Identifying Programs That Impact Teen Pregnancy, Sexually Transmitted Infections, and Associated Sexual Risk Behaviors

Review Protocol

Version 4.0

Review Authors

Mathematica Policy Research
Child Trends
Contact: pprer@mathematica-mpr.com

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BACKGROUND

The consequences of adolescent sexual activity remain a troubling issue in the United States. Nationwide, 24% of high school students report having had four or more partners by graduation, and nearly 40% of sexually active students had not used a condom during their last sexual intercourse [1]. These behaviors increase the risks of pregnancy and sexually transmitted infections (STIs), including HIV. National data for 2012 indicate there were approximately 29.4 births per 1,000 females 15 to 19 years of age [2], a rate higher than in most other industrialized countries. In addition, estimates suggest that adolescents and young adults account for half of all new STI cases in the United States every year [3].

To help identify programs effective in reducing these risks, since 2009, the U.S. Department of Health and Human Services has contracted with Mathematica Policy Research and Child Trends to conduct a systematic review of research on programs to reduce teen pregnancy, STIs, and associated sexual risk behaviors. The review identifies, assesses, and rates the rigor of program impact studies and describes the strength of evidence supporting different program models. Findings have been used to help inform two ongoing federal grant programs: (1) the Office of Adolescent Health (OAH) Teen Pregnancy Prevention (TPP) program and (2) the State Personal Responsibility Education Program (PREP), administered by the Family and Youth Services Bureau (FYSB) within the Administration for Children and Families (ACF).

REVIEW PROTOCOL

The review is conducted following a prespecified protocol. The protocol was first developed in fall 2009 to identify and assess studies released from 1989 through January 2010. The study team revises the protocol each time the review findings are updated to include more recent research. The current version of the protocol (Version 4.0) was developed to review studies released from April 2013 through July 2014.

OBJECTIVES

The objectives of the review are to:

1. Identify, assess, and rate the rigor of studies examining program impacts on teen pregnancy, STIs, and associated sexual risk behaviors.
2. Describe the strength of evidence supporting different teen pregnancy prevention program models.
3. Strengthen the evidence base by identifying key gaps in the literature and setting standards for study quality and evidence of program effectiveness.

SEARCH STRATEGY

Studies are identified for review in five ways: (1) reviewing published research syntheses, (2) reviewing the websites of relevant research and policy organizations, (3) issuing public calls for studies to solicit new and unpublished research, (4) conducting keyword searches of electronic databases, and (5) scanning relevant research journals and professional conference proceedings.

1. REVIEW OF RESEARCH SYNTHESES

For the initial review of the evidence, the review team identified relevant studies by scanning the reference lists of seven syntheses of research studies related to adolescent pregnancy prevention (see Table A.1 for list).

2. WEBSITES OF RELEVANT RESEARCH AND POLICY ORGANIZATIONS

Additional studies are identified by searching the websites of federal agencies and research or policy organizations with links to the topic of teen pregnancy prevention. The review team searches the websites of nine such agencies or organizations (see Table A.2 for list).

3. CALL FOR STUDIES

New studies and unpublished studies of relevance are identified through periodic public calls for studies. To date, the review team has issued four such public calls, in September 2009, December 2010, February 2013, and September 2014. Authors are typically given six to eight weeks to submit materials. Submissions are accepted by email.

