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National Center on Birth Defects and Developmental Disabilities

Records of the Meeting of the

**National Task Force on
Fetal Alcohol Syndrome and Fetal Alcohol Effect**

February 28-March 1, 2007

**Meeting held at the
SpringHill Suites Atlanta Buckhead
Atlanta, Georgia**

Table of Contents

Wednesday, February 28, 2007

Call to Order	3
Introduction of Task Force Members, Liaisons, and Attendees	3
Opening Remarks.....	4
Behavioral Counseling to Reduce Risky and Harmful Alcohol Use in Primary Care: Systematic Review for the U.S. Preventive Services Task Force.....	5
Overview of NTFFAS FASD Prevention Report Activities.....	19
Community Interventions to Prevent FASD Literature Review Summary.....	20
Deliberations on Prevention Recommendations / Development of the Final Report / Next Steps.....	30
FEDERAL UPDATES:	
Interagency Coordinating Committee on Fetal Alcohol Syndrome.....	40
National Institute on Alcohol Abuse and Alcoholism	42
Substance Abuse and Mental Health Services Administration.....	44
Public Comment/Adjourn	48

Thursday, March 1, 2007

Report from the Post-Exposure Working Group	48
Summary of FASD Prevention Report Discussion.....	58
LIAISON UPDATES:	
American Academy of Pediatrics	59
American College of Obstetricians and Gynecologists	60
The Arc	62
Center for Science in the Public Interest.....	62
March of Dimes	64
National Organization on Fetal Alcohol Syndrome.....	66
FEDERAL UPDATES (continued):	
Centers for Disease Control and Prevention	68
OTHER BUSINESS:	
Update on Task Force Sunset/Communication Process for Task Force Products/Letter to ACOG	72
Dates for Next Task Force Meeting.....	72
Public Comment/Adjourn	72

**Centers for Disease Control and Prevention
National Center on Birth Defects and Developmental Disabilities
National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect**

**Minutes of the Meeting
February 28-March 1, 2007**

A meeting of the National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect (NTFFAS/FAE) was convened on February 28-March 1, 2007, in Atlanta, Georgia by the Centers for Disease Control and Prevention (CDC), National Center on Birth Defects and Developmental Disabilities (NCBDDD).

Wednesday, February 28, 2007

Call to Order

Dr. Louise Floyd, Acting Executive Secretary, called the meeting to order at 8:30 a.m.

Introduction of Task Force Members, Liaisons, and Attendees:

Chair: Jean A. Wright, MD, MBA, Backus Children's Hospital, Savannah, GA
Acting Executive Secretary: R. Louise Floyd, DSN, RN, Fetal Alcohol Syndrome Prevention Team, DBDDD, NCBDDD, CDC
Designated Federal Official: Mary Kate Weber, MPH, Fetal Alcohol Syndrome Prevention Team, DBDDD, NCBDDD, CDC
Standing Member: Kenneth R. Warren, PhD, National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH) Washington, DC

Task Force Members Present:

Kristen L. Barry, PhD, Serious Mental Illness Treatment Research and Evaluation Center, Ann Arbor, MI
James E. Berner, MD, Alaska Native Tribal Health Consortium, Anchorage, AK
Carole W. Brown, EdD, Catholic University of America, Washington, DC
Grace Chang, MD, MPH, Brigham and Women's Hospital, Boston, MA
Mary C. DeJoseph, DO, Philadelphia College of Osteopathic Medicine, Philadelphia, PA
Lisa A. Miller, MD, Department of Public Health and Environment, Denver, CO
Colleen A. Morris, MD, University of Nevada School of Medicine, Las Vegas, NV
Mary J. O'Connor, PhD, ABPP, David Geffen School of Medicine at the University of California, Los Angeles (UCLA), Los Angeles, CA
Melinda M. Ohlemiller, BA, MA, Saint Louis Arc and parent of a twelve-year-old with FAS, St. Louis, MO
Heather Carmichael Olson, PhD, University of Washington FAS Diagnostic Clinic, Washington State FAS Diagnostic and Prevention Network, Seattle, WA

Task Force Members Absent:

Raul Caetano, MD, PhD, MPH, The University of Texas School of Public Health, Dallas, TX

Liaison Representatives Present:

American Academy of Pediatrics (AAP): George Brenneman, MD, FAAP
American College of Obstetrics and Gynecology (ACOG): Robert J. Sokol, MD, Department of Obstetrics and Gynecology, C.S. Mott Center for Human Growth and Development, School of Medicine, Wayne State University, Detroit, MI

March of Dimes (MOD) Elise Linden Antrobus, RN, PhD for Karla Damus, PhD, Washington, DC
The Arc: Sharon Davis, PhD, Health Promotion and Disability Prevention Committee, Silver Springs, MD
Center for Science in the Public Interest (CSPI): George A. Hacker, JD, Alcohol Policy Project, Washington, DC
National Organization on Fetal Alcohol Syndrome (NOFAS): Tom Donaldson, for Kathleen T. Mitchell, MHS, LCADC, Washington, DC

Speakers:

Evelyn P. Whitlock, MD, MPH, Co-Director, Oregon Evidence-based Practice Center; Senior Investigator, Kaiser Permanente Center for Health Research
Frank DeStefano, MD, MPH, RTI International, Atlanta, GA
Kimberly Leeks, PhD, MPH, RTI International, Atlanta, GA

Other Attendees:

Kendall Anderson, MPH, Deputy Chief, Prevention Research Branch, DBDDD, NCBDDD, CDC
Jacquelyn Bertrand, PhD, Developmental Psychologist, FAS Prevention Team, DBDDD, NCBDDD, CDC
Colleen Boyle, Director, DBDDD, NCBDDD, CDC
Elizabeth Parra Dang, MPH, Behavioral Scientist, FAS Prevention Team, DBDDD, NCBDDD, CDC
Sarah Dilley, Emory Language Development Study
Yvette Dominique, Battelle Contractor
Zarina Fershtyn, Battelle Contractor
Callie Gass, Project Director, SAMHSA, FASD Center for Excellence, Rockville, MD
Patricia P. Green, MSPH, Epidemiologist, FAS Prevention Team, DBDDD, NCBDDD, CDC
Melissa Hogan, Battelle Contractor
Karen Howell, MD, Emory University School of Medicine
Alison Johnson, Acting Director, NCBDDD, CDC
Eileen Miles, MPH, Battelle Contractor
Christine E. Prue, MSPH, PhD, Chief, Prevention Research Branch, DBDDD, NCBDDD, CDC
Brenda J. Rowe, Department of Human Resources and Public Health, State of Georgia
James Tsai, MD, Epidemiologist, FAS Prevention Team, DBDDD, NCBDDD, CDC
Myra Tucker, Division of Adult and Community Health, NCCDPHP, CDC
Leslie O’Leary, PhD, Surveillance Branch, DBDDD, NCBDDD, CDC
Jacqueline Vowell, Committee Management Specialist, FAS Prevention Team, DBDDD, NCBDDD, CDC
Stephanie Wallace, Writer-Editor

Opening Remarks

Mary Kate Weber, MPH

Dr. Floyd called the meeting to order on behalf of Dr. Wright who had been delayed. Ms. Weber greeted members and indicated that March of Dimes Liaison, Karla Damus, was unable to attend so Elise Antrobus from the Georgia Chapter would be joining them. In addition, Tom Donaldson will be sitting in for Kathleen Mitchell, the NOFAS Liaison. Ms. Weber also congratulated Sharon Davis, Arc Liaison, on her recent retirement. Ms. Davis is still an active member of the Arc’s National Health Promotion and Disability Prevention Committee, and has agreed to continue to represent the Arc as a liaison to the Task Force.

With respect to the day’s agenda, Ms. Weber noted how fortunate they were to have Dr. Evelyn Whitlock with them to present the findings on behavioral counseling interventions that were reported by the U.S.

Preventive Services Task Force (USPSTF). This information should be extremely helpful to them as they begin to draft prevention recommendations. In addition to the other presentations on the agenda, a significant amount of discussion time has been set aside to obtain input and ideas from the Task Force members on prevention recommendations, and to lay out a plan of action for how they would complete and finalize their report.

**Behavioral Counseling to Reduce Risky and Harmful Alcohol Use in Primary Care:
Systematic Review for the U.S. Preventive Services Task Force**

Evelyn P. Whitlock, MD, MPH

Kaiser Permanente Center for Health Research

Dr. Whitlock indicated that the Oregon Evidence-Based Practice Center (EPC), which she was there representing, had been supporting the USPSTF for almost 10 years. During that time she has had the privilege of working closely with some excellent people at the Agency for Healthcare Research and Quality (AHRQ) and the USPSTF. Dr. Whitlock acknowledged other team members at the Oregon EPC, as well as the USPSTF liaisons who worked with them in setting up the review and ensuring the quality, integrity, and match of the review to the interests of the Task Force. AHRQ funded this review, and it was supplemented to some extent with additional funding from the Robert Wood Johnson (RWJ) Foundation to look more intensely at intervention elements and behavioral counseling interventions.

The USPSTF has been making recommendations on clinical preventive services for primary care since 1989. Currently, there are about 89 screening, behavioral counseling, and chemoprevention topics. These are all oriented toward primary care, which Dr. Whitlock stressed was important to keep in mind. There have been clinical guides published in 1989, a second edition update in 1996, and since 1998, the USPSTF has been paneled and has a rolling membership with a continuous updating of its recommendations and delivery of new recommendations. Since 1998, the Oregon EPC has conducted systematic reviews to support new and updated USPSTF recommendations.

The USPSTF methods have evolved along with other methods in the evidence-based medicine community such that, although there were rigorous reviews of the evidence earlier, they were not systematic reviews. However, these have been systematic reviews since 1998. With that in mind, Dr. Whitlock offered a brief overview of the methods of the USPSTF, with some emphasis on the things she thought were important for the NTFFAS to understand about the methodology in order to consider the relevance and validity of what was done to the NTFFAS's deliberations. The first thing that happens with any topic is that the topic is selected and must be scoped; that is, the extent of the review has to be laid out. It takes about two months to complete the process that involves literature scanning, as well as numerous interactions with the USPSTF to define elements around populations, interventions, outcomes, and relevant study designs. Once all of that is done, the Oregon EPC undertakes a systematic review, which includes literature searches, retrieval, and review of abstracts and articles for relevance and quality. The included articles are abstracted and are synthesized either qualitatively or quantitatively, and then the findings are discussed in a report and are often published in a peer reviewed manuscript. Dr. Whitlock stressed that it was important to understand that these systematic reviews undergo an extensive peer review process, both by federal partners and experts in the field. Prior to them being presented to the USPSTF, federal partners such as the National Institutes of Health (NIH), CDC, Food and Drug Administration (FDA) if that is relevant, Veteran's Administration (VA), and often Cochran reviewers, research experts, and others in the field. Once the review is finalized the USPSTF, which is separate from the Oregon EPC and is an independent body also separate from the federal government, makes its own independent recommendations based on its interpretation of the evidence.

Regarding USPSTF evidence standards, the "hierarchy" of research design is something that people have heard a lot about in terms of evidence based medicine. A hierarchy of evidence is placing studies, in terms of research design, in a fairly fixed hierarchy to say that one type of design is always better than

another. This was where evidence-based medicine started in the late 1980s and early 1990s, recognizing that threats to validity could best be dealt with in randomized controlled trials (RCTs). As the field has matured, people have increasingly recognized that first of all, RCTs cannot answer every kind of evidence question. Also, a well done cohort, case-control study, or controlled clinical trial (CCT) may be better than a poorly done RCT. What the USPSTF works on now, which is the standard for evidence-based medicine, is that while the type of research design is very important because threats to validity do indeed vary by the type of design, critical appraisal of evidence is very important. Determining applicable designs that have the minimum level of internal validity for a particular question is important. Looking critically at each of those and then considering the body of evidence as a whole is really how the field has moved. Also, there is much more emphasis on applicability. The research may be valid, but it should actually apply to the population of interest rather than having been done in such highly controlled settings that it does not tell much about real world practice or real patients. The hierarchy outlined below is what was used in the methods paper for the USPSTF in 2002:

I	Evidence from ≥ 1 proper RCTs
II-1	Evidence from well-done CCTs
II-2	Evidence from cohort or case-control analytic studies & multiple sites
II-3	Evidence from multiple time series; dramatic uncontrolled experiments
III	Expert opinion

In general, particularly for an effectiveness trial, evidence from ideally more than one properly conducted RCT would be valued higher than evidence from well done CCTs, which would be valued generally above evidence from cohort or case-control analytic studies (which should ideally be done at multiple sites), which would be valued higher than evidence from multiple time series or from dramatic uncontrolled experiments, which would be valued higher than expert opinion. Dr. Whitlock noted that during her tenure, she had never seen the USPSTF make a recommendation on expert opinion. They have made recommendations on levels II and III on cervical cancer. There has never been an RCT on cervical cancer screening, but dramatic observational ecologic evidence show that cervical cancer screening was associated with reductions in evasive cervical cancer. So, it is possible that it does not have to be an RCT.

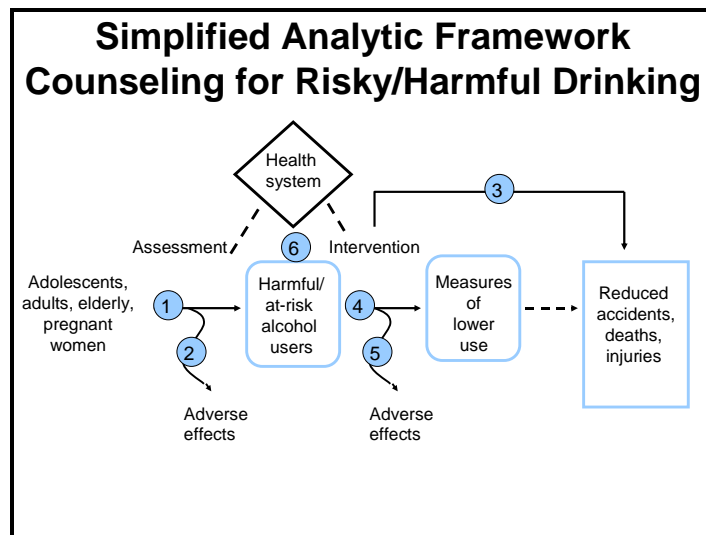
Dr. Whitlock then reported on the 1996 review and the 2004 USPSTF recommendations for primary care clinicians on problem drinking and alcohol misuse. She discussed key review-related decisions to focus the review and results from a 2003 systematic review conducted for the USPSTF. She then briefly touched on upcoming USPSTF reviews for potential relevance. Already the 2004 alcohol misuse recommendation has been prioritized for an update, and the Oregon EPC plans to present their evidence review on counseling to reduce sexually transmitted infections (STIs) to the USPSTF.

In 1996, the USPSTF made a recommendation for screening for problem/risk drinking. The evidence table below was used for this review. There has been some evolution in the meaning of recommendations since that time. For example, because Criteria C mixed two different types of findings, one which needs more research because there is not enough evidence, and one in which it does not look like it makes a lot of difference but there is a lot of research. The USPSTF has now broken apart Criteria C so that these are not mixed in the future.

A	strong evidence; substantial benefit
B	weaker evidence or lesser benefit
C	small/variable benefit or insufficient evidence

In 1996, the recommendation level was a (B) for all adolescents and adults and a (B) for all pregnant women. In terms of advising limited use / abstinence, the level was (C) for preconception / pregnant women and (B) for persons under legal age of use. It is important to understand the difference in the evolved levels versus the 1996 levels because the evidence then was really insufficient in terms of preconception and pregnant women. The information about detecting was there, but it was not clear so much about what to do in terms of impacting that.

Moving forward to 2004, now a (B) recommendation means that there is at least fair evidence, and the health benefits outweigh harms; and an (I) recommendation means that there is insufficient evidence with uncertain benefits or harms. At this time, it was clear that patients could be identified, but now there was an emphasis on what primary care could do. Based on the Oregon EPC's review, the USPSTF found that they could recommend screening and behavioral counseling interventions in primary care to reduce alcohol misuse in adults, including pregnant women. This was combined in the recommendation with a (B) level recommendation. The evidence for adolescents was insufficient. They were able to locate one study that was marginally relevant to the USPSTF.



Dr. Whitlock referred to the above fairly simplified analytic framework, indicating that it guided this evidence review. This type of framework is created for each of the topics. She pointed out that each number represented what was known as “a key question,” so each generally leads to a literature search and independent review in order for each question to be answered. The analytic framework in itself leads logically from the identification of the population through outcomes, in this case identification of alcohol users, reduced alcohol use, and to health outcomes. Population is at the left; health outcomes at the right. The focus was on the interventions and the question was: What can primary care do? The ideal evidence is called “overarching” where it can be demonstrated directly that an intervention has had an impact on health outcomes. Often that information is not available for a number of reasons, in which case a chain of evidence can be applied. If there are only measures of a change in behavior and their valid measures, and there is a relationship between those behavioral measures and health outcomes, that can be connected together. They were not asked to review this evidence because it was viewed to be sufficient, although sometimes they are asked to establish the relationship between a behavioral outcome and a health outcome. The analytic framework also looks at adverse effects. Because prevention should be held to a higher standard, it is doing something to people who are not asking that anything be done to them. Therefore, it is always important to consider both potential benefits and harm. Four different populations were considered separately. Those clinical populations differ in terms of the prevalence and patterns of drinking, the risks associated with drinking, screening approaches, and the goals of treatment.

Still referring to the above framework for the risky/harmful drinking review, the key questions were as follows:

- Arrow 1: How are risky/harmful alcohol users identified for behavioral intervention?
- Arrow 2: What are the harms of assessment?
- Arrow 3: Do behavioral counseling interventions (BCI) reduce morbidity and mortality?
- Arrow 4: Do behavioral counseling interventions reduce alcohol misuse?
- Arrow 5: What are the harms of intervention?
- Arrow 6: What health care system supports are needed to effectively identify and intervene?

The first decision they had to make was how to define both drinkers and categories of use. The estimate that she is aware of is that 44% of the adult population has consumed 12 or more drinks in the last year. Therefore, it would not make sense to target 44% of adult primary care necessarily. In addition, all use is not harmful. For Key Decision #1: Drinker Categories and Definitions, they used a strata of three categories with definitions that were taken from the most consistent, evidenced-based findings in the literature. This is the National Institute on Alcohol Abuse and Alcoholism (NIAAA) definition, which is consistent with a number of other definitions and actually has some population-based evidence showing that there is a difference between negative outcomes in people in this category and other categories. This definition is also useful because as they get into looking at the impact of intervention on the proportion of people drinking safely, this same measurement was the standard that was generally used in the literature.

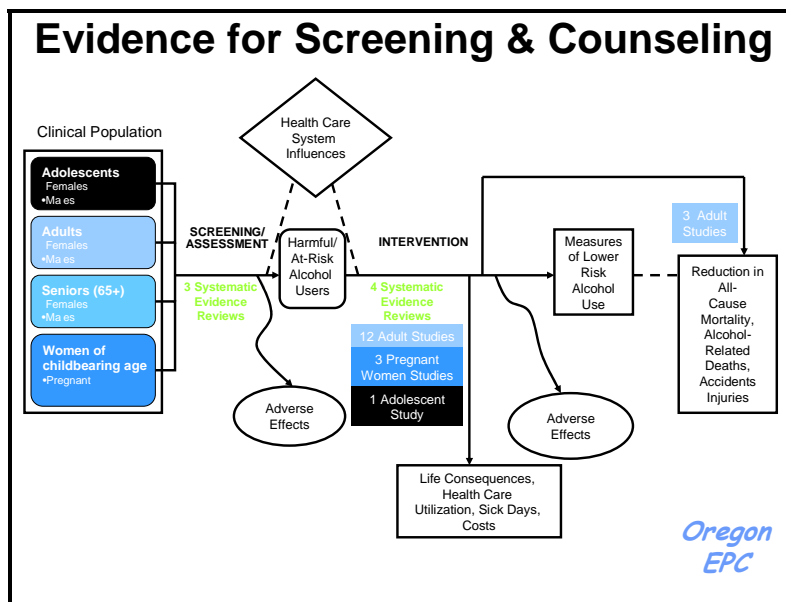
1. Low-risk/moderate users: Females ≤ 7 drinks/week and 3 drinks/occasion; males ≤ 14 drinks/week and 4 drinks/occasion.
2. Risky/harmful users: Exceed daily, weekly, or occasion thresholds and usually have mild harms or problems. This is the area they really focused on because it is where the highest prevalence of drinkers with problems are, particularly those who are in primary care.
3. Abuse/dependent drinkers: Meet DSM-IV, ICD-10 diagnostic criteria for abuse or dependence. These were viewed to be those needing referral and specialty treatment.

As they defined their topic, based on the definitions and criteria, they focused on non-alcohol dependent adults (male and female over age 65), pregnant women, and adolescents. They looked at settings in which primary healthcare is delivered by a clinician, excluding emergency settings. They did not focus on emergency settings, given that there is a fair amount of literature about intervention with injuries and alcohol users in those settings. Many of them are intoxicated at the time and it did not seem to be exactly applicable to primary care. They focused on either primary care feasible or referable interventions reporting health or behavioral outcomes. They looked at what screening and screening-related assessment occurred with those interventions. If the interventions worked, they were very interested in what worked as well as the issue of system supports because behavioral types of interventions are not typically a strong point of primary or routine care.

In conducting the literature search, they looked at the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effectiveness (DARE) from the University of York, Cochrane Controlled Clinical Trials Registry, MEDLINE, PsychInfo (1994-2003), unpublished research (meeting abstracts, author contacts), and bibliographies of many key articles (including the *1996 Guide to Clinical Preventive Services*). The inclusion/exclusion criteria were that the research had to be human studies; English-language; either CCTs or RCTs (for behavioral counseling interventions there is a fair body of evidence there, so it made sense to have that criteria); the population was > 12 years, non-dependent drinkers, co-morbid populations excluded (so if the study focus was on alcohol users and drug users, it

would not have been included); primary care settings only; interventions were excluded if no behavioral counseling element was included (e.g., strictly pharmacologic approaches to treatment were not included); and study quality criteria were fairly strict using USPSTF design methods supplemented by criteria used by the Cochrane drug and alcohol workgroup specific to this literature.

They went through 4,331 abstracts, many of which were not relevant. Of those, 4,230 abstracts were excluded and 101 were included. For the articles review, they retrieved 163 articles total (119 were excluded, 27 included for other key questions, 16 RCT/CCTs met the inclusion criteria. Of the 16, 12 focused on adults (and older adults), 3 for pregnant women, and 1 for adolescents.



Going back to the larger framework, the above diagram offers a sense of how the evidence laid out. They had three systematic reviews that helped supplement what they have on screening and assessment, so they found that in the interventions, many used validated screening instruments. They were able to comment on those through three systematic evidence reviews. There were four previous systematic evidence reviews that looked at behavioral counseling interventions. They did not include all of the studies that the Oregon EPC did, but they used these four as source documents. There is a mismatch between their population, no studies targeting seniors, and most of their evidence was in non-pregnant adults. Three of the 12 adult studies actually gave them some information on health outcomes, while all of the rest gave them only behavioral measures.

Key Decision #2 pertained to behavioral counseling interventions. The behavioral counseling interventions are not the same, so they had to determine the most important ways to stratify the behavioral counseling interventions so that they were comparing like and like. They felt that duration and intensity was an important way to think about these in terms of intensity of effort and duration contact. They originally created four strata that described all of the literature, but for the adult literature it made sense to collapse those into two strata. They defined “brief” as 1-15 minutes of initial contact and no or optional follow-up contacts at the discretion of the patient and the provider, and “brief multi-contact” as less than 15 minutes of initial contact and multiple scheduled follow-up contacts. Dr. Whitlock stressed that “brief” is in the “eye of the beholder.” Some people called something “brief” if it was less than four sessions, others less than an hour, for a primary care clinician it is one to three minutes, et cetera. So, even between behavioral interventions, they do not always find themselves using the same definition.

The one they chose was the one which they presumed to be the upper limit of what primary care probably could do (e.g., 15 minutes).

Dr. Whitlock then presented the systematic review findings. With respect to whether behavioral counseling interventions reduce risky/harmful alcohol use in pregnant women, they found three fair to good quality RCTs of current drinkers or high-risk women in U.S. primary care prenatal settings. Null results were found in two of the studies, which were single contact (45-60 minute) motivational interviewing interventions. One of the studies, an RCT (n = 42), addressed pregnant current drinkers, and the other larger RCT (n=250) addressed high-risk women identified by the T-ACE (not necessarily current drinkers). There were marginally significant results in quit rates (19%) and average drinking (.78 drinks / month) in currently drinking pregnant women (n=78) after one 10-minute intervention with phone call follow-up and a self-help manual (p=.06). When this was sent out for peer review, no additional studies were identified by peer reviewers, including the ACOG reviewer. This evidence by itself was insufficient to make a separate recommendation for pregnant women. Dr. Floyd has since made her aware of three other studies that she has now reviewed.

Pertaining to whether behavioral counseling interventions reduce risky/harmful alcohol use in adults, the three main behavioral outcomes were organized into three major categories: 1) Average consumption (mean drinks/week) -- This is the measure that has been most studied in the epidemiologic literature and it is related to long-term disease outcomes and mortality. This is where most of the evidence was available. 2) Proportion reporting binge use -- This is generally reported as greater than five drinks per occasion, with no gender specific per occasion thresholds unfortunately. Fewer studies either targeted this kind of use in recruiting their patients, or had their intervention focused on this, and fewer measured this. However, more current studies do look at binge use. 3) Proportion reporting achieving safe/recommended use represented another behavioral outcome. This varied by study somewhat, but they took what the studies said to consider the proportion who reported achieving safe use.

