Task 6: Identifying Promising FASD Practices: Review and Assessment Report

Substance Abuse and Mental Health Services Administration
Fetal Alcohol Spectrum Disorders
Center for Excellence

April 13, 2007

Submitted by:
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2101 Gaither Road, Suite 600
Rockville, Maryland 20850
Contract No. 277–01–6068

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SAMHSA
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I. Background and Purpose

The Substance Abuse and Mental Health Services Administration (SAMHSA) created the FASD Center for Excellence (the Center) in 2001 to address fetal alcohol spectrum disorders (FASD) in the United States. "FASD" is an umbrella term describing the range of effects that can occur in an individual whose mother drank alcohol during pregnancy. These effects may include physical, mental, behavioral, and/or learning disabilities with possible lifelong implications. The term "FASD" is not used as a clinical diagnosis. It refers to conditions such as fetal alcohol syndrome (FAS), alcohol-related neurodevelopmental disorder (ARND), and alcohol-related birth defects (ARBD). FASD affects approximately 40,000 babies per year (May and Gossage, 2001), which represents an incidence of about 10 per 1,000 births in the general U.S. population, with higher rates in some subgroups.

A major responsibility assigned to the Center by Congress in 2001 was to investigate innovative clinical intervention and service delivery approaches for the prevention and treatment of FASD. Under the direction of SAMHSA, the Center was charged with the task of identifying best practices in the prevention and treatment of these disorders (Task 6 of the Statement of Work). This task involved developing, maintaining, and expanding an inventory of all viable FASD prevention and treatment practices, identifying and using appropriate criteria to assess best and promising practices, and reporting the results to SAMHSA.

After initial review of a number of practices, it was decided that this task should focus on promising practices, that is, those that demonstrated the potential for future inclusion in SAMHSA's National Registry of Evidence-Based Programs and Practices (NREPP), subject to further expert review under the direction of the agency. In 2006, NREPP was expanded and refined to include interventions to prevent the onset and reduce the progression of mental illness, substance abuse, and substance-related problems affecting adults, youth, and children (Federal Register, March 14, 2006). NREPP now functions as a decision support tool to facilitate expanded adoption of evidence-based interventions in community prevention and treatment settings by increasing the availability and accessibility of the most appropriate, effective, and highest quality prevention and/or treatment services to individuals at risk for or experiencing mental health and/or substance use disorders (Federal Register, March 14, 2006). NREPP serves as "…a voluntary rating and classification system designed to provide the public with reliable information on the scientific basis and practicality of interventions that prevent and/or treat mental and substance use disorders. Descriptive information and quantitative ratings are provided across several key areas for all interventions reviewed by NREPP" (Federal Register, June 30, 2006, p. 37590). As will be described in more detail in the next section of this report, SAMHSA has identified and described key criteria for evaluating individual interventions to ensure that the methods used to assess their effectiveness are based on sound science (Federal Register, March 14, 2006).

For this task, the SAMHSA definitions for interventions, programs, and practices were used. As stated in the June 30, 2006, Federal Register (p. 37590), "For NREPP purposes, SAMHSA defines interventions as programs, practices, and/or environmental strategies designed to change behavioral outcomes among a definable population or within a definable geographic area." Thus, the term "intervention" is synonymous with practice and programs aimed at changing health behavior.

The majority of the many FASD prevention and treatment initiatives identified by the research team consisted of interventions or practices that involved more than one activity or service. For example, one intervention identified as a promising practice, the University of Washington's Parent-Child Assistance Program (PCAP), provided postpartum women and their newborn children with case management

services, including regular home visits; counseling; advocacy; and practical help in accessing substance abuse treatment, medical care, and other community services. Another selected intervention, Project BALANCE, used motivational interviewing techniques to reduce alcohol use and provided counseling on effective contraception to prevent future alcohol-exposed pregnancies (AEPs) among college students. The Center's investigation and assessment, therefore, have focused on interventions to determine which ones represent promising practices. Also, much of the literature reviewed for these tasks refers more often to "interventions" than "practices."

For this investigation, the term "promising FASD practice" has been defined as an intervention for which a well-designed evaluation has provided evidence that it produces positive behavioral outcomes in the populations that it targets (e.g., reducing alcohol consumption among pregnant women who drink). *However, more evidence from one or more large-scale replications of the original study is needed for this intervention to qualify as an "evidence-based practice."* Promising practices thus include interventions that have the potential to achieve positive behavioral changes in target populations that can prevent FASD or help those affected by these conditions cope more effectively with its effects. Also included are interventions in studies that may not be able to show a direct relationship between these interventions and the desired outcomes but nevertheless have identified some important benefits for those who participated, as well as provided some valuable insights in relation to the prevention of FASD.

The purpose of this report is to describe the methods used by Center staff to identify and develop an inventory of FASD prevention and treatment interventions and to assess them in accordance with key NREPP criteria, to present the results, and to discuss their implications for SAMHSA and those providing FASD prevention and treatment services across the country. The report concludes with lessons learned and recommendations for SAMHSA.

II. Methods

Center staff performed two main tasks for this project: (1) research to identify FASD interventions and related practices in the United States and development of a database to list them and (2) evaluation to describe and assess these interventions to identify those that represent promising practices.

Research Tasks

Preliminary research on the promising FASD practices project occurred from December 2001 through June 2002. FASD Center staff conducted a comprehensive search of all U.S. and Canadian FASD prevention and treatment practices, collected available data on them, and entered these data into a database specially constructed for this purpose. However, a review of the database content revealed major information gaps in relation to outcomes and evaluation methods and results. At that time, work stopped temporarily with the plan to revisit the issue at a later date. In March 2005, work on this task was resumed by research staff in consultation with evaluators at Conwal, a Center subcontractor, to reexamine and restructure the promising practices project. It was ultimately decided to focus only on interventions implemented in the United States.

To identify FASD interventions, the research team:

- Conducted extensive online and literature searches
- Sought input from FASD experts
- Obtained additional information from contact persons on their interventions
- Developed a database to document this information

The research team limited its search to publicly accessible information to comply with Office of Management and Budget (OMB) regulations.

Conduct Online and Literature Searches

A comprehensive search of the scientific literature and numerous Web-based searches was conducted to obtain information on FASD-related practices. Government and nonprofit resources also were examined to locate possible practices.

Sources accessed for online searches included:

- Medsite
- PubMed
- PsychInfo
- Virtual Medical Center/Martindale's Health Science
- Virtual Hospital Search
- Yale/Newhaven Medical Search
- Stanford University/Lane Medical Library
- BioHunt
- @Life/Internet Health Finder
- About/The Human Internet
- University of Washington Web site
- The Centers for Disease Control and Prevention (CDC) FASD Web site
- Web sites of specific FASD programs
- The SAMHSA Treatment Locator[1]

Sources accessed through literature searches included:

- Journal articles
- Books
- Booklets, brochures, and fact sheets
- Newspaper and magazine articles (including those posted on online news)
- Curricula
- Training manuals
- Reports

Key words for identifying journal articles and other materials describing interventions to prevent FASD included "prevention," "pregnancy," "prenatal alcohol exposure," "substance use," "fetal alcohol syndrome," and "FASD." Searches for materials on treatment for persons affected with an FASD included "substance abuse treatment," "fetal alcohol syndrome," "fetal alcohol spectrum disorders," and "prenatal alcohol exposure."

[1] This source was used to identify substance abuse treatment facilities providing services for women with alcohol problems.

Gather Information From FASD Organizations, Meetings, and Conferences

The team also obtained FASD-related interventions from these sources:

- The National Organization on Fetal Alcohol Syndrome (NOFAS).
- The Minnesota Organization on Fetal Alcohol Syndrome (MOFAS).
- A report published by the State of New Jersey entitled "Changes and Challenges: Securing Our Children's Future," which provided a list of public education projects from 1995 to 2005, many of which addressed FASD.
- Conference and meeting programs and proceedings. For example, staff scanned presentations given at the Center's Building FASD State Systems meetings and an American Public Health Association (APHA) annual conference, as well as presentations given by Steering Committee members, to locate information on FASD-related prevention or treatment interventions.

Obtain Input From FASD Experts and Contact Persons

FASD experts were consulted for information on interventions. These individuals included members of the FASD Steering Committee and experts working at the Center.

Center staff sent e-mails to the contact persons for each intervention to explain that the Center was compiling details on FASD prevention and treatment programs and to ask them to verify the information that had been collected on their particular intervention.[2] These contact persons typically were the principal investigators or project or program directors identified by the research team. The team welcomed any additional information that these contacts provided. Contact persons were informed that their interventions would be entered into a database being developed by the Center. When work resumed on Task 6 in 2005, these persons were contacted again, informed that the database needed to be updated, and asked whether any updates needed to be made to the current information that the Center had on their interventions. The research team also requested evaluation reports, journal articles (both in press and published), and any other available written materials on their interventions or programs.

Some respondents provided the information requested, while others referred the Center's research team to their Web site. Contact persons received followup e-mails asking them to clarify details if needed. If they did not respond, they were contacted by telephone.