4. KEYWORD SEARCH OF ELECTRONIC DATABASES

Additional studies are identified by conducting keyword searches of electronic citation databases. For the first review of the evidence, the review team coordinated with Mathematica's professional research librarians to conduct a search of 12 electronic databases (see Table A.3 for list). For more recent updates to the review, the search has covered an expanded list of 14 electronic databases (see Table A.3), using the following keyword combination:

pregnancy OR pregnant OR "HIV" OR "AIDS" OR "STD" OR "sexually transmitted"

OR sex education OR "sex education" OR abstinence*

AND (prevention OR clinic) AND (adolescent OR teen*)*

AND (evaluation OR stud*) AND (effect* OR impact*)*

5. SCAN OF JOURNALS AND CONFERENCE PROCEEDINGS

When updating the review findings, the study team scans the tables of contents of 10 academic research journals (see Table A.4 for list) and the conference proceedings of five relevant professional associations (see Table A.5 for list). The team also searches schedules from other relevant conferences related to teen pregnancy prevention, such as the Healthy Teen Network's Conference and the National STD Prevention Conference. When potentially relevant studies or presentations are identified, the review team contacts the study author by email with information about the review and public call for studies. Authors then have the opportunity to submit their research through the public call for studies.

ELIGIBILITY CRITERIA

TYPES OF PARTICIPANTS

The review considers studies on U. S. youth ages 19 or younger. Studies with a subsample outside of this age range are considered for review if the study establishes that the majority of sample members are 19 or younger. There is no lower bound on age.

TYPES OF PROGRAMS

The review focuses on programs that intend to reduce rates of teen pregnancy, STIs, or associated sexual risk behaviors through some combination of educational, skill-building, and/or psychosocial intervention. Programs may be delivered either one-on-one to individuals or in groups, in any type of public, private, or institutional setting. Examples include classroom-based health curricula, individualized programs delivered by health professionals in clinics or other settings, community-based or afterschool programs, and specialized programs for youth in the juvenile justice or child welfare systems. The review excludes programs that (1) focus primarily or entirely on the provision of clinical services (such as condom distribution programs) or (2) may affect sexual risk behavior and health outcomes only indirectly or through spillover effects on other outcomes (such as school dropout prevention, early childhood education, or job training programs). The review likewise excludes studies of state- or federal-policy changes, such as policies affecting access to contraception through Medicaid.

TYPES OF STUDIES

Studies must examine the effects of a program using quantitative data, statistical analysis, and hypothesis testing.

TYPES OF OUTCOMES

Studies must measure program impacts on at least one measure of sexual risk behavior or its health consequences. Measures meeting this definition include those examining: sexual activity (initiation, frequency, number of partners); contraceptive use; STIs; pregnancies; or births. Most studies use self-reported measures, but biological measures of STIs and administrative data (for example, birth records) are also considered. Measures with limitations in terms of their quality or interpretation (for example, reports from males of their female partners' use of birth control pills or scales of behavioral risk and contraceptive use, which combine multiple measures into a single "black box" scale) are excluded from the review.

ASSESSMENT OF INDIVIDUAL STUDIES

Studies that meet the review eligibility criteria are assessed by teams of two trained reviewers for the quality and execution of their research designs. The first reviewer conducts a detailed assessment of the study using a modified version of the rating tool first developed by the U.S. Department of Education's What Works Clearinghouse (WWC). The second reviewer checks and verifies the assessment for accuracy and completeness. Differences of opinion are resolved through consensus.

As a part of the assessment process, the reviewers assign each study a quality rating of ***high***, ***moderate***, or ***low*** according to the risk of bias in the study's impact estimates (see Table 1). In brief, the high rating is reserved for well-implemented randomized controlled trials. The moderate rating is considered for (1) quasi-experimental comparison group designs and (2) randomized controlled trials that do not meet the criteria for the highest rating. The low quality rating is applied to studies that do not meet the review criteria for either a high or a moderate rating. The rating scheme was developed by Mathematica and approved by the U.S. Department of Health and Human Services in fall 2009.