Regarding whether behavioral counseling interventions reduce average alcohol consumption in adults, Dr. Whitlock reported that all of the studies contained information on average consumption. These studies were all conducted in primary care. This is an international literature that has accrued over about 14 years (1988-2002). Some of the studies are quite old, and the older studies tend to have higher average use than the more recent studies, mostly to look at the very high users and not so much the other patterns of use. Of the studies reviewed, 11 were good to fair quality RCTs and 1 was a fair quality CCT. When the studies were stratified by the type of intervention, 5 studies tested brief interventions (single contact <15 minutes), of which 4 showed no effect on mean alcohol use (drinks per week); 7 studies tested brief multi-contact interventions, of which 5 showed significantly reduced mean alcohol use, with the range of 13% to 34% net reduction, which is 2.9 to 7.4 fewer mean drinks per week; and 1 of these studies reported maintenance of reduced alcohol consumption after 4 years (overall and in reproductive-aged women). This was a good sized, fairly consistent body of evidence of good quality.

Dr. Whitlock stratified the results by gender because other earlier research had suggested that women and men respond differently to interventions. In the brief interventions, there was one study that had a significant effect after a brief intervention in men and on mean drinks per week. This was done early and with very high average intake of men, something like 36 or 37 mean drinks per week, which was the highest of all the studies. A similar study in women had no impact. Brief intervention in an HMO in Seattle had no impact. One study had two intervention arms: a brief advice and a more extensive motivational contact. There was a slight effect here, but they were not clear whether it was a real effect or contamination. The rest were brief multi-contact interventions, which all showed a statistically significant effect in women compared to men. They did not view this as showing any differential effect.

Then they looked at whether brief counseling interventions reduce binge alcohol use in adults and the proportion reporting binge use at the end of intervention. Only 7 RCTs provided this information, of which 3 were fair or good quality brief interventions and 4 were good quality brief multi-contact interventions. Mixed intervention effects were found. There was reduced bingeing in 2 of the 4 brief multi-contact interventions, and in 1 of the 3 brief interventions (very heavy users, men only). Most important was that after intervention, among both intervention patients and controls, large proportions of interventions and controls reported binge use after intervention at a range of 31% to 69%. So, even if there was an impact, many people were still bingeing. Dr. Whitlock and her colleagues thought that part of that was because many of the earlier interventions did not specifically address binge use in study recruitment or in intervention content, although more recent studies did. This is disturbing because binge use is so relevant to short-term outcomes, and it is quite relevant to the issues of the FAS Task Force. There is much work to be done in this area.

With regard to whether brief counseling interventions increase the proportion reporting safe or recommended alcohol use, they had results for 10 of the 12 studies. Of the 10 RCTs, 5 were good quality brief multi-contact and 5 were fair to good quality brief interventions. In 6 of the 7 there were good-quality interventions, and in 1 of 3 fair-quality interventions, more intervention participants than controls achieved recommended or safe drinking levels. All 5 brief multi-contact interventions increased those with recommended or safe drinking patterns (10-19%), and 2 of 5 brief interventions improved safe drinking among men only. The overall evidence here was considered to be good.

For the total sample, with regard to the percent achieving recommended drinking levels/patterns at follow-up, 10 studies (3 fair and 7 good quality) reported the proportion achieving recommended drinking levels. Definitions varied by study, but included proportion drinking within safe/recommended limits; proportion not drinking excessively; proportion with safe weekly intake and no bingeing; and proportion not reporting any at-risk drinking, including driving after drinking 3 or more drinks). Of the good quality studies, 6 of 7 (all except Senft, et al. which was brief) showed significantly more intervention participants achieved recommended drinking patterns than controls (10% to 18% more). The three ineffective studies also did not affect average consumption and/or binge drinking. In the Fleming, et al. study done in the U.S., the percent achieving recommended drinking levels/patterns for follow-up was 85%; 80% in Senft, et al.; lower levels in the Curry study that targeted bingeing as one of the inclusion criteria, and lower levels in Ockene, et al. Looking by gender, there was a male only study, which was one of the few brief interventions that showed an impact on bingeing behavior. Overall, they did not really see a gender effect.

In terms of the clinical benefit after a brief multi-contact intervention at 6-12 months, they did not find any evidence on harms. They looked for it, but assumed these to be negligible. Non-pregnant adults typically reduced their drinking 3.5 to 5.0 drinks per week more than controls (13-34% net reduction in drinking). Binge use was less commonly reduced and remains prevalent at 31-69% still bingeing, and 10-19% more intervention participants reported recommended or safe drinking. Almost all of the studies were 12-month outcomes at minimum, although one study was 6 months.

Regarding reproductive-aged women, there is limited research on pregnant women and pregnancy-related risky alcohol use in primary care. Pregnancy was often an exclusion criterion for many of the adult primary care trials. Dr. Whitlock said she does believe that women and men equally benefit from brief multi-contact primary care interventions. The Manwell study, which is a subgroup analysis of the Fleming 1997 study reported in the *Journal of American Medicine (JAMA)*, indicated that reproductive-aged women reported 7.36 mean drinks per week at 12 months and 48 months. However, this was not statistically significant in controls because controls began to decrease their average use at somewhere between 24 and 48 months. They also showed some reduced bingeing and suggested that the earlier

primary care intervention may have affected drinking in subsequent pregnancies differently than controls, which was a very interesting finding.

The way that the studies identified risky/harmful drinkers was by separating out risky/harmful from dependent users. A two-stage process to identify those risky/harmful drinkers is common: screening (identify) is followed by screening-related assessment (qualify). This was often “masked,” meaning that the way this was done in primary care was often imbedded in other kinds of health behavior questionnaires. Screening was often used to identify alcohol misusers using questions or questionnaires (e.g., AUDIT, CAGE plus Quantity/Frequency and maximum per occasion). The yield in primary care in these studies was about 11-18% of people screened positive. There also needed to be a screening-related assessment (confirmation/diagnosis) involving clinical interview and judgment. The final yield of risky/harmful drinkers was about 7%. Some of these would have gone on for specialty treatment and some of them would have been shown through the screening-related assessment confirmation to not really have a problem. This would be the proportion of primary care patients who would need intervention based on the research they reviewed.

The screening approaches in the studies do correspond to screening instruments that have been recently systematically reviewed. Dr. Whitlock said that the bottom line was that AUDIT is the best single tool to identify risky/harmful use and/or dependence for all populations except pregnant women. She said it was amazing how much people do not understand that CAGE. This instrument is not sensitive for risky/harmful alcohol use and for abuse/dependence in certain populations. The TWEAK and T-ACE are preferred instruments for pregnant women, with the T-ACE being more similar to CAGE and the TWEAK being more similar to the AUDIT. For teens, tools need adaptation and development, although some work has been done in this area recently. Older people and women need different cut points for screening tools. For a lot of the analyses here, sensitivity and specificity, looking at AUDIT and TWEAK in adults, older men, pregnant women, and adolescents, a lot of times the cut points for men and women were not different. Therefore, the sensitivity might be better in this case if the cut points were more gender-specific for the AUDIT. This also indicates, depending upon the subject, that different instruments should be used.

Once the Oregon EPC completed their exhaustive review of the literature and presented it to the USPSTF, their next question regarded what this all meant and how the USPSTF could apply it to primary care recommendations. This led to Key Decision #3, the applicability of review results. Given the maturity of the research in this field, the Oregon EPC believed they could afford to be very particular in selecting studies with both reasonable quality and relevance to primary care, at least for adults. The strengths of this literature, in terms of behavioral counseling topics, risky and harmful alcohol use is the second best literature for what primary care can do (tobacco is the first best literature). There are numerous primary care based trials in adults, which were relatively applicable. Unfortunately, the literature on pregnant women and teens was quite limited. There are still questions even when a relatively consistent impact is shown on behaviors, such as: Does it mean anything? Does reducing mean drinks per week from 3.5 to 5 have any clinically meaningful health benefits? If these interventions work, what works about them? Are there reproducible intervention elements? Could primary care really do this? That is, would the intervention be feasible for real-world primary care settings?

There were three studies that provided some direct evidence on morbidity and mortality. There is very limited direct evidence on mortality. This is limited primarily to younger-aged adults and cause-specific mortality as well as all-cause mortality, and more intensive interventions than were even relevant to the Oregon EPC review. Dr. Whitlock included all of them so that the USPSTF could see what is known about alcohol reduction and health outcomes. In the brief multi-contact intervention (e.g., the Fleming study) total mortality was non-significantly reduced in men and women after 4 years. Mortality was significantly reduced in younger men after 3-21 years with a very extended intervention. In a very

extended intervention, part of the study done in Sweden or Denmark many years ago, they began screening the entire population. They found that alcohol-related mortality was significantly reduced in middle-aged men and men of all ages after 3-21 years with a very intensive, extended intervention. While this was not the kind of study they looked at, it did indicate that there is some impact on changing alcohol use and long-term alcohol-related mortality. In a very brief (even less than 15 minutes and one contact) or brief intervention, no long-term differences were found in alcohol consumption, morbidity, or mortality after 10 years in the Australian arm of the World Health Organization (WHO) trial. Most of these kinds of interventions also did not have any impact on alcohol behavior in the short-term, so Dr. Whitlock did not think there was reason to believe it would have an effect over the long-term either. Overall, the evidence related to morbidity and mortality outcomes was reported as fair by the Oregon EPC.

They provided some epidemiological data to the USPSTF to inform the drinking results that were presented in the review. The main factors that were useful were the relationships between heavy average and binge use. These users have higher risks of a myriad of alcohol-related consequences, including diagnosis of abuse and dependence. A 28% reduction in sometimes immoderate daily drinkers' usual consumption would reduce the prevalence of abuse/dependence by 3%. Moderate average drinking is associated with reduced risk of injuries and short-term alcohol-related problems, but may depend most on reduced binge use—this was not always seen in these trials. Bingers who binge as infrequently as 3-6 times per year have 50-150% of the injury risk of non-bingers who drink the same average amount. It does appear that focusing on bingeing is really going to be important for future alcohol research. All-cause mortality rates in adults over 35, drinking at recommended levels or patterns, are the same or lower than non-drinkers.

The USPSTF felt that these, along with the consistent findings in terms of impact on alcohol use and the limited data on longer term morbidity and mortality were strong enough to make a health recommendation. It was agreed that the elements of effective interventions related to the intensity of the intervention (brief, multi-contact), follow-up contacts (primarily repeat visits which extended over 2 to 12 months), goal setting (commonly used along with feedback, advice, and repeated assistance) and on-going assistance (offering a variety of approaches and personnel).

Finally, the Oregon EPC thought it was important to acknowledge that certain healthcare system supports needed to be in place for behavioral counseling interventions to be effective. In all of the studies that were effective, clinicians and staff were trained prior to starting the intervention. Training times ranged from .25 to 2.5 hours. Research staff identified at risk users; the clinical staff did not have to do screening and assessment. A system must be set up to support doing this in the primary care setting prior to the visit or outside clinical care. That is an important caveat in understanding the applicability. In the studies, other supports were generally provided to assist the clinician, including summarizing the assessment results, timely intervention materials, and staffing other than the clinician to conduct follow-up contacts. Implicit in this kind of program that identifies the more severely affected drinkers is to have referral resources available.

The alcohol misuse topic has been re-prioritized for updating recently by the USPSTF. Dr. Whitlock anticipated that the review for this would not be done until late 2007 or early 2008, which is important because there could be opportunities for this Task Force. One is that the USPSTF is open to input from people about the important ways to prioritize their topics. This topic has not been scoped yet, so there would be an opportunity potentially for the sister agencies, CDC and AHRQ, to talk to each other about whether there are important things that CDC would like to know when this review is redone. Similarly, it is not uncommon that other federal partners will commission a part of the work to be done specific to their interests. Reviews for the USPSTF are sometimes commissioned entirely by CDC, such as the one on Genetic Screening for Breast Cancer. Also, groups sometimes will engage in a cooperative type of activity. The second USPSTF topic for potential counseling recommendations is sexually transmitted

infections (STIs). The Oregon EPC has recently completed this systematic review, to be presented at the March 12-13, 2007 USPSTF meeting. This review does not focus on risky and harmful alcohol use, although these risk behaviors do travel together. It does focus on effective means to reduce the incidence of STIs, including partner choices and contraception. There may be some applicable evidence for the this Task Force about the effectiveness of contraceptive use that they could use. Most of the evidence for the STI recommendation is focused on high risk populations, meaning sexually active adolescents, largely in females and in specialty settings (e.g., STI or psychiatric settings versus regular primary care). In addition, most of the interventions are quite intensive.

In conclusion, Dr. Whitlock stressed that what might be another important point of interest for the Task Force is that sometimes, one of the strongest things the USPSTF can do is to call for the right kind of research. The Oregon EPC recently conducted a review, published in *Pediatrics*, on screening and interventions for pediatric overweight, which is a very “hot topic.” The literature is abysmal, so one of the strongest things the USPSTF could do was use its “bully pulpit” to call for research.

Issues for future research include three main areas: 1) **applicability** focused on primary care populations, setting, and clinical staff delivery; 2) **measurement of health outcomes** or validly measured behavioral outcomes clearly linked to health outcomes; and 3) adequately addressing key **quality issues** is important, including: adequate random assignment, allocation concealment, minimal attrition bias, and measured intervention delivery.

Discussion:

- Dr. Berner suggested that groups like Dr. Whitlock’s could make contributions focused on what has been presented for the public to look at. For instance, recently there was an Associated Press article that discussed a large meta-analysis of all-cause mortality related to alcohol intake. In fact, it optimized the U-shaped curve that all-cause mortality occurred with four drinks per day. That would be a remarkable recommendation to the population at large and would produce a different effect than the mathematical modeling effect that the meta-analysis produced. He wondered if anybody saw this as an important preventive measure in itself to acquaint the public on pitfalls and constraints of a meta-analysis, followed by a summary recommendation to the public, which is what this article amounted to.
- Dr. Whitlock responded that this was a really good point. Those in science and public health sciences fight against the media and advertising all of the time. Her understanding was that *Consumer Reports* has been looking at perhaps packaging some of the USPSTF recommendations in a way that is more accessible to the public. They have been doing a similar program with AHRQ’s Effective Healthcare Program looking at comparative effectiveness, trying to get information packaged to the public. In terms of moderate alcohol use, Oregon did not go deeply into that literature for this recommendation because there are flaws in that literature and it is not such that a positive recommendation could be made for somebody who is not drinking to start drinking, for example. It is just not that kind of literature. There are all sorts of selection factors associated with who drinks and who does not. In terms of the broader question of whether somebody is taking responsibility for the media presenting results in a context (which they do not, they give one single research study and provide no context), or for responsibly communicating that or even talking about who the funder is. There is good evidence, at least in pharmaceutical trials, that there is a significant association between the type of funder and the probability of a positive outcome in pharmaceutical research. While Dr. Whitlock did not have a direct answer to Dr. Berner’s question, she agreed that this was a problem.
- Dr. Chang commented on some of the challenges in demonstrating efficacy in these trials. When carefully done, many of the participants are subjected to very careful assessments. There is enough evidence to suggest that assessment in and of itself is a form of treatment and can result in reductions

in drinking, so that control groups will also show improvement. This is very important to keep in mind, although it may be too nuanced for something like what Dr. Whitlock is doing. For example, she noticed in Dr. Whitlock's table that she listed two studies done by Steve Maisto as being of fair quality, but actually he has written a very influential article about how assessment itself will change the course of drinking. Another study was recently published in which, in order to be included in the study, women had to be interviewed six times before being admitted into the actual clinical trial. There was a sharp reduction at every interview. By the time the women finally got into the study, there was no further reduction to be had. Hence, that is something that may be difficult to pick up, for example, in the larger study of 250 pregnant women, the control group also reduced use because they also had the assessment. On another issue, Dr. Chang mentioned that she has also looked at using the AUDIT in pregnant women and she agreed it was totally unacceptable in that population.

- Dr. Whitlock agreed, noting that they did not feature the dramatic changes in the control and intervention groups, although perhaps that is an omission. The problem with all of that is they have no idea what would have happened anyway. They would need good natural history data in order to say that this does not ever happen, or some other way of creating a comparison condition that is believable. What a recommender would take from that is: Does that mean they should just assess people or assess people multiple times? While she understood that this was good quality research, the translation into how to recommend an intervention from that is challenging. Therefore, it is very helpful to have researchers who are very experienced in a particular area, and who know how to validly conduct the research to demonstrate an effect, in contact with people who are doing reviews in order to reach an understanding of how to conduct research that will demonstrate the kind of effect that policy makers are looking for. One approach in the USPSTF has been to randomize populations so they would have an untouched population, if they have health outcomes they can look at.
- Dr. O'Connor indicated that they found the same thing in their intervention with pregnant women, that the control group reduced their drinking significantly. They did have outcomes measures that, in spite of this reduction, in the heavier drinking women, the babies had better outcomes in the brief intervention group. She also commented on her thoughts about dismantling this research. She would hate for the message to be that giving an intervention that is 15 minute or less in a doctor's office is not effective. It seemed to her that follow-up may be the significant factor that makes the difference. So, the direction they might want to go is that they want to continue to recommend brief interventions, but with multiple follow-ups. She also thought that even though the Manwell study was a small sub-sample of Fleming's study, it was powerful in terms of the effect on pregnant women, which should be emphasized.
- Dr. Whitlock thought that was a very good observation. In looking at other behavioral interventions, duration of contact may be more important than intensity because people do not just change after one contact.
- Dr. Warren pointed out a study by Dawson and Grant that was published about a year previously, which looked at the National Epidemiologic Study of Alcohol-Related Conditions (NESARC) population. This included over 40,000 people, about half of whom were women. Of the approximately 20,000 women, approximately 2,000 to 3,000 were pregnant. A variant of the AUDIT, the AUDIT-C, was validated and worked very well. The AUDIT-C is only the first three questions of the AUDIT related to quantity. The full AUDIT, the 10-question version, was originally designed for alcohol use disorders, not for risky drinking in the population and certainly not in pregnancy. Someone does not have to be alcohol dependent to be drinking in a manner that poses risks to a pregnancy. He was somewhat intrigued because Dr. Chang also said that AUDIT did not work in her population of pregnant women. He assumed that Dr. Whitlock's report, in which she also said it did not work, was pre-Dawson. He noticed all of the references were 2003, while Dawson was published

in 2006. He said that there is a certain face validity to the AUDIT-C, and he wondered if it was limited to this, it would work. NESARC did make adjustments because the AUDIT was developed in Europe where the standard drink is 10 grams, while in the U.S., it is 12.5 grams, which makes a lot of difference. He also realized that Dr. Whitlock indicated that emergency room visits were excluded; however, he wondered whether she had any comment since the few studies that have been done in emergency room settings have shown that interventions in that setting appear to be quite effective.

- Dr. Chang responded that the AUDIT-C needs to be tested. They recommended, for example, that the AUDIT, at the time they tested it, needed to have its cut points adjusted, and that the two most important questions in the AUDIT are the first two, so that makes sense that AUDIT-C might work.
- Dr. Whitlock responded that the USPSTF spend a great deal of time in the scoping stage trying to figure out if emergency department data were applicable, because there are good quality, impressive data. People in these settings are typically identified by blood alcohol levels rather than by screening tests and some would have been intoxicated. They felt that since they were looking at behavioral interventions, the fact that the motivation of the individual in the emergency care setting (e.g., falling off of a ladder) might be different caused them to exclude this group. It was felt that the population would not be generalizable, the motivation and method of identification were different, and it would not be a referable situation. They did discuss this extensively and did not want to exclude a good body of literature that might be beneficial. She stressed that two things Dr. Warren pointed out were important for the broader group to realize. She shared information from a review that was published in 2004 that has not been updated. Therefore, much has been done since that time. Second, these reviews are limited to recommendations for primary care. It is important that they be partnered with recommendations, and they feel strongly that the *Clinical Guide* and *Community Guide* are partners because they cover evidence-based recommendations for complementary settings.
- Dr. Sokol said that the report was extraordinarily helpful in selling the effectiveness of this kind of work to clinicians, and he did not have a single suggestion for the next time. With respect to the strict splitting of pregnant and non-pregnant women in the screening, that recommendation has caused him no end of difficulty because there is no evidence that TWEAK works better in pregnant versus non-pregnant women. There are more studies on the T-ACE and non-pregnant women than on the TWEAK, so he did not understand upon what basis that recommendation was made. There must be a way to look across reproductive-aged women. The optimal time to do this is just before pregnancy, when women are considering pregnancy. The notion of splitting pregnancy from alcohol is sound. It would be very helpful if the way that question is asked is re-thought. In terms of the kinds of screening that get used, he thought they needed to do both things: One that asks about consequences (which could be the T-ACE, TWEAK), and then the AUDIT, which basically follows up and asks the question about how much. They just published one abstract on that. It has never been formally tested that that is correct. He thought from screening 30,000 women that would be a very helpful thing to change. He has reviewed all of the papers on T-ACE and he was impressed. People have used it for men and for non-pregnant women. Similarly, TWEAK has been used much more broadly.
- Dr. Whitlock responded that they relied on other systematic reviews for the screening tests. She said she thought what she understood Dr. Sokol to be saying was that TWEAK and T-ACE may be more broadly applicable than just for pregnant women and that would be important to consider. Sometimes in an update process, the USPSTF will look at established bodies of evidence and not necessarily update all of those. It sounded like it would be important for them to look again at screening instrument performance in broader populations and also the AUDIT-C as an adaptation that is going to be very important.

- Dr. Warren said he thought Dr. Chang's information on non-pregnant was important, and they get certain kinds of answers depending on how questions are asked. The way it is designed, they have to come up with different screens that split off pregnancy. The fact is, when applying this to primary care, they do not do this just during pregnancy. They are doing this in women who might be pregnant or who are newly pregnant. With the CDC-sponsored preconceptional care activities, with ACOG, it is not just people who take care of pregnant or non-pregnant women. It is a continuum. These are the same women.
- Dr. O'Connor indicated that the original Bradley study compared all of these measures and they found that the TWEAK and T-ACE worked fine for non-pregnant women.
- Dr. Chang said they had looked at the T-ACE in male partners of all of the pregnant women in their study, so they have data on about 600 men. They have also looked at the T-ACE in infertile women and in psychiatric outpatients. A study was conducted in a family practice using the T-ACE, so she thought Dr. Sokol's point was well taken.
- Dr. Whitlock said she thought the other thing she heard Dr. Sokol say, and with which others seemed to agree, was that it is going to be important to reframe gender effects in just prenatal settings versus primary care. They looked at gender effects, but within women, they did not look at reproductive aged women. It will be important to ask the question about reproductive aged women and maybe within that, stratify pregnant or not, depending upon what the literature is. She thought his point was well taken about the fact that some primary care is mixed together.
- Dr. Sokol said that a number of people in the room worked very hard with the ACOG in trying to apply the USPSTF findings to the real world. This was a sticking point. They ended up on a one-hour phone call arguing specifically this point. What they really need are reproductive-aged women as the target audience and those who take care of them, whether they are pregnant or not, and preferably before they become pregnant.
- Dr. Whitlock said she knew the agency and the USPSTF processes very well, and any time the product is not meeting needs, they want to know about it because these will be updated. If people are having problems putting recommendations into practice, they should offer feedback to the USPSTF. While many focus groups are undertaken, they may not represent some of the perspectives.
- Dr. O'Connor added that if a pediatrician sees a child with a fetal alcohol spectrum disorder, that he or she should immediately counsel the mother on her current drinking, particularly if she plans to have future pregnancies.
- Dr. Whitlock asked whether there was any evidence on that.
- Dr. Berner responded that there is some evidence that speaks to identification of women with current drinking problems and their subsequent risks in future pregnancies. This is based on the population that participates in their residential treatment program for Alaskan Native pregnant women. This has not been published because it is considered both confidential and proprietary. If it was up to the Indian Health Service (IHS), it would be published. Pregnancy seems to be a teachable moment, at least for Alaskan Native women. While not 100%, there is a significant reduction that they have tracked over the years in the number of children they have identified with FASDs.
- Dr. Miller thought that although they had excluded abuse and dependence because of the focus on primary care, she thought this was an important group of women that was being missed with the *Community Guide* and the USPSTF report (e.g., abuse-dependence piece). She wondered if, in their

review of the literature, there existed a systematic review that addresses that population, or if Dr. Whitlock had a sense of the data of that literature and what it would take to do a review.

- Dr. Whitlock replied that she did not. She conducted all of the adult literature, while Michael Polen handled primarily pregnant women. Therefore, she was unable to say whether there were any studies which focused on pregnant women with abuse and dependence screened out. This raised a question that in looking at some of the studies that have been published, whether it was even sensible to screen out women with abuse and dependence in primary care. She posed the question to the Task Force: Would they go to specialty treatment or not?
- Dr. Sokol responded that he would be surprised if a single study could be found on what happens with the rare dependent woman age 25 to 30 who is picked up either around pregnancy or during pregnancy. CDC and ACOG looked at pregnancy women statewide in Michigan about 10 years ago and there was not one woman referred for care in the entire state. There are studies in Michigan and Florida for drug dependence.
- Dr. Whitlock noted that it may be because of stigma and even punitive legal situations in some states, that those would largely be managed in primary care, so it is another way that the considerations around that population might differ in the next review.
- Dr. Barry commented that they have conducted a lot of research in primary care and brief interventions, and also in the emergency department. She suggested they review a number of the newer emergency room studies because they generally use screening to get people into the study. Most of the people who come into the emergency rooms who wind up in studies do not have a lot of alcohol on board because they cannot sign consent forms. So, it might be worth looking again at emergency room studies that use screening with quantity, frequency, binge drinking, et cetera measures. They have also looked a lot at the AUDIT. The AUDIT-C has been a very good measure from what they have seen. The only issue she would say there is in doing screening, particularly in studies, is that the questions in the AUDIT are categorical, they are not continuous. So, if trying to get a finer sense of what people are drinking, particularly if they are cutting back on drinking, these are big populations. They may be cutting back, but if they do not meet abuse and dependence criteria, their cutting back is not huge, so in order to show an effect, sometimes the AUDIT may not get to that kind of fine level, which is a reason to use other types of instruments that are more continuous in quantity and frequency. With respect to health outcomes, Dr. Barry indicated that she and Mike Fleming wrote these studies. They looked at health outcomes over a number of years, but most studies cannot do that because there is not funding. Keeping studies funded long enough to be able to look at people over a five year period is really unusual. Sometimes they piggyback those folks onto another study. Health outcomes are a monitor that everybody understands, but takes a lot to get to that, particularly in a younger not unhealthy population. Both large sample sizes and a long follow-up period are necessary.
- Dr. Floyd agreed with Drs. Chang and O'Connor with respect to the assessment effect. They found that in Project CHOICES, which focused on preconception women. It is not uncommon in women's and probably men's studies. The NIAAA funded one of the Project CHOICES principal investigators (PIs) to look at this. They adapted the four-session, two of which were follow-up sessions really. In many multi-session interventions, they are follow-ups of initial information that is shared during the first two sessions. An adaptation of Project CHOICES to one session is being delivered to women in communities. They are looking at assessment only, assessment and intervention, and assessment and a Web-based intervention. It is entirely true that consideration must be given to how to measure inertly what to compare that to. If they did not have an assessment, what would you compare that to as part of the answer to the full question? Nevertheless, they encounter this all of the time in studies.