Develop and Update the FASD Database

A Microsoft Access database was developed to record critical information about the FASD interventions and practices the research team identified. This database contains 31 fields, which are listed in Appendix A. Key points of information on the different interventions were:

- Practice name
- Name, address, and e-mail of contact person
- Brief description of intervention/practice
- Type of practice (e.g., prevention, treatment)
- Target population
- Goals and objectives

[2] Since this method of gathering information did not entail the use of a questionnaire, OMB clearance was not required for this investigation.

- Duration of services offered
- Evaluation conducted
- Evaluation methods
- Data analysis
- Evaluation findings

Also included for the interventions selected as eligible for rating against specific NREPP criteria were the scores given to them for addressing six requirements for strength of evidence. (More details about these scores are provided in the section Evaluation Tasks below.)

The database was updated continually until the end of September 2006. However, it was eventually decided to focus assessment of promising practices on those implemented in the United States and to exclude those from Canada due to time and resource constraints. Thus, a separate database listing only U.S. interventions was developed to facilitate the work of the evaluation team responsible for reviewing and identifying promising practices.

EVALUATION TASKS

To identify and assess promising practices in FASD prevention and treatment, our evaluation team:

- Reviewed the interventions and practices that had been entered into the database to determine their eligibility for rating against NREPP criteria
- Identified interventions and practices that met NREPP criteria for design and strength of evidence
- Described how the selected interventions met these criteria
- Rated these interventions on the basis of these criteria

It should be noted that these tasks were performed to identify promising practices and not evidence-based ones. Thus, not all the requirements for inclusion in NREPP—as detailed in the March 14, 2006, Federal Register—were addressed to identify these promising practices. Instead, the evaluation team followed the advice of experts to focus on specific NREPP eligibility requirements: the research design, inclusion of objective/measurable outcomes and indication of their statistical significance, and, most importantly, the six criteria demonstrating strength of evidence (see the section Rate Interventions Against NREPP Strength of Evidence Criteria for definitions of the criteria).

Review and Assess Interventions for Eligibility

All the U.S. interventions recorded in the database were reviewed in detail to determine which ones would be eligible for assessment against NREPP criteria. To be eligible, these interventions had to:

- Address FASD directly or indirectly
- Involve changes in behavior in the target population, demonstrated by one or more significant behavioral change outcomes
- Include outcomes that are objective and measurable and reflect intervention goals
- Include an evaluation
- Be published in or accepted for publication by a peer-reviewed journal

Address FASD: Among the interventions in the database that addressed FASD directly were (1) parent-child interaction therapy for children and youth with FAS, ARBD, or ARND and their parents, (2) behavioral consultation for families raising children with FAS and challenging behavior problems, and (3) counseling using motivational interviewing techniques to decrease alcohol consumption by pregnant women. Interventions addressing FASD less directly included (1) counseling to reduce the risk of AEP among women of childbearing age and (2) case management for pregnant and/or parenting women with alcohol problems, including services such as residential or outpatient treatment, parenting education, social services, and medical care for the women and their children. Interventions that addressed drug use only were not included.

Involve behavioral change in the target population: Educational initiatives to raise awareness about FASD (e.g., classroom sessions, media campaigns, materials including videos), provider training programs, and training curricula were not eligible for assessment because they did not include behavioral outcomes such as reduced alcohol use or improved social functioning.

Address objective, measurable outcomes: Interventions that lacked behavioral outcomes that were objective and measurable could not be included. Acceptable behavioral measures included reduced quantity and frequency of alcohol consumption, abstinence, neonatal outcomes such as birth weight and length of body at birth, and child cognitive and physical development indicators.

Include an evaluation: Interventions that had not been evaluated could not be assessed for effectiveness; thus, the many interventions in the database without evaluations had to be excluded. Also, evaluations had to assess outcomes and not just focus on processes of intervention development and implementation.

Be published or accepted for publication in a peer-reviewed journal: While much of the information on the interventions and their evaluations was recorded in the database, additional information from journal articles was needed to ensure that scientifically sound methods—including appropriate statistical analyses and the use of objective measures as required by NREPP—had been used.

Assess Research Design of Selected Interventions

Experts advised the evaluation team to assess FASD interventions and related practices using NREPP criteria for design and strength of evidence. Studies assessing FASD interventions had to be based on one of the following designs to be acceptable for NREPP rating (Federal Register, March 14, 2006, p. 13137):

- Single randomized controlled trial (RCT)
- Single quasi-experiment
- Single group pre- and posttest

These designs allow investigators to assess the effects of specific interventions on behavioral outcomes. Of the three, the RCT is considered more appropriate than the two other kinds of designs because it provides stronger evidence that a specific intervention is effective. Even higher ratings would be given by NREPP for designs involving meta-analysis and systematic research reviews by experts and/or replication across well-designed quasi-experiments or RCTs, but none of the FASD intervention/practice study designs had these features.

NREPP does not accept any assessments of interventions that were based on pilot studies, case studies, or observation.

Rate Interventions Against NREPP Strength of Evidence Criteria

Interventions and related practices that met the NREPP design requirements described above were assessed and rated using six criteria for strength of evidence that interventions must address adequately to be included in the national registry (Federal Register, March 14, 2006). These criteria, and their definitions—derived both from a review of the literature and from descriptions of them listed in the Federal Register (March 14, 2006, pp. 13137–13138), are as follows:

- ***Reliability:*** The extent to which the outcome measures in an instrument or test produce the same results in repeated administrations (e.g., interrater, test-retest, interitem). Reliability also may represent the extent to which scores obtained on a measure are reproducible in repeated administration, given the same measurement conditions. A commonly used coefficient of reliability is internal consistency (Cronbach's alpha). To get the highest rating, studies must indicate that all relevant types of reliability are documented to be at acceptable levels by independent investigators.
- ***Validity:*** The extent to which the specific outcome measure in an instrument or other study tool measures what it is designed to measure and is accepted as valid by experts in the field.
- ***Intervention fidelity:*** Evidence that the intervention/practice being assessed in the study was implemented in accordance with the guidelines, methods, and procedures established by those responsible for its design and development (e.g., the principal investigators). Acceptable evidence includes judgment by experts and systematic collection of data (e.g., time spent in training); adherence to guidelines or a manual; and the use of instruments that have tested, acceptable psychometric properties, such as interrater reliability or validity, as indicated by positive association with outcomes.
- ***Missing data/attrition:*** Study results were not biased by high participant attrition, and/or statistical analyses were performed to control for any missing data. Missing data and attrition also may be taken into account by simple estimates of data and observations or evidence of similarity between remaining participants and those lost to attrition.
- ***Appropriate analyses:*** Acceptable statistical methods were used to infer relationships between the intervention/practice and the desired outcomes, and sample size and power were adequate.
- ***Potential confounding variables:*** Appropriate statistical analyses were conducted to address all known potential confounding variables to allow causal inference between the intervention and reported outcomes.

Methods to rate the eligible FASD interventions according to these criteria were:

- Record on individual cover sheets descriptions of the research design, intervention, data collection methods, and outcomes for each intervention/practice and include summaries of how each one of them addressed the six NREPP strength of evidence criteria
- Include a table at the bottom of each cover sheet for at least two reviewers to score each intervention/practice according to the six strength of evidence criteria
- Have two reviewers conduct independent assessments and scoring based on their careful review of information on the cover sheets and relevant journal articles
- Get reviewers to share their scores with each other and discuss and justify any significant differences in scoring

The information recorded on the cover sheets was derived both from the FASD practices database and from journal articles reporting on the interventions and providing essential details on their research/evaluation design, methods for data collection and analysis, outcomes, and ways in which NREPP strength of evidence criteria were addressed.

The reviews and ratings were conducted by the two doctorate-level reviewers—both with extensive experience in evaluation and substance abuse prevention and treatment—who work for the Center. These reviewers maintained regular e-mail and telephone contact throughout the process. Interrater reliability in these reviewers' ratings was ensured; much of their scoring was the same, and consensus was quickly reached on the remaining scoring differences, which were minor (never more than 2 points). These differences in scoring were resolved after adequate justification was provided by one or the other reviewer for her particular score. Had scoring differences not been resolved, another senior evaluator (doctorate level) would have been asked to rate these interventions.

Reviewers used the scoring guidelines for strength of evidence listed in the March 14, 2006, Federal Register (pp. 13137–13138) to rate the individual interventions. Scoring was done using a Likert-type scale, with 0 for the absence of evidence, 2 for an acceptable level of evidence, and 4 for the strongest kind of evidence for each of the six criteria, with a grand total of 24 across the six criteria. For example, for potential confounding variables, an intervention/practice would get 0 if no statistical analysis was conducted to account for the potential influence of these factors on outcomes, 2 if one or more factors were not completely addressed through statistical analysis, and 4 if statistical analysis addressed all known potential confounding factors adequately.

Once the scoring was completed, the interventions were ranked by their total score.

Data Analysis

Content and cross-case analyses were performed on the data recorded on the FASD intervention/practice cover sheets in order to:

- Locate and describe important similarities and differences in their designs, prevention or treatment services, outcomes, and ways in which they addressed the strength of evidence criteria
- Rate and rank these interventions according to the NREPP criteria
- Explain scoring differences across the interventions

Another major goal for the data analysis was to identify important lessons learned from the process of identifying promising FASD interventions along with recommendations for enhancing the capacity of FASD practitioners and providers to assess the effectiveness of their prevention and treatment initiatives.