TABLE 1. SUMMARY OF STUDY QUALITY RATINGS

Criteria Category	High Study Rating	Moderate Study Rating	Low Study Rating
1. Study design	Random or functionally random assignment	Quasi-experimental design with a comparison group; random assignment design with high attrition or reassignment	Does not meet criteria for high or moderate rating
2. Attrition	What Works Clearinghouse standards for overall and differential attrition	No requirement	Does not meet criteria for high or moderate rating
3. Baseline equivalence	Must control for statistically significant baseline differences	Must establish baseline equivalence of research groups and control for baseline outcome measures	Does not meet criteria for high or moderate rating
4. Reassignment	Analysis must be based on original assignment to research groups	No requirement	Does not meet criteria for high or moderate rating
5. Confounding factors	Must have at least two subjects or groups in each research group and no systematic differences in data collection methods	Must have at least two subjects or groups in each research group and no systematic differences in data collection methods	Does not meet criteria for high or moderate rating

1. STUDY DESIGN

The highest study quality rating is reserved for randomized controlled trials and similar studies that randomly assigned subjects to their research groups. Studies using random assignment provide the strongest evidence that differences in the outcomes between the treatment and control groups can be attributed to the program. (Designs based on functionally random assignment, such as alternating based on last name, date of birth, or certain digits of an identification number, are also eligible for this highest rating.)

Quasi-experimental designs with an external comparison group are eligible for at best a moderate rating. In such studies, subjects are sorted into the research groups through a process other than random assignment; therefore, even if the treatment and comparison groups are well matched based on observed characteristics, they may still differ on unmeasured characteristics. We therefore cannot rule out the possibility that the findings are attributable to unmeasured group differences. The moderate study rating is also applied to random assignment designs that do not meet other criteria for the highest rating (that is, attrition or reassignment), as explained in more detail below.

Quasi-experimental designs *without* an external comparison group (for example, pre-post designs) are given a low study rating. These designs are not considered for either the high or moderate rating because they offer no credible means to assess what the sample's outcomes would have been absent the intervention—a necessary condition for obtaining an unbiased impact estimate. Quasi-experimental and random assignment studies that do not meet the other criteria for a high or moderate rating are also assigned the lowest rating.

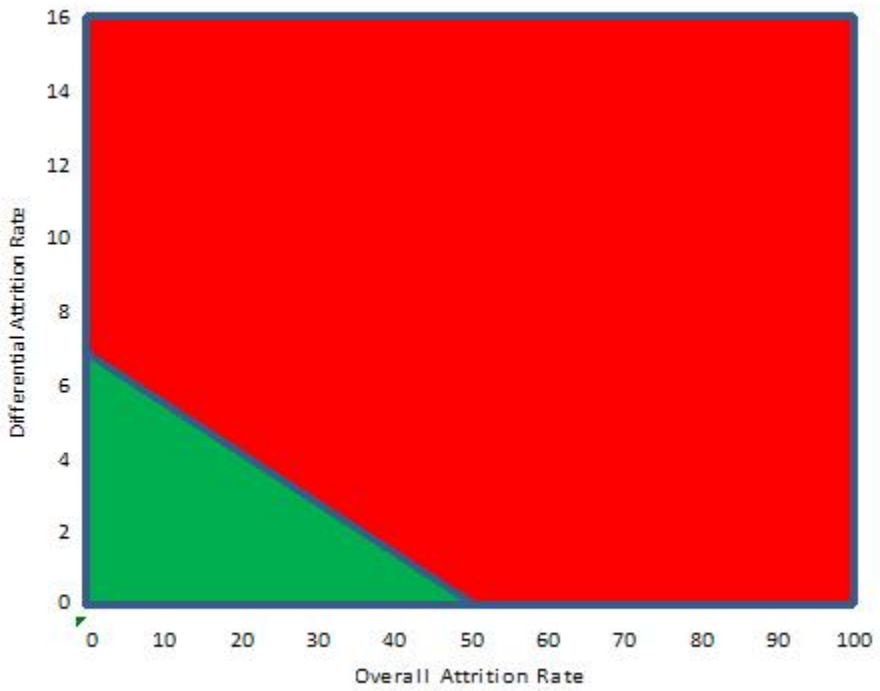
2. ATTRITION

In random assignment studies, a loss of study participants can bias the study's impact estimates by creating differences in the characteristics of the treatment and control groups. Bias can arise from overall attrition (the percentage of study participants lost among the total study sample) or differential attrition (the difference in attrition rates between the treatment and control groups).