She could only find one study in the early 1990s that attempted to look at this. This is something the Task Force may want to think about in terms of recommendations for further research. This can be very informative in terms of what the effect of assessment is. It is pretty easy to assess people. It is important to consider whether something can be added subsequent to that assessment with respect to feedback and another kind of intervention, be it a referral to an existing quit line or things like this. They should remember this in their discussions about research gaps.

- Dr. Warren reported that NIAAA is supporting multiple investigators who are involved in Project CHOICES, which is an indication of collaboration across agencies.
- Dr. Whitlock indicated that if there is good natural history information, that can sometimes serve as a comparison and it might get around the issue of the intensity of assessment that goes with this in order to determine outcomes. She also noted that while there may be some compelling reasons to conduct a 3-month study (e.g., because a shorter effect might be anticipated, or someone might want to know the trajectory of effect), the USPSTF generally does not look at anything less than 6 months and is happier with at least 12 months. So, there is always a balance in efficacy and effectiveness.
- Dr. O'Connor stressed that if they could get a pregnant woman to stop drinking for at least nine months, that is an extremely important outcome.

Overview of NTFFAS FASD Prevention Report Activities

Mary Kate Weber, MPH

Ms. Weber provided an overview of the Prevention Working Group's activities since its inception. This group was established in June 2004 after the completion of the CDC FAS Guidelines report on referral and diagnosis. The group, which included Raul Caetano, Lisa Miller, Karla Damus, Raquelle Myers, Mark Mengel, Kristine Barry, James Berner, Robert Sokol, and George Hacker, decided to create a report that described evidence-based FASD prevention strategies and to develop recommendations based on these. Key assumptions that evolved from working group discussions included the following considerations: 1) strategies must be evidenced-based; 2) the full spectrum of interventions should be considered; and 3) they should look broadly at women of childbearing age, not just high risk women, but also special populations, such as young women, based on the evidence.

A draft outline was developed focusing on both individual-level and community-level interventions. The outline included various topic areas, including background, prevention recommendations to date, criteria to evaluate strategies, population-level strategies, specific strategies targeting at-risk women, outcomes and evaluation, research and practice gaps, and recommendations. The Working Group requested that consultants be identified to conduct a review of the literature. The National Center for Birth Defects and Developmental Disabilities (NCBDDD) staff met with CDC's *Community Guide* staff. The Task Force on Community Preventive Services makes recommendations for population-based interventions based on evidence gathered in rigorous and systematic scientific reviews of published studies conducted by the review teams of CDC's *Community Guide*. The *Community Guide* summarizes what is known about the effectiveness, economic efficiency, and feasibility of interventions to promote community health and prevent disease. It is also important to note that the Task Force on Community Preventive Services selected "alcohol use and abuse" as a key priority topic for systematic review. Examples of reviews currently underway include increased taxes, enhanced enforcement of laws prohibiting sale of alcohol to minors, and alcohol outlet density. Ms. Weber noted that Randy Elder was in the audience, so he could share more about these ongoing activities if anyone had questions. Since reviews of population-based interventions were already underway by the *Community Guide*, it was decided to focus specifically on community interventions to prevent FASD targeting women of childbearing age.

As indicated earlier today, a review of behavioral counseling interventions has been completed, so the group decided to work with the *Community Guide* staff, focusing on community-based interventions to prevent FASD. The decision was made, with working group support, to work with the *Community Guide* staff. She reminded those present that in February 2006, the *Community Guide* staff (Dr. Peter Briss and Dr. Randy Elder) presented to the Task Force, which voted in favor of using the *Community Guide* process to review FASD prevention interventions. In August 2006, RTI International was awarded a contract to conduct a review on community-based FASD prevention interventions. In September 2006, RTI International outlined a plan for conducting the initial phase of the contract, which is a literature review. Task Force feedback was requested on the proposed approach and search terms. There was additional follow-up after the meeting regarding articles of interest. RTI International conducted a review of the literature and drafted a report to the Task Force. In February 2007, there was a request for Task Force feedback on report findings. Drs. Caetano and Miller, along with CDC staff, provided feedback on the initial draft of the report. The report was then revised and forwarded to Task Force members for review about two weeks prior to this meeting.

In conclusion, Ms. Weber reiterated that the activities the Task Force needed to engage in during this meeting included deliberations on the prevention interventions presented; brainstorming about potential prevention recommendations, limitations of existing intervention studies, gaps in the research, and future research directions. Also, the Task Force needs to decide how these various pieces will come together to as a Task Force product and to determine if work with the CDC's *Community Guide* should continue as originally proposed. Ms. Weber then introduced Drs. DeStefano and Leeks to present the findings from the literature review.

Community Interventions to Prevent FASD Literature Review Summary

Frank DeStefano, MD, MPH

Kimberly Leeks, PhD, MPH

Dr. DeStefano reported that this project was intended to have two parts. He indicated that this presentation was to highlight the culmination of Part I. Part I of the literature review was defined as follows, "Part I will involve an inventory and synthesis of existing recommendations, evidence-based reviews, evidence-based programs and single intervention studies from the *Community Guide* and other 'evidence-based' sources on Fetal Alcohol Spectrum Disorders (FASD) and a summary of these reviews and recommendations which will be communicated in one or more print or web products." If undertaken, a subsequent step will involve Part II, which is defined as, "Part II will involve conduct of one or more new reviews of the effectiveness and cost effectiveness of interventions for Fetal Alcohol Spectrum Disorders (FASD) working with the Task Force on Community Preventive Services" and other relevant stakeholders."

The key questions for Part I focused on community interventions to prevent FASD, and community interventions to prevent alcohol use during pregnancy. The definition of a community intervention, as defined by the *Community Guide*, is "an intervention (activity) that prevents disease or injury or promotes health in a group of persons; not an intervention delivered in an individual, one-on-one clinical setting. This was distinction was designed to avoid overlap with *Guide to Clinical Preventive Services*.

Dr. Leeks then presented the search details for the review. The inclusion criteria were that the primary research had to be published in a peer reviewed journal (although they did find one dissertation study that was included). In addition, studies had to be in the English language and had to have been conducted from 1973 to present. The search also included subject-specific inclusion criteria, which were: community-based interventions; multi-level interventions (e.g., school-based, policy, labeling); intervention effectiveness; childbearing aged women; FASD prevention; and reducing alcohol-exposed pregnancies. Exclusion criteria included general population studies that focus on alcohol consumption

and not specific to FASD; and clinic-based studies conducted primarily in health-care settings on a one-on-one basis by a health care provider.

The follow search terms were used: Fetal Alcohol Syndrome [MeSH]¹; Prevention and Control [subheading] OR Primary Prevention [MeSH] OR Counseling [MeSH] OR Health Education [MeSH]; Alcohol-Related Disorders [MeSH]; Drinking Behavior [MeSH]; Pregnancy [MeSH] OR Fetus [MeSH]; Child-Bearing Age; Incarcerated Pregnant Women; Provider Education; Labeling; Mass Media; Points of Sale Signage; and Motivational Interviewing. Dr. Leeks explained that the term [MeSH] meant that several other terms fell under that. So, for example, the term Alcohol-Related Disorders [MeSH] includes: Alcohol-Induced Disorders; Alcohol-Induced Disorders, Nervous System + Cardiomyopathy, Alcoholic; Fetal Alcohol Syndrome; Liver Diseases, Alcoholic + Pancreatitis, Alcoholic; Psychoses, Alcoholic; Alcoholic Intoxication; Alcoholism; and Wernicke Encephalopathy.

For identification of articles, the databases searched included PubMed, PsychInfo, CINAHL, Sociological Abstracts, and Cochrane. They also reviewed bibliographic reference lists in the studies they reviewed, and consulted with the Task Force and other experts in the field. The search resulted in the identification of 632 unduplicated articles, of which 17 met the specific review criteria. This body of evidence revealed several intervention approaches. One study included mass media (e.g., messages delivered to large audiences by media including television, radio, billboards, and newspapers), one study included small media (e.g., leaflets, brochures, flyers, newsletters, informational letters, videos, or similar interventions), two studies included labeling (e.g., labels on alcoholic beverages convey simple and easily understood messages about the risk associated with alcoholic beverage consumption) one study pertained to policy (e.g., the passage by local governments and agencies of laws and regulations that are designed to promote health actions among multiple components of a community), 12 studies pertained to one-on-one education (e.g., an educational counseling session conducted by a healthcare or allied professional such as health educators), and four studies pertained to motivational interviewing (e.g., a client-centered counseling style used to elicit behavioral change by helping clients to explore and resolve ambivalence). The primary outcomes evaluated included: risk for alcohol-exposed pregnancy (AEP), abstinence from alcohol use, prevalence of alcohol use, use of consistent and reliable birth control, and participation in alcohol or drug treatment programs.

Regarding characteristics of the populations that were included in the review, 7 studies focused on women who were not pregnant, while 10 studies focused on pregnant women. It is important to note that several studies also focused on women at risk for alcohol-exposed pregnancies as well as substance abuse. Eight studies were either randomized trials or had concurrent comparison groups, while 9 employed pre/post comparisons. The sample size had a median of 229 (with a range from 19-7,349). There was a median of 7.5 months for follow-up (with a range of same day to 2.5 years).

Dr. DeStefano then highlighted the results of the review. There were many more outcomes and measures that were evaluated, but they tried to select the ones that seemed to be either more present in various studies, or the outcome that would be more relevant such as abstinence from drinking or alcohol-exposed pregnancy risk. He presented the results by pregnancy status and drinking status.

¹ MeSH stands for **M**edical **S**ubject **H**eading. MeSH terminology is used by the National Library of Medicine to assign topic headings to every article that is entered into Medline. This is known as indexing.

Regarding the three studies that were conducted among non-pregnant women who were current drinkers, Dr. DeStefano first reported on Dr. Floyd's Project CHOICES study. This was a behavioral intervention with a motivational interviewing component with follow-up. It focused both on alcohol and contraception use and had a 9-month follow-up. This study had a concurrent comparison group where the women were randomized to the intervention or the comparison group. The main measure used in terms of the findings was alcohol-exposed pregnancy (AEP) risk, which in this case would be consistent use of effective contraception and/or below risk drinking behavior (defined as 8 drinks or more per week or 5 or more drinks on occasion). In the Floyd 2007 study, AEP risk was increased by 14.8%. In most of these studies, where there was a comparison group, the comparison group usually had changes in behavior of a decrease in drinking, which sometimes was fairly substantial. The difference of 14.8% here, and in all of the other studies where there was a concurrent comparison, was the effect above what the decrease was in the comparison group. So, the intervention group had about a 15% greater reduction in risk than did the comparison group.

The Ingersoll 2003 was the feasibility study to Project CHOICES. Both studies were multi-state and women were identified for the interventions in a variety of settings, such as jails, primary care facilities, etc. The 2003 Ingersoll study had a pre/post intervention and a 6-month follow-up. With this pre/post intervention, there was no comparison group. Women's drinking behaviors were compared from baseline before the intervention to 6 months after the intervention. Here, the 31.5% is the difference between baseline and post. For the three post measures, the effect seemed to be larger, which has been found even in the comparison groups and tends to be some sort of an effect in which just an assessment seems to lead to a decrease, at least in reported drinking behavior.

The Ingersoll 2005 study had a very brief, one-month follow-up with a randomized concurrent comparison group. This was conducted with college women. This was also a behavioral intervention with a motivational interviewing component focusing both on alcohol use and contraception. The AEP risk was about 20%.

Turning to the non-pregnant women with substance abuse disorders studies, Dr. DeStefano indicated that these substance abuse disorders were not only alcohol—usually it was a mix of alcohol and/or drug abuse disorders. A series of studies have been reported by Grant and colleagues in the Seattle, Washington area. Basically, there was an initial study that did have a concurrent comparison group and had about a three-year intervention component. They were intervening with women who had substance abuse disorders. Some of them were identified through hospitals post-partum, some of them were referred from various sources, so it was a mixture. Also from the original study, it appears that they started initially doing some systematic randomized assignment, but not for all of the women. So, it is not totally randomized although it had a randomized component to it. Women were followed up through three years, and measurements were taken throughout that time in the original study. Those women were then followed after the program for up to 2.5 years. So, it was definitely a long-term follow-up. To add to the complexity, they did a replication study in Tacoma and Seattle three years later and ran those later, although they did not have comparison groups in those either. Or, a lot of their comparisons in those were from the comparison group from the original study. For post program evaluation, there is just a pre/post comparison of the original 45 women who were in the original intervention study. There the main effect measure was abstinence from alcohol or drugs. They did show some effect. A statistically significant result was not reported, but it looks like there was an 11% improvement. This was a multi-component, very intensive, one-on-one intervention. It was like each woman had a caseworker to assist her in a variety of issues, including getting into substance abuse treatment, social and family services, etc. This was in addition to the alcohol and contraception piece.

Referring to the 3-year in program study (Ernst, 1999), Dr. DeStefano indicated that this is the one where there was a comparison group. Abstinence for greater than one year in the intervention group had a 5%

greater effect than the comparison group, while reliable birth control was at an 11% greater increase in the intervention group. Within this program being run in the Seattle area, Grant and colleagues also identified a subgroup of women who themselves had FASD and substance abuse or alcohol abuse. They tailored a more specific intervention to deal with cognitive problems and other difficulties that individuals with FASD may have and they reported results of this more specific intervention in 2004. This was a small number of women, with a pre/post design, which showed an increase in abstinence of 42% and an effective birth control increase of 32%.

The Loudenburg 2003 study was a multi-state, multi-component intervention in women who had substance abuse problems (e.g., drug and/or alcohol abuse). The intervention did not focus just on getting them into substance abuse treatment, but social and other services as well. Loudenburg 2003 reported only pre/post findings on the intervention group. In the methods, they indicated that they had a concurrent comparison, but the results for them were not reported in this publication. They used perception scores of alcohol use and problems related to alcohol use. On that measure they showed an increase in perception scores after the intervention.

Turning to the studies that focused on pregnant women and the more general population studies, Dr. DeStefano reported on Belizan 1995. This was the only study conducted outside of the U.S., in a few South American countries. This was a multi-component intervention in which they were trying to identify women at risk for adverse pregnancies. They tried to intervene on a number of factors, so alcohol use was not the major factor. They identified women during pregnancy and followed them up for 14 weeks. This was a large study, with over 2,000 women who were randomized. Their alcohol finding was a decrease in daily alcohol use of 5.5%, which was not significant, although it was also not the major focus of the intervention. The study by Eustace in 2000 had a 12-week follow-up. This study consisted of small media (including a pamphlet) and positive or negative reinforcements. Kinzie 1993 was a small study basically evaluating the immediate effect of a computerized video program on alcohol use. Not surprisingly, right afterward, intention to use alcohol in a social setting decreased.

Regarding the studies focusing on pregnant women who are current drinkers, Dr. DeStefano reported on three. Handmaker 1999 was a small study that had a concurrent randomized component, and which had a motivational interviewing component. The end outcome measure was abstinence, which showed an 11% increase in the intervention group. Another study was recently published by O'Connor, which followed up women to the third trimester of pregnancy. These women were concurrently randomized. O'Connor reported the odds ratio (OR) for abstinence, which was a fairly strong association with the intervention group and which was statistically significant. This was done with women in the WIC program and included small media, education, and a brief intervention. Reynolds 1995 was a small study that had a follow-up of women who were two months into their pregnancy. This study had a randomized component and was conducted in public health clinics. Abstinence increased by 19% in the intervention group compared to the comparison group.

Other studies included a mass media study by Glik in 2001. This study included a pre/post evaluation of posters and tear-off cards for a mass media intervention. African American and Latina adolescents showed improvement in knowledge of harms to their baby from alcohol exposure during pregnancy. There was also a small media study by Walker in 2005 that showed improved knowledge scores immediately after reading a pamphlet. In a labeling study by Hankin in 1993 and 1996, ecological analyses were conducted on reported drinking by women attending a Detroit prenatal clinic. No overall decrease was seen after the warning label began, although there were significant decreases among “non-risk” drinkers and nulliparous women. A policy prohibition study by Bowerman in 1997 did an ecological analysis pre/post on a ban on alcohol possession in an Alaskan community. Significant decreases were noted in first trimester alcohol abuse (-32%).

In summary, most studies they identified used one-on-one education. There seemed to be an overall increase observed in abstinence, or a general decrease in reported alcohol use. There was an increase in consistent use of effective contraception in the four studies that included a contraception component. The four studies that included a motivational interviewing component showed consistent beneficial results. There were few studies of other approaches. Limitations of the studies make it difficult to draw firm conclusions. Limitations included: self-report, participation bias, loss to follow-up (0-31%), short follow-up, and lack of randomization and/or comparison group. Most of these studies did fairly well at maintaining follow-up. The shorter studies did better; however, the longer the studies ran, the more loss there was to follow-up. Several studies had less than six months of follow-up. Of the studies that did have a comparison group, most did randomize, although some only partially randomized or did not have a randomized group. Studies with pre/post evaluations have to be “taken with a grain of salt.” No studies actually looked at the health outcome of preventing a fetal alcohol exposed birth.

Other considerations include whether they want to focus on other populations (e.g., general populations, risky drinkers, substance abuse). These would all have different issues, approaches, and strategies to consider. The timing of intervention is also a consideration (e.g., preconception, during pregnancy). Again, there would be different issues, approaches, and strategies to consider depending upon timing.

Dr. DeStefano concluded that the review identified a small number of studies of community-based interventions to prevent FASD. These studies used a variety of intervention approaches, although one-on-one education was the most common. Motivational interviewing appeared to be a promising strategy. Effectiveness was enhanced by the inclusion of a contraception component. Ultimately, Dr. DeStefano would argue that the quantity and quality of the evidence remains limited.

Discussion

- Dr. Floyd clarified that Ingersoll 2003 was the Phase I Project CHOICES study. At study entry, all of the women were at risk for an alcohol-exposed pregnancy. At six months, two thirds of them were no longer at risk.
- Dr. Warren inquired as to how the distinction was drawn between a community and a clinical setting, given that it is difficult to tell the difference between those that were included like Project CHOICES and those excluded like Dr. Chang’s study, which also used motivational interviewing. It is a very thin line distinction.
- Dr. DeStefano replied that this issue has been bandied about since the beginning of this review. How he saw the distinction was that a non-clinical intervention component would be someone who was not a health care professional delivering the one-on-one intervention, or it is being delivered in a non-health care setting. The ones they included may have had some component of a clinical intervention and also had components in which the community definition fit, so at least there was a mix of some clinical and some community.
- Dr. Floyd commented that she was not sure where Project CHOICES fit in terms of being a community or clinical intervention. She thought it was clinical because most of the populations received one-on-one interventions, but those populations were reached in alcohol and drug treatment community-based settings. This was a group of women, although they were approached and individually counseled. There was also a media-recruited group. The media went out to a community of women who self-selected to respond and then received one-on-one counseling. There were aspects that were not as clear-cut, for example one setting was an obstetric clinic at a major university in inner city Richmond, Virginia. These women were screened, consented, and given the intervention. Clearly, that was clinical intervention. It made her think that maybe they have a hybrid. She asked Dr. Whitlock whether she would include Project CHOICES in her clinical review.

- Dr. Whitlock responded that they included the Handmaker and Reynolds studies, which were both in public health prenatal settings or an academic medical center. Therefore, it fit Oregon’s criteria. She did not know about the other ones. In terms of Project CHOICES, when she looked at the recruitment settings, which were fairly broad, what would help them evaluate whether it is applicable for the *Clinical Guide* is to know the proportion of patients recruited from each of those settings. Mark and Linda Sobell have done a huge number of studies on problem drinkers. None of their research was applicable to the *Clinical Guide* because all of the patients were recruited through newspaper advertisement. The type of patient who volunteers to be in a study on problem drinking because of an advertisement is very different from people presenting for clinical care for other reasons to primary care. Similarly, because she did not know the proportion of patients from each setting, she could not evaluate this. In the *Clinical Guide*, there will be a judgment made. It is not cut and dry. If in Project CHOICES it was 50% or greater, or the results could be stratified by recruitment source, it would be more likely to be applicable.
- Dr. Warren said that for him, an ideal community setting is something like alcohol screening day, depression screening day, anxiety disorder screening day where in shopping centers people have the opportunity to take a screening question. That is different from a newspaper advertisement because ads say, “Do you think you have a drinking problem?” Screening day has nothing to do with whether someone thinks they have a problem. He was not clear whether they thought those types of settings had been evaluated in the literature. He thought alcohol screening may have been evaluated to some extent, although not related to pregnancy. He did not know about depression screening day. The line between what constitutes community and clinical is not clear. A screening day at a shopping center is like bringing the clinic into the community rather than the patient to the clinic.
- Dr. Whitlock said that in order to operationalize a better distinction between the *Clinical Guide* and the *Community Guide*, for pediatric overweight review (because they coordinated with the *Community Guide* which is also conducting a review at the same time) they created a slide that shows the type of intervention (e.g., individual, group), the focus of the intervention, the setting, etc. in order to show the distinct areas that each guide deals with and the overlap, which is at the health system level. That is somewhat helpful; however, at the individual study level, it can be difficult to make a systematic distinction. They adopted the Institute of Medicine (IOM) definition for “primary care” so that will come in to play when looking at a clinical setting. They operationalized the definition for “primary care conducted or feasible.” Still, there can be judgment involved about what is applicable. They do have terms and definitions they apply when trying to determine whether a study is relevant.
- Dr. Sokol commented that the setting is very interesting, but he thought that was irrelevant. Instead, it was how the question was asked. The fact is, this is one-on-one clinical intervention. A WIC clinic is a healthcare setting that is paid for by Medicaid for healthcare. He was the co-author on the labeling studies reported on and they basically found no effect. That was a very expensive, complicated NIAAA study. Another paper came out of that which showed that the principal deterrent of drinking was not the warning label, which had no effect on any heavy drinking, it was the economic status of the respondent (e.g., how much social stress women were under). Labeling is a community-based intervention. It seemed to him that the correct conclusion from this study is that there is no evidence that community-based interventions have any impact on alcohol exposure and on risk drinking in reproductive aged women. What does work, and what they should be focusing on, is one-on-one interventions. Both sets of evaluations that were done show that where they need to pay attention, supporting the work, and publicizing information pertains to contraception and separating pregnancy from alcohol.

- Dr. O'Connor thought they needed to qualify the limitations of this. Regarding the limitation of self-report, in addition to retrospective reports, which seem to be pretty valid, there is also some research that shows if a woman is asked about her drinking during pregnancy, she tends to report more honestly than collateral reports (e.g., from spouses, etc). So, those data could be suggested in the limitations section. Also with regard to self-report, some of these had comparison groups. Most of these studies have a lot of assessment, so they know they are not supposed to drink. Some of these studies also have standard of care, which is an active intervention. It would seem that the bias would be the same across both groups, which might eliminate the self-report criticism. Regarding the participation bias, she thought they must look carefully at the studies. In her study, 30% of women refused to participate. In WIC, there is ongoing research and 30% typically do refuse to participate in any kind of research, so it is consistent with the populations they were working with. In addition, when looking at follow-up, it is a very mobile population, so the number of women lost to attrition was consistent with the number of women lost to attrition in WIC over a nine-month period. In addition, there was no difference in that attrition between the standard of care and the research intervention. The limitations come off so strong, it suggests that the studies were not that useful. The other issue about the short-term follow-up, a nine-month intervention with pregnant women is all that is needed if she stops drinking during those nine months. A little more discouraging are the studies that show what women do after they have the baby—they tend to go back to drinking. That is why Project CHOICES is such an important intervention to suggest. With regard to Dr. O'Connor's study, there were some inaccuracies in the presentation. They looked at abstinence and absolute reduction in drinking, but the editor said the paper was too long, so he told them to do one or the other, which was why they did not report both. Both groups were drinking about two drinks on average per drinking occasion. In the treatment group, they got a reduction of almost zero, and in the non-treatment group they were still drinking about half a drink. Regarding the conclusions, specifically she did not think they wanted to say that the most promising interventions are motivation interviewing because, of the four studies on motivational interviewing, three were the same study. Hers was not just an education intervention. It was a cognitive behavioral intervention. It did not use motivational interviewing, but certainly used cognitive behavioral approaches. So, they should say both because motivational interviewing is a unique counseling intervention and training is required. She used a manualized approach that did not require those kinds of skills. Also, while they want to say that they would recommend counseling on sexual behaviors and pre-pregnancy, Dr. O'Connor thought that anytime a woman stopped drinking during her pregnancy is important. Therefore, she would tweak that section somewhat. It says, "The more successful intervention targeted not only drinking behaviors, but also sexual behaviors." She did not think that was the only most successful intervention—there were others.
- Randy Elder pointed out that when doing a *Clinical Guide* or *Community Guide* review, it is very important to make distinctions between studies and whether they are most appropriately considered clinical or community interventions because they are speaking to certain audiences. It seems that the clear distinction between community- and clinical-based may be less relevant than what the actual intervention is. It seems that the motivational interviewing type of approach could be adapted either to the clinical setting where it is basically delivered to people coming in for clinical treatment that is not specifically related to alcohol consumption, or it could be applied in a community through approaches to actively screen for these people, whether it is through newspaper articles, health fairs, college campus settings, etc. It seemed for these specific interventions, it was applicable in both community and clinical intervention settings. To make an artificial distinction may give less than a full picture of the potential utility of this intervention than from saying what there is on an intervention across the board and perhaps stratifying by setting. His point was that while this distinction was very important for the *Clinical Guide* and *Community Guide*, it is not necessarily that critical for the purposes that the FAS Task Force.