III. Results

The final version of the database, submitted to the evaluation team at the end of September 2006, contained information on 257 U.S. interventions for the prevention and/or treatment of FASD. Of these interventions, 132 focused on prevention, 110 focused on treatment, and 15 provided both prevention and treatment services. The evaluation team reviewed the available interventions and selected the ones that should be examined in more detail to identify those ultimately eligible for rating against key NREPP criteria and inclusion as promising practices. At a minimum, these 40 interventions addressed FASD directly or indirectly, were aimed at outcomes representing behavioral changes in the target populations, and included evaluations. Additional information from contact persons and any available journal articles was sought on these interventions to assess their ultimate eligibility for NREPP rating.

ELIGIBLE INTERVENTIONS

Only eight interventions were found to be eligible for NREPP rating and identification as promising FASD practices because they:

- Included well-designed evaluations (i.e., RCTs or quasi-experimental designs were used to assess the effects of the interventions on outcomes)
- Aimed to achieve behavioral outcomes that were measurable
- Were able to show statistically significant relationships between their interventions and desired outcomes in the target populations or subsets of these populations
- Addressed the six NREPP criteria for strength of evidence
- Were published in one or more national peer-reviewed journals

The remaining 32 interventions were unacceptable for NREPP rating because:

- They had only been pilot-tested.
- They were evaluated only with qualitative methods, including case studies.
- They did not include any outcome evaluations.
- They used sample sizes that were too small for inferential analysis.
- Their evaluations were not yet completed.
- Their results were not yet published or accepted for publication.
- Their contact persons failed to respond to repeated requests for more information.

The following eight interventions and the studies assessing their effectiveness met the requirements for NREPP rating for design and strength of evidence:

- *The AR-CARES (Arkansas Center for Addictions Research, Education, and Services) Program,* University of Arkansas at Little Rock, Center for Research on Teaching and Learning
- *Brief Intervention (BI) for Alcohol Use in Pregnancy,* Brigham and Women's Hospital, Department of Psychiatry; Harvard Medical School, Department of Obstetrics and Gynecology
- *Brief Intervention With Support Partner,* Brigham and Women's Hospital, Department of Psychiatry; Harvard Medical School, Departments of Psychiatry, Medicine (Biostatistics), and Obstetrics and Gynecology
- *Brief Intervention for Alcohol Use During Pregnancy,* UCLA, David Geffen School of Medicine, Department of Psychiatry and Bio-Behavioral Sciences
- *Cognitive Behavioral Intervention,* University of Alabama at Birmingham, Department of Health Behavior
- *Parent-Child Assistance Program (PCAP),* University of Washington, Department of Psychiatry and Behavioral Sciences and Department of Epidemiology
- *Project BALANCE* (Birth Control and Alcohol Awareness: Negotiating Choices Effectively), Virginia Commonwealth University, Department of Psychiatry, Division of Addiction Psychiatry
- *Project TrEAT* (Trial for Early Alcohol Treatment), University of Wisconsin-Madison Medical School, Center for Addiction Research and Education

DESCRIPTIONS OF INTERVENTION STUDIES

Table 1 presents summaries of critical information on these eight interventions, the populations targeted, their evaluation designs and data collection methods, and the outcomes they achieved. Analyses of these data revealed a number of common characteristics. See Appendix B for citations of relevant journal articles on these eight interventions.

Types of Intervention Services, Strategies, and Resources

The service components of the eight interventions included the following:

- Prenatal care (n = 5)
- Provision of take-home manual/workbook (n = 4)
- Brief intervention including motivational interviewing (n = 4)
- Case management (n = 2)
- Contraception counseling (n = 2)
- Education and self-help (n = 1)
- Two physician counseling sessions (n = 1)

All but three of the interventions offered prenatal care to women in both the control and intervention groups (see Table 1). Four of them gave intervention participants take-home manuals or workbooks to help them reduce alcohol use and/or adopt other desired behaviors. Four interventions included the use of motivational interviewing techniques during single sessions with individual participants. The case management services for women and children provided by PCAP and the AR-CARES Program included home visits; counseling; and assistance in accessing needed community services such as alcohol and other drug (AOD) treatment, health care, mental health services, parenting classes, vocational education, housing, and employment. One intervention focused on self-help, while another used primary care physicians to counsel participants.

Target Populations

As Table 1 indicates, the different populations targeted by the interventions were as follows:

- Pregnant women at risk for an AEP (n = 4)
- Pregnant women at risk for an AEP and their partners (n = 1)
- Women of childbearing age at risk for an AEP (n = 2)
- Postpartum women at risk for an AEP (n = 1)
- Infants (n = 2)

Table 1: Interventions, Evaluations, and Outcomes

Description of Intervention/Practice[3]	Target Population	Evaluation Design and Sample Size	Data Collection	Outcomes
Brief Intervention (BI) With Support Partner, Brigham and Women's Hospital, Department of Psychiatry; Harvard Medical School, Departments of Psychiatry, Medicine (Biostatistics), and Obstetrics and Gynecology				
The BI used motivational techniques including knowledge assessment with feedback, goal setting and contracting with subject to achieve goals, behavioral modification, and planned behavioral changes discussed with subject and partner. Subjects and partners then got a summary of the session.	Pregnant women receiving prenatal care who were T-ACE positive, at risk for alcohol-related pregnancy, and gestation of <28 weeks, and their selected partners.	RCT: 304 women and selected partners were assigned randomly to the BI (n = 152) or control group receiving assessment only (AO) (n = 152)	Women were screened for alcohol use (T-ACE). Those eligible for the study and their partners were given separate diagnostic interviews at study enrollment and again postpartum.	Both BI and control groups reduced alcohol consumption after study enrollment. But, the interaction between the BI and prenatal alcohol use was significant ($p < .01$), indicating the BI was more effective in reducing frequency of use among women with the highest initial consumption. Also BI effects were significantly enhanced when a partner participated ($p < .05$).
Parent-Child Assistance Program (PCAP), University of Washington, Department of Psychiatry and Behavioral Sciences and Department of Epidemiology				
Case management involving regular home visits, advocacy, and assistance in accessing comprehensive community services. Services included alcohol and drug (AOD) treatment, health care, mental health services, education, vocational training, parenting/child care classes, family planning, and social services.	Low income, postpartum women and their newborn children.	Quasi-experimental design conducted at an original demonstration site (OD) with 65 women in the intervention group and 35 controls. The intervention was then replicated at 2 other sites, and a pretest/posttest comparison of outcomes was made between the 60 OD women and the 156 clients at the 2 other sites that remained in the study for the 3 years.	All clients completed interviews at intake and 36 months thereafter. Also, the clients and target children were assessed at 4, 12, 24, and 36 months after the intervention began.	The OD intervention group had significantly higher average scores than the control group ($p = .04$), with 85% completing AOD treatment, 75% using birth control regularly, and all better linked to community services. Clients at the two replication sites performed significantly better than the OD clients ($p < .02$), adjusting for baseline, in completing AOD treatment, abstinence, and employment. At all three sites, most women were no longer at risk of another AEP, and more than 90% of children in custody of their families received well-child care.

[3] In the tables, the interventions are presented in the order that reflects their ranking in relation to the scores they were given for addressing NREPP strength of evidence criteria. See Table 2 in Appendix C for details on how the interventions addressed these criteria and the scores they received.

Table 1: Interventions, Evaluations, and Outcomes

Description of Intervention/Practice	Target Population	Evaluation Design and Sample Size	Data Collection	Outcomes
Brief Intervention (BI) for Alcohol Use During Pregnancy, UCLA, David Geffen School of Medicine, Department of Psychiatry and Bio-Behavioral Sciences				
Conducted by WIC nutritionists giving clients nutrition education, the BI involved a comprehensive assessment of alcohol use, alcohol/health education and feedback, cognitive-behavioral techniques, goal setting, and contracting aimed at reducing alcohol use during pregnancy. A standard workbook was used for this intervention.	Pregnant low-income minority women (71% Latina, 17% African American, 7% White) in WIC programs. (Average weeks of gestation at study enrollment was 18.)	RCT: 255 women who were assigned to the BI (n = 117) or to AO (n = 138). The latter group received advice to stop drinking during pregnancy.	Screening for alcohol use included use of the TWEAK and quantity-frequency measures. Those screening positive and enrolled in the study received a comprehensive assessment of alcohol use including the Health Interview for Women and MAX (maximum drinks per drinking occasion). Data were collected at study enrollment and postpartum.	BI was significantly related to abstinence ($p < .04$), with the BI group over 5 times more likely than those in the AO group to be abstinent by the third trimester. Infants of AO women consuming >2 drinks/occasion were significantly shorter than those of mothers in the BI group who were high or low consumers of alcohol and those in the AO group who drank less at enrollment. A lower rate of fetal deaths was found among BI mothers (n = 1) than among AO mothers (n = 5).
Project TrEAT (Trial for Early Alcohol Treatment), University of Wisconsin-Madison Medical School, Center for Addiction Research and Education				
Two 15-minute physician counseling sessions included advice, education, and contracting with subject to stop drinking using a scripted workbook, review of problem drinking prevalence, adverse effects of alcohol, worksheet on drinking cues, a drinking agreement in the form of a prescription, and drinking diary cards. Based on protocols developed for the Medical Research Council trial. Subjects received a followup phone call from a clinician 2 weeks after each session.	Women of childbearing age (18 to 40 years) who were problem drinkers.	Longitudinal RCT: 205 female primary care patients were randomized to the intervention (103) or the control (102) group.	Initial screening using the CAGE was followed by a baseline assessment interview with a researcher and followup telephone interviews at 12, 24, 36, and 48 months.	The intervention was associated with significantly reduced 7-day alcohol use ($p = .0039$) and binge drinking episodes ($p = .0021$) over the 48-month followup period as compared to the control group. Women who became pregnant had the most dramatic decreases in alcohol use.