We assess the level of sample attrition against standards established by the WWC. As seen in Figure 1 (next page), the WWC standards recognize a trade-off between overall and differential attrition. Namely, for an expected level of bias, studies with a relatively low level of overall attrition can meet standards with a relatively high level of differential attrition, whereas studies with a relatively high level of overall attrition require a lower level of differential attrition. Thus, the cutoff for an acceptable level of sample attrition is tied not only to the extent of overall attrition or differential attrition but rather to a combination of the two. For example, for studies with a relatively low overall attrition rate of 10 percent, the WWC standard allows a rate of differential attrition up to approximately 6 percent. However, for studies with a higher overall attrition rate of 30 percent, the WWC standard requires a lower rate of differential attrition, at approximately 4 percent. Only random assignment studies meeting the standard for acceptable combinations of overall and differential attrition are considered for the highest study rating. Random assignment studies that do not meet these standards are considered for the moderate study rating.

For cluster randomized trials, in which individuals are assigned to treatment and control conditions in groups (for example, schools or classrooms), the review team first assesses the level of attrition for the clusters or groups. If the combination of overall and differential attrition at the cluster level meets the WWC attrition standards, the review team then assesses attrition at the sub-cluster (or individual) level. Random assignment studies with low attrition at the cluster level but high attrition at the sub-cluster level are assigned the moderate study rating. Cluster randomized trials also receive a moderate rating if sample members were added during the intervention period—for example, if a study of a multiyear pregnancy prevention program for high school students added to the sample new students who transferred into the school the year after the program began.

FIGURE 1. STANDARD FOR ASSESSING SAMPLE ATTRITION IN STUDY QUALITY RATINGS



Source: What Works Clearinghouse. *Procedures and Standards Handbook, Version 2.* Washington, DC: U.S. Department of Education, 2008.

In calculating the rate of sample attrition, the review team compares the number of clusters and individuals at the time of random assignment to the size of the final analytic sample. Thus, any sample exclusions made after random assignment may factor into the attrition calculation. Depending on the specifics of the research design, these sample exclusions may arise from participant nonconsent, nonresponse, nonparticipation, or any number of other factors. The key determination is whether the exclusion in question presents any risk of bias to the study's impact estimates. Any sample exclusion that occurs after random assignment and presents a risk of bias will be factored into the attrition calculation.

The attrition standards are not applied to quasi-experimental studies, because we evaluate these studies on the basis of their final analytic samples, from which there is no attrition. We explain this criterion in greater detail below.

3. BASELINE EQUIVALENCE

In quasi-experimental comparison group studies and random assignment studies with high attrition, the use of well-matched treatment and comparison groups can minimize the risk of bias in the impact estimates. Therefore, in order to receive the moderate study rating, quasi-experimental comparison group studies and random assignment studies with high attrition are required to demonstrate that the intervention and comparison groups were similar at baseline ($p > .05$, two-tailed test) on three key demographic characteristics: age or grade level, gender, and race/ethnicity. For studies with sample members at least 14 years old at baseline (or eighth grade or higher), the study authors must also establish baseline equivalence on at least one behavioral outcome measure (for example, rates of sexual initiation).

This criterion is not applied to studies with younger sample members because rates of sexual risk behaviors are typically low for this age group.

Only those outcomes for which baseline equivalence is established are considered for possible evidence of program effectiveness. For example, if a study examined program impacts on three relevant outcome measures—sexual initiation, contraceptive use, and pregnancy—but established baseline equivalence for only one of the three measures (sexual initiation), the study meets the criteria for a moderate study rating, but only the impact findings for that one outcome measure (sexual initiation) are considered for possible evidence of program effectiveness. Studies are also required to control for these measures in their analyses, to ensure that any marginal differences in outcome measures at baseline did not bias the impact estimates at follow-up.