- Dr. Miller agreed, pointing out that they were getting off track because of this false dichotomy the interventions have been placed in.
- Dr. Boyle reminded everyone that the reason they began going down the *Community Guide* route was to use these two processes that sanction the evidence: the *Community Guide* and the *Clinical Guide*. The charge of the FAS Task Force is to generate their own report that coalesces across site and setting. One unanswered question is whether it makes a difference where the information is delivered in terms of a brief intervention. Consideration must be given to whether an important variable is for the primary care physician to have a good working relationship with the patient, for example. That is a research question that could be addressed through further studies later on. Right now the body of evidence suggests that brief interventions, regardless of setting, seem to have an impact.
- Dr. Bertrand asked the Task Force members to keep in mind that not only could they promote what should be done, but also they could suggest what areas of research need to be addressed. She stressed that they could go way beyond what the *Community Guide* and *Clinical Guide* have done. They specifically included terms in the systematic literature review that they thought the FAS Task Force would want to address, such as “incarcerated women.” That is a policy issue that often arises, and the clinical tells them that it does not work very well, but there is no research to support it.
- Dr. O’Connor thought that based on the two presentations they had earlier, it sounded like delivering the intervention in the doctor’s office was not as effective as delivering it in the community. She wondered if that was too simple a generalization. She stressed that she did not want the message to cause people to conclude that brief interventions are not effective.
- Dr. Floyd thought that these suggested that the intervention must go beyond the doctor’s office.
- Dr. Chang did not think the two reports they had earlier were exactly comparable in terms of methodology. The first report subjected all studies to a fairly rigorous review of standards, while the second one used a very different type of approach. She thought the list of limitations was trite and that it actually could go beyond what it does.
- Dr. DeStefano reminded everyone that he was reporting only on Phase I, while Phase II was supposed to get at a process more akin to what the clinical preventive service report did. Phase I was to lay out in general what the limits are.
- Dr. Sokol pointed out that he and Dr. O’Connor drew the exact opposite conclusions. He thought it was very clear that the only thing that had a shot at working was brief intervention from both reports. The difference was that the USPSTF does not have the newer studies. At least from this committee’s perspective, it did not seem like the key was location. The key is the approach, which is a one-on-one intervention. He suggested that the FAS Task Force should focus on that. Perhaps they should try to get an up-to-date look at that kind of intervention. If that pans out as an effective approach, they need to get the information out and working for them.
- Dr. O’Connor clarified that she was simply trying to think of it terms of someone who did not know the current studies. With that in mind, it was somewhat discouraging.
- Dr. Warren reflected on the IOM terminology, noting that in their model on having universal, selected, and indicated prevention, what they really see is that indicated prevention, which is really working one-on-one, works. So far, there is no evidence that universal prevention works or that it does cause policy makers to feel good. There is no evidence that it has any long-lasting effect beyond

a blip. Whether selective prevention has an effect remains to be determined. That is a level higher than universal prevention targeted to specifically high-risk groups.

- Dr. Floyd said she thought they were all talking about what works and needed to just take off the blinders of what to call it. She referred members to page 13 of Dr. Whitlock's presentation, pointing out that it does not say who specifically must deliver the intervention. It can be delivered by a variety of persons in a variety of settings. She thought this was where they should focus.
- Randy Elder cautioned the members not to take universal interventions off the table, because what was presented earlier specifically excluded the types of universal interventions that were most likely to have an effect—universal interventions directed at the entire population, not just those directed at women of childbearing age. There are plenty of universal interventions that are very likely to have important effects on high risk drinking, which is very likely to have subsequent effects on FASD.
- Dr. Floyd requested that Randy Elder comment on what his group had reviewed so far that he would consider promising approaches that would affect the condition they are trying to prevent.
- Randy Elder responded that one review they are just wrapping up pertains to the effect of alcohol taxes on excessive alcohol consumptions and its related harms. Certainly, the way the evidence is panning out, it is looking fairly evident that taxation would be an intervention that would work (e.g., a substantial increase in alcohol taxes will result in a substantial decrease in high risk drinking). Nobody ever evaluates FASD, so he thought they would have to have a leap of faith at some point regarding that. Recently they had a Task Force recommendation on alcohol outlet density which was found to be an effective intervention. Alcohol outlet density is applied in a much more narrow population, so he would not expect it to have effects on FASD. It would more likely have effects on assaults and other injuries. The bottom line was that for anything that would affect high risk drinking, they could make a pretty strong case that it would affect FASD as well.
- Dr. Bertrand suggested that what Randy Elder's group has done could be included as a segment of the FAS Task Force report. She stressed that they should not "throw the baby out with the bath water" on universals for two reasons: 1) just because they do not have evidence right now, it may be that they are not detecting a change yet; they just have not developed the methodology and there needs to be more research; and 2) they should take a very long view and think of the smoking issues; it took 30 years of raising the floor of knowledge and awareness before they started to get a windfall of changes that were effective and picked up on population-based surveys.
- Dr. Hacker commented that another issue related to the potential synergies among many different interventions, including universal approaches. No one measure itself may appear to be effective, but combined with others, they may together have a beneficial effect, which is worth addressing.
- Dr. O'Connor suggested that they should also look not just at statistical differences, but also clinical differences.
- Ms. Ohlemiller emphasized something that Dr. Warren raised, which was that they have a gap between very large universal techniques and then they ratchet all the way down to one-on-one. There is a huge world between those. It was hard for her to believe, as a person in a community doing some of this work, that there was not something larger than one at a time they could do in a more cost-effective way to impact this issue. None of these studies has anything of substance in the middle ground. That is partly because many people doing this work do not evaluate it in way that it can be peer reviewed. What is peer reviewed probably got left off due to the exclusion standards in both

reviews. She thought their final recommendations must focus on the middle ground to some extent or they risked losing credibility with the community. This cannot be done one at a time.

- Dr. Sokol stressed that the way the question is asked makes a difference in the answer. He thought the reviews were good; however, it is a leap of faith that universal prevention will work when there is no evidence for that. This report should say that.
- Dr. Floyd stressed that this is not an exclusive review of everything that exists. The Sobells have done some excellent work recruiting individuals from the community who want to change their drinking habits, providing them with one session and self-guided materials. This works. That is a community-based intervention. That would be among the listings. There is evidence of that. There is evidence of pharmacotherapy working. Certain medications are just as successful as the 12-step programs. There is Alcoholics Anonymous, which has been very helpful to people. At this point, she wondered if they needed to figure out the scope of the issues they wanted to consider and add to that. They cannot cover everything, nor do they need to. She thought they were looking for the most salient interventions that were more likely to work, about which they could make comments and recommendations for the future.
- Dr. O'Connor suggested that maybe universal prevention was too broad a topic, and that perhaps they should leave the focus at one-on-one, given that they really had not covered universal interventions adequately.
- Dr. Ohlemiller stressed that if they were going to use the word "community" in the title, they should have some discussions about what that would mean to people. She has seen things implemented and working, but was not sure whether they could say much about that beyond the fact that there is a gap in the literature. Still, she thought it was worth saying.
- Dr. Miller recalled that their original intent was to try to cover the whole gamut of interventions from universal to one-on-one. Because they have a review that evaluates the literature as it exists and talks about labeling, she agreed that they should at least be able to say something. While they did not need to spend a lot of time on this, it certainly warranted at least a paragraph. Others agreed.
- Dr. Sokol suggested that they also include comments about point of sale signage. It is not in the report, but should be there. Dr. Bertrand responded that they did ask RTI to look at that, and they were able to confirm that there is not any research, so the Task Force has the flexibility to include this information.
- Dr. Warren pointed out that cigarette warning labels vary around the world in terms of size and strength of message, and there have been peer reviewed studies that show that the effectiveness varies depending upon the strength of the message. From his travels around the world, to his knowledge only two countries have bottle labeling: U.S. and France. Point of sale signage is seen all over the U.S., but they vary state to state. He was in Australia in September and their messages cannot be missed. They are "in your face" at points of sale. A study of that nature certainly would be useful; that is, comparing the effectiveness as was done in terms of smoking across countries related to the packaging of the message.
- Dr. Hacker added that there was a recently published study that demonstrated that Canadian and U.K. type warnings, which are pictorial, are much more powerful than the U.S. bland message. Unfortunately, while there is research on the tobacco side, there is very little if any on the alcohol side.

- Dr. Sokol commented that this represented another recommendation they could make, that there is relevant research from related fields that might be useful in this prevention effort.
- Dr. Bertrand added that about twenty U.S. states have point of sale signage, so comparisons could be done.
- Dr. Brown thought they did need to look at message, both in terms of packaging and what the messaging is. She pointed out that the women in a longitudinal study she has been working on, there is a question asking women, at the time their children are nine months: Are you drinking now? Did you drink in last three months of pregnancy? Did you drink in the three months before pregnancy? Close to 40% of women drank something, even small amounts, in the three months before. Less than 3% drank in the last three months of pregnancy. The number goes to almost pre-pregnancy rate after nine months. So, women evidently were not getting the message that if they are drinking before pregnancy, they probably are drinking at the time of conception.
- Dr. Miller suggested that perhaps Phase II, rather than going more in-depth in this direction, needed to focus on the integration of everything they had been discussing. While she did not know what role RTI would play in that, it warranted further discussion.
- Dr. Floyd concluded this session, indicating that the information they received from Drs. Whitlock, DeStefano, and Leeks was very useful. She thought they were beginning to put some form around what they wanted to do.

Deliberations on Prevention Recommendations/Developing the Final Report/Next Steps

At this time, Task Force members and liaisons deliberated on prevention recommendations, the development of the final report (e.g., type of product, timeline), and next steps. The following outline was developed during this discussion period as a framework to be fleshed out later through conference calls, emails, etc. Also, comments and discussion related to the listed items follow for further clarification and rationale.

Intervention Strategies for Preventing and Reducing the Risk of Alcohol Exposed Pregnancies

What We Know...

Evidence Level 1

- Strongest evidence points to brief interventions and motivational interviewing
 - Do not over emphasize limitations
 - Separate studies of pregnant and non-pregnant women
- Dual focus interventions are effective in reducing risk of AEPs via both routes of reducing drinking and preventing pregnancy

RECOMMENDATION: This type of intervention should be widely disseminated, supported, and integrated into medical, social service, and other venues as soon as possible.

- Treatments for women, pregnant women, and others for alcohol abuse / dependency have been shown to be effective (stepped care approach)

RECOMMENDATION – all levels and components of stepped care for women using, abusing, or dependent on alcohol should be available and implemented in all communities with priority for already pregnant women.

- Medications (no pregnancy data)

Evidence Level 2

- Universal strategies
- Guiding Points
- Use/incorporate findings of the community guide regarding alcohol and preventative services clinical guidelines
 - Some universal approaches have been shown to be effective for reducing alcohol abuse, and by extension could be assumed to aid in prevention of AEPs
 - Workforce issues
 - One-on-one education from *Community Guide* and *Prevention Guide* reviews
- Incorporate National Business Group on Health recommendations regarding screening for alcohol
- Preventing alcohol use during the nine months of pregnancy is a success, regardless of long-term (non-pregnant) alcohol use
- For pregnant women, we are going for total abstinence; for non-pregnant women we are aiming for harm reduction
- Review SAMHSA's women's treatment coalition report
- Provider education should be expanded (CDC regional training centers)

What We Still Need to Find Out

- Research areas that still need to be addressed
 - Either no evidence or evidence does not meet inclusion criteria
 - Emergency room-based studies
 - Use of technologies
- Translational research (science-to-practice)
 - We know some things that can be implemented now (see above)
 - Expand provider education research and practice
 - Implementation literature (Dr. Whitlock's student)
- Populations at particular risk for AEPs (Alaskan Native, Native American, etc.)
- Adolescents
- Individuals with co-morbid conditions
- Evidence-based interventions for alcohol dependency for childbearing aged women (e.g., treatment beyond brief intervention/motivational interviewing)
- Research on "dismantling" essential components of MI and / or BI (minimal time/sessions, minimal training/qualifications, modalities, cultural issues)
- Universal and selected strategies (evidence, potential programs, etc.; Alcoholics Anonymous; court/criminal consequences)
- Overcoming limitations of current research/evidence based studies
- Work from related fields (e.g., marketing) that may inform development of potential strategies and/or research.
- Including relevant questions on national surveys (NHANES, BRFSS, HealthStyles, Alcoholics Anonymous member survey, etc.)
- Coordinate with other agencies regarding warning symbols
- Studies of pregnant women and medications to prevent/reduce alcohol use

Potential Additional Literature Searches

- Update USPSTF *Clinical Guide* findings

Comments and Discussion

- Dr. Floyd stressed that they basically have six months to complete a product, so they must be realistic in what is covered. One approach could be to choose a particular aspect (e.g., selected interventions, such as brief interventions) and work primarily on that, while at the same time acknowledging that for

universal and indicated interventions, the body of evidence is not there, but there are possibilities for future research that can inform those levels of care.

- Dr. Berner suggested that they recognize that, in spite of the work they have done, there are groups at risk for FAS that they have specifically not addressed. One of the guidances in the original charter of the Task Force was for specific subpopulations at risk, such as American Indians/Alaskan Natives (AI/AN). Most Alaskan Natives have co-morbid disorders. What they have discussed thus far during this meeting did not address this. The searches specifically looked at people who were not specifically screened for co-morbid conditions. If they had them, they were probably in the group that failed the brief intervention, so many of them would not have been included. One of the major unmet needs they should recognize and highlight in their final publication is the need to look specifically at these at risk groups that produce large numbers of children with documentable FAS who have co-morbid disorders that, if not addressed, no interventions will be seen to work very well.
- Dr. O'Connor indicated that they have a study that looked at depression as a risk factor in drinking during pregnancy after a woman knew she was pregnant and after receiving advice from a physician to stop drinking. There are other studies that show depression as a serious risk factor that needs to be addressed. In terms of moving the literature forward, at the end of the day, they must think about pragmatics. That is, they need to dismantle the studies to look at the shortest time an intervention can be done, whether everybody can deliver the intervention once trained, whether training is needed in motivational interviewing or just using a workbook or picture would suffice, etc. Dismantling studies would help them understand the optimal interventions that can be used with the least amount of professional and non-professional time.
- Dr. Miller thought there is an entire area related to treatment that had not been addressed in terms of what is effective for abuse and dependence. This is only a segment of the at-risk population, which they could argue is at even higher risk of producing an alcohol-affected pregnancy.
- Dr. Brenneman thought adolescent females needed special attention. A large number of pregnancies occur at age 20 and younger, which is higher with certain ethnic groups. This group requires special kinds of intervention.
- Dr. O'Connor pointed out that there are numerous studies funded by NIAAA that look at motivational or one-on-one interviewing with adolescents, so maybe they could incorporate that.
- Dr. Olson commented that they should start the document by discussing what populations are at the highest risk for having alcohol-exposed births, and of those who is at high risk for having an actual affected birth. That would be how they could make their case for what populations they would focus on reviewing the evidence for. That would then direct the entire document.
- Referring to the Early Childhood Longitudinal Database, Dr. Brown noted that the American Indian population was drinking at very high to mid level, while other groups had comparatively larger amounts in the very high level. The only group that did not show high levels was the Asian population. The patterns of moderate to high in these groups were different at different points, but if looking all together at the highest level, it was pretty close for Blacks, Whites, Native Americans, and Latina women, which was unexpected from what she understood. She offered to provide a copy of this data for the next day.
- Dr. Floyd asked for discussion about the literature on computer-assisted interventions. She noted that Sandra Laphan, IHS, published a study about five years ago using computer-assisted intervention that was successful. Dr. Barry responded that little had been done with that yet. The Veteran's

Administration has a couple of studies, one in the emergency room and one in primary care, that use some computerized interventions. One is a National Institute on Drug Abuse (NIDA) study and one is NIAAA. These are brief interventions. This work is about halfway completed. While the computer-assisted area has not progressed a lot, she thought it was a good area to consider.

- Dr. Sokol suggested that under “research agenda” they could delineate information for which there is evidence and that for which more evidence is needed.
- Ms. Weber pointed out that while they know that certain interventions work within the research setting, consideration should be given to the practicalities and challenges of getting these into the field and implemented. For example, there have been challenges in getting Project CHOICES adaptations implemented into practice settings. With that in mind, Dr. Floyd suggested they include in their outline some discussions about how to integrate interventions into systems of care in order to increase accessibility and sustainability.
- Dr. Miller reported that there is a CDC Request for Proposals currently out about translational research.
- Referring to the outline under “the strongest evidence points to brief intervention,” Dr. Olson thought another bullet point had to pertain to why the apparent limitations of the research should not stop them from moving forward. One of the reactions she had to the documents in the presentations earlier in the morning was that the limitations are showcased, so one conclusion that might be drawn is that there is not enough evidence to move forward. That should be addressed at the outset and the limitations put into context. Then below they could address how the limitations could be overcome. Dr. Floyd agreed, noting that some of that could also be accomplished in terms of the tone of the document, focusing on what is known and not known and making a strong statement that there is still enough information to do something that is not currently being done.
- Dr. O’Connor thought it would be a good idea to separate pregnant from non-pregnant women with regard to the literature reviews, which would take care of some of the issues pertaining to follow-up.
- Dr. Olson noted that the title of the document is, “Prevention of Fetal Alcohol Syndrome: Literature Review Summary,” which may need to be changed. With the field leaning toward a spectrum of deficits, perhaps the Task Force should move beyond simply trying to prevent FAS and into thinking about the wider spectrum. Dr. O’Connor added that she would go even further to say that preventing an alcohol-exposed pregnancy was really what they were talking about. Then they would not have to get into spectrum issues. She suggested changing the title to, “Interventions for Prevention of the Risk of an Alcohol-Exposed Pregnancy.”
- There was wide agreement that both the USPSTF and the *Community Guide* information should be used as the evidence base for the document.
- Regarding the range of information not covered, Dr. Sokol reminded everyone that the way both reviews were conducted basically asked for randomized trials, high level evidence, and maybe they needed to state what other kind of interventions there are and at least document something about the level of evidence that is available. It was suggested that this was covered under the first research bullet, pertaining to the areas where there is no evidence or the evidence does not meet the inclusion criteria, which would include some of the broader policy or community issues. Dr. Bertrand added that then they would preserve the rigor of what is in the top, but still address the other issues. There is a balance in that as they expand, they have more credibility with the clinical community, but would lose some credibility with legislators and other scientific groups.

- Dr. Hacker reiterated that there needs to be recognition that population-based approaches, along with individual interventions, are necessary to do as good a job as possible. To the degree they could document that some of those population-based approaches are effective to reduce alcohol consumption among certain of the related high risk groups, they should do that in this document without necessarily suggesting that they be primary nominees for programs on this issue. This would include alcohol screening, general mass media messages, warning labeling, posters in stores and restaurants, taxation, messages in advertising, reductions in access—all of those things that might help to reinforce or at least make the environment less noxious for those people who receive motivational interventions. Ms. Weber thought that those issues have or will be covered in the alcohol reviews being done by the *Community Guide*. Also, some of the feedback on the initial draft of the RTI report was acknowledging the importance, regardless of the evidence, of some of these population-based approaches. There is a short blurb in the RTI report that acknowledges the importance of population-based interventions.
- Dr. Sokol thought they still had to say that there ought to be some evidence for population-based approaches. It was fine to say they know it works, but it would be very nice to show something that says that advertising does something and that some effort should be put into it. He also thought they should say something about the work from related prevention fields, which might be relevant in designing strategies for this.
- Dr. Hacker thought they should make very strong recommendations for the research where the evidence is suggested, but is lacking otherwise.
- With regard to alcohol screening day and the evaluation of that, Dr. Warren said he did not know how much had been done on the evaluation. There have been some screenings, and certainly there has been process evaluation in terms of the numbers and types of individuals. He did not know the number who were identified and who were followed-up on as having an alcohol use disorder, so it would be worthwhile to determine what has been published on this. NIAAA paid for the study, so hopefully there are evaluations from that. He reiterated that what he mentioned earlier was that alcohol screening day was not oriented around pregnancy, although pregnancy brochures were available in the packages. It was general screening with a major focus on alcohol use disorders. There most likely would be pregnant women among the general population screened, but there would not be any specific discussion. In the materials distributed at the various sites around the country, information would have been included about alcohol use and pregnancy. Thousands of sites across the country received a package of materials, which included the brochures developed by NIAAA related to alcohol and pregnancy. However, he did not know if there were any follow-up data that would indicate the number of individuals who were pregnant out of all who were screened. He agreed to check with NIAAA to determine what information they have to support the Task Force's report.
- Dr. O'Connor suggested that they also give thought to the national surveys in which the question would be asked: "In addition to how much you are drinking now, have you seen public health announcements or have you noticed on bottles?" as part of the next round. That would represent a good population sample as well. Dr. Floyd thought that may be something the Task Force could consider in terms of recommendations. Ms. Weber added that the Behavioral Risk Factor Surveillance system (BRFSS) does modules, one of which was on binge drinking, although members pointed out that there is a lot of competition to get questions into the BRFSS. It was agreed though that they could identify surveys which could address universal interventions. Other suggestions included NHANES, HealthStyles, and the Alcoholics Anonymous member survey.

- Worksite employee assistance programs were suggested as a potential resource. Drs. DeStefano and Leeks indicated that nothing came up in the RTI search, although they were not specifically searching for worksite information. It was noted that the *Community Guide* has dealt with worksite interventions, although they are not targeting alcohol specifically. In the assessment of health risk reviews, various outcomes were targeted such as smoking, diet, nutrition, and alcohol. That was one of the outcomes for the assessment of health risk review, which was recommended by the Community Guide Task Force recently. When it is written up, it will be divided out by outcomes, but it is a part of the intervention of the assessment of health risks that the *Community Guide* views as interventions. Robin Soler, the *Community Guide* coordinating scientist for worksite health promotion, could give them further information.
- Dr. Boyle suggested mentioning the *Health Insurer's Purchasing Guide* by the National Business Group on Health, which specifically includes recommendations for insurers, about alcohol use screening and treatment. Brief interventions are recommended in that. So, Blue Cross/Blue Shield, or whatever companies provide benefits to employees of major corporations, has advocated for alcohol treatment, and brief interventions are incorporated into that.
- Dr. Floyd asked if there was any evaluation of the impact of that guide. Dr. Boyle responded that they could just acknowledge it.
- Dr. Warren found the French warning label, which Dr. Bertrand said raised another idea the group may want to recommend with respect to using the symbol of the red line through the pregnant woman, which is becoming a standard symbol for a lot of things women should not have. Although, others pointed out that there is some research indicating that people are not perceiving this as women should not drink alcohol. Instead they interpret it as a message pertaining to contraception.
- Dr. O'Connor said she worried about identifying special populations, given that the bias would depend upon who someone happened to be studying. She preferred to focus on any women of childbearing age from their first period on. Otherwise it could have some political implications. There are certainly high risk women who need this, but she did not think they should pinpoint certain populations.
- Dr. Brown thought it was fair to have a recommendation to work with the Native American population because of the rate at which the women are drinking and the rate at which children are being born with problems. There must be some resources directed at that. Dr. O'Connor still thought this was a generalization because in some tribes it is not a problem from what she understood.
- Dr. Floyd added that CDC prevalence studies showed that the highest prevalence was in AI/AN for the four states, and overall it was .4 per 100, and for Alaska it was 1.5 and that was driven by the native population, which was about 6 per 1000 versus White populations.
- While she did not want to argue the point, and she was not saying these women should not receive service, Dr. O'Connor maintained that it was another generalization and that this issue pertains to all women of childbearing age.
- Ms. Weber suggested that they couch it in terms of acknowledging cultural differences in terms of the acceptability of these types of interventions with certain populations of women.
- Dr. Berner commented that in the groups with whom he has worked, the intervention methods used were generally accepted by the native population. What was not accepted was that the treatment community was unwilling to accept pregnant patients, so they developed a different approach with

their own treatment facilities that were directed at pregnant patients. Hence, a lot this was moot, at least with them, because they developed their own programs, which were beginning to make a slow difference. They are quite acceptable to the population. He thought they were slowly becoming effective because they do address co-existing disorders, which are a huge factor in treatment efficacy. He did not think the incidence of those co-existing disorders had been looked at as carefully in other Native American populations as he had been able to do it. He thought a lot of treatment efficacy may, in fact, be related to how often those things are screened for and appropriately treated. This was why he thought it ought to be mentioned as an issue that needs further evaluation. Although he agreed that a blanket statement about Native Americans as a special group was probably not indicated. Perhaps they could state it as a special population identified as being at greater risk with a footnote that discusses the populations.