Table 1: Interventions, Evaluations, and Outcomes

Description of Intervention/Practice	Target Population	Evaluation Design and Sample Size	Data Collection	Outcomes
Brief Intervention (BI) for Alcohol Use in Pregnancy, Brigham and Women's Hospital, Department of Psychiatry; Harvard Medical School, Department of Obstetrics and Gynecology				
The BI included motivational interviewing techniques and involved a review of the subject's general health, pregnancy, and lifestyle changes; goal setting and reasons for goals; drinking risk situations and healthy alternatives; planning behavioral changes; and recording a summary of the session in a take-home manual.	Pregnant women receiving prenatal care who were T-ACE positive, gestational age of <28 weeks, and had consumed alcohol during the past 6 months.	RCT: 250 women randomized to the BI (123) or to receive an assessment only (n = 127).	T-ACE was used to screen for alcohol use, and multiple instruments were used at assessment and postpartum to collect data from the BI and AO groups.	A 17% reduction in drinking found in both BI and control groups, but significantly higher rates of abstinence were found among BI women who were abstinent while pregnant and pre-assessment. Reduced drinking occurred among BI women who set abstinence as their goal ($p = .002$) and cited FAS as a reason not to drink ($p = .001$) as compared to women who did not do so.
Project BALANCE (Birth Control and Alcohol Awareness: Negotiating Choices Effectively), Virginia Commonwealth University, Department of Psychiatry, Division of Addiction Psychiatry				
Designed to reduce drinking and increase effective contraception: a 60-75 minute individual counseling session used motivational interviewing techniques, including decisional balance, resisting temptation, confidence charts, goal setting, and plans to change drinking and contraception behavior. Counselor also recorded 90-day timeline follow-back drinking data and data on contraception use. A research counselor conducted the intervention right after assessment to students randomly assigned to this group.	Female college students age 18 to 24 at risk for an AEP.	RCT: 228 students (114 control group receiving an assessment only and 114 receiving the intervention).	Screening followed by an assessment at baseline and 1-month followup of the students enrolled in the study (as controls or intervention participants). A larger-scale study assessing longer-term intervention effects is under way.	25% of women in intervention group reported no risk drinking as compared to 15% of controls; greater use of effective contraception among intervention women (64%) than among controls (48%) ($p < .03$). Significantly more intervention women (74%) no longer at risk for AEP as compared to controls (54%) ($p < .005$).

Table 1: Interventions, Evaluations, and Outcomes

Description of Intervention/Practice	Target Population	Evaluation Design and Sample Size	Data Collection	Outcomes
The AR-CARES (Arkansas Center for Addictions Research, Education, and Services) Program, University of Arkansas at Little Rock, Center for Research on Teaching and Learning				
The intervention evolved over 5 years with client/staff input to an individualized family treatment plan of comprehensive community services that were made available to women with AOD problems. Services to which women were linked included AOD treatment, prenatal care, child health services, group and individual counseling, parenting and health education, child care, 12-Step meeting attendance, and transportation.	Low-income women with AOD problems and their children (majority African American). Services provided to women during pregnancy and postpartum.	Quasi-experimental design: 95 women, with 72 assigned to the intervention and 23 others who declined to participate in the intervention and were assigned to the control group.	Women were interviewed by trained clinical staff in a clinical setting at intake, delivery, and when their children were 6, 12, and 18 months old. Urine toxicology tests also were used to assess AOD use at intake and delivery.	Alcohol and drug use among intervention women declined significantly more than among controls ($p = .02$ for alcohol; $p = .0001$ for drugs). These women also had a shorter hospital stay than the controls along with a lower incidence of premature labor and maternal infections. Their babies had significantly higher birth-weight, with 2 weeks more gestational age than infants of nonparticipants, and as the children aged, they enjoyed normal growth and normal cognitive development.
Cognitive Behavioral Intervention, University of Alabama at Birmingham, Department of Health Behavior				
Based on Bandura's social cognitive theory, the 10-minute educational self-help (SH) session addressed fetal effects of alcohol use and distribution of a 9-step SH manual to be completed at home in 9 days. The manual contained information on FAS and on how to identify drinking patterns, to build self-efficacy to quit, and to elicit social support. Other topics included removing alcohol from home and avoiding drinking locations. Women were called 1 week after recruitment to assess their progress and answer questions.	Low-income women (67% African American) receiving prenatal care at public health maternity clinics and identified as having problems with drinking.	RCT: 78 women, with 42 assigned to receive the SH intervention and 36 to receive only the usual clinical care.	Screening on alcohol consumption, using the T-ACE, knowledge and psychosocial variables, and posttest 2 months after recruitment. Pre- and posttest measures included outcome expectancies, social norms, self-efficacy, and social influence.	A higher quit rate of 88% was found in the SH group as compared to 69% of usual care participants ($p < .058$). The intervention seemed most effective with African Americans and women who were light to moderate drinkers. Participation in the SH intervention increased the likelihood that a women would stop drinking ($p < .03$).

Through initial screening, participants in five of the intervention studies were pregnant and at risk for an AEP. Two other studies tested interventions designed for women of childbearing age who were at risk for an AEP, as were the women who had just given birth and were receiving case management services in another study (PCAP). The newborn children of PCAP participants and of those in the AR-CARES Program also received services, including health care.

The ages of the women participating in the eight interventions ranged from 18 to 40 years, with an average age of 27 years.

Although participants in all the studies were ethnically diverse, the majority in five studies were White. Most participants in two other studies were African American, and most were Hispanic-Latina in the remaining study. Four of the studies assessed interventions targeted to low-income women, as shown in Table 1.

Evaluation Designs and Sample Sizes

The evaluation design of all but two of the interventions was based on a randomized controlled trial, as shown in Table 1. Specifically, the following designs were used:

- Randomized controlled trial (n = 6)
- Quasi-experimental design (n = 1)
- Quasi-experimental design at original demonstration site with replications of the intervention at two other sites (n = 1)

Overall sample sizes including both the intervention and control groups ranged from a low of 78 for the Cognitive Behavioral Intervention, which was implemented at one site, to a high of 256 for PCAP, which involved an initial demonstration project with two replications (see Table 1). Sample sizes for only the intervention groups ranged from 42 in the Cognitive Behavioral Intervention to 152 for the Brief Intervention With Support Partner (although the intervention group participants in the 3 PCAP sites totaled 221). In five studies, sample sizes of the control and intervention groups were more than 100 each and were either equal (as with Brief Intervention With Support Partner and Project BALANCE), or almost equal (as with Project TrEAT and the two other brief interventions for alcohol use during pregnancy).

Data Collection

Subjects were screened to determine their eligibility to participate in the studies. Subsequent data collection from those eligible for participation involved the administration of a battery of instruments at study enrollment (assessment) and again at one or more designated followup periods ranging from 1 month postintervention to 4 years thereafter (see the Validity section of Table 2 in Appendix C for details on the instruments used). Data on the same measures were obtained from participants at baseline and again during followup interviews to assess the effects, if any, of the intervention. Thus, findings based on the data collected were compared between the intervention and control groups. Factors assessed at baseline and followup included alcohol use (quantity and frequency and severity of problems related to this behavior), other drug use, psychosocial variables, physical health, health behavior, and child development.

As Table 1 indicates, followup periods in these studies were as follows:

- Postdelivery (n = 3)
- Postdelivery and 6, 12, and 18 months thereafter (n = 1)
- 1 month (n = 1)
- 2 months (n = 1)
- 12, 24, 36, and 48 months (n = 1)
- 4, 12, 24, and 36 months (n = 1)

Followups for the three brief interventions (BI for Alcohol Use During Pregnancy, BI With Support Partner, and BI for Alcohol Use in Pregnancy) occurred after delivery. Participants in the AR-CARES Program and PCAP interventions were contacted four times after enrollment, as were those receiving counseling from physicians through Project TrEAT. The shortest followup time was 1 month after enrollment (Project BALANCE), while participants of the Cognitive Behavioral Intervention were contacted 2 months after signing up for the study. PCAP participants were the only ones in the eight studies to be first interviewed after delivery.

