotion with contraception group than other groups. Other descriptive variables related to attitudes to condoms were similar in all groups. These included whether the student would use a condom at intercourse (young women 77% (1,175/1,518) vs 73% (1,120/1,518) of young men), would interrupt sex to use a condom (young women 93% (1,004/1,082) vs 81% (960/1,183) of young men), or would condition sex on condom use (young women 99% (1,132/1,132) vs 99% (1,132/1,132) of young men). Sexual activity (young women 16% (192/1,174) vs 19% (192/1,036) of young men).

Table 1: Characteristics of students who participated in a school based HIV prevention programme in Mexico at 16 months’ follow-up; intention to treat analysis. Values are numbers (percentages; 95% confidence intervals) unless stated otherwise

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control group</th>
<th>Condom promotion group</th>
<th>Condom promotion with emergency contraception group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female students</td>
<td>868/1867 (46; 44 to 49)</td>
<td>117/2619 (43; 35 to 50)</td>
<td>1,130/2,989 (44; 40 to 48)</td>
</tr>
<tr>
<td>Male students</td>
<td>n=987</td>
<td>n=1,433</td>
<td>n=1,660</td>
</tr>
<tr>
<td>Age (years)</td>
<td>16.7 (16.6 to 16.8)</td>
<td>16.8 (16.5 to 16.9)</td>
<td>16.7 (16.5 to 16.8)</td>
</tr>
<tr>
<td>Reported having a partner</td>
<td>422/978 (43; 38 to 48)</td>
<td>302/837 (36; 33 to 39)</td>
<td>767/1,451 (53; 50 to 56)</td>
</tr>
<tr>
<td>Age of partner (years)</td>
<td>18.6 (18.2 to 19.0)</td>
<td>17.1 (16.8 to 17.3)</td>
<td>19.2 (18.8 to 19.6)</td>
</tr>
<tr>
<td>Knowledgeable about HIV (score 0-45)</td>
<td>41.6 (39.9 to 41.4)</td>
<td>40.2 (39.5 to 41.1)</td>
<td>41.6 (40.2 to 41.0)</td>
</tr>
<tr>
<td>Knowledgeable about emergency contraception</td>
<td>585/935 (63; 56 to 69)</td>
<td>509/1,009 (59; 53 to 64)</td>
<td>516/990 (58; 53 to 63)</td>
</tr>
<tr>
<td>Would use a condom</td>
<td>395/529 (75; 67 to 82)</td>
<td>641/850 (75; 72 to 78)</td>
<td>789/980 (81; 77 to 84)</td>
</tr>
<tr>
<td>Would stop sex to put on a condom</td>
<td>665/716 (93; 92 to 94)</td>
<td>1,038/1,115 (93; 92 to 95)</td>
<td>1,263/1,483 (94; 92 to 96)</td>
</tr>
<tr>
<td>Would make sex conditional on condom use</td>
<td>838/857 (96; 97 to 99)</td>
<td>788/860 (82; 90 to 92)</td>
<td>941/1,038 (88; 97 to 99)</td>
</tr>
<tr>
<td>Sexually active</td>
<td>162/965 (17; 14 to 19)</td>
<td>220/823 (27; 22 to 31)</td>
<td>260/1,026 (16; 13 to 19)</td>
</tr>
</tbody>
</table>

 Schools were identified as primary sampling units to adjust for the cluster design.

†P<0.05 between intervention group(s) and the comparison group. P<0.05 between men and women within the group.
first or last intercourse. A higher proportion of young men in the condom promotion with contraception group reported using a sex worker or casual partner (85%; 81/95) than in the control group (70%; 39/56). A higher proportion of young women in the condom promotion with contraception group (30%; 77/245) and condom promotion with contraception group (31%; 75/247) reported a sexual partner five or more years older more often than young women in the control group (23%; 35/149), although the difference was significant only in the condom promotion with contraception group.

We estimated the impact of each intervention on selected outcome variables by using multivariate logistic regression and a fixed effects model to correct for cluster design (table 3). Knowledge of emergency contraception increased in the group that was taught about it, and young women in this group reported using this form of contraception. Both interventions had a significant impact on knowledge of HIV but not on sexual behaviour (except for use of emergency contraception). Education about emergency contraception had no significant effect on the use of condoms. Use of condoms decreased with age and time, although this result was affected by the drop-out rate. Young men were significantly less positive about the use of condoms than women, but they were significantly more likely to report that they used a condom when they last had sex. A significantly lower proportion of sexually active adolescents reported the intent to use condoms than young people who were not sexually active.