- With regard to gaps, Dr. DeJoseph reflected on earlier comments about substance abusing and alcohol dependent women. She pointed out that women have been treated in Alcoholics Anonymous (AA) successfully since 1935. This would include adolescents, co-morbid disorders, Native Americans—all special populations really. However, they have so little information about what happens there. What they do see there is the same diversity observed when trying to characterize and describe the behaviors of the affected children—that alcohol affects the whole range of women’s brains just as well. By targeting high risk, they would miss many women. She said she would be willing to look into the AA population, although she stressed how difficult it is to infiltrate. As they keep moving toward criminalizing women for using substances during pregnancy, if women are coming to the attention of the courts, they will be sentenced with AA the same way drivers are. In AA, women are treated with no training, no computer terminals, no special manuals, etc.
- Dr. Warren thought there was some research now on AA, although one problem is that because of the anonymous nature of AA, it has always been difficult to conduct research directly with the organization. AA does publish its own survey regularly. This is a very useful document, which is very honestly done. He said he had not thought specifically of looking at AA in that context. He emphasized that AA and other alcohol dependence treatment entities are geared more toward the individual who has been identified and recognizes themselves as having a significant problem with alcohol. One problem with the younger population, which is at the higher risk of pregnancy and unplanned pregnancy, is that many are drinking in a risky manner who are not likely to acknowledge that they have a problem with alcohol, and who may not have one except during the period of pregnancy because they are drinking at levels that are teratogenic, but would not otherwise meet the criteria for alcohol dependence. Project MATCH had a 12-step facilitation program, but it was not really AA. It basically encouraged and facilitated the participation of individuals within AA. He indicated that one NIAAA investigator who studies AA is Scott Petitjean. In PubMed, Dr. Warren found a number of publications on this topic within the last six months, for example “The Impact of Self-Help Group Attendance on Relapse Rates after Alcohol Detoxification in a Controlled Study of Alcoholics Anonymous.” So, there is research related to AA much more than in the past and this is just in the last few months.
- Dr. DeJoseph added that there is Women for Sobriety (WFS), which is a group focused on a special population, but she was thinking about it as community programs that engage in prevention because once someone is there, she is less likely to have subsequent exposed pregnancies. In the last 10 years, the trend in age is older. Women in their 20s or 30s are not in enough trouble yet to be in AA. There is something to be learned from that model as they consider resources and prevention.
- Dr. Ohlemiller added that one nice thing about the AA is that one of the differences, and a really good idea about why they need to sort out studies with pregnant women and those with non-pregnant women, is because in pregnant women they are clearly going for abstinence. In non-pregnant women

they are trying to go to harm reduction. Because it is an abstinence-based model, AA fits with what they need to do with pregnant women. She did think they needed to keep that dichotomy alive in their document—that there is a difference in harm reduction strategies and abstinence strategies. They need to be clear about that because the general community gets confused about it. They need to be clear that they are going for abstinence for 9 or 10 months.

- Ms. Weber commented that it was also important to think about what they wanted this product to look like and who they wanted it to target. The length would be important to consider based on whether they were targeting policy makers, clinicians, etc.
- Dr. Berner commented that one way to address that was that many of these much larger reports than theirs include a summary for policy makers where that is appropriate, like the IPCC's recent report. Then there are summaries for clinicians and for the public. They could certainly tailor a wide range of products, including at least one short version for policy makers if appropriate.
- Dr. Miller wondered about doing this in a peer reviewed journal, which is what the USPSTF does. That may be seen more widely and have a higher stature.
- Dr. Floyd reminded everyone that the first set of recommendations put out by the Task Force went into a *Morbidity and Mortality Weekly Report (MMWR)* and their guidelines have gone through there. They have remarkable coverage with publications in the *MMWR*.
- Dr. Bertrand noted that with the diagnostic guidelines, developing multiple documents had a real advantage. Everybody was able to say what they wanted to say. She stressed that this was their one chance to say what they had to say. Smaller documents like the *MMWR* are also valuable in that it does get it widely disseminated and boils it down to the important bullet points and people can put that in front of their legislators and others. They could still develop a peer reviewed document, like a letter to the editor or an article to the editor. The thing about the peer review is that the comments coming back must be incorporated, and they may or may not agree with the Task Force. Then there is less clarity about *who* made the recommendations.
- Some members wondered whether there was time to go through a peer reviewed process, particularly given that this committee may sunset. Dr. Floyd pointed out that if they completed it before the Task Force sunsets, even if it was not published until after it sunsets, they could still publish it under the name of the Task Force.
- Dr. O'Connor indicated that the paper ACER published on reducing the effects was in the format of a brief commentary, which was peer reviewed and published immediately. That was about 1,500 words.
- Dr. Boyle commented that the way to make this the most useful and to give it a life years beyond the Task Force, was similar to the *Guidelines for Diagnosis*. Perhaps they could use that to frame this as well. This could serve as a practical guide to what is known about preventing alcohol exposed pregnancies. It should include not just brief behavioral intervention strategies, but for women who are abusing alcohol or using alcohol at higher levels, there should be a component about treatment and referral—whatever it is they know and for which there is good scientific evidence. They could then develop a commentary from that to get it into the published literature, which would help highlight it. There is a lot of useful information, so they must give consideration to how to put it out in the most effective way with respect to what kinds of actions can be taken immediately relative to intervening with women, which would be very important.

- In terms of a stepped approach with regard to treatment, for example, Dr. Floyd said she had sensed for a while there is a move to get physicians to prescribe medications such as Naltrexone and Acamprosate. She wondered whether this should be done, and if they should encourage more research in this area for pre-pregnancy.
- Dr. Warren responded that pharmacotherapy is covered in the latest *Clinical Guide*. Clearly, NIAAA does support their use. The results of the combined study were that the Naltrexone was found within that study to be effective. It is still probably not the most effective drug that could ever be developed for the treatment of alcohol dependence, which is why NIAAA still has a major medical development program. However, for some individuals, for reasons related to pharmacogenomics or genetics, the drug Naltrexone is highly effective. It is still not highly effective with every individual. The latest combined study did not show that Acamprosate was any better. That is, Acamprosate did not come out as being effective in the study population. There have been many studies in Europe where it appears effective, so why it is effective in Europe and not in the U.S. is unclear. Maybe the population in the U.S. was more severely affected than the population in Europe, which is one of the hypotheses that has been put forth. In the context of individuals who are not pregnant and are not planning to become pregnant, the use of those drugs for the treatment of alcohol dependence is clearly something NIAAA supports. From a teratogenicity perspective, he would be concerned about recommending that in any sort of a pregnancy context unless they knew that those drugs were safe during pregnancy, which has not been established.
- Dr. Sokol commented that there is evidence on Naltrexone in pregnancy suggesting that it is probably safe, but this is a very small group of dependent women, while they have a much broader group in which they are interested. He did not believe there were data for Acamprosate at all in pregnancy. He did not think the Task Force could speak to that, although he did think they had evidence that there is an intervention that works. Following the NIH roadmap, they are dealing with a second kind of translational research, which is getting it out from research to application. It seemed to him that they should be deliberating how they could get brief interventions into practice. Acamprosate falls under Pregnancy Category C, which is defined officially as “Animal reproduction studies have shown adverse effects on the fetus. There are no adequate, well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.”
- Dr. Whitlock indicated that there may be a meta-analysis they could use. Bill Miller of the University of New Mexico has done a cumulative meta-analysis on alcohol treatment programs for years, which is known as Mesa Grande. That might be a readily synthesized source of information on treatment. She did not know whether it was focused on reproductive-aged women.
- Dr. Chang commented that Mesa Grande was not focused on reproductive aged women. She also noted that NIAAA issued an RFA AA00507 to address the effective ingredients of treatment. Basically, at the end of day, most treatment works more or less, but they still do not know why. For the Mesa Grande study, the best available evidence is for brief interventions. There is another great review by Ann Moyer that also supports brief interventions. Hence, she thought they were “beating a dead horse.” Brief interventions work and they should be happy about that. She thought what they were offering was a spectrum of approaches for a spectrum of problems. They have a menu and options, and there are lots of research questions that remain to be answered. For example, she would be very curious to know how all of the SAMHSA work fits in. She hoped there would be a floodgate of information opening on community interventions. So, they could not presume to answer all of the questions. However, they could say what is known at present to make recommendations based on that.

- Ms. Gass indicated that separate from what they have done at the FASD Center for Excellence, SAMSHA has a Women's Treatment Coalition (it may now be the Collaboration on Women's Treatment) in the Center for Substance Abuse Treatment (CSAT), which has also been studying these issues. She suggested checking with Sharon Amatetti at CSAT. They have also been looking at policy questions around how to keep women in treatment, etc. They are very aware of the FASD problem as well.
- Dr. O'Connor thought they should not separate women who are alcohol dependent or abusers from those who are moderate drinkers because brief intervention actually facilitates their entrance into treatment.
- Ms. Ohlemiller wondered whether there was something they should be including in terms of lessons learned from the regional training centers, given that much of what they have discussed pertains to getting training into the hands of healthcare providers and other persons, which was also supposed to be the focus of the CDC Regional Training Centers. She could visualize a paragraph that includes existing dissemination research to community models and the two mentioned: FASD Centers for Excellence and Regional Training Centers.
- Dr. Floyd thought that this was a good idea in terms of policy level strategies or provider education as interventions. While they did not have a lot of evidence yet on the impact of that on provider behavior, it is an important strategy within the mix of things that need to happen.
- Ms. Weber pointed out that there is a lot of information they need to gather in order to develop specific recommendations. In terms of process, they needed to think of a mechanism for getting those generated. The working group in place has about nine people, so she thought perhaps a group would be willing to engage in conference calls to help flesh out the recommendations based on the information that is gathered. If the existing working group was willing to move forward with that, she could facilitate the process. Others not on the group were certainly welcomed to join that group as well. If necessary, if they got as far along as the fleshed out document, they could convene a formal meeting of everyone.
- Dr. Floyd's greatest concern was that for any recommendation, they must have a very well documented review of the literature, and who they would turn to for assistance with that. While very difficult for Task Force members to take on substantial pieces, she thought perhaps some of them would be willing to do so and may have something already developed.
- Dr. Whitlock commented that what they need is the intervening evidence. They could go without it, but there is more evidence around the prenatal focus. It would be nice to have that incorporated. Nevertheless, the evidence on adult intervention is strong enough to stand on its own. The updated USPSTF guidelines will not be completed in time for this Task Force. She suggested that they get one person or one group to look across the one-on-one education that was identified for the *Community Guide* and *Clinical Guide*, so that they are not two separate bodies of literature looked at by two separate groups. There is some literature on implementation of these in clinical practices. It is not a huge literature, but it does focus on the science of translation and how to get these things brought into care. If they wanted to commission additional work, given that they had that as their very highest level evidence, that might be something to consider as another high yield strategy.
- With respect to the writing of the report, Dr. Chang noted that a number of them had written various pieces that could easily be modified or adapted pretty readily. For example, there is Dr. Sokol's article in *JAMA* and all of Dr. O'Connor's work. Dr. Chang has written a lot about screening and

intervention. Many people could contribute pieces that would be fairly substantial. Dr. Bertrand indicated that this is what they did with the guidelines and she served as the coordinating writer.

- At this point, the group decided that they had enough information outlined that they could move on.

FEDERAL UPDATES:

Interagency Coordinating Committee on Fetal Alcohol Syndrome (ICCFAS)

Kenneth R. Warren, PhD

Dr. Warren reminded members that the purpose of the Interagency Coordinating Committee on Fetal Alcohol Syndrome (ICCFAS) is to improve communication, cooperation, and collaboration among disciplines and federal agencies that address issues related to prenatal alcohol exposure. Themes around which the ICCFAS bases the foundation of its work include prevention of drinking during pregnancy; intervening with children and families affected by prenatal alcohol exposure, improving methods for diagnosis and case identification; increasing research on etiology and pathogenesis; and increasing information dissemination.

Reporting on the November 16, 2006 ICCFAS meeting, Dr. Warren indicated that one topic of discussion pertained to “Developing a Common Understanding of Evidence-Based Practice.” At times it seemed that the group did not have the same understanding about what criteria define “Evidence-Based Practice,” what “best practices” means, and what “promising practices” means. This meeting was for the group to establish a shared understanding of the general topic. At a second meeting, they plan to discuss FASD-related practices. They had several presentations followed by discussion among the ICCFAS members. Presentations were from: Dr. Collins-Sharp, the Director of the Evidence-based Practice Centers Program at the Agency for Healthcare and Research Quality; Ms. Janet Heekin, a Biomedical Librarian/Informationist at the NIH Library; and Dr. Anne Smith, an Education Research Analyst in the Office of Special Education Programs at the U.S. Department of Education. Other agenda items at the November 2006 meeting included: 1) agency updates on FASD-related activities; 2) discussion of ways to increase collaboration, cooperation, and communication; and 3) potential agenda items and formats for the May and July ICCFAS meetings.

Reporting on recent activities of ICCFAS member agencies who were not presenting in person at the FAS Task Force meeting, Dr. Warren first discussed the Department of Education, Office of Special Education & Rehabilitative Services activities. He indicated that the National Association of State Directors of Special Education (NASDSE) Project Forum issued a brief policy analysis in January 2007 “Fetal Alcohol Spectrum Disorder: Several State Initiatives” as part of its cooperative agreement with the U.S. Department of Education Office of Special Education Programs. The purpose of this document is to describe the characteristics of FASD, identify several federal level initiatives that emphasize education, and describe four state-level FASD initiatives (e.g., in Arkansas, Florida, Maryland, and North Dakota).

Dr. Warren indicated that Department of Justice, Office of Juvenile Justice & Delinquency Prevention (OJJDP) has little funding specifically designated for FASD research, but hopefully in FY2007, several FASD-related proposals will be received in response to general solicitations. OJJDP was disappointed that more FASD-related applications were not received in spring 2006. He reminded them that the spring 2006 solicitations for Field-Initiated Research and Evaluation projects resulted in 145 proposals, only one of which was FASD-related. He requested that FAS Task Force members think about future possibilities and tell their colleagues to expect additional solicitations in spring 2007, although he cautioned that the lead time may not be long. He noted that interested parties could contact Karen Stern, OJJDP’s representative to the ICCFAS, for more information. Her contact information can be found in the ICCFAS section of the NIAAA website.

Regarding the Indian Health Service, Dr. Warren reported that a working group was formed in 2004 between Canadian and U.S. health groups that consists of 9 Canadian members and 12 U.S. members. The purposes, goals, and objectives of the collaboration are to facilitate understanding, networking, and cooperation among First Nations and American Indians, and Inuit and Alaska Natives in order to build capacity for prevention and early intervention and to transfer knowledge about promising practices.

In collaboration with NIAAA, NIH's National Institute of Child Health and Human Development (NICHD) is funding four cooperative agreements to create the Prenatal Alcohol in SIDS and Stillbirth (PASS) Network. Phase II of the PASS project is a longitudinal cohort study of 12,000 pregnant American Indian and South African women and their infants to determine the role of prenatal alcohol exposure and other variables in the incidence of FASD, SIDS, and stillbirth. Researchers plan to obtain markers (e.g., physiological measurements, genetics information, biochemical studies of placenta) during infancy for babies at risk for FASD. Enrollment begins in spring 2007.

Regarding HRSA's Maternal and Child Health Bureau (MCHB), Dr. Warren reported that in FY2006, NoFAS worked with five HRSA-sponsored Community Health Centers (CHC) through a grant from the HRSA, Bureau of Primary Care. This project will continue in FY2007 with funding from the HRSA Maternal and Child Health Bureau. Ira Chasnoff is the principal investigator (PI) who will work with NoFAS at the five CHC sites served last year. In addition, three HealthyStart sites were added to the project this year. Those MCH sites provide prenatal, perinatal, and postnatal care. The population served at those sites includes children up to age two and often their older siblings.

Dr. Warren indicated that the mission of the Agency for Healthcare Research and Quality (AHRQ) is to improve the quality, safety, efficiency, and effectiveness of healthcare for all Americans. AHRQ achieves that mission by supporting a broad program of health services research and by working with partners to promote improvements in clinical and health systems practices that benefit patients. Although AHRQ does not have a specific FASD-related research program, relevant FASD-related research grant applications could be funded under this special emphasis notice. In November 2006, AHRQ announced that its highest priority for FY2007 unsolicited applications would be on research on systems and organizational interventions for improving healthcare quality for low-income people served in under-resourced settings and communities.

With regard to upcoming ICCFAS meetings, Dr. Warren reported that on May 9, 2007, a closed meeting of the ICCFAS subcommittees (Juvenile Justice Working Group; Education Working Group; and Women, Drinking, and Pregnancy Working Group) will be convened. The May 10 meeting will be an open meeting at NIAAA, which will include discussions on a common understanding of evidence-based practice; best practices, promising practices, and other such topics relevant to FASD-related issues. The agenda will also include reports from the ICCFAS members and the Working Groups.

The plan is that each of the ICCFAS Working Groups will have the lead on a special focus meeting within the next five-year period. The education focus meeting in July 2007 is the first such meeting. On July 12-13, 2007, there will be an FASD-related education meeting at NIAAA, sponsored by the ICCFAS Education Working Group, the ICCFAS members, and the NIH on FASD-related education issues: specifically learning and behavior. Topics to be discussed include: model systems, promising practices, and recent advances in relevant research. The format for the meeting will be workshop style (e.g., briefing book with recent review articles for presenters and discussants, short presentations, and discussion of topics). A proceedings will be published. The dates selected fall near the RSA and FASD Study Group meeting dates in July 2007 in Chicago. The 2007 Office of Special Education Programs Project Directors' Meeting will also be convened in Washington, D.C. on July 16-19, 2007.

In conclusion, Dr. Warren shared the link to member organizations' contact information and website:

<http://www.niaaa.nih.gov/AboutNIAAA/Interagency/>

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

Kenneth R. Warren, PhD

Dr. Warren reported on two major NIAAA FASD-related activities, which included the issuance of an RFA for the competitive renewal of cooperative agreement applications under the Collaborative Initiative on FASD (CIFASD), as well as a review of the NIAAA-FASD Extramural Research Portfolio and Program Directions by the Extramural Advisory Board (EAB) of NIAAA.

He reminded everyone that CIFASD is a Network of 12 research projects plus core support facilities addressing a number of important clinical questions that can only be approached through a collaborative international effort. The projects focus on the: identification/recognition (diagnosis) of FAS and FASD; refinement of the technologies for case recognition, including advances in 3-D imaging technologies to identify individuals with FAS; elucidation of the neurobehavioral phenotype of FAS and determination of its applicability to ARND (FASD); exploration of the role of nutritional factors as protective agents in FAS and FASD; initiating of controlled studies of cognitive interventions targeted to learning and executive function deficits in FAS/FASD; and development of target pharmacologic agents that may be applicable to the prevention of FASD injury, or the amelioration of that injury. CIFASD is international in scope, involving six countries on three continents.

Dr. Warren shared data from an FAS Cognitive Intervention (Adnams et al). This was presented at the RSA meeting in June 2006. This cognitive intervention was undertaken by 9 and 10 year old students in the population that CIFASD has been working with in the Western Cape of South Africa in a farming community. This was a test of three different interventions with children who have FASD as well as control groups, so there was a non-FASD control group and an FAS control group who did not receive the interventions. The three interventions included: 1) cognitive control therapy, a type of meta-cognition therapy; 2) language and literacy training; and 3) a parenting intervention, which has been shown at least in the U.S. to be effective in ADHD. This particular intervention was not effective at all, with respect to improvement over baseline. The non-FASD children improved over a six-month period. Even the FAS children who were not treated improved somewhat, but there was significant improvement in cognitive control and language and literacy training. This is only the halfway point in basically what is a one-year intervention. Dr. Warren said he wanted to share this information because he was excited by these findings. To him it said something about the abilities of children who have FAS or FASD to be able to respond to these types of therapies. He expressed his hope that Colleen Adnams, whose data these are, would be able to present to the FAS Task Force at their next meeting.

Turning his attention to the application of 3-D technology for facial recognition of FAS, Dr. Warren pointed out that his illustration involved only angles of the face, not the measurement. One of the advantages they have in the CIFASD study is that they have the ability to control for ethnic variability. They have Finnish Caucasians, who are the most homogeneous population; Cape Town Mixed Ancestry; North American Caucasians; and African Americans. Comparing FAS to non-FAS within these populations, there are differences, which vary depending upon the ethnic background. Dr. Warren thought obtaining baseline data of this nature would be important for aiding in the recognition of cases in the future.

Dr. Warren then pointed out that each research area supported by NIAAA is at some point reviewed by the EAB, which is a Working Group under NIAAA's Advisory Council. Expertise on the Board is quite broad, spanning many disciplines from within and outside the alcohol research area. Reports of the Board are sent to the full Council. The portfolio area most recently reviewed by the EAB was FASD research activities. It was noted that FASD has been a significant component of NIAAA's research mission for over 30 years. In FY 2006, 94 research project grants were funded for over \$25 million, in addition to

career, fellowships, training grants and components within centers. Given the large and long-term investment in alcohol and pregnancy research, it was timely to examine whether the NIAAA research portfolio is adequately addressing issues critical to the recognition and diagnosis of FAS and FASD, and laying the foundation to prevent or ameliorate deficits, particularly neurodevelopmental deficits.

It was agreed from the outset that the FAS research area was too broad to fully cover in a single meeting. Although considered to be important, certain areas were not included in the EAB discussion, including: public policy, clinical and behavioral interventions to prevent or reduce alcohol use by pregnant women; and health services research related to access and finances of FASD prevention and clinical care. Nonetheless, research focused on the prevention of drinking during pregnancy is a major aspect of NIAAA's FASD research portfolio (23% of FASD portfolio in FY2006). The EAB meeting focused on research opportunities to lay a foundation for the development of: 1) interventions to prevent or ameliorate prenatal alcohol elicited injury to the embryo and fetus; and 2) interventions, both pharmacological and behavioral, to address CNS deficits derived from prenatal alcohol exposure in the affected child. So, they are concerned about the embryo, the fetus, and the affected child.

It is recognized that knowledge guided development of preventive and ameliorative interventions requires an understanding of the mechanisms by which alcohol elicits injuries to the embryo and fetus, leading to the various attributes of FASD. This is particularly important given the diverse sites and stages where alcohol appears to induce injury, for example in alterations in the expression patterns and timing of key developmental genes; trophic factors (ADNF, ADNP, Insulin, etc.); apoptotic control mechanisms; levels of oxidative stress, and epigenetic regulation. There may be impairments in energy metabolism, mitochondrial structure, and function; neuronal and glial cell development and migration; cell adhesion and communication among others. Given the many adverse effects caused by prenatal alcohol exposure, it is clear that either or both of two events are occurring: 1) alcohol causes many different effects, each of which is dependent upon the quantity and timing of gestational exposure; and 2) initial alcohol perturbation brings about additional adverse developmental events. If so, interventions to prevent or ameliorate injury as early as possible (upstream) offer the clearest potential for benefit.

A very provocative question that was raised is: How much do we need to know about the etiology of FASD in order to meet the challenge of treating affected individuals? It is also of note that interventions can only be implemented if the affected fetus or child is recognized. Therefore, the description and diagnosis of FAS and FASD were included as key discussion areas. Among the issues discussed was the identification of children with FAS, for which there are some significant problems. Early case recognition of FAS neonates and infants is difficult, primarily owing to difficulty in discerning facial features and neurobehavioral deficits at this age. Also, an issue is the difficulty in case recognition among older age children, particularly for non-specialists, owing to such factors as the subtle nature of facial dysmorphology, ethnic variability in facial features, and differential diagnosis from other neurodevelopment disorders.

A number of approaches have been proposed, some of which are under testing, to aid in the identification of FAS cases, including: prenatal ultrasound (for facial or structural brain features); testing of biomarkers for prenatal alcohol exposure (e.g., detections of non-oxidative metabolites of alcohol—FAEE, ethyl glucuronide, phosphatidyl ethanol, etc.); a search for metabolomic or proteomic biomarkers of prenatal alcohol injury; computer-assisted 3-D facial analysis; CNS structural imaging (MRI, etc.); neonatal transfontanelle ultrasound for brain imaging; and establishing a “neurobehavioral phenotype” to aid in FAS case recognition (a major goal of the CIFASD). The problems associated with the identification of infants and children with ARND are even greater than for FAS, given the absence of the characteristic facial features and/or growth impairments. Other difficulties in case recognition include a wide range of phenotypic expression derived from differences in quantity, frequency, and timing (QFT) of the alcohol exposure, as well as differential diagnosis of ARND from other neurodevelopmental disorders, (e.g.,

ADHD, William's syndrome, etc.). Some efforts proposed or underway to address ARND case recognition, many of which are similar to those for FAS, include: development of biomarkers of prenatal alcohol injury and exposure (as with FAS); characterization of the neurodevelopmental profile of FAS which will also aid in the identification of ARND; non-invasive imaging (MRI, etc.), given that the characteristic FAS brain structural deficits are often present even in absence of growth impairment or facial features; and computer-assisted 3-D facial analysis, which may be able to identify a facial feature signature even when the human eye cannot.

Dr. Warren concluded with key questions posed to the EAB regarding description and diagnosis, CNS/neurodevelopment phenotype of ARND, whether etiology matters, and pharmacological interventions including the following:

Description and Diagnosis

- Do we sufficiently understand the expression of FAS and FASD and have adequate criteria for their diagnosis?
- Can new imaging approaches (brain and facial features) assist in diagnosis by the dysmorphologist and non-specialist?
- What is the utility of prenatal ultrasound, trans-fontanelle ultrasound, non-invasive imaging technologies?
- Is there a future for biomarker development for FAS and ARND?

CNS / Neurodevelopment Phenotype of ARND

- Is there, indeed, a neurodevelopmental signature of FAS applicable to ARND?
- If so, is the neurodevelopment phenotype either unique or specific to prenatal alcohol exposure?
- Are the deficits within FASD (e.g., arithmetic skills, language abilities, executive function, geo-spatial ability, social skills, etc.) phenotypically distinct from deficits in the same attributes in other disorders?
- What do we know about plasticity for FAS and FASD neurodevelopmental deficits? To what extent can they respond to ameliorative interventions, and at what time points in life?

Does Etiology Matter?

- Is the underlying structural/functional nature of the neurobehavioral deficits in FAS/FASD sufficiently similar to other neurobehavioral disorders to allow the application of interventions for those disorders with FAS/FASD?
- Or, is the underlying structural and functional substrate sufficiently distinct to require distinct intervention approaches?