Outcomes

As indicated in Table 1, all the interventions were linked to favorable outcomes. The most reported outcomes for intervention participants as compared to those in the control groups were:

- Greater reductions in drinking rates than controls (n = 2)
- Higher quit rates during pregnancy (n = 4)
- Increased linkage to community services (n = 2)
- Better birth or developmental outcomes for infants (n = 2)

Six of the interventions were effective in reducing the risk for AEP. Typical examples of outcomes achieved by the interventions and their statistical significance are as follows:

- The BI was significantly linked to abstinence ($p < .04$), with the BI group five times more likely than the control group to be abstinent by the third trimester (BI for Alcohol Use During Pregnancy).
- Clients at the two PCAP replication sites did significantly better ($p < .02$) than those at the original demonstration site (adjusting for baseline) in completing alcohol and other drug treatment, remaining abstinent, and getting a job.
- Alcohol and other drug use decreased significantly more among the AR-CARES Program intervention women than among those in the control group ($p = .02$ for alcohol, and $p = .0001$ for drugs). The babies of intervention women also had significantly higher birth weight and a 2-week greater gestational age than those of the women who did not receive case management services.

Useful findings also were reported for the BI With Support Partner study. Researchers found that the intervention was associated with reduced subsequent drinking for women who were the heaviest drinkers at study enrollment ($p < .01$) and that its effects were significantly enhanced when the woman's partner was involved ($p < .05$).

See Table 1 for more details on the outcomes achieved by the eight interventions.

Ratings for NREPP Strength of Evidence Criteria

All eight interventions and their evaluations addressed the six NREPP strength of evidence criteria as shown in the short summary descriptions and scores presented in Table 2 in Appendix C. Ratings for these criteria by the two FASD Center for Excellence reviewers resulted in the following scores out of a total of 24:

- Brief Intervention With Support Partner: 22
- PCAP: 20
- Brief Intervention for Alcohol Use During Pregnancy: 20
- Project TrEAT: 19
- Brief Intervention for Alcohol Use in Pregnancy: 18
- Project BALANCE: 18
- The AR-CARES Program: 17
- Cognitive Behavioral Intervention: 17

Explanations for the reviewer's scoring of these projects shown in Appendix C are as follows:

- None of the studies were given a top score of 4 for *reliability* (see Appendix C), because they do not appear to have used any independent investigators to assess their methods for achieving acceptable levels of reliability, as required by NREPP (Federal Register, March 14, 2006, p. 13137).
- *Brief Intervention With Support Partner* received the top score *(22 of 24)* because, with the exception of reliability, the study more than adequately addressed the strength of evidence criteria and showed conclusively that the BI was effective (see table in Appendix C). Statistical methods and the inclusion of the subject's designated partner were used to address reliability, while validity was achieved through use of a battery of instruments to assess the subject's alcohol use and health behavior at study enrollment and after delivery. To ensure fidelity, the clinicians who conducted the intervention were observed and their summaries and other notes were reviewed for consistency with the medical model of documentation. Researchers obtained a 95 percent response rate at postpartum followup. They also used appropriate statistical methods for data analysis and also to account for confounding variables including demographics, alcohol use history, and high-risk pregnancy status.
- *PCAP (20 of 24)* received a score of 2 for *confounding variables* because insufficient evidence was provided to show why some of the outcomes were due to its intervention services rather than to recent State legislation that provided low-income families with assistance in housing and employment. However, PCAP has been so successful that it has been replicated in 12 other sites in the United States and Canada.
- *Brief Intervention for Alcohol Use During Pregnancy (20 of 24)* conducted at WIC (Special Supplemental Nutrition Program for Women, Infants, and Children) sites in Southern California was scored at 2 for *missing data/attrition* because the postpartum followup rate was only 74 percent (see Appendix C). Although it was reported that this response rate is typical for WIC clients, more explanation would have been useful, especially as other interventions with much longer followup periods were able to maintain contact with higher percentages of subjects from low-income population groups (see Appendix C).
- *Project TrEAT (19 of 24)* received a score of 2 for *intervention fidelity* because there appear to have been no provisions, other than initial and followup training, to ensure that the physicians adhered to

any standard protocol for implementation. A standardized intervention manual would have helped address this problem. Also, in regard to *missing data/attrition*, more discussion about the 15 percent of subjects lost to followup would have raised this project's score of 3 to 4.

- *Brief Intervention for Alcohol Use in Pregnancy (18 of 24)* would have received a higher score than 2 for *intervention fidelity* if the study had included an objective method (e.g., observation by an independent investigator of a random sample of the brief interventions being conducted by the principal investigator) to ensure consistency. A score of 2 was given for *confounding variables* because statistical methods to address these factors were not described.
- *Project BALANCE (18 of 24)* was given a score of 2 for *missing data/attrition* because the 1-month followup questionnaires, paper forms that were mailed to study participants, were returned with some incomplete or indecipherable responses so that data on one or more outcome variables were missing from 13 cases. It appears that no further effort was made to contact these students to address these data gaps. The project also received a score of 2 for *confounding variables* because outcomes may have been influenced by the informed consent process and baseline assessment, which may have alerted participants to their risk for an AEP, and because potential mediators of behavioral change—including psychiatric distress, personality factors, illicit drug use, and readiness to change—were not addressed. However, these variables will be examined in future research exploring longer-term outcomes for this intervention.
- *The AR-CARES Program (17 of 24)* achieved a score of 3 for *validity* because data collection on alcohol use and related problems was limited to self-reports from interviews and urine toxicology screens for the women. None of the instruments widely used in the field to assess alcohol use and related problems (e.g., TWEAK, Timeline Follow-Back interview, Alcohol Use Disorders Identification Test [AUDIT], Addiction Severity Index [ASI]) were used. However, Bayley Scales of Infant Development were used with the children in this study. A score of 0 was given for *missing data/attrition* because so many of the participating women and children were lost to followup (38 percent of those in the intervention and 43 percent of the others). Numbers of children dwindled from 16 at 6 months to 6 at the end of the 18-month study period.
- *Cognitive Behavioral Intervention (17 of 24)* received a score of 2 for *intervention fidelity* because no measures were taken to check the ongoing delivery of the 10-minute self-help sessions for consistency by the educators who had been trained to conduct them. A score of 3 was given for *missing data/attrition* because the loss of 6 participants to followup (3 from the intervention and 3 from the control group) was quite significant for the small sample (n = 78) and for such a short followup time of only 2 months after study enrollment. A score of 2 was assigned for *appropriate analyses* because of the small sample size.

As mentioned previously, the scores given for the eight intervention projects discussed above must be viewed as preliminary only. Further review by experts designated by SAMHSA would be most useful in confirming or challenging the assessments of these projects by the two FASD Center for Excellence reviewers. Also, the main goal for rating these interventions was to identify promising practices and not evidence-based practices. Thus, not all the NREPP requirements for the latter were addressed in this review.

Ratings for Criteria Across the Eight Studies

It is useful to compare the scores given for each of the six strength of evidence criteria across the eight projects to identify common strengths and weaknesses. As indicated in Table 2 in Appendix C, the highest scores achieved out of a possible cross-site total of 32 were for:

- ***Validity (31 of 32):*** Researchers collected data on alcohol use and other relevant factors using instruments that have been widely used and accepted as valid in the field for a number of years. These tools included the CAGE, T-ACE, TWEAK, ASI, Timeline Follow-Back interview, and Bayley Scales of Infant Development. Other instruments used in some studies to gather data on other relevant variables included Health and Habits Surveys, the Health Interview for Women, the Diagnostic Interview Schedule based on the *Diagnostic and Statistical Manual of Mental Disorders, Third Version, Revised* (DSM III-R), the Situational Confidence Questionnaire, and the Brief Symptom Inventory (BSI).
- ***Appropriate analyses (30 of 32):*** Researchers used the appropriate statistical methods (e.g., t-tests, chi-square analyses), to assess the impact of their interventions on alcohol use, neonatal effects, and other outcomes.

Studies also did quite well addressing *intervention fidelity* and *confounding variables*, for which the cross-site scores were 26 out of 32. Steps to ensure fidelity included training those delivering the intervention, providing standard workbooks for them and/or the participants, and checking on their performance to ensure consistency of delivery. Almost all the studies described the statistical methods used (e.g., regression models) to account for confounding variables and were able to report no statistical differences between their intervention and control groups.

As discussed in the previous section, some studies did less well in regard to *missing data/attrition* (with a total cross-site score of 22 out of 32), mostly because they lost so many participants to followup.

Despite receiving the lowest cross-site score for *reliability* (16 out of 32), the studies used various methods to address this important criterion. As shown in Table 2, Appendix C, these methods included:

- Checking self-report baseline and followup data from intervention participants with data from their designated partners
- Using the Outcomes Questionnaire-45 (along with the BSI) because of its good test-retest reliability in student samples
- Testing key measures in pretest and posttest questionnaires with Cronbach's alpha for reliability

PRACTICES WITH FUTURE POTENTIAL

The review of FASD prevention and treatment interventions revealed two programs that likely will meet the qualifications for inclusion with the eight projects described above when their evaluations have been completed and the results have been published. These are:

- *Early Start Plus*, an enhancement to the Early Start (ES) services for pregnant women with alcohol and other drug problems provided by Kaiser Permanente, which focuses on getting women who drink to stop doing so during pregnancy. This large-scale, National Institute on Alcohol Abuse and Alcoholism–funded randomized clinical trial involving three groups of 600 women (ES only, ES plus, and a control group) is being conducted in collaboration with the Alcohol Research Group, which is conducting the evaluation.