Table A-C on bmj.com show the results of analysis of the actually treated groups. The descriptive statistics show small differences between the actually treated and the intention to treat groups. The results of multivariate analyses are similar for the two groups, with small differences in the size of associations.

### Table 2: Characteristics of sexually active students who participated in a school-based HIV prevention programme in Mexico at 16 months' follow-up; intention to treat analysis. Values are numbers (percentages; 95% confidence intervals)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control group</th>
<th>Condom promotion</th>
<th>Condom promotion-emergency contraception group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female students</td>
<td>Male students</td>
<td>Female students</td>
</tr>
<tr>
<td>Used condom at first intercourse</td>
<td>88/157 (43; 31 to 56)</td>
<td>83/219 (38; 33 to 44)</td>
<td>119/268 (44; 40 to 49)</td>
</tr>
<tr>
<td>Used condom at last intercourse</td>
<td>68/156 (44; 35 to 52)</td>
<td>50/116 (48; 40 to 56)</td>
<td>116/232 (44; 38 to 50)</td>
</tr>
<tr>
<td>Intercourse with sex worker or casual partner</td>
<td>10/170 (6; 3 to 15)</td>
<td>9/168 (5; 2 to 13)</td>
<td>16/170 (8; 3 to 15)</td>
</tr>
<tr>
<td>Used condom with sex worker or casual partner</td>
<td>2/3 (67; 30 to 78)</td>
<td>0/1 (0; 0 to 0)</td>
<td>2/3 (67; 60 to 75)</td>
</tr>
<tr>
<td>Used emergency contraception</td>
<td>33/158 (21; 13 to 28)</td>
<td>29/204 (14; 8 to 20)</td>
<td>61/262 (37; 24 to 39)</td>
</tr>
<tr>
<td>Sexual partner ≥5 years</td>
<td>35/149 (23; 12 to 25)</td>
<td>45/201 (22; 10 to 27)</td>
<td>75/247 (30; 23 to 37)</td>
</tr>
<tr>
<td>Experienced breakage of condom</td>
<td>37/116 (32; 22 to 42)</td>
<td>51/158 (32; 28 to 37)</td>
<td>44/193 (23; 15 to 31)</td>
</tr>
</tbody>
</table>

Schools were identified as primary sampling units to adjust for the cluster design.

*P<0.05 between intervention group(s) and the comparison group.
†P<0.05 between men and women within the group.
‡P<0.05 between men and women within the group.
Discussion

We directly evaluated and compared the impact on adolescents of comprehensive education on HIV prevention, including condom promotion, with the same comprehensive education with emergency contraception backup. Neither strategy affected the use of condoms (positively or negatively) at one year follow-up. Our study adds to the growing body of evidence that current HIV prevention efforts based in school do not alter risky behaviour. Our results suggest that current interventions educate effectively but do not change sexual behaviour.

Limitations and strengths of the study

One weakness of our study is the absence of biological outcomes that were measured before and after intervention. Such outcomes (pregnancy, sexually transmitted diseases, and HIV) are useful markers of risky sexual behaviour, which can help validate self reported behavioural data. A common criticism of evaluations of behavioural interventions is that self reported data on behaviour are subject to reporting bias. Students exposed to the intervention know that the researchers expect them to reduce their risk behaviour and thus they might under-report their true risk behaviour, which leads to overestimates of the effectiveness of interventions. Given that most well designed studies that have measured reported sexual behaviour have not shown improvements, positive results are unlikely to be seen with the use of biological markers.

If we had found evidence of an effect of either intervention on self reported risky sexual behaviour, the lack of biological outcomes would have been an important limitation. This was not the case, however, and it is unlikely that students who had been taught about preventing HIV and pregnancy would over-report risky sexual behaviour. The lack of effectiveness in our study cannot be explained by lack of power, poor study design, or poor implementation of the intervention.