Pharmacological Interventions

- What is the potential for pharmacologic interventions to either prevent or ameliorate prenatal injury? They noted that the literature reports on over 50 drugs that have been used with FASD children, most of which are directed at attention deficits (stimulants) and antidepressants. Some case reports suggest that stimulants are effective in 50% of FAS/D clients, which is about the same as effectiveness for drugs used in ADHD. This leads to many questions including whether appropriate differential diagnosis has been done with respect to FASD as well as those with ADHD.

SAMHSA FASD Center of Excellence

Callie B. Gass, Project Director, FASD Center for Excellence

Ms. Gass reminded everyone that Northrup Grumann was approaching the end of their contract with SAMHSA, so they have many activities currently wrapping up. The current contract for the FASD Center for Excellence ends on May 30, 2007. That means that all 33 subcontractors end on April 30, 2007 because they have to end 30 days before the FASD Center for Excellence so they can close the

contracts out. Currently, there is not a solicitation out for the follow-up work; however, it was her understanding that funding has been approved in the SAMHSA budget that will allow for a solicitation. There will likely be a time lag before the re-competition because time has simply run out to do an open solicitation, evaluate a series of proposals, and make a contract award. Although it is not clear yet what the scope of work will look like for a new center, it will have to be scaled down because the funding is not what it was at the height of the center. This will have to go through a proper procurement process.

She reminded everyone that at the start of the FASD Center for Excellence, they were charged with identifying all of the effective and promising practices, of which there were zero. In the last year, they began looking again. Given that they are a SAMHSA organization, they use slightly different criteria from the work CDC is doing. They are using the criteria of the “National Registry of Evidence-based Programs and Practices (NREPP),” which is how SAMHSA classifies its substance abuse and mental health interventions. Therefore, their criteria are similar to but not exactly the same as the CDC criteria.

Mandate 1 in Section 591D of the 2000 Children’s Health Act required the study of innovative clinical interventions and service delivery improvement strategies for individuals with FASD and their families. The “FASD Promising Practices Study” addresses that mandate by identifying and assessing promising practices in FASD prevention and treatment. For this study, online and literature searches were conducted, input was sought from FASD experts, a database of interventions was created, and practices were identified that addressed NREPP criteria. Originally, the study identified 257 interventions and practices, 40 of which were selected for review against the criteria for inclusion in NREPP. Of the 40 interventions and practices, eight were deemed eligible for an NREPP rating. Most would fit into the category of brief interventions. The Center’s researchers were able to review outcome information from eight programs in which, when compared to control groups, those who received the interventions saw greater reductions in drinking rates, had higher quit rates during pregnancy, saw larger reductions in AEP risks, and had better birth outcomes. A report detailing these findings and identifying the “effective” practices will be released in 2007.

Their job as the FASD Center for Excellence was primarily to test whether the science can be implemented in real, existing agencies. By SAMHSA decree, they were not doing primary prevention. It was all targeted toward women who had come to the system’s attention in some way as high risk. They have 33 subcontractors, 16 of which addressed prevention through interventions with women at high risk for an alcohol-exposed pregnancy, 14 addressed treatment for individuals with FASD; and 2 tried to address both the women and their children. Most of them conducted only the prevention of an alcohol-exposed pregnancy piece. One problem with that was that there simply was not enough funding for most of them to do both. They found that the projects that were more focused had the best results, while those that tried to conduct a more global program did not have the best results.

The FASD Center for Excellence trained these groups to deliver integrated evidence-based practices into service delivery organizations. For these, they do have process results, but not outcome data. Alcohol treatment programs could add contraception. Five alcohol treatment programs added a contraception intervention, which they had not previously addressed. Most subcontractors that addressed prevention with intervention of women at high risk for an alcohol-exposed pregnancy adapted the Project CHOICES intervention. All of the programs that used the CHOICES model are beginning to show good data. Three used Planned Parenthood onsite or referrals as part of intervention. Four of the five report that the intervention is integrated and will be sustained, and one is searching for funding. They were only allowed to use programs that had peer reviewed evidence at that time, which did not give their sites many choices. Another problem is that these programs were supposed to go five years, but they were shortened to three years. Programs were able to incorporate elements of Project CHOICES that were missing previously, which was important to them. Basically, they were able to show that with limited funding, some training, and a lot of technical assistance, they were able to integrate these programs.

This work also shows that dependency courts can identify infants and children with prenatal alcohol exposure. One dependency court screened 323 youth, of which 134 screened positive due primarily to prenatal alcohol or drug exposure (often a cause for removal of the child from the parent). Most were too young to diagnose with an FASD, but they are monitored every six months for developmental milestones. Nine completed diagnostic evaluation, and three were diagnosed with an FASD. The dependency court will continue the program.

Also, juvenile courts can identify youth with FASDs. One court screened 606 youth referred for a mental health assessment and on probation, of which 112 screened positive primarily based on confirmed prenatal alcohol exposure. Eighty percent (48) of those completing diagnostic evaluations received an FASD diagnosis. About half have completed the FASD diagnostic evaluation. The diagnostic evaluation reports are key to tailoring interventions and accommodations. Schools are a key source of services and accommodations. The juvenile court will continue the program as well. Of the various groups, the juvenile courts have had the most significant results. The FASD Center for Excellence is working on a paper pertaining to this.

A positive aspect of the court efforts is that Minnesota and several others have been able to integrate this program. Given the restrictions they cited, they are using their own types of screening that they developed with the Expert Panel. This works in the court system, and they have at least two programs that will continue after the FASD Center for Excellence ends. Minneapolis Juvenile Court System has already finished their integration into the ongoing service provision and they have de-obligated all of their subcontract funding and turned it back to the FASD Center for Excellence, with the exception of their evaluation dollars because they are currently up and running as part of the court system for the screening component. The greatest barrier there is diagnostic capacity. They can screen and refer, but they cannot get the children diagnosed. Hence, a number of recommendations will be forthcoming from the FASD Center for Excellence pertaining to the lack of diagnostic capacity and the problem they have in implementing these programs due to the lack of consensus regarding what the other alcohol-related disorders are and because of the extremely limited capacity in the rest of the state. Virtually all of the children they screened really do need intervention, so while they cannot make a clear diagnosis, they were certain that all of the children truly needed intervention. Therefore, it is not a lost cause.

The FASD Center for Excellence reviewed FASD diagnostic evaluation reports from nine diagnostic centers and identified the needs of those using the reports. The diagnostic centers used either the 4-digit code or the IOM criteria. It would be ideal if they could have one system. Minnesota used a hybrid of these, which included CDC FAS criteria, the 4-digit code, and some diagnostic categories proposed by IOM. A key need in the field is diagnostic capacity. Diagnostic evaluations came from multidisciplinary diagnostic centers and those evaluation reports were key for interventions and accommodations. It is important that the diagnoses came from the centers as opposed to physicians. Many question the utility of a diagnosis. The diagnosis is only useful because of the assessments made, not because of the FASD label applied, although the label is important for prevention and policy. The FASD label without the diagnostic evaluation report is not really useful. Given the wide variation among the FASD population, intervention for “FASD” is not available because of this variability.

Nearing completion are the curricula and distance learning courses. All are in the final stages of development. They plan to deliver them to SAMHSA in the next several weeks. Regarding the Curriculum for Addiction Professionals (CAP 2), Ms. Gass reported that a significant majority (80% on both days) rated the overall quality of the course content as “excellent.” The pretest and posttest scores tell them that the pilot training resulted in quantifiable gains in knowledge. The average pretest score was 69.5% and the average posttest score was 94%, an average increase of 24% points. New York State rolled out a modified “Tools” for use in training juvenile justice professionals. CAP 2 trainees successfully pilot tested CAP 1, rating the course as excellent (72%) or good (28%).

- How will we expand the current and successful FASD integration efforts?
- How will we move toward use of a standard diagnostic scheme?
- How will we continue to reach and educate policymakers?
- How will we provide oversight of science to service and service to science and continue to build bridges between the two?

Ms. Gass concluded that there may be a gap in funding between contracts. It is typically SAMHSA's policy to keep a website static until a new contract is awarded. The FASD Center for Excellence will have a number of final reports coming out in the next two months, and will have one final steering committee meeting.

Public Comment/Adjourn

In view of the time, it was agreed that the CDC update would be moved to the second day of the meeting. With no public comments offered or further business raised, the meeting was officially adjourned.

Thursday, March 1, 2007

Call to Order

Dr. Jean A. Wright, NTFAS Chair, called the second day of the meeting to order. She indicated that the group would first hear the preliminary report from the Post-Exposure Working Group, followed by the liaison updates, and then the CDC federal update, which was moved from the previous day.

Report from the Post-Exposure Working Group

Brief Research & Policy Report: FASD—An Ongoing and Significant Public Health Concern

Heather Carmichael Olson, PhD

Dr. Olson stressed that this report represented an extremely rough draft only, for which further input from the full body was invited. She began with an anecdote to illustrate why the Post-Exposure Group had made an attempt to put forth what she thought would focus their discussion and potentially create a product. In the process of developing this draft outline, she was searching the Internet. She decided to review what is known as an extremely good website launched to guide people's thinking and advocacy on education issues. It is a beautiful government-funded website, designed to help advocacy groups and parents obtain information about various disabilities so that they can advocate with schools and obtain services for their children. While she found all sorts of extremely low prevalence disabilities, her search of the site resulted in absolutely nothing at all about FASD, despite its prevalence and despite the fact that its prevalence is much higher than many of the disabilities that were presented on this site so beautifully and in such a focused manner.

Therefore, she wrote to the sponsor of the site stating that she was a researcher and clinician, and that she advises families daily about how to obtain the services in the educational system for their children. She reminded the members that searching this site was part of the work to follow up on her efforts with the Task Force to impact the process of DSM-V and the letter to the Department of Education pertaining to the Individuals with Disabilities Education Act (IDEA), reviewing some of the testimony for the reauthorization of the IDEA. She received a rapid reply from the web site sponsor basically stating that because FASD is not named in IDEA, and that this website is designed to serve people who are using IDEA, they would not include FASD as a search term into their database. They are caught in an incredible cycle of an under-recognized disability that is not categorically labeled, so that she cannot direct families to this particular website because they will not find their disability named there. Because it does not have a name, it does not have funding, and because it does not have funding, it does not have a name.

Given that, Dr. Olson was even more compelled to work on this product because she hopes that the voice of this Task Force, even if it sunsets, can have some impact in terms of later advocacy. Families raising

children with FASDs should not find themselves without information about how to obtain the services that their children need. In truth, that is the momentum behind attempting to develop a product using the combined expertise, willpower, and status that the members of this Task Force have in their respective organizations and to attempt to come to terms with the messages they might want to put forth. Sharing this message may someday get FASD on the website so that people can find it and advocate for services for these children. Dr. Olson stressed that while there was a personal commitment driving her desire to complete this product, it did not mean that the group as a whole has to decide to move forward on this product. She expressed her hope that by the end of the day, they could make a decision based on the potential outline and additional member input.

What the Post-Exposure Working Group moved to do was create a product that can educate and provide guidance for various partners. The proposed title of this potential product is “Fetal Alcohol Spectrum Disorders: An Ongoing and Significant Public Health Concern.” The proposed purpose of the product, based on the intent of the motion, was to address the following:

- Make considered research and policy recommendations focused primarily on diagnosis and intervention
- Provide technical assistance for education and advocacy efforts for appropriate organizations
- Keep attention on identification, diagnosis, and intervention
- Point out accomplishments of focused leadership and interagency coordination, and the momentum this has generated
- Highlight that an evidence base is beginning to grow
- Coordinate efforts with an upcoming leadership institute (sponsored by Marcus Institute in October 2007) on FASDs, which is designed to accomplish some of these purposes to think about how the field of diagnosis and intervention may move forward. Thus, they wanted to dovetail or coordinate the efforts of the Task Force with that leadership, perhaps by generating a product which could then be presented to the folks attending that leadership institute and then be disseminated further from there.

The bottom line message is “don’t stop now.” The hope was that this product, at its heart, would accomplish this. If they planned to move forward, they would need a timeframe and process for the Post-Exposure Working Group activities and Task Force approval. The motion was made in September 2006 to move forward with a product intended to advise continued momentum on diagnostic and intervention research, which should be produced before the sunset of the Task Force. To that end, the Working Group engaged in several conference calls following the September 2006 meeting, receiving input as appropriate from CDC about the best ways to accomplish the motion’s intent. There are certain things they can and cannot do, and also there are better ways to influence the process and less skillful ways. The product as it exists now is not yet honed to be nimble enough, short enough, and clear enough to accomplish those purposes. The idea that came from the conference calls and input from CDC was that a brief research and policy report seemed most appropriate, not necessarily a white paper, given that there is not funding to develop a major intervention research review, and not something redundant with efforts already underway elsewhere. A draft of the report was produced and then critiqued by the Post-Exposure Working Group, with the second draft being presented to the full Task Force during the first day of this Task Force meeting to consider the viability of the report and the dissemination process. If they decided to proceed with this product, the suggested timeline would be as follows:

Timeframe and Process:

- *March 2007:* Receive input from the full Task Force by email, calls, and drafts at meeting
- *June 2007:* Circulate new draft for final critique to full Task Force via email
- *July 2007:* Conference call for approval of draft
- *During July/August 2007:* Submission to CDC and Secretary of Health & Human Services

- *At September 2007 meeting:* Disseminate final report to the Task Force
- *October 2007:* Ongoing dissemination, which might begin at the leadership institute being sponsored by the Marcus Institute, Emory

Proposed Sections of the Report:

Scope of the problem

- What are FASDs?
- How common is the problem of FASDs?
- What are the costs and can FASDs be treated?
- Prevention is one approach to the public health problem of FASDs
- Accurate detection & diagnosis of FASDs, intervention for affected individuals & systems change are essential (consideration must be given to how to make it shorter):

Reasons for action now

- Why act now?
- Federal interagency cooperation through the National FAS Task Force
 - Need to emphasize gaps that exist at this time

A recommended research and policy response

Questions from the Group:

A question was raised by Dr. Sokol raised previously regarded whether they should make the research recommendations, or if they should keep this to the policy recommendations. In fact, the research recommendations are for research that is underway at this point. Perhaps they could simply recognize that the research is underway and then they could move into policy recommendations. She requested that the Task Force give consideration to what additional evidence should be presented in the report, to whom it should be disseminated and how, and whether any additional recommendations should be included or omitted. For instance, there is no recommendation, at least in the research section, about health services research. If they planned to proceed, they would need to receive all comments now and during the coming months. Dr. Olsen proceeded to review the proposed recommendations:

Research Recommendations:

- Clarify diagnostic criteria for the full spectrum of deficits resulting from prenatal alcohol exposure, to make possible accurate diagnosis and subtype identification
- Identify effective methods for the very earliest forms of intervention
- Continue basic research to better understand how alcohol damage occurs and what can be done to prevent or reduce damage
- Identify and systematically evaluate a continuum of promising and/or effective family support and individually-focused health, social, and educational interventions for FASDs
- Systematically disseminate and translate research findings into practice to rapidly make information accessible to the public

Policy Recommendations:

- Continue and enhance strong, collaborative, interagency leadership at the federal and state levels to inform legislators, policymakers and the public (*add generic national group of individuals here—unique interdisciplinary group of individual that can deliberate and recommend?*)
- Establish case definition for the full spectrum of deficits related to prenatal alcohol exposure
- Establish ongoing surveillance systems to identify individuals with FASDs, including use of accessible specialty diagnostic clinics and screening systems
- Establish adequate access to diagnostic & referral systems for individuals with FASDs across the lifespan

- Modify categorical classification systems to recognize and provide appropriate services for those with FASDs, specifically: *IDEA 2004; part H/CAPTA; DSM-V & ICD-10; Medicaid and insurance coding; Other? Developmental disabilities—functional definition—use federal definition*
- Expand the current interagency coordinating efforts to develop a continuum of care for individuals with FASDs and their caregivers
- Recommend professional education on FASDs in multiple service systems, & inclusion of questions on FASDs in licensing certification & board examinations

General Input on the Recommendations and Report (*these bulleted items are further described in the Discussion section that follows*)

- Perhaps call this document a “Call to Action”
- Shorten research section (use references)
- Stress unique aspects of the condition that warrant specific action/intervention
- “Own condition”
- Research to date that addresses these unique aspects, 19,000 papers; include animal intervention studies
- Possible Audiences:
 - FAS Task Force liaisons
 - Policy makers
 - Department of Education; local education agencies
 - Mental health
 - State governments (FASD state coordinators)
 - Evidence supports that interventions work; information from town hall meetings indicates that we should act; literature reviews (McGee & Riley), background papers from Ken Warren
 - University Centers for Excellence in Developmental Disabilities Education, Research, and Service (UCEDD), Leadership Education in Neurodevelopmental and Related Disabilities (LEND)
 - Juvenile justice systems
 - ICCFAS/member agencies
 - Bureau of Indian Affairs
- Drop research recommendations; perhaps review existing recommendations (NIAAA/CDC); retain in terms of broad descriptions; endorse NIAAA/CDC; concise, but not main focus. Why should we support this? Still a need for focused intervention research; arenas that have not been systematically designed/supported; few good studies
- Promising results/momentum; what could we be doing better? Diagnostic guidelines being used? Improve diagnostic capacity?
- All systems need to view the family as the point of support needs, and not just the individual child.
- Support families to advocate and access information
- Help families learn how to enhance their child’s development and advocate at schools, etc\
- Essentially the report would define the edge of what has been done, lay out some of the challenges, pass on the torch, and charge the next group to carry on these purposes and actions

Appendices:

- Strategic Plan from NIAAA
- Accomplishments of the Task Force
- CDC strategic plan
- FASD Center for Excellence website

Discussion:

- Dr. Davis suggested a slightly different title. Instead of calling it a “Brief Research and Policy Report” name it a “Call to Action” because this has a lot more vibrancy and will allow them to state their recommendation in ways that are action oriented.
- Dr. Floyd suggested that rather than going through all peer reviewed research, they could just reference it to make the product shorter, to show that it is possible to develop interventions that address the unique aspects of FASD. It seemed they would also want to make a case that this condition has unique aspects such that it warrants consideration as an individual condition. Then they should describe FASD.
- Dr. O’Connor pointed out that there are animal intervention studies that work, so they should include research to support this also.
- Dr. Davis suggested that another audience to include would be the Consortium for Citizens for Disabilities.
- Dr. Warren thought policy makers should be the main audience. It was not research recommendations to the research community because the research is underway and they are far ahead in terms of thinking of the issues. It really is about conveying a message that there are many individuals who are affected, and that the limitation currently is that many of these individuals are being missed. There are also autism spectrum disorders that are being missed. Still, they should address the problem for the individuals who they can identify. There is a lot of evidence that what has been tried works. In summary, expert opinion and what evidence there is supports that interventions can work, and that the needs defined by the Town Hall meetings, etc. require that they act. He also agreed that the animal literature is good and has been well-reviewed in the last couple of years. He agreed to send Dr. Olson the information he has collected from McGee and Riley.
- Dr. DeJoseph recommended continued partnership with education.
- Dr. Miller suggested clarification about what constituted “policy makers.” The term alone seemed too broad to be helpful in the document.
- Dr. Olson responded that the FASD state coordinators may be eliminated after the FASD Center for Excellence departs and there is no central organization. That was one place she envisions disseminating this product so that they would talk to their states about the importance of having centralized attention to FASD. That represented one set of policy makers to her. Others would include those making policies related to education, billing codes for mental health services, and mental health categorizations.
- Dr. Wright suggested making a statement that every time somebody writes “FAS” they should consider whether “FASD” applied, which would then put the burden of proof about why it did not apply upon anyone making a decision about this. Dr. Olson suggested that this point could be made in the “Call to Action” to reflect that this is a disability that approaches or exceeds the problems of autism spectrum disorders and to not serve it requires explanation.
- Dr. Morris stressed that this really needed to get to state level for implantation. She thought it was very important to add the part about intervention so there is less hopelessness, especially among educators.

- Dr. O'Connor suggested including any other organizations that deal with developmental disabilities, such as the University Centers of Excellence in Developmental Disabilities (UCEDD) and Leadership Excellence in Neurodevelopmental and Related Disabilities (LEND) programs.
- Dr. Floyd commented that the Office of Juvenile Justice has a presence at the state level and often deals with individuals who are affected. If intervention began early, perhaps these individuals would not appear in the system, so the Office of Juvenile Justice may be another audience.
- Dr. Olson noted that ICCFAS has all of the representatives of all of these systems, so she wondered if this was something that would be useful to them for their systems or whether they already have what they need.
- Dr. Warren responded that he thought it would be useful to have the ICCFAS as an audience. The advantage is that each of the individual agencies have their own networks, which gives ICCFAS the opportunity to disseminate even further through these many organizations. For example, the Department of Juvenile Justice clearly has a network in all states around the country. Other members include the Department of Education and the Office of Special Education, HRSA, Indian Health Service, etc. Every service related organization that would be important is connected in some manner with the ICCFAS.
- With respect to Native American populations, Dr. Brenneman suggested that the Bureau of Indian Affairs would be an important audience. Justice and education programs are managed by this office as well.
- Dr. Olson requested further discussion about dropping all of the research recommendations.
- Dr. Davis thought the policy recommendations were the most important recommendations.
- Dr. Warren said they could basically review the research agenda because it is ongoing. It is well-described by CDC and NIAAA. The strategic plan for NIAAA is mentioned in the outline, which has an entire chapter devoted to the FASD issue. These are easily citable and can be updated with a short paragraph describing the types of research in progress. SAMHSA does not have a research agenda, although they are valuable because they can work with NIAAA and CDC. When that happens, NIAAA and CDC have an ability to take advantage of the populations that they have in research, but SAMHSA has not been able to conduct research directly for at least the last four to five years.
- Dr. Myra Tucker from the Division of Reproductive Health encouraged the Task Force to retain the research information because big picture policy makers often determine and influence research. This is a loop to keep that information going back to those decision makers. Retain this in terms of describing in broad strokes what it is and then refer people to the places where the systematic plans are outlined because that informs policy. Others suggested that perhaps they could endorse these plans.
- Dr. Sokol said he was not against including the research in the product; however, he was against having recommendations to investigators about what to do because there is already a great deal of investigator-initiated research in progress. Where this could help is to encourage support, funding support in particular, for important research.
- Dr. Barry thought that could be done in a concise manner so that it would not appear to be the main focus of the report. Given the groups they had discussed as being their audience, most of them want to have something to give to their other constituents. Therefore, it must be short, to the point, and

include recommendations that will fit (in a broad sense) policy for what their organizations are working with.

- Dr. Brown commented that in education, they do need research and early intervention recommendations. It does not have the same level of sophistication as other research.
- Claire Coles agreed that they should not be telling individual researchers what to investigate; however, she did agree with education questions because there is not a lot of funding or focused RFAs on the intervention questions that exist. The only ones she knew of were those supported by CDC. They should not give the impression that they already know all of this. She was thinking particularly that health services research had not been done at all.
- Dr. O'Connor thought they could say that research is ongoing, but that includes very little intervention research. There are a few good studies, but not many.
- Dr. Floyd cautioned against talking too much more about "what is not known" because this may be discouraging and could fuel the "why diagnose it" attitude. While she agreed with what had been said, there are promising efforts moving forward that the CDC grantees have been working on. There are things they could be doing better. They should, for example, consider the guidelines the Task Force presented with respect to whether they are being used for screening and diagnosis. This would be a place to say that, as a policy, they need to improve diagnostic capacity.
- Dr. Olson recapped that the group had essentially said that the research recommendations are for what is being done already, so they could just say that and remove the entire section of specific recommendations. That said, she turned the group's attention to the policy recommendations and requested input about these.
- It was noted that because all members of the Task Force are Special Government Agents (SGEs) when engaged in the business of the Task Force, they must be careful about how they pose their recommendations. Given that they are operating under the Executive Branch of the federal government, there are rules and regulations with which they must comply, particularly with respect to advocating for allocation of resources. Ultimately, it was suggested that they make the case that research must continue so that the momentum is not lost, but eliminate any reference to funding allocations per se.
- Dr. Miller pointed out that the sophistication of autism surveillance compared to that of FAS is miles apart. The prevalence of autism can be stated with a lot more certainty than can be the prevalence of FASD. The differences in surveillance systems and in national capacity are enormous, and they should state that the surveillance system for FASD should be improved considerably.
- Dr. Floyd said that the problem for FASD was that they have only one condition that has any recognition, and even the diagnostic definition for that is contested among experts throughout the country. Autism spectrum disorder could speak to this, given that the conditions that would go along that spectrum have been identified and have diagnostic concurrence. She pointed out that when the experts who were developing case definitions deliberated this, there was enough concurrence to identify different conditions on the spectrum. This is simply not the case for FASD. Dr. Bertrand agreed that the autism surveillance was further along in the evolutionary process.
- Dr. O'Connor reminded everyone that one issue regarded the fact that they were experiencing difficulty about how they would reference the 1 in 100. The literature is very thin in that area, so they cannot support a direct comparison of the prevalence of FASD to autism.