- *Families Moving Forward*, which is being implemented by the University of Washington with a randomized controlled trial. This intervention comprises bimonthly home visits for 9 to 11 months by trained support specialists to teach parents to cope more effectively with their children ages 5 to 11 years who have FAS and challenging behavioral problems. This initial study, involving parents of 52 children, is assessing the intervention by comparing its outcomes with those related to standard community care.

Another potential candidate for FASD promising practices is Project CHOICES, a CDC intervention that has been piloted successfully in multiple sites, including Nova Southeastern University, Florida, University of Texas Health Sciences Center, and Virginia Commonwealth University. This intervention currently is being assessed in a large-scale randomized controlled trial.

IV. Key Findings, Conclusions, and Recommendations

Key Findings

The results of the Center's investigation, review, and assessment of FASD interventions to identify promising practices can be summarized as follows:

- Eight intervention studies/evaluations qualified for NREPP rating for design and strength of evidence criteria out of a total of 257 FASD interventions in the database.
- None of the FASD-related treatment interventions for children, youth, adults, and their parents qualified for NREPP rating.
- The main focus of all eight interventions was the prevention of FASD, whether during or after pregnancy or among women of childbearing age. The case management approach used by two of the interventions, PCAP and the AR-CARES Program, also included treatment services or enhanced linkages to these services for the women and their children.
- All the interventions were designed to prevent AEP, five targeted to pregnant women, two to women of childbearing age, and one to postpartum women.
- The most common type of intervention involved one-on-one motivational interviewing techniques, which proved effective in reducing AEPs. Similar results are reported in other studies (Floyd, et al., 2007; Handmaker, Miller, and Manicke, 1999; Ingersoll, et al., 2005).
- Case management services used for two other interventions also were found to be effective in reducing AEP risk, as well as helping postpartum women and their infants get better access to critical health and social services in their communities.
- All but one study used randomized controlled trials to assess their interventions (with the remaining study using a quasi-experimental design), and sample sizes were adequate in seven out of the eight studies.
- The most frequently reported outcomes for the intervention groups as compared to controls were greater reductions in drinking rates and higher quit rates during pregnancy. Newborns had better birth outcomes in one study, and infants fared better in terms of development and access to adequate health care in two other intervention studies.
- Most of the favorable outcomes were significantly related to the interventions rather than other factors.
- Intervention studies receiving the highest scores for the six strength of evidence criteria were Brief Intervention With Support Partner (22 of 24), PCAP (20 of 24), and Brief Intervention for Alcohol

Use During Pregnancy (20 of 24). Those with the lowest ratings were the AR-CARES Program and the Cognitive Behavioral Intervention (both with scores of 17 of 24).

- Across the eight interventions, studies were most successful in addressing the criteria of validity (31 of 32) and appropriate analyses (30 of 32). In the first case, they used instruments with measures widely recognized as acceptable for assessing alcohol use and other relevant favors. In the second, they used the correct kinds of statistical methods to assess the relationship between their interventions and outcomes.
- Several intervention studies were less successful in achieving top scores for missing data/attrition because of the number of participants lost to followup. However, the populations targeted by the interventions are known to be particularly difficult to trace because they face multiple challenges, including addiction, unstable housing, and economic difficulties.

CONCLUSIONS

The results discussed above lead to the following conclusions:

- All eight interventions qualify as promising practices because their evaluations were well designed and have addressed the six NREPP strength of evidence criteria. Six intervention studies provided sufficient evidence of statistically significant relationships between intervention strategies and outcomes. These outcomes reduce the risk for AEPs among pregnant and childbearing-age women and, thus, decrease the risk of FASD among their children.
- Results of two studies—Brief Intervention for Alcohol Use in Pregnancy and Brief Intervention With Support Partner—did not show any significant differences in outcomes between intervention and control groups in terms of alcohol consumption. However, they did report some useful findings that suggest that with some enhancements, their interventions may have a greater impact on the alcohol use of participants during their pregnancy as compared to the control group. It also may be worthwhile investigating in future studies why both the intervention and control groups reduced alcohol consumption after enrollment.
- Future evaluations of FASD interventions need to address all the NREPP strength of evidence requirements, especially in terms of meeting all requirements for reliability and missing data/attrition. It is especially important to keep track of study participants in both intervention and control groups from baseline through followup to ensure that evaluation results are viable.
- At present, very few FASD prevention and treatment interventions being implemented in the United States could qualify as promising practices because they lack an evaluation component to determine whether what they are doing is effective and what improvements should be made to enhance their interventions.
- There is a critical need for more resources and technical assistance (TA) to enable current and future FASD interventions to be evaluated in accordance with the NREPP requirements. *This need is especially great for programs providing treatment services to children, youth, and adults with FAS and related problems and support to their families and for programs designed for low-income racial/ethnic minority populations.*

Also, some key lessons have been learned from the Center's review and assessment of FASD interventions:

- Women should be screened for prenatal alcohol use to prevent AEPs.

- Brief interventions using motivational interviewing are low cost and effective in reducing the risk of AEPs.
- Pregnant women getting brief interventions may be less likely to drink if their partners are involved.
- The brief intervention study in the WIC centers suggests that nonmedical professionals serving pregnant, low-income, minority women could incorporate brief interventions with their other services.
- Primary care physicians have great potential to reduce drinking among childbearing women, as indicated by Project TrEAT.
- Comprehensive services involving case management can produce long-lasting benefits for low-income women and their children.

RECOMMENDATIONS

Based on the Center's review, assessment, and ratings of current FASD prevention and treatment interventions as described in this report, the Center offers the following recommendations for SAMHSA's consideration:

- Offer additional resources, training, and TA to build evaluation capacity in community health care and other organizations that have SAMHSA grants or can apply for this kind of support to provide FASD prevention and treatment services. Capacity building should include assistance in designing evaluations that meet all the NREPP requirements for evidence-based practices.
- Promote greater collaboration between FASD researchers and practitioners to facilitate the development, testing, and delivery of promising and evidence-based practices. It is noteworthy that all eight intervention studies were conducted by researchers affiliated with universities and/or medical schools.
- Work with the Center to promote expanded sharing of information and resources on such items as intervention strategies that work and well-designed evaluations among FASD prevention practitioners, treatment providers, and evaluators in the future.
- Encourage the inclusion of longer followups for interventions to ensure sustainable positive outcomes for women and children. Studies with 1- to 2-month followups do not provide adequate evidence of long-lasting intervention effects. It would be useful to know, for example, whether women who stop drinking during pregnancy remain abstinent thereafter or return to former patterns of alcohol consumption.
- Support the expansion and replication of all FASD prevention and treatment interventions that are found to be effective, along with well-designed evaluation components. As reported previously, PCAP has been replicated at 12 sites in the United States and Canada.

In sum, the important lessons learned from the Center's investigation of promising practices and the recommendations resulting from this study may prove useful to SAMHSA and others working to support the development and adoption of evidence-based practices in FASD prevention and treatment in the future.

REFERENCES

Floyd, R.L.; Sobell, M.; Velasquez, M.M.; Ingersoll, K.; Nettleman, M.; Sobell, L.; Mullen, P.D.; Ceperich, S.; von Sternberg, K.; Bolton, B.; Skarpness, B.; Nagaraja, J.; Project CHOICES Efficacy Study Group. 2007. Preventing alcohol-exposed pregnancies: A randomized controlled trial. *American Journal of Preventive Medicine* 32(1):1–10.

Handmaker, N.S.; Miller, W.R.; and Manicke, M. 1999. Findings of a pilot study of motivational interviewing with pregnant drinkers. *Journal of Studies on Alcohol* 60(2):285–287.

Ingersoll, K.; Floyd, L.; Sobell, M.; Velasquez, M.M.; Project CHOICES Intervention Research Group. 2003. Reducing the risk of alcohol-exposed pregnancies: A study of a motivational intervention in community settings. *Pediatrics* 111(5 Part 2):1131–1135.

May, P.A., and Gossage, J.P. 2001. Estimating the prevalence of fetal alcohol syndrome: A summary. Alcohol Research & Health 25(3)159–167.

Substance Abuse and Mental Health Services Administration. 2006. Changes in the National Registry of Evidence-Based Programs and Practices (NREPP): Substance Abuse and Mental Health Services Administration. *Federal Register* 71(49):13132–13155 (March 14).

Substance Abuse and Mental Health Services Administration. 2006. Notice regarding Substance Abuse and Mental Health Services Administration's National Registry of Evidence-Based Programs and Practices (NREPP): Priorities for NREPP reviews. *Federal Register* 71(126):373590–37591 (June 30).