These baseline equivalence criteria are assessed on the study's final analysis sample. In some cases, studies assess equivalence for all youth who completed a baseline survey, but then present impact estimates for only a smaller subset of youth who completed a follow-up survey. These studies do not meet the baseline equivalence criteria of this review, because equivalence was not established for the smaller subset of youth on which the program impacts were based. Similarly, studies are not considered for the moderate rating if they present baseline equivalence statistics separately for subgroups defined by age, gender, or race/ethnicity, without also establishing equivalence for the full analytic sample. Some studies, for example, present baseline equivalence statistics separately for males and females or for subgroups of older and younger youth, but not for the overall combined sample.

Random assignment studies that otherwise meet the criteria for the highest rating are not required to establish baseline equivalence, because randomization is expected to produce groups that are equivalent, on average, on both observed and unobserved characteristics. Nevertheless, randomization sometimes can produce chance differences between groups and, to meet the criteria for the highest study rating, random assignment studies that show evidence of statistically significant baseline differences on behavioral outcome measures or demographics (age, race/ethnicity, or gender) are required to control for these differences in their statistical impact analyses. Random assignment studies that do not control for statistically significant baseline differences are assigned the moderate rating.

4. REASSIGNMENT

In random assignment studies, deviation from the original random assignment (for example, moving youth from the treatment to the control group) can bias the study's impact estimates. Therefore, in order for a random assignment study to meet the criteria for the highest rating, the analysis has to have been performed on the sample as originally assigned. In order to receive a high rating, subjects cannot be reassigned, based on actual treatment they received, for reasons such as contamination, noncompliance, or level of exposure. Random assignment studies that somehow alter the original random assignment must establish baseline equivalence of their final analysis sample in order to be considered for a moderate study rating.

For similar reasons, random assignment studies cannot statistically control for measures of program dosage, participation, or any other factors that effectively alter the composition of the treatment and control groups as originally assigned. Any impact estimates resulting from such analyses are excluded from our subsequent data extraction and assessment of program effectiveness (described below).

5. CONFOUNDING

In certain cases, a component of the research design or methods lines up exactly with the intervention being tested, undermining the credibility of attributing an observed effect to the intervention. For example, if a study assigns only one subject or group (for example, classroom or school) to the treatment or control condition, there is no way to distinguish the effects of the program from the particular effects of that one assigned subject or group. This can happen, for example, in quasi-experimental comparison group studies that estimate program impacts by comparing a single school or school district that implemented a pregnancy prevention program with a neighboring school or school district that did not have the program. In these cases, there is no way to distinguish the effects of the program from other characteristics of the particular school or district that implemented the program. A confounding factor can also arise from systematic differences in data collection methods for the treatment and comparison groups—for example, if program staff collect data from all subjects in the treatment group but an independent group of staff collect data from the control group. In this case, the mode of data collection cannot be separated from the effects of the intervention. Because the presence of such confounding factors severely weakens the credibility of a study's findings, a low rating is assigned to random assignment or quasi-experimental comparison group studies with either (1) only one subject or group in the treatment and control condition or (2) systematic differences in data collection procedures between the treatment and control groups.

DATA COLLECTION/EXTRACTION

All impact studies meeting the criteria for a high or moderate study quality rating are considered eligible for providing credible evidence of program impacts. For these eligible studies, the review team documents the impact estimate(s) for all relevant outcome measures, and uses this information to assess a program's evidence of effectiveness. Studies receiving a low rating are not subject to data collection and extraction, as the information provided in these studies is considered not to provide credible estimates of program impacts.