The planning and implementation of our intervention were as optimal and rigorous as possible, but several other limitations deserve mention. Firstly, although teachers were trained and closely monitored, our observation of classes was limited. Despite the intensive training, teachers rarely change their preconceptions about adolescent sexuality. In Mexico, young women are not meant to have sex before marriage, whereas boys are encouraged to do so. Secondly, we have no measure of student attendance at the course, although it was part of the required curriculum. Thirdly, although the course was intended to last longer than the recommended 14 hours (it was 30 hours), it was not followed up or reinforced the next year. Fourthly, the central message of the course was self determination of decision making, responsible action. Some experts believe this message is too vague. Fifthly, although the questionnaires were anonymous, confidential, and completed in the presence of adults, privacy may not have been optimal. Sixthly, only a small proportion of students were newly sexually active during the course, and these students cannot be identified, although they are the most likely to benefit from the course during the period of observation. In addition, although condoms and emergency contraception are available without prescription at any pharmacy, access to both forms of contraception is probably limited for young Mexicans for cultural, psychological, and economic reasons, and this could have affected our results. Finally, since data collection was school based, the follow-up survey did not include students who received the intervention in 10th grade and dropped out of school before the questionnaire was administered in 11th grade.

Although the intervention could have been monitored more closely, it is unlikely that monitoring would be any better if the intervention were implemented across the country. Teachers were trained by university professors, so the quality of training was far better than would occur under full scale implementation. Lack of follow-up of dropouts caused some loss of power, but it probably did not bias the results. However, the dropout rate does affect our capacity to estimate trends, as our follow-up sample is a subset of the baseline sample. Dropout rates did not differ between the three arms of our study. We do not think that the interventions increased the dropout rate of students who had safer behaviour and reduced that of students with riskier behaviour, thus masking a positive intervention effect. Data from a small sample of students who dropped out at the first follow-up showed that the proportions of boys who dropped out who were sexually active and who used a condom at the last sexual intercourse were similar to boys still in school, whereas a higher proportion of girls who dropped out were sexually active and a lower proportion used condoms compared with girls still at school.

Implications

Combining the condom and emergency contraception messages did not increase risky sexual behaviour, which refutes the notion that providing information and access to emergency contraception will increase frequency of sexual activity, number of partners, or sex without a condom. Thus, promoting condom use with emergency contraception backup is a good way to reduce high rates of unplanned pregnancy and sexually transmitted diseases. Future studies should measure the direct impact of education about emergency contraception on unplanned pregnancy and sexually transmitted diseases.

Immediately after the intervention, condom use at last sex was significantly increased in the condom promotion with contraception group only, but this effect was lost at one year follow-up. These results show how important it is to evaluate longer term effects.

Innovative approaches designed to decrease adolescent risk behaviour are urgently needed. Possible approaches include integrating school based efforts to prevent HIV and sexually transmitted diseases into reproductive health services, and other community based strategies. New approaches could also add components that directly consider social norms, both within the school and within the broader community, including families and youths who do not attend school. A combined parent-adolescent intervention has not received much study, especially in developing countries.

Whatever the innovations, evaluations need to incorporate biological outcomes (for example, using screening tests for herpes simplex type 2 or human papillomavirus) because they are important in their own right and validate self reported data on behaviour. Existing interventions that rely on publicly declaring intended behaviour (such as abstinence pledges) might be more compatible with the knowledge based interventions that we implemented if pledges and group reinforcement focused more on safety (whether via abstinence, condom use, or testing and mutual fidelity) than abstinence alone. Finally, a considerable proportion of large scale programmes currently being rolled out must be phased in as cluster randomised trials to permit rigorous evaluation if we are to learn how to reduce adolescent risk behaviour.

Conclusion

New strategies are urgently needed to combat HIV and other sexually transmitted diseases and unplanned pregnancy among
adolescents. Great care should be taken in using data related to school based education and prevention, especially when evidence of benefit relies on changes in knowledge or self-reported behavioural change, or both. Cost effectiveness analyses have assumed that existing school education approaches are more effective than current data show.19 Those analyses support continued use of existing approaches and do not encourage the innovation and rigorous evaluation needed to improve effectiveness. Our data indicate that it is time to consider and evaluate new approaches to HIV prevention interventions based in schools.

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Contributors: DW conceived and designed the study and oversaw implementation of the intervention and data collection and analysis. She was primarily responsible for drafting and revising the article. JG helped design the study and was primarily responsible for data management and analysis. JG contributed greatly to the content and revision of the article. PT was primarily responsible for overseeing teacher training, implementing the interventions, and applying the questionnaire. She was the overall field manager and contributed greatly to the writing and revision of the article. SB was the principal investigator for the parent study and helped at every stage of the study. He contributed greatly to the study design, analysis, interpretation of results, and editing and revision of the article. DW is guarantor.


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