APPENDIX A

FASD Intervention/Practice Database Fields

APPENDIX A: FASD INTERVENTION/PRACTICE DATABASE FIELDS

The following fields are represented in the practices database:

- Practice (intervention) name
- Brief description of practice
- Type of practice (prevention or treatment; specific, adapted, or general)
- Target population
- Native American
- Goals and objectives
- Duration of services offered
- Eligibility requirements
- Screening conducted
- Enrollment procedures
- Fee charged for adopting practice
- Curriculum for training/education
- End date of practice
- Specific population with targeted components of practice
- Listed in NREPP or other practice guidelines
- Point of contact name
- E-mail address of point of contact
- Phone number of point of contact
- Address of practice location
- Practice Web address (URL)
- Evaluation conducted
- Number of evaluations
- Date of evaluations
- Evaluator/author
- Brief description of evaluation
- Characteristics of study participants
- Methods (e.g., data collection)
- Data analysis
- Summary of evaluation findings
- Additional relevant information
- Recordkeeping items
  - Search terms
  - Update complete
  - Contact comments
  - Record closed
- Ratings for NREPP strength of evidence criteria[4]

[4] The last field applied only to those interventions/practices found to be eligible for NREPP rating.

APPENDIX B

Background Literature on Eligible FASD Interventions

APPENDIX B: BACKGROUND LITERATURE ON ELIGIBLE FASD INTERVENTIONS

Parent-Child Assistance Program (PCAP)

Ernst, C.C.; Grant, T.M.; Streissguth, A.P.; and Sampson, P.D. 1999. Intervention with high-risk alcohol and drug-abusing mothers: II. Three-year findings from the Seattle model of paraprofessional advocacy. Journal of Community Psychology 27(1):19–38.

Grant, T.M.; Ernst, C.C.; Streissguth, A.; and Stark, K. 2005. Preventing alcohol and drug exposed births in Washington State: Intervention findings from three Parent-Child Assistant Program sites. *The American Journal of Drug and Alcohol Abuse* 31:471–490.

Brief Intervention for Alcohol Use in Pregnancy

Chang, G.; Goetz, M.A.; Wilkins-Haug, L.; and Berman, S. 2000. A brief intervention for prenatal alcohol use: An in-depth look. *Journal of Substance Abuse Treatment* 18:365–369.

Chang, G.; Wilkins-Haug, L.; Berman, S.; and Goetz, M.A. 1999. Brief intervention for alcohol use in pregnancy: A randomized trial. *Addiction* 94(10):1499–1508.

Brief Intervention With Support Partner

Chang, G.; McNamara, T.K.; Orav, E.J.; Koby, D.; Lavigne, A.; Ludman, B.; Vincitorio, N.A.; and Wilkins-Haug, L. 2005. Brief intervention for prenatal alcohol use: A randomized trial. *Obstetrics & Gynecology* 105(5):991–998.

Cognitive Behavioral Intervention

Reynolds, K.D.; Coombs, D.W.; Lowe, J.B.; Peterson, P.L.; and Gayoso, E. 1995. Evaluation of a self-help program to reduce alcohol consumption among pregnant women. *The International Journal of the Addictions* 30(4):427–443.

Project TrEAT (Trial for Early Alcohol Treatment)

Manwell, L.B.; Fleming, M.F.; Mundt, M.P.; Stauffacher, E.A.; Lawton, B.; and Lawton, K. 2000. Treatment of problem alcohol use in women of childbearing age: Results of a brief intervention trial. *Alcoholism* 24(10):1517–1524.

Project BALANCE (Birth Control and Alcohol Awareness: Negotiating Choices Effectively)

Ingersoll, K.S.; Ceperich, S.D.; Nettleman, M.D.; Karanda, K.; Brocksen, S.; and Johnson, B.A. 2005. Reducing alcohol-exposed pregnancy risk in college women: Initial outcomes of a clinical trial of a motivational intervention. *Journal of Substance Abuse Treatment* 29:173–180.

The AR-CARES (Arkansas Center for Addictions Research, Education, and Services) Program

Whiteside-Mansell, L.; Crone, C.C.; and Conners, N.A. 1999. The development and evaluation of an alcohol and drug prevention and treatment program for women and children. *Journal of Substance Abuse Treatment* 16(3):265–275.

Brief Intervention for Alcohol Use During Pregnancy

O'Connor, M.J., and Waley, S.E. 2007. Brief intervention for alcohol use with pregnant women in the WIC setting. *American Journal of Public Health* 97(2):252–258.

APPENDIX C

Table on NREPP Criteria: Descriptions and Ratings

Table 2. Addressing NREPP Criteria for Reliability, Validity, and Intervention Fidelity: Descriptions and Ratings

Reliability[5]	Validity	Intervention Fidelity	Missing Data Attrition	Appropriate Analyses	Confounding Variables
Brief Intervention (BI) With Support Partner, Brigham and Women's Hospital, Department of Psychiatry; Harvard Medical School, Departments of Psychiatry, Medicine (Biostatistics), and Obstetrics and Gynecology (Total rating: 22/24)					
All analysis replicated with mean substitution to verify findings from the multiple imputation. Data from subjects compared against data from their partners. ***Rating: 2***	Baseline and postpartum instruments administered to women were: Alcohol Timeline Followback; Alcohol Abstinence Self-Efficacy scale, and to their partners, the NIAA quantity-frequency questions on personal and partner's alcohol consumption and Health and Habits Surveys. ***Rating: 4***	Clinicians conducting the BI were observed and their intervention summaries and other notes reviewed for treatment consistency with the medical model of documentation. ***Rating: 4***	Used multiple imputation with 5 imputations and 95% of subjects were reached at postpartum followup. ***Rating: 4***	Used Wilcoxon or Fisher exact tests to compare baseline demographics and behavioral characteristics of control and intervention groups. Used ordinary least-squares regression models to evaluate the effect of the intervention on number of drinks/day, percent of drinking days, and a combined quantity-frequency measure after study enrollment. ***Rating: 4***	All regression models included demographic variables, history of prior drinking, temptation, and confidence in managing temptation to drink in different situations, cigarette use, and high-risk pregnancy status. Found no significant differences between the control and intervention groups. ***Rating: 4***
Parent-Child Assistance Program (PCAP), University of Washington, Department of Psychiatry and Behavioral Sciences and Department of Epidemiology (original demonstration project and two replications) (Total rating: 20/24)					
Good item to scale reliability: Cronbach's Alpha .91 for baseline score and .82 for endpoint score. Also, >95% concordance in responses from women and their advocates at 4-month followup. Researchers at the three sites were trained to use standardized procedures and follow standard instructions to ensure interrater reliability. ***Rating: 2***	Administered 50-minute structured baseline and 3-year followup interviews (researchers used in prior studies) with women; after 1996, used ASI (5th edition) with additional questions. Children assessed at baseline and 3-year followup with Bayley Scales of Infant Development. ***Rating: 4***	Advocates received intensive training and detailed instruction manuals to ensure use of standardized procedures across the three sites. ***Rating: 4***	Three-year followup rates for the original demonstration (OD) were 92% for the intervention group and 87% for the control group. At the two replication sites, 15% (28 from a total of 184) were lost to followup. ***Rating: 4***	Data analysis across the OD and two replication sites included a comparison of enrollment and exit data using t-test or chi-square. Endpoint summary variables were compared across the three sites using three-group analysis of covariance, adjusting for the baseline variable to test for differences. Descriptive statistics were used to compare clinically relevant outcomes across the three sites. ***Rating: 4***	No significant differences were found between the intervention and control groups in the OD, and few differences were found among women across the three sites, except more replication site women were married and had been victims of domestic violence. Increased State services may have influenced some outcomes, e.g., housing and employment, but the enhancements for PCAP women were greater than those indicated by State outcome data. ***Rating: 2***
Brief Intervention (BI) for Alcohol Use During Pregnancy, UCLA, David Geffen School of Medicine, Department of Psychiatry and Bio-Behavioral Sciences (Total rating: 20/24)					
Nutritionists achieved 100% reliability administering the Health Interview for Women before interviewing participants. Researchers checked completed interviews daily for scoring accuracy. For interrater reliability, an independent scorer used a checklist of the primary BI content to score a random sample of audiotaped sessions collected during the study period. ***Rating: 2***	Two-page alcohol screeners with quantity/frequency measures and TWEAK used to assess women's alcohol use; those screening positive were administered the Health Interview for Women and MAX (maximum drinks per drinking occasion). All instruments were at fourth grade reading level and in English and Spanish. ***Rating: 4***	WIC nutritionists used a standard workbook and received training to conduct the BI as well as to score the screening and assessment instruments and maximize self-report of alcohol use. Researchers visited the women each month to ensure they adhered to study protocol and met with them quarterly to observe them doing the BI. ***Rating 4***	Of the original 345 women selected for the study, 255 (74%) continued to return to their original WIC center into their third trimester—a number consistent with the overall population of pregnant women in WIC, who move frequently. ***Rating: 2***	Descriptive statistics were used to analyze demographics, education, income, and gestational age at pregnancy recognition and on enrollment in WIC; MAX, and TWEAK scores. Use of substances, including illicit drugs, and chi square and t-tests for independent samples were used to compare differences between the BI and AO groups on these variables. ***Rating: 4***	All demographic and other baseline variables were examined as possible covariates of alcohol abstinence at the third trimester followup. Infant outcome measures were analyzed using a two-mixed effects ANCOVA with the WIC center as a random effect while controlling for statistically significant baseline covariates. No significant differences were found between women in each group. Gestational age was analyzed both as a dependent variable and as a potential factor in relation to the other newborn outcomes. Also no statistically significant effect was found in relation to the different WIC centers where the BI was administered. ***Rating: 4***

[5] NREPP criteria for a score of "4" were not met by any of these studies; the types of reliability they document were not reviewed for acceptability by any independent investigators.