For each relevant impact estimate from an eligible impact study, the review team collects and records the following information: the name and description of the outcome measure, length of follow-up, analytic sample used to estimate the program impact (full sample or subgroup of interest defined by (1) gender or (2) sexual experience at baseline), the reported statistical confidence interval or associated standard error of the estimate, the reported *p*-value or other associated test statistic, and statistical significance level as reported by the study authors. The review team extracts this information only for eligible outcome measures as defined in the review protocol.

In the case of random assignment studies with multiple follow-up periods, this information is documented only for follow-up periods meeting the standard for low sample attrition. For follow-up periods not meeting the attrition standard, the information is treated as if it was based on a moderate quality study and documented only if the study establishes baseline equivalence for the analysis sample of that follow-up.

The review team documents all of this information as the author(s) reports it. For example, studies can report the magnitude of the impact estimates in many forms—as log-odds ratios, differences in probabilities, or effect size units—and the review team documents each magnitude as it is reported. To help users of the review make sense of these estimates and better understand the magnitude of program effects, the review team encourages study authors to report both an unstandardized and a standardized

estimate of magnitude for each impact estimate, regardless of the level of statistical significance. In some cases, the review team may also follow up with study authors to request missing information on program effect sizes. To date, however, information on the magnitude of program effects has been used only for descriptive purposes and is not a formal requirement of the review.

ASSESSMENT OF PROGRAM EFFECTIVENESS

Based on the information collected and extracted from the eligible impact studies, the review team qualitatively describes the strength of evidence supporting each program model and identifies those programs showing evidence of program effectiveness. To meet this criterion, the program's supporting research study must show evidence of a positive, statistically significant impact on at least one priority outcome measure for either the full analytic sample or a subgroup defined by (1) gender or (2) sexual experience at baseline. The priority outcome measures are sexual activity (initiation; frequency; rates of vaginal, oral, and/or anal sex; number of sexual partners), contraceptive use (consistency of use or one-time use, for either condoms or another contraceptive method), STIs, and pregnancy or birth.

Statistical significance is assessed with a two-tailed hypothesis test and a specified alpha level of $p < .05$. For studies in which the unit of assignment is a group (or cluster) of individuals (for example, schools or classrooms), study authors must appropriately adjust statistical significance tests for the correlation in measurement among individuals within the same group (intra-cluster correlation). If the tests are not appropriately adjusted, the review team may follow up with study authors to request adjusted estimates. If adjusted estimates are unavailable, the evidence in question will be excluded from the review.

Although commonly featured in the literature, evidence from subgroups defined by sexual activity at follow-up is not considered when assessing program effectiveness. As with other endogenous subgroups that are defined by behavior emerging after the start of the program, the composition of those who are sexually active at follow-up may be affected by program participation. As a result, even with an experimental design, the treatment and comparison groups within such subgroups may lack equivalence, leading to biased estimates of a program's impact for these groups.

ASSESSMENT OF IMPLEMENTATION READINESS

For programs meeting the review criteria for evidence of effectiveness, the review team conducts an independent assessment of each program's readiness for implementation. This assessment is based on the team's review of available program materials and documents. The team also requests input from program developers and distributors about availability of implementation materials and resources.

On the basis of this assessment, the team calculates an implementation readiness score comprised of three component scores: (1) curriculum and materials, (2) training and staff support, and (3) fidelity monitoring tools and resources. The component scores are combined into a total score, which ranges from 0 to 8, with higher scores indicating the programs most ready to implement.

CONFLICTS OF INTEREST

None.

REFERENCES

1. Centers for Disease Control and Prevention. “Youth Risk Behavior Surveillance—United States, 2011.” *MMWR*, vol. 61, no. SS-4, 2012, pp. 1–162.

2. Martin, J.A., B.E. Hamilton, M.J.K. Osterman, and T.J. Mathews. "Births: Final Data for 2012." National Vital Statistics Reports, vol. 62, no. 9. Hyattsville, MD: National Center for Health Statistics, December, 2013.