- Dr. Miller agreed, suggesting that perhaps they may want to place more emphasis on establishing and developing case definitions for FASD.
- Dr. Floyd agreed that this was an ongoing issue. In order to proceed, they need a comfortable level of evidence they can rely on to establish diagnostic criteria, which they must have in order to proceed to surveillance. Hence, that needs to be on the agenda.
- Dr. Bertrand stressed that the comparison with autism is not completely off the table. Autism has 40 years of diagnostic wrangling that FASD is still going through. It took many years for the DSM to work on that. She requested that Leslie O’Leary, who is heading up CDC’s FAS surveillance program, speak to the issue with respect to what would help her strengthen the program to the level of birth defects or development disabilities.
- Leslie O’Leary responded that based on what she had seen so far with regard to surveillance, they still have work to do with just FAS without getting into FASD. Part of that does, indeed, have to do with not having diagnostic criteria. In FAS surveillance, there remains a fair amount of work to be done to get to the level of surveillance they have with birth defects. That takes time and resources. There were the previous CDC cooperative agreements known as FASS-NET. They were able to determine surveillance methodology for FAS. Now other programs are funded, for which they are using that methodology, but they are finding that refinement is still needed. It remains difficult to truly capture cases of FAS.
- It was also noted that, at the education level, children are often grouped in the “other” category, so it is difficult to quantify.
- Dr. Bertrand noted that in their state programs, the primary places they are finding children are diagnostic clinics they set up as part of that program rather than through established developmental disability or genetics clinics. Children are being referred to special diagnostic clinics like Seattle’s and the Marcus Institute. For many birth defects and development disabilities, a specialty clinic is not needed, given that they come through the regular system. However, for FAS, it appears that a concentrated level of expertise and diagnostic capabilities are needed.
- It was suggested that the term “tracking” be eliminated from “surveillance and tracking” although there was sentiment that leaving “tracking” in would be important. Dr. Bertrand commented that “tracking” could mean many things, depending upon how they were using the word. If they wanted to track children into services, which was the original idea, this does not work very well because of privacy issues. If they wanted to track an individual child across separate systems, that would be different. Dr. Floyd clarified that if they were simply talking about surveillance, they would want to identify the children. If done properly, it would be looking in multiple places. Dr. Bertrand suggested that they should probably include something else that talks about looking at children with services. That is, they should pull services away from the surveillance system because establishing a prevalence number is so important in and of itself. One of the problems that surveillance programs get into is that they try to do too much with the data beyond prevalence. It was ultimately agreed that “track” should be eliminated. Then a separate recommendation would be a statement that children need access to diagnostic, screening, and treatment clinics for clinical reasons.
- With regard to the recommendation to modify categorical classification systems, it was noted that part H/CAPTA requires child welfare professionals to refer drug and alcohol exposed children to early intervention systems. However, children whose IQs are deemed too high are not being classified as needing services. With that in mind, Ms. Gass suggested language about the developmental disability

systems in terms of the fact that states now have the option of whether to use the federal definition, which is functionally based, or the IQ cutoff definition. She thought there should be movement to force states to use the federal functional definition, given that children functionally need service, but cannot receive it in some states due to the IQ cutoff, excluding many children.

- Regarding the recommendation to expand the current interagency coordinating efforts into outreach, they already said they wanted to support continued efforts, so they could just leave this as is. However, they care about comprehensive and continuing care and a central system that promotes that. Dr. Floyd suggested saying, “expand current interagency coordination in development of a continuum of care for individuals with FASD, which would go from screening and diagnosis through referral.”
- Dr. Brenneman noted that the American Academy of Pediatrics often refers to this as a “medical home” for children with chronic needs. Ms. Ohlemiller suggested that this was even bigger than a “medical home” model, given that they were not just considering health and developmental care, although it would be a nice start for a recommendation.
- Regarding the recommendation on professional education, Dr. Sokol said the chance that this would be helpful for physicians who are licensed by states through a weird and ancient system, would be minimal. He thought it would be unlikely for a state to institute a requirement, particularly given that it was not clear what they could require. They should recommend that various disciplines include information about FASD in educational materials, etc. Ms. Ohlemiller responded that Regional Training Centers are working on this already and are targeting board exams for a number of professionals, as well as local and regional licensure exams for individual health providers. They are having some success getting some questions put in, which drives curriculum. Dr. Sokol agreed, but suggested rewording to reflect this more clearly.
- Though not sure how to incorporate it, Dr. Davis suggested including something about families, given the importance of families advocating for getting their needs met.
- Dr. Donaldson agreed that this was a critical addition to any publication. He stressed the importance of this document with respect to informing some of what is happening in D.C. currently with respect to re-introducing the FASD bill. Numerous individuals are anxious to do something in the near-term prior to September. He expressed hope that there would be a way, even if this document was not complete, to ensure that many provisions are included. They want to ensure that everybody is comfortable with the bill and that it goes forward from where they are currently. Senate 1722 was introduced last session. It was a carry over from 2003-04. That language was already outdated by the time it was introduced, although it did play a role. NOFAS is committed to working with the Task Force in trying to convey to key staffers in Congress the absolute best content for that bill so that it is brought up to date. In looking at the proposed policy recommendations outlined, they represent many of the components of the next generation bill.
- Dr. Brown enumerated a list of items that could be included: Support families to access information from dissemination resources like parent information centers. Learn to work to enhance their child’s development. Learn to advocate for services for schools. Learn to advocate for diagnoses.
- Ms. Ohlemiller thought they had to start this differently because they could not write a recommendation to families. They have to write this in systems language, so it could read something like, “All systems need to view the family as the point of support needs, not just the individual child.” It would still include the concepts suggested by Dr. Brown.

- Dr. Miller suggested removing the references to the *Community Guide*, given that it may not exist in the form it is now.
- Dr. Olson requested that members turn to page 7 in the document that discussed the Task Force itself, because Dr. Sokol raised the idea that one of the other possible functions of this document would be to point out the accomplishments of and advocate for continuing the Task Force. This concept was in the original motion, but not in the second version of the motion in the minutes. She wondered whether that piece should remain in the document, given that it could be construed as an inherent conflict of interest and reduce the credibility of the document if it appeared to be self-serving. This group has done a lot, so at the least, that should be included.
- Dr. Floyd suggested including a generic recommendation that there continue to be, or consistently be, an established forum whereby parents, advocates, professional organizations, and experts in field could deliberate over these issues from the multiple perspectives that are needed to fully deal with the issues that are important. Dr. O'Connor suggested using the term "national" group of some sort.
- Ms. Ohlemiller suggested including a couple of appendixes to pull it out of the main body of the document. For example, they could include the NIAAA strategic plan around this issue as one appendix. Another could delineate the accomplishments of the Task Force. That takes it out of the flow of the document. Accomplishments of other groups could be included in additional appendixes if they thought this was appropriate.
- Dr. Sokol's thought was that in making recommendations, they would be defining the edge of where they are and telling people that there is more to be done. If this group continues, this would lay out the challenges. If the Task Force does not continue, they would "pass the torch," which would charge the next group(s) involved with areas they think are important to work on.
- Ms. Ohlemiller stressed that they also did not want to provide a disservice to NOFAS, which is advocating for the reauthorization of a number of things. They should not develop a document that would make it look very easy to "pass the torch."
- Dr. Olson noted that one goal was to prepare this report in time to share it with the Marcus Leadership Institute. She requested that Claire Coles report briefly on the Institute. Dr. Bertrand added that they must also vote on sending a representative group from the Task Force to the Institute.
- Claire Coles reported that the Marcus Institute was provided with a private gift, the donor of which wished they would establish a leadership institute to support the ideas about better services with individuals with FAS. They plan to convene this institute in October 2007. At this point, they are sending letters requesting people's presence. They decided this would be a wonderful way to integrate and carry on some of the work of the Task Force. It was proposed that this document be presented at that meeting and used as a basis for discussion. This is a private enterprise, so she presumed they could say whatever they pleased. She said she would be delighted to speak with anyone who wished to participate, and she expressed her hope that they could count on the support of the Task Force.

With respect to moving forward on this product and sending representatives to the Leadership Institute, the following motions were made:

Motion

Dr. Olson motioned that a group of individuals representing the Task Force be directed to attend the Leadership Institute to be convened by the Marcus Institute in October 2007. Dr. Sokol seconded the motion, which carried unanimously.

Motion

Ms. Ohlemiller motioned that the Task Force endorse the work of the Post-Exposure Working Group and the document put before the Task Force during this meeting for further work, development, discussion, and finalization. Dr. O'Connor seconded the motion, which carried unanimously.

In conclusion of this session, Dr. Olson thanked everyone for their input and support, noting what a fine group of minds was assembled to work on this. She acknowledged the Post-Exposure Working Group members as well as the CDC staff who were instrumental in developing the draft document. She indicated that the Working Group would proceed forward with sending a new draft to the members as soon as possible, and send out a new draft for review and comments to the Task Force. She stressed that they should not comment further on the current draft they had been using since a revised version will be sent out. She also suggested track changes electronically so that she would know who submitted it. Ms. Weber acknowledged Dr. Olson's work on the draft, stressing that she was far too modest about how much work she put into the development of the document.

Summary of FASD Prevention Report Discussion

Lisa Miller, PhD, Co-Chair, Prevention Working Group

Dr. Miller recapped the discussion from the previous day pertaining to the final prevention document from the Task Force. During that session, they captured and, to some extent, organized their thoughts. They heard presentations from the USPSTF pertaining to what is known about behavior counseling interventions to prevent alcohol misuse, and from the RTI review about community interventions to prevent FASD and alcohol-exposed pregnancies. They discussed coalescing those two reviews rather than attempting to delineate what constituted "community" and "clinical" interventions and to discuss the bulk of the evidence that points to brief interventions as what there is the strongest evidence for. They also need to include in that what is known about treating women with abuse and dependence as well, given that the two reviews of evidence did not cover that level of intervention. The other major component of the product pertains to what is not known, for which the group generated a list. Tasks remaining with respect to this product include: 1) Updating the USPSTF document since it was published in 2004, and perhaps there is a way to use contracting resources in order to accomplish this; and 2) there was a commitment from several individuals to contribute to the writing (e.g., Barry, Chang, O'Connor, DeJoseph). They may be able to utilize contracting resources to have someone compile all of the written components. Dr. Miller stressed that the timeline is extremely tight. They are starting with even less time than the Post-Exposure Working Group in that they do not even have a draft yet. While they have large pieces of the outline laid out, the Task Force must complete a lot of work by conference call fairly quickly in order to meet the October 2007 deadline. They briefly discussed the format, with suggestions put forth to perhaps follow the model used for the *Clinical Guidelines*, and perhaps developing an *MMWR* article, with the idea that numerous spin-off articles/pieces could be constructed from that large document such as shorter summaries, peer reviewer articles, etc.

Discussion

- Dr. Bertrand suggested that the group consider having their own document similar to the *Clinical Guidelines*, given that the *MMWR* process is very long and can be quite complicated. An *MMWR* could actually be one of the spin-offs from their full report.
- Dr. O'Connor thought that there was already an *MMWR* published on screening and brief interventions. Dr. Floyd responded that they have published *MMWRs* that addressed issues from datasets, but there is not one on screening. In 2002, the Task Force came out with broad recommendations that were published in an *MMWR*, but there was no literature review. It was not like the diagnostic guidelines document, so this would be a unique document.
- Dr. Miller added that it would be broader than just brief intervention. They are trying to cover what is known about intervention strategies and prevention of alcohol-exposed pregnancies, although the bulk of what they know works and for which they have evidence is the brief intervention.
- Dr. Floyd remembered that on the previous day they discussed treatment for women. It was not clear how much they wanted to do with that. Her sense was that the decision was made that they would look at indicated preventions, screening and brief interventions, and that for pregnant women treatment options do not include pharmaceuticals. She wondered if they still planned to include a piece on treatment options beyond screening and brief interventions.
- Dr. Miller thought they needed to look at the treatment recommendations and the current evidence for treatment of women at the level of abuse and dependence. Clearly, the USPSTF excluded that group. They looked only at the group with misuse.
- Dr. DeJoseph said that even if this was in the form of a summary paragraph, it would be beneficial. One reason there is a problem finding the most severely affected children is because the mothers are hiding in AA, with their children undiagnosed. Other groups have already outlined information about addiction medications, so really this can be a short synopsis piece.
- Dr. Floyd also noted that there were some recommendations about workforce sites for community level prevention, so they will look into some other community-level interventions, and they do have a resources in this area from the *Community Guide*. She asked whether the group was interested in pursuing the emergency department data.
- Given the timeframe and funding, Dr. Miller thought that if there was already a good review, perhaps they could use that. Dr. Warren responded that there are some key papers in emergency rooms and trauma centers, for which there is separate research. Larry Gentilello, University of Washington at Seattle, is the primary individual who has published on this issue. The Berkeley prevention investigators have published on this topic and have also published with the Kaiser group from Oakland. Dr. Barry added that there was a book published on this from meeting in Washington two or three years ago. Dr. Floyd indicated that they would include this topic in the additional RTI reviews.

LIAISON UPDATES:

American Academy of Pediatrics

George Brenneman, MD, FAAP

Dr. Brenneman reported that they did try to respond to the article in the *New York Times* titled, "The Weighty Responsibility of Drinking for Two." However, by the time the letter was written, it missed the deadline by which the *New York Times* would accept it. It is a very good letter written by Dr. Janet Williams, who is a member of the American Academy of Pediatrics (AAP) Committee on Substance

Abuse. A copy of this article and two others were shared with the Task Force. Two articles were published in *Pediatrics* in the last month, one of which considers two counties that had similar demographic characteristics that showed a wide difference in the diagnosis of FAS in those two counties. According to the authors of the article, this seemed to be related to a very energetic, experienced, and well-trained pediatrician who made more diagnoses in one county. The other article addressed prenatal alcohol exposure based on a longitudinal study. This article considered outcomes for children who were exposed to very low levels of alcohol in utero, even as few as one drink per week. There did appear to be statistical differences in the emotional and mental behavioral aspects of the children, particularly in females. This supports the idea of total abstinence during pregnancy. The specific information about the articles is as follows:

Druschel CM, Fox DJ. 2007. Issues in estimating the prevalence of fetal alcohol syndrome: Examination of two counties in New York state. *Pediatrics*, 119:2, e384-e390.

Sayal K, Heron J, Golding J, Emond A. 2007. Prenatal alcohol exposure and gender differences in childhood, mental health problems: A longitudinal population-based study. *Pediatrics*, 119:2, e426-e434.

The AAP has a policy on FAS that was written in August 2000. Currently, the AAP Committee on Substance Abuse is rewriting this policy. Unfortunately, it is only in draft format so he had nothing to pass on to the Task Force, although he thought it would be extremely apropos to their current endeavors. However, he expressed his hope and offered his assurance that he would push for an emphasis on increased FASD training in residency programs. Residents complete pediatric training knowing very little about FAS. Also important to support is that clinicians be encouraged not to miss opportunities, particularly during the adolescent years. Pregnant teens are often referred to obstetricians, so the pediatrician is not as involved as much as they should be with the family. Pediatricians see children/adolescents for so many reasons, this is a wonderful opportunity to do some brief interventions on the spot, so pediatricians ought to be aware of this. He alluded to the idea of the “medical home” earlier. He was thinking in terms of the fact that the pediatrician, at the community level, is often involved in being the spokesperson and leader to pull agencies and disciplines together to focus on children’s needs. Pediatricians need to be encouraged to assume that role.

Dr. Brennehan noted that his entire professional career has been primarily involved with the American Indian and Alaskan Native (AI/AN) populations. With that in mind, he stressed that when they write policy and allude to the AI/AN populations, they must remember that there are currently 550 recognized tribal groups. These are considered to be sovereign nations and they oftentimes do not like to be grouped as a minority. They are each one nation and, in that regard, they do not view themselves as a minority. Each has its own cultural, spiritual, and historical background and it is important to recognize that. Dr. Brennehan announced “The 2nd International Meeting on Indigenous Child Health: Solutions, Not Problems” scheduled for April 20-22, 2007, to which he invited Task Force members. The AAP Committee on Native American Child Health, in partnership with the Canadian Pediatric Society and their Committee on First Nations and Inuit Child Health, are putting together the second international conference to be held in Montreal. A large component of that conference will involve presentations, workshops, and posters dealing with FAS. Both nations have a similar problem with respect to American Indians and Aboriginal people.

American College of Obstetricians and Gynecologists
Robert J. Sokol, MD

Dr. Sokol reminded everyone that when last he updated the Task Force, the American College of Obstetricians and Gynecologists (ACOG) had been working on an FASD Prevention Tool Kit for clinicians. The tool kit was launched by ACOG in October 2007 with a description and order form

enclosed in the ACOG monthly resource and newsletter mailing that is distributed to all ACOG members. Prior to the launch, a promotional article describing the tool kit appeared in the September 2007 edition of the newsletter, *ACOG Today*. As a result of the newsletter article, ACOG received over 100 email requests for the tool kit from physicians and clinic offices. As of February 12, 2007 they have processed approximately 950 individual orders and have distributed over 9,000 tool kits. Orders for the tool kits continue at a rate of 40 per week; however, many of the current orders are from public health and community programs that order 20 to 500 copies for dissemination at conferences, training, within health system programs, and promotional events. Physicians, mid-level providers, and community workers have equally embraced the tool.

The tool kit was posted on the ACOG public website in December 2006 and was promoted on the website in late February. Several large listservs devoted to maternal and child health, FASD, and women's health have highlighted the tool kit with access information. Some major organizations have promoted the tool kit to members, including: Planned Parenthood Federation of American; Federal Title X Family Planning Regional Networks; Title V State and Territorial MCH Organizations; State Women's Health Coordinators; Indian Health Service: Maternal and Child Health Services; March of Dimes; Federal Healthy Start Programs; Healthy Mothers, Healthy Babies; Association of Women's Health, Obstetric and Neonatal Nurses (AWHOON); NoFAS; FASD Center for Excellence; and New York State OASAS Coordinators.

The tool kit was distributed at major public health conferences in November and December, including the American Public Health Association (APHA) and the CDC's Maternal and Child Health Epidemiology Conferences. In conjunction with these promotions, ACOG has developed a short PowerPoint presentation for state and community organizations to improve involvement of women's health care providers in the guide's recommended screening and brief intervention tools for alcohol use for all women of reproductive age.

Approximately 50 physicians who have received the tool kit have returned the evaluation form for CME credits. All have ranked the tool kit highly. Most commented that the major change they will make in their practice is to screen all women of reproductive age for alcohol use. An annotated report of the evaluation forms will be forthcoming in summer 2007. Dr. Sokol pointed out that it was rare for ACOG to do anything that did not result in the receipt of at least some cranky comments, but thus far, they have received nothing but praise for this tool kit. In order to get a measure of the impact of the tool kit, in the early summer, the ACOG Research Section will field a CARNS survey to approximately 1,000 members to determine physician knowledge, attitudes, and practices regarding FASD prevention. This survey has a portion devoted to awareness and utilization of the tool kit.

The tool kit, *Drinking and Reproductive Health*, has been well accepted by ACOG fellows as well as other clinicians and community members involved with women of reproductive age. It is remarkable that no negative feedback was received on the product. It will continue to be promoted through the occasional articles in *ACOG Today*, the ACOG website, and through other provider networks.

In conclusion, Dr. Sokol commented that efforts such as the work they do on the Task Force and the ACOG tool kit take a long time. In 2004, the USPSTF released their report that said brief intervention works. That same year, ACOG had a committee that recommended screening. It took from 2004 to 2007, which is record time, to get the tool kit out to show people how to do this. It will take more time to get penetration into practice. Measuring that will be important, as will working out some follow-up. He expects that the challenge over the next few years will be to keep this "on the front burner" enough to determine whether they can get the Practice Committee to address it. While it may be very difficult, he also thought an important effort would be to get alcohol screening questions into the official antenatal care form, which can be self-administered via computer. Unfortunately, that form was just revised a couple of

months ago. It will have to go through a committee process, so they could not expect something major happening next year.

The Arc

Sharon Davis, PhD

Dr. Davis indicated that she retired as an Arc staff member to become a volunteer of the Arc on its National Health Promotion and Disability Prevention Committee. The Arc works through their chapters and that national committee provides guidance to the board. Since the last Task Force meeting, the Arc has had their national convention. Three hours of the conference focused on prevention, most of which was on FASD prevention. They had a panel of parents, which was very informative. They featured their FASD curriculum, for which they are still receiving requests. They also sponsored a National Research and Prevention Luncheon, during which the committee chairperson gives awards to chapters for small amounts of funding. Five of those went to chapters that are conducting FASD prevention awareness activities. Three focused on youth. The Arc of Arizona indicated their plans to use their funding to coordinate the Arizona Task Force on FASD, which the state had been funding but decided no longer to do so. So, that chapter is going to try to hold that task force together. The Arc has about 900 chapters across the country, so they are not entirely clear how many are engaged in activities related to prevention. This certainly raised the question regarding how they could be clear about what is effective, and how they go about finding out what is working.

Center for Science in the Public Interest

George A. Hacker, JD

Dr. Hacker indicated that FASD is only one small part of what the Center for Science in the Public Interest (CSPI) does, although in the last few months they did meet with Tom Donaldson and Kathleen Mitchell to discuss some plans both for CSPI's efforts on the hill and for a new campaign. CSPI plans to expand the use of on-site warning signs about drinking during pregnancy, which is currently under development.

During the last Task Force meeting, Dr. Hacker reported on the "Sober Truth on Preventing Underage Drinking Act (STOP)" that they expected to pass at any time. In its last few days, it was revised somewhat by industry influence, which was the only way it was going to pass, but ultimately it did pass and was signed by the President in December 2007. This will provide some funding for state grants for a number of activities, including: underage drinking prevention; initiatives on college campuses; monitoring of alcohol advertising; federal coordination of a corresponding body similar to the ICCFAS known as the Interagency Coordinating Committee to Prevent Underage Drinking (ICCPUD); research; and continuance of a current public service announcement campaign on underage drinking that is run by the Ad Council. Now they must follow-up with the ICCPUD to ensure that all activities that were authorized are actually appropriated as well.

They have been waiting for about two years for a Surgeon General's "Call to Action" on underage drinking. This will be announced on March 6th in Washington, D.C. Dr. Hacker said he was not hopeful that it would contain a lot of aggressive prevention ideas, but it will focus on underage drinking as a childhood developmental issue. At least it will help to have the Surgeon General's imprimatur on the issue.

In January 2007, the Federal Trade Commission (FTC) issued compulsory orders for special reports that went to 12 manufacturers of alcoholic beverages essentially demanding from those companies a wide range of information related to their alcohol advertising expenses, the operations of their responsibility campaigns, as well as their compliance with industry voluntary self-regulatory efforts. They expect that those orders will be in soon, and that by summer or fall, the FTC will issue another report on how the industry is doing with regard to alcohol advertising practices and their self-regulatory system. The

requests this time are quite extensive and much more detailed than the previous requests that the FTC has made of industry, so the CSPI is hopeful that some good information will come out of this effort.

Apropos to that issue and with respect to the fact that they have a long way to go, he shared a story of something that occurred in the last couple of days. CSPI noticed on a website in the D.C. entertainment area that a group called SMASHED, young guys interested in using heavy drinking to support charitable causes, was organizing what used to be a pub crawl that is now called an Idiotarod. This encourages teams of six young men and a shopping cart to pull their shopping carts through the streets of D.C. from bar to bar. This website was sponsored by Bud Lite and a local D.C. bar and was about getting smashed. It said basically, "Prepare your liver; it's a great time to make a fool of yourself" and other heavy drinking messages. Hence, the CSPI immediately complained to both Anheuser-Busch and the Beer Institute because this is an obvious violation of their self-regulatory voluntary advertising and marketing codes. In less than 24 hours, that website was thoroughly sanitized and the Bud Lite sponsorship was gone. This told them that they must monitor what this industry does constantly because they seem to take risks all of the time and go way beyond their public statements about responsibility.

One major issue they expect to get attention, which is certainly getting some attention in the state arenas, and which was mentioned in a *USA Today* article on February 28th, regarded taxation. With the Democrats now in control of Congress, and with some plans of spending that many of the members would like, they will be under a pay-go formula, which means that for anything they want to spend they must find the revenue. There are people interested in looking at alcohol excise taxes as one means of funding programs that they want to support. Thus, CSPI is doing a major push in Congress this year to keep alcohol excise taxes on the table. The argument is not only for revenue, but also to keep people informed of the public health implications. They have also been working with activists, state legislators, and others in 12 to 15 states where there are proposals to increase alcohol taxes. There has not been a tax increase at the state level since 2005.

As an aside, the World Health Assembly is meeting in Geneva in May when they will consider whether to adopt a directive for WHO to develop a global strategy on alcohol, which will assist developing countries where alcohol policies are rudimentary and where, for the first time in the last few years, industry involvement and growing marketing of alcoholic beverages is a major issue. CSPI is working to help the World Health Assembly pass the requisite resolution in that area, which will contain some reference to the fetal effects of alcohol.

Discussion

- Dr. O'Connor asked whether Dr. Hacker had any ideas about a mechanism that might reward the media for the message that women should not drink during pregnancy, as opposed to punishing them.
- Dr. Hacker responded that there are in others areas related to underage drinking and addiction. On a regular basis, groups provide awards to directors and producers, mostly in the creative area, for excellent portrayals of the addiction issue. One could conceivably do the same for news coverage and public service advertising by having an award or contest for the best messaging developed by a network or a program. Whenever someone sees something that is good or a good report, it is valuable to contact the reporter or producer of that show to tell them that they got the message right. Conversely, if they get it wrong, it is very important to let them know and keep educating them. There are some models of award programs. The question is making it big enough so that it will stimulate them to do the right thing. It is important even to do local briefings for media on what the message is, although media people do not like to be preached to about what to say.
- Ms. Weber indicated that CDC has a program known as the Sentinel Health Awards. This pertains to story lines that depict a variety of health issues. For example, "The Young and the Restless" once

had a story line about FAS. One of CDC's targeted media campaign grantees from a number of years ago used a piece of the "Young and the Restless" story line for educational purposes within the intervention they were providing in Iowa with women in WIC clinics. People can apply for consideration and the application goes through a review process. It was noted that U.C. Davis Hollywood, Health, and Society Norman Lear Center does a lot of outreach to writers, Hollywood, directors, etc. to educate them about the importance of including accurate health information in programming. Dr. Floyd added that "Law and Order" recently had a story line that received some positive attention.