Table 2. Addressing NREPP Criteria for Reliability, Validity, and Intervention Fidelity: Descriptions and Ratings

Reliability	Validity	Intervention Fidelity	Missing Data Attrition	Appropriate Analyses	Confounding Variables
Project TrEAT (Trial for Early Alcohol Treatment), University of Wisconsin-Madison Medical School, Center for Addiction Research and Education (Total rating: 19/24)					
Health interviews were conducted at 12 months after intervention with 172 family members to corroborate subjects' self-report data. Medical record audits were conducted at 12 and 48 months. ***Rating: 2***	The CAGE and Health Screening Survey were used to assess alcohol use and health status, and 30-day Timeline Follow-Back questions on alcohol use were asked at follow-ups. Measures for depression, childhood conduct disorder, and adult antisocial personality disorder taken from the Diagnostic Interview Schedule, which is based on the DSM III-R. ***Rating: 4***	Physicians trained to administer intervention protocol using role-playing and general skills techniques at each of the clinics and given booster sessions as subjects were randomized into the trial over a 9-month period. ***Rating: 2***	To handle any missing measures in postintervention data on subjects, the missing data items were assigned the value of the subjects' postintervention average. Study had a high physician retention rate and patient followup rate of 85% (174 out of a total of 205) at 48 months. ***Rating: 3***	Outcome measures, i.e., 7-day drinking total and 30-day binge drinking episodes, were analyzed using a repeated-measures ANOVA approach. Significance of differences between both groups at each followup point were assessed using the CONTRAST(1) option of PROC GLM in SAS, where the experimental/control variable was factored into the hypotheses for between-subject effects. ***Rating: 4***	A logistic regression model was used to assess the independent effect of treatment status on a 20% reduction in alcohol use after controlling for age, tobacco use, depression, adult personality disorder, childhood conduct disorder, and illicit drug use. No statistically significant sociodemographic or other differences in relation to the above-described measures were found between the intervention and control groups at baseline. ***Rating: 4***
Brief Intervention (BI) for Alcohol Use in Pregnancy, Brigham and Women's Hospital, Department of Psychiatry; Harvard Medical School, Department of Obstetrics and Gynecology (Total Rating: 18/24)					
Women in the BI group were asked to identify a collateral reporter to provide information about their health habits and drinking at baseline and postpartum. Also, different researchers conducted the assessments and the followup data collection; the latter researchers did not know the initial assessment results. ***Rating: 2***	Assessment protocols included AOD modules from the Structured Clinical Interview for DSM-III-R (SCID), ASI, AUDIT, SMAST, Timeline Follow-Back interview, Alcohol Craving Scale, Global Assessment of Functioning (GAF), and Situational Confidence Questionnaire. Followup protocols included ASI, Timeline Follow-Back Situational Confidence Questionnaire, Alcohol Craving Scale, and collateral report of antepartum drinking. ***Rating: 4***	After completing the assessment, women in the BI group met individually with the principal investigator for the intervention, which was given shortly after initiation of their prenatal care. The BI was designed to follow the same structured sequence with each subject. ***Rating: 2***	Of the 280 women in the study (123 BI, 127 AO), 99% returned for followup at an average of 57 days postdelivery. ***Rating: 4***	Chi-square tests of significance were used to compare baseline and followup data between the BI and AO groups, and survival analysis was used to assess antepartum alcohol use. The semiparametric Cox proportional hazards regression was used to model the relative risk of antepartum drinking after the intervention or assessment only. Data from 123 BI subjects also were analyzed to assess relationship of drinking goals, reasons for goals, recognition of temptations to drink, and antepartum alcohol consumption using descriptive statistics and the Pearson chi-square statistics or Fisher's exact test to analyze associations between categorical variables. ***Rating: 4***	No statistically significant differences were found in demographics and history and use of substances between the two groups. ***Rating: 2***
Project BALANCE (Birth Control and Alcohol Awareness: Negotiating Choices Effectively), Virginia Commonwealth University, Department of Psychiatry, Division of Addiction Psychiatry (Total rating: 18/24)					
The Brief Symptom Inventory (BSI) was supplemented with the Outcomes Questionnaire-45 because its test-retest reliability in student samples ranges from .66 to .86; its internal consistency is usually above .90 for the total and symptom distress scales; and range for interpersonal functioning and social role scales is between .70 and .90. Also used Five-Factor Inventory, which includes 5 major domain scales with high internal consistency. ***Rating: 2***	During the 1½-hour assessment, the following instruments were administered: the Five-Factor Inventory (to assess normal adult personality), the BSI, and the Outcomes Questionnaire-45 (both to assess psychiatric stress) while drinking was assessed using the Timeline Follow-Back interview. Study-specific questions were adapted from recent studies assessing AEP risk, including the Project CHOICES feasibility study. ***Rating: 4***	All sessions were audiotaped, and the tapes were used in weekly individual and group supervision sessions conducted by the senior authors. ***Rating: 4***	One-month followup data were analyzed from responses sent by 94 students in the intervention group (82%) and 105 students in the control group (92%). Some followup responses were returned incomplete or indecipherable because they were written on paper forms. ***Rating: 2***	Descriptive statistics were used to analyze demographics, drinking, contraceptive use, and AEP risk, while t-tests and chi-square analyses were used to compare outcomes between the intervention and control groups. ***Rating: 4***	A hierarchical logistical regression analysis was conducted to identify multivariate predictors of reduced AEP risk. Further research will assess longer-term outcomes and potential mediators of change, e.g., psychiatric distress, personality factors, illicit drug use, and readiness to change behavior. ***Rating: 2***

Table 2. Addressing NREPP Criteria for Reliability, Validity, and Intervention Fidelity: Descriptions and Ratings

Reliability	Validity	Intervention Fidelity	Missing Data Attrition	Appropriate Analyses	Confounding Variables
The AR-CARES (Arkansas Center for Addictions Research, Education, and Services) Program, University of Arkansas at Little Rock, Center for Research on Teaching and Learning (Total rating: 17/24)					
Self-report AOD use among women was compared to results of urine toxicology test conducted at intake and delivery. Urine toxicology tests of intervention women randomly performed during study period. Child growth and development data collected at 6, 9, and 18 months were compared to published normative data. ***Rating: 2***	Self-reports and urine toxicology screens were used to assess women's AOD use at intake and delivery, and the Bayley Scales of Infant Development were used to assess their children's developmental status in the first 2½ years of life. ***Rating: 3***	Clinical staff received training to conduct maternal interviews and child development assessments in a clinical setting. Clinical staff and research assistants were trained to gather child development data according to standards set by a Center for Substance Abuse Prevention national cross-site study. ***Rating: 4***	Many women were lost to followup: with data collected at delivery from 38% of the 72 women in the intervention group and 43% of the 23 nonparticipants. Numbers of children in the intervention group fell from 16 at 6 months to 9 at 12 months and 6 at 18 months. ***Rating: 0***	Paired t-tests were used to assess and compare alcohol and other drug use from intake to delivery between intervention participants and nonparticipants. Ordinary least-squares linear regression was used to assess the effects of length of participation on outcome measures. ***Rating: 4***	Similarities in demographic characteristics were found between participants and nonparticipants along with alcohol and other drug use at intake, marital status, family history of alcohol and drug use, and week of pregnancy at intake. ***Rating: 4***
Cognitive Behavioral Intervention, University of Alabama at Birmingham, Department of Health Behavior (Total rating: 17/24)					
Key measures in pretest and posttest questionnaires were tested with Cronbach's alpha for reliability, e.g., positive and negative outcome expectancies, social norms, self-efficacy, and social influence. ***Rating: 2***	Used T-ACE to identify problem drinkers. Intervention was based on Bandura's social cognitive theory, and the manual for administering it was reviewed by an expert panel and focus groups of 33 women, tested for readability, and pilot-tested. Posttest included nine items to assess threats to internal validity. ***Rating: 4***	Educators administering the intervention were trained before delivering it to the principal investigator and to two women. Their performance was assessed for quality and accuracy. ***Rating: 2***	A validated "bogus pipeline" procedure, stating that subjects' blood and urine samples would be tested for alcohol, was used to reduce underreporting. Confidentiality was assured and measures administered by study personnel. At 2 months postintervention, 92% of the 78 women remained in the study (3 from the self-help [SH] and 3 from the usual care [UC] group). ***Rating: 3***	Methods included the chi-square test and Fisher's Exact Test to assess the effect of the intervention and t-tests to compare quantity/frequency of alcohol use between the SH and UC groups. (Sample size was small: only 78 women.) ***Rating: 2***	Logistic regression was performed to identify variables accounting for differences in quitting beyond the intervention, e.g., heavy versus light drinking, positive outcome expectancies for drinking, social norms, and perceived self-efficacy. Also no significant differences were found between the two groups for alcohol use, demographics, religion, or number of weeks pregnant. ***Rating: 4***