3. Centers for Disease Control and Prevention. “Sexually Transmitted Disease Surveillance 2011.” Atlanta, GA: U.S. Department of Health and Human Services, 2012.

Appendix A: Search Strategy

TABLE A.1. RESEARCH SYNTHESES

1. Advocates for Youth. *Science and Success,* 2nd edition. Washington, DC: Advocates for Youth, 2008.
2. Guide to Community Preventive Services. "Prevention of HIV/AIDS, Other STIs and Pregnancy: Group-Based Abstinence Education Interventions for Adolescents." (http://www.thecommunityguide.org/hiv/abstinence_ed.html).
3. Guide to Community Preventive Services. "Prevention of HIV/AIDS, Other STIs and Pregnancy: Group-Based Comprehensive Risk Reduction Interventions for Adolescents." (http://www.thecommunityguide.org/hiv/riskreduction.html).
4. Kim, C. C., and R. Rector. "Abstinence Education: Assessing the Evidence." Washington, DC: The Heritage Foundation, 2008.
5. Kirby, D. *Emerging Answers 2007: Research Findings on Programs to Reduce Teen Pregnancy and Sexually Transmitted Diseases.* Washington, DC: National Campaign to Prevent Teen and Unplanned Pregnancy, 2007.
6. Oringanje, C., M. M. Meremikwu, H. Eko, E. Esu, A. Meremikwu, and J.E. Ehiri. "Interventions for Preventing Unintended Pregnancies Among Adolescents." *Cochrane Database of Systematic Reviews*, no. 4, 2009.
7. Scher, L., R. A. Maynard, and M. Stagner. "Interventions Intended to Reduce Pregnancy-Related Outcomes Among Adolescents." *Campbell Systematic Reviews*, no. 12, 2006.

TABLE A.2. RELEVANT WEBSITES

1. Advocates for Youth
2. Centers for Disease Control and Prevention (HIV/STD Prevention Research Synthesis)
3. Guttmacher Institute
4. Healthy Teen Network
5. National Abstinence Clearinghouse
6. National Abstinence Education Association
7. National Campaign to Prevent Teen and Unplanned Pregnancy
8. Sociometrics (Program Archive on Sexuality, Health, and Adolescence)
9. Child Trends (LINKS database)

Note: The U.S. Department of Health and Human Services Web Site Disclaimers are available at: [http://www.hhs.gov/disclaimer.html]. Accessed August 2, 2016.

TABLE A.3. KEYWORD SEARCH DATABASES

Database	Initial Review of the Evidence	Updates to the Review
Academic Search Premier	X	X
CINAHL with Full Text	X	X
Cochrane Methodology Register	X	X
Cochrane Central Register of Controlled Trials	X	X
Cochrane Database of Systematic Reviews	X	X
Database of Abstracts of Reviews of Effect	X	X
Dissertation Abstracts	X	X
Education Research Complete	X	X
ERIC	X	X
Health Policy Reference Center		X
Mathematica's in-house E-journals database		X
MedLine	X	X
PsycInfo	X	X
SocINDEX with Full Text	X	X

TABLE A.4. JOURNALS INCLUDED IN TABLE OF CONTENTS SEARCH

1. American Journal of Maternal Child Nursing
2. American Journal of Public Health
3. Archives of Pediatric and Adolescent Medicine
4. Journal of Adolescent Health
5. Journal of AIDS Education and Prevention
6. Journal of Consulting and Clinical Psychology
7. Journal of School Health
8. Perspectives on Sexual and Reproductive Health
9. Public Health Reports
10. Sexually Transmitted Diseases

TABLE A.5. PROFESSIONAL ASSOCIATIONS INCLUDED IN SCAN OF CONFERENCE PROCEEDINGS

1. American Public Health Association
2. Association of Maternal and Child Health Programs
3. Society for Prevention Research
4. Society for Research on Adolescence
5. Society for Research in Child Development