- Ms. Ohlemiller noted that during the last Task Force meeting, Dr. Hacker reported on some progress that had been made with major networks and sports advertising. She wondered where they were with that effort.
- Dr. Hacker responded that this was the Big Ten Athletic Conference, which created its own sports network channel. Its agreement with FOX Cable Channel, which is its partner in that effort, specified that there would be no alcohol advertising for that entire network. Since that time, the University of Minnesota eliminated alcohol advertising on its radio broadcasts and a couple of other schools have joined CSPI's effort, which is called "The College Commitment." The most notable is Texas Tech, which recently joined in those efforts. However, they are still fighting to influence policy at the NCAA and other conferences. It is slow going. The person who was managing that campaign left for a variety of personal reasons, so CSPI is looking for a replacement.
- Dr. O'Connor noted that there is also a move afoot at UCLA, which is considering whether they will sell alcohol on campus. This seems to be a trend that universities are considering.
- Dr. Hacker replied that there are many activities and potential policy changes at the university level related to the sale of alcohol during games and even tailgating. Students at the University of Wisconsin challenged the administration's proposed alcohol policy for organizations on campus. There is also an effort by a former college president at Middlebury who started an endeavor to challenge the age 21 drinking laws, given that they are such a headache for college presidents.

March of Dimes

Elise Linden Antrobus

Ms. Antrobus reported on the March of Dimes' National Prematurity Campaign. She first indicated that based on some of the newest statistics on premature birth in the United States, as of 2005, the preterm birth rate had risen to 12.7% of all babies born. This is much higher than in previous years. Since 1985, there has been more than a 30% increase in the number of babies being born prematurely. The March of Dimes launched their campaign in 2003 to fight premature birth. Since that time, there has been a significant increase. Now more than 1 out of 8 babies is being born prematurely in the United States. In certain states, that rate is much higher, Georgia being one of them. The goals of their campaign are in line with the Healthy People 2010 goals and objectives. To move them toward the Healthy People 2010 goal, the March of Dimes has set two campaign goals: 1) Increase public awareness of the problems of prematurity to at least 60% for women of childbearing age and 50% for the general public by 2010. The baseline awareness measure is 35% according to a March of Dimes survey conducted in 2002; and 2) Reduce the rate of preterm birth from 12.3% in 2003 to the HP2010 objective of 7.6%. The preterm birth rate in 2000 was 11.6 per 1,000 babies. Their goal would be to have a rate of 9.9 per 1,000 births by the year 2007. Another way to understand what this means is that currently, approximately 1 in eight babies are born preterm. Their goal would be to have one in ten (or less). A 15% reduction of the current 467,000 premature babies would mean that less than 400,000 babies are born premature each year. They are now seeing that about 40% of the general public is aware that premature birth is a serious health problem, which is an increase of where they were in 2003.

Since launching the campaign, there have been numerous March of Dimes National Preterm Birth Initiatives, including the following:

- Preconceptional Care Summit, June 2005 (www.marchofdimes.com)
 - *MMWR April 21, 2006 Recommendations*
- Late Preterm Conference, July 2005
 - *Seminars in Perinatology Supplement (Vol 1 and 2, 2006)*
 - *My 9 Months*
- Institute of Medicine (IOM)
 - *Environmental Toxicants and PTB 2001*
 - *Preterm Birth Causes, Consequences, and Prevention 2006*
- Invitational Preterm Research Conference, November 2005
- Prematurity Awareness Day (PAD) - Prematurity Summits
- JJPI-MOD national grand rounds program
- Family Medicine Continuous Quality Improvement PTB/LBW Initiative
- PREBIC (Preterm Birth International Collaborative)
- MomVans for prenatal/perinatal care (4 in Los Angeles and 1 in Mississippi)
- Kentucky Demonstration Project to reduce singleton PTB

One trend that they are seeing with the rate of premature births is that the rate for premature babies (32 or less weeks of gestation) have remained relatively consistent since 1990. However, the rate of premature births among 34 to 36 weeks, late preterm birth babies, is increasing greatly, which is an issue they are beginning to address with their campaign. Also of note is that in 1992, about 40 weeks was the average gestation. In 2002, this moved to 39 weeks. That is, the average length of gestation among the general population is trending downward.

They launched their preconception health plan, which is part of their prematurity campaign. Thalia is their spokesperson for this campaign. One of the main themes is the impact that alcohol use has prior to conception on the mother's body and ultimately on the body of the baby.

The March of Dimes is examining clinical interventions regarding smoking cessation, progesterone use, and infertility and multiple births. The March of Dimes National Research Agenda for Preterm Birth focuses on six key areas of research, including: Disparities, Inflammation/Infection, Genetic/Gene-Environmental Interactions, Stress, High Risk Interventions (multifetal, ART), and Promising Clinical Interventions. Half the time a baby is born prematurely, it is unclear why. Hence, research is a key part of their campaign.

The March of Dimes believes that premature birth meets the definition for a common complex disorder. In 2006, they launched the Prematurity Research Initiative (PRI) grants funded by their national office solely focused on premature birth and intervention. They announced six projects in 2006 that were funded through this initiative, which included the following:

- A Comprehensive Study of Genetic Susceptibility to Preterm Delivery
- Pharmacological Investigation of Novel Anti-inflammatory Therapeutic Strategies for the Treatment and Prevention of Preterm Birth using Human Ex-Vivo Models
- Maternal and Infant Genetic Contributions to Preterm Birth: the Inflammatory Response
- Abruption-induced Preterm Delivery Elicits Functional Endometrial Progesterone Receptors
- Progesterone Receptor Dysregulation and Preterm Birth
- Cytokines from Peridontal Disease Induce Premature Birth

They plan to fund eight new projects in 2007, which are just now being announced to applicants. The 2008 process is now open, information can be found on the March of Dimes website at www.marchofdimes.com. All of the applications, abstracts, timelines, and other information can be downloaded.

Some exciting new information is that they have a gene clue to premature birth. A potential genetic marker that could help to predict the risk of an unexpected preterm birth has been discovered. It may also help explain why African-American women seem to be more at risk of having a preterm birth than other women. African-American babies are three times more likely than babies of European descent to carry the key genetic variant. SERPINH1 controls the production of the protein collagen, a key component of many body tissues, including cartilage, ligaments, tendons, bone and teeth. A variation of the gene was identified that resulted in reduced amounts of collagen. This could lead to weakened fetal membranes, increasing the chance of rupture triggering preterm birth.

With respect to preventing the preventable, there is so much that is not known about premature birth. It is known to be a complex problem for which there is no “magic bullet.” Nevertheless, it is also known that there are some specific risks that put a woman at greater risk of having a preterm baby, so they can focus on preventing the preventable in order to impact her risk. Alcohol is at the top of the list.

The “PREEMIE Act” is legislation that they have been working on with Congress for about two and a half years. This act passed and was signed by the President at the end of 2006, in the very last hours, of the very last session, of the last Congress at about 3:00 a.m. This is a very important piece of legislation. This act authorizes expansion of research into the causes and prevention of prematurity and increases federal support of public and health professional education as well as support services related to prematurity. Specifically, this act will convene a Surgeon General’s conference to look at preterm birth and to develop some national recommendations around prevention of preterm birth. It includes a consensus research plan for HHS on prematurity and low birth weight, and a report to the Secretary and appropriate committees of Congress pertaining to current efforts. While there is a lot going on in the government, private, and non-governmental sectors, there is no collaboration necessarily among all of the agencies and other groups to have a centralized location for all of this information.

In conclusion, Ms. Antrobus indicated that the March of Dimes website includes a lot of information about what they are doing throughout the country to fight preterm birth and about preconception and other initiatives that the MOD is undertaking.

National Organization on Fetal Alcohol Syndrome Tom Donaldson

Mr. Donaldson reported on NOFAS activities. He reminded everyone that NOFAS is helping to disseminate the ACOG tool kit, for which they have also received a lot of interest and extremely positive feedback. NOFAS will have a small role in the ACOG run at their annual conference to promote the issue of FASD with the ACOG members. The media discussion is very important. With respect to the *New York Times* article, NOFAS responded along with many others. Unfortunately, to get something printed it must be glib and submitted immediately and it is not always printed in context. Nevertheless, NOFAS does attempt to be opportunistic, so anytime there is a comment or article in the electronic media about the issue, they do try to respond. Sometimes it is a pregnant celebrity who has made some cavalier remark about alcohol consumption. Thus, NOFAS has been diligent and assertive over the last year in responding whenever and wherever they can. When he talks to people who write these articles, policy makers, and others they almost always will say, “Well, I didn’t know that.” There are a lot of misconceptions about this issue. When they do not have restrictions, they should be talking to the media about this issue.

NOFAS is entering their 18th year of existence. The organization was incorporated in South Dakota by Senator Daschle and his wife. Although it soon moved to D.C., it does have that base which is still involved. NOFAS has 16 autonomous affiliates currently, made up of a lot of parent groups around the country. They are trying to develop the affiliate program in order to have an open line of communication to share resources and materials and coordinate advocacy. This is an important initiative for them.

The organization is in its 12th year in several medical schools where they offer electives on the issue of FASD. They are happy to present the core competencies developed by the CDC RTCs in various formats. At Georgetown Medical School this is delivered in eight sessions, while at George Washington University the format is a two-hour lecture, for example.

The NOFAS clearinghouse receives increasingly more requests from practitioners and families. Sometimes they feel they are not marketing as well as they would like; however, they simply do not have the resources to do more currently. Nevertheless, people are finding them. At the next meeting, they hope to share data on how people find NOFAS and the types of things they are asking for.

With respect to the media in terms of story line placement in programs, Dr. Neil Baer, who is an Executive Producer of “Special Victims Unit” version of “Law and Order,” is considering how he can include another story line related to this issue.

There will be an FASD bill that Senators Johnson (D-SD) and Murkowski (R-AK) are going to take the lead on. They are very anxious to get something introduced. It is critical that it be a comprehensive bill with up to date provisions. That is in process. Mr. Donaldson encouraged those who could appropriately do so to weigh in through the NOFAS office. Senator Johnson’s health is one consideration in terms of the timing for introducing the bill. They would like to do it in May, but it could be a month or two after that. On June 12-13, NOFAS will engage in a series of activities during their 5th Annual Hill Day on Capital Hill, with FASD advocates. At the same time, they have an awards reception to recognize policymakers and people in the field who have made significant contributions. He invited Task Force members to participate.

The Task Force reauthorization is a priority in terms of the legislation. Several of the offices have suggested incorporating that into the new bill. They have discussed this with the Health Committee and Senator Kennedy (D-MA). NOFAS’s sense has been to try to move that reauthorization independently to assure that it can move forward. They are likely to do that, but there is some uncertainty about how that will go forward. In terms of looking on the horizon about what might happen with the bill, the hope is to look at the Task Force reauthorization, and perhaps a couple of other provisions, and then try to aggressively push the revised legislation through for 2007. When the bill is introduced, NOFAS will likely deliver a briefing on the Senate side, and then when the companion bill, co-sponsored by Frank Pallone (D-NJ) and Jim Ramstad (R-MN), NOFAS will offer a briefing then as well. Those are very important because staff members are keenly interested in where the field is and what is on the horizon. Currently, one of their frames of reference is the autism issue because of recent visibility. There are some comparisons that are valid in terms of a process, although the FASD issue is somewhat behind autism. Nevertheless, it helps to put the issue into context for policymakers. On a separate track from the appropriations process, because there are some key people in both chambers on the appropriations committee, they will, as always, try to find any funds that can be enhanced. They are reforming the earmark process and there are some discussions now about how they will agree to do that. In past years, some money has been added. There is still plenty work to do.

FEDERAL UPDATES (continued):
Centers for Disease Control and Prevention
R. Louise Floyd, DSN, RN

CDC presented on several program activities as part of their update to the Task Force. Dr. Floyd reported on Project CHOICES and the RCT study. Based on the latest Behavioral Risk Factor Surveillance System (BRFSS) data, she indicated that there was little change with respect to alcohol consumption prevalence over time. The 2004 data are a little lower than 2003, but still about 2% of pregnant women report drinking five or more drinks on at least one or more occasions in the past 30 days during pregnancy. Any drinking during pregnancy remains at about 1 in 8. Among non-pregnant women, over half of the population in 2004 reported any use, while about 12% reported binge drinking. Data from SAMHSA's National Household Survey of Drug Use may give higher proportions of numbers of women reporting bingeing because they now are using four drinks per occasion as their definition for a binge. BRFSS will soon be converting to that measure as well.

The ultimate goal of Project CHOICES is to develop an effective behavioral intervention for reducing alcohol-exposed pregnancies in high risk women in the preconception period. The collaborative sites included: Nova Southeastern University in Ft. Lauderdale, Florida; University of Texas at Houston in Houston, Texas; and Virginia Commonwealth University in Richmond, Virginia. Women eligible for the study had to be 18-44 years of age, fertile, sexually active in the past 6 months, using ineffective or no contraception, not pregnant or planning to become pregnant, and drinking 8 or more drinks per week or drinking 5 or more drinks on one or more days in the past 3 months.

The settings selected by the grantees included alcohol treatment centers and jails in Houston, Texas; a large inner-city, university-based gynecological clinic, and publicly funded primary care clinics in Richmond, Virginia, and a media-recruited group of women who responded to newspaper advertisements in the Ft. Lauderdale area and a large primary care clinic system in Ft. Lauderdale, Florida. They estimated that overall, approximately 1-2 % of all childbearing-aged women were at risk for an alcohol-exposed pregnancy. Rates for the identified settings ranged from 5% to 24%. Combining all sites, this group of women was 7 times more likely to be at risk than women in the general population. So, the CHOICES epidemiological survey confirmed that indeed these settings were appropriate for conducting the planned study.

Project CHOICES included four sessions of motivational counseling with a family planning visit that occurred somewhere in between the first three visits. They basically allowed a window of time of 14 weeks for this to occur, and they followed the women at 3, 6, and 9 months. They piloted the intervention in a feasibility study that followed the women for 6-months post intervention. Six months following the intervention, over two-thirds (68%) of the women were no longer at risk for an alcohol-exposed pregnancy. Routes to reducing the risk for an AEP for the study population were to reduce drinking (18%), use effective contraception (34%), or do both (48%). Following this, they conducted a randomized controlled trial in these same settings. The control group received information only, which consisted of a healthy lifestyle booklet that addressed diet, weight, exercise, alcohol use, tobacco use, and other topics relevant to childbearing-aged women. The intervention group received information, as well as the 4 counseling sessions and a contraceptive services consultation visit.

Participant characteristics at baseline were: predominantly African-American and Caucasian; annual incomes less than \$20,000; approximately half were single; the majority had a high school education or greater; high rates of illicit drug use and smoking; and more than half met DSM-IV criteria for alcohol dependence. Only about 11% were married, most were single, others were living together, divorced, or separated.

The aim of the RCT was to reduce risk for an alcohol-exposed pregnancy. There were two alternate routes to achieving this. The woman could reduce risky drinking or she could engage in effective contraception use, or do both. With respect to the odds ratios for the 3, 6, and 9-month follow-up points, the odds of reducing risk for AEP among women in the intervention group were twice that of women in the control group. The odds ratios for effective contraception were similarly higher for intervention women versus controls, and reduced risky drinking was also higher as well. Actual % differences for reduced AEP risks were 18%, 17%, and 14.8% at 3, 6, and 9-months all of which were statistically significant with p-values <0.001. They looked at the proportion of women in intervention and control groups who reported changing both risk behaviors, which would provide the most optimal safeguard against having an alcohol-exposed pregnancy. Significantly more women in the intervention group reported changing both behaviors as compared to control women at 3, 6, and 9 months.

Related activities using the CHOICES model have included the following: one session adaptation for college-aged women (Project BALANCE); comparison of one session adaptation, assessment only, and assessment plus video information in community women (Project EARLY); community trials using mailed and web-based interventions; state-based pilot projects aimed at integration into public health settings; dissemination of findings from the Project CHOICES RCT and other follow-up studies; and implementation of the CHOICES model in additional diverse settings.

State-based FASD Prevention Projects

Patricia Price Green, MSPH

Ms. Green reported that in FY2004, CDC funded five states to develop comprehensive state and community-based programs for FASD prevention. In FY2005, two additional states were added. All seven states have multiple components, with an emphasis on translating Project CHOICES and Guided Self-Change interventions into community settings to intervene with women at risk for an alcohol-exposed pregnancy. The states are also conducting surveillance for FAS, and identifying affected children and linking them and their families to the services they need.

The FASD Prevention Projects are:

- Colorado Department of Public Health & Environment
- Michigan Department of Community Health
- Minnesota Department of Health
- Missouri Department of Health and Senior Services
- University of South Dakota (in collaboration with North Dakota FAS Center)
- Oregon Department of Human Services (funded in 2005)
- University of Wisconsin Medical School (funded in 2005)

The interventions of women who are at risk for an alcohol-affected pregnancy are of two types: 1) Individual Level; and 2) Guided Self-Change, both of which adapt the Project CHOICES materials in selected communities. Adaptations of Individual-Level FASD Interventions generally consist of two in-person sessions with a counselor or health professional (using a brief motivational interviewing (MI) approach); personalized feedback; decisional balance worksheet; readiness rulers; goals and plan; and telephone follow-up. Adaptations of Guided Self-Change FASD Interventions generally consist of guided self-change materials; fact sheets (AEP, alcohol, contraception); personalized feedback; decisional balance worksheet; readiness rulers; goals and plan; journal log; referral resources; and telephone follow-up. This is for women who cannot attend the one-on-one sessions or who prefer to go through the materials on their own.

With regard to next steps, the states will continue to implement the intervention components of these programs. They will also evaluate the programs for primary outcomes including AEP risk, reduced drinking levels, and contraception effectiveness. They will also evaluate process measures.

Developmental and Intervention Research Projects for FASDs

Jacquelyn Bertrand, PhD

Dr. Bertrand reported on the preliminary findings from Phase I and the beginning of Phase II of CDC's Developmental and Intervention Research Projects for FASDs. This group of grantees met on January 28-29, 2007 during which time each presented on progress to date and what will be done in Phase II. On the second day, they had the opportunity to present at a pre-conference workshop at the Child Maltreatment Center in Anaheim, California. Before this program began, there were no systematically scientifically validated interventions for children with FAS. To date, information and strategies have been gleaned from other disabilities, parents, informal networks, trial and error, and luck. In 2001, CDC provided the first federal funding to develop and test systematic, specific, and scientifically evaluated interventions. The program announcement went out for both children and adolescents. They did not receive any intervention applications for adolescents unfortunately.

Through their preparatory work for sending out that announcement, they knew that there were several components that must be included in the interventions (e.g., comprehensive in nature including educational, psychological, social service, family, and medical elements). The intervention plan needed to be tied to an assessment of the individual child because this is a very heterogeneous group of children and one intervention will not fit all children. Each group also had to target a specific vulnerability in the context of more general deficits. Comprehensive medical, psychological, and environmental assessments had to be offered by all projects. These were to use a randomized control design aiming for at least 50 children and families in each intervention and control group. They had to offer comprehensive referrals for things like occupational therapy, family assistance, social services, medical interventions, etc. The intervention groups received a targeted intervention. Parent education had to be a component, and they also were all to be involved in the development of a collaborative database.

The five grantees that were funded include: Marcus Institute (learning readiness and math); University of California at Los Angeles (friendships and social skills); University of Washington in Seattle (behavior regulation and social communication); Children's Research Triangle (stability and behavior); and Oklahoma University Health Sciences Center (social skills and behavior).

University of California at Los Angeles' participants included children with FAS and ARND who were 6-8 years of age and their parents. Their targeted area is development of friendships. Their intervention includes 12-week group sessions for the child and parents with instruction, practice, and homework. There is an emphasis on play dates. For these subjects, quality of play and social skills improved as measured by parent ratings for 74% of children; measures of self-image/self-esteem improved; and problem behaviors decreased as measured by parent and teacher ratings for 68% of children.

The Marcus Institute's participants included children with FAS and ARND who were 3-9 years old and their parents. Their targeted area was math and executive functioning skills related to math, and learning readiness. Their intervention consisted of the Key Math Curriculum, one-on-one tutoring, and a parent support group. With respect to the math results, 88% of participants improved math skills; 9% increased in knowledge of math concepts; and parents improved knowledge, attitudes, and behaviors regarding FAS, which in turn decreased behavior problems.

Oklahoma University Health Sciences Center participants included children with FAS and ARND who were 2-7 years old and their parents. Their targeted areas were challenging behaviors, escalating outbursts, and social interaction skills. Their intervention included parent-child interaction therapy in which parents practiced interaction skills *in vivo* with therapist coaching, as well as a parent support group. Results for this study were that mean scores on the aggression scale of the CBCL were reduced to

below clinical threshold; mean parental stress ratings were reduced; and mean number of tantrums/outbursts per week were reduced.

Children's Research Triangle participants were children with FAS and ARND who were 6-12 years old in foster care and their caregivers. The targeted areas were placement stability and social skills, emotional/behavioral regulation, and learning/memory. Their intervention included neurocognitive habilitation with 12-week group sessions, case management, and a parent support group. Results included improvement in executive functioning, as measured by BREIF; and the conduct problems scale of the CBCL improved to below clinical thresholds.

University of Washington's population included children with FAS and ARND who were 5-11 years old, their parents, and school staff. The targeted areas here were challenging behaviors, socialization, and parent stress/empowerment. The intervention included individualized behavior consultation, parent education, and teacher consultation. The results in Washington State included improved behavior, as measured by CBCL; parent stress reduction; and improvement of adaptive skills.

With respect to findings across sites, Dr. Bertrand reported that interventions are effective for children with FASDs. Non-targeted behaviors often improve in addition to targeted behaviors and parent education regarding their child's condition, deficits, and "parenting differently" is very effective.

Phase II is focused on research to practice. Each site is partnering with a community agency, and tested interventions (described above) are adapted to the resources and infrastructure of the community agency. They will obtain cost data from this phase. The community agencies are:

- Illinois: Champaign-Urbana Foster Care Advocacy & Referral group
- California: Child & Family Guidance Centers
- Georgia: Do2Learn.com & Afterschool Programs
- Washington: University of Washington Children's Hospital & Institute for Family Development
- Oklahoma: Native American Local Health Councils

From the grantee meeting in January 2007, they do plan to develop a short summary article on the various Phase I programs and results, the working title for which is "Yes, There is Something You Can Do. In Fact, There are Several Things You Can Do For Kids with FASDs."

Discussion

- Dr. O'Connor, UCLA, clarified that the bottom line in their study was that, for social skills improvement, there was a significant difference on the Social Skills Rating Scale according to parent reports in the experimental group versus the control. Children improved their social skills by about a 15-point standard score. They moved from being in the clinical deficit range in social skills into the normal range. They also learned the social skills material and retained that information over the three-month follow-up period and their social skills improved at three-month follow-up. Also, their problem behaviors decreased at the end of treatment and stayed low three months later. She clarified that when she attended the grantees meeting, she was not aware that she was supposed to report, so these were older data. The updated Phase I data were published in 2006.
- With regard to Seattle, Dr. Olson clarified that because they were targeting the caregiver, which fits well with the clinical wisdom in the field, they were interested not only in reductions in behavior problems, but also in whether the caregivers, who felt their needs were met, took better care of themselves. They had very significant findings in that area.

OTHER BUSINESS:

Update on Task Force Sunset / Communication Process for Task Force Products / Thank You Letter to American College of Obstetricians and Gynecologists

Ms. Weber updated the members on the Task Force sunset, October 24, 2007. She has had some conversations with CDC's Committee Management representatives to determine what they could do internally to attempt to continue the Task Force's activities. They recommended drafting an internal memo that would go to the Director's office. CDC is restructuring a lot of their committees, so it was not clear whether this would fit into the purview of that restructuring. However, they plan to move forward to draft something that provides a rationale for why they should be continuing. Having input from members about why they believe the Task Force should continue would be beneficial to integrate into a letter. With respect to the communications process for Task Force products, Ms. Weber indicated that she would work off line with the Post-Exposure and Prevention Working Groups to discuss the communication procedures for Task Force products as the groups continue to move forward in the development of their specific products. Ms. Weber also noted that the thank you letter to ACOG regarding the development of the tool kit had been completed and that she would get it signed and sent out later in the afternoon.

Discussion

- Dr. Floyd reported that CDC's Office of Public Health Research (OPHR) recently released an RFA addressing translational research across CDC. NCBDDD has an entry in that RFA that addresses implementation of CDC's preconception healthcare recommendations, with particular attention to risk factors with evidence-based interventions, including alcohol, tobacco, folic acid, etc. Dr. Floyd will send the URL for that RFA to the Task Force and they can pass it on. Ten million dollars has been set aside for this RFA. The highest ranking applications will be selected and sent to the relevant CDC Center where they are addressing the issue. The amounts are \$350,000 to \$450,000 per award for up to three years.
- Ms. Ohlemiller inquired as to whether any contracting resources would be available for the Post-Exposure Working Group's product, and what the process would be if they needed something.
- Ms. Weber responded that because they were going the route of the *Community Guide* with the Prevention Workgroup, they had specifically garnered funding for that activity. Dr. Floyd added that they have a contract with RTI, which is who they would use. Given that RTI developed the initial report, they could be asked to update that in the ways which were discussed earlier in the meeting. With respect to the Post-Exposure Working Group, they do not have a contract for a task of any specific activity under that. However, if the group needs something, they could simply contact the program to discuss whether it can be obtained. If they need a consultant, that is one thing, but other resources such as a report writer would be more difficult as they do not have an existing contract.

Dates for Next Task Force Meeting

Ms. Weber indicated that the next meeting would most likely be convened in September 2007. They cannot have a meeting in October 2007, given that the fiscal year ends in September. Jackie Vowell will send out meeting dates as soon as they are confirmed. The next meeting will likely be sometime between September 10th-21st. This would allow time for any additional work should the Task Force sunset.

Public Comment/Adjourn

With no public comments offered or further business raised, Dr. Wright officially adjourned the meeting.

Minutes approved on 05/29/2007
by Jean A. Wright, MD, MBA
Chair, National Task for on FAS/FAE