Substance Abuse, Pregnancy and Fetal Development: Early Start Intervention and Success

Nancy Goler MD
Early Start Regional Medical Director
Kaiser Permanente
Northern California Region

October 28, 2010
Agenda

- Usage in Pregnancy
- Opiates and Buprenorphine
- Early Start Intervention
- Appendix Slides
No Conflicts of Interest in Presentation
No Disclosures
IN VINO FERTILIZATION

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Results from the 2008 National Survey on Drug Use and Health: National Findings

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Office of Applied Studies
http://oas.samhsa.gov/NSDUH/
2008: Past month illicit drug usage by age
Young Adults Age 18-25, past use 1 month
Current Substance Use among Pregnant Women Aged 15-44, by Age, 2006-2007 combined

<table>
<thead>
<tr>
<th>Substance</th>
<th>15-17</th>
<th>18-25</th>
<th>26-44</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Illicit Substance</td>
<td>22.6</td>
<td>7.2</td>
<td>3.0</td>
</tr>
<tr>
<td>Alcohol Use</td>
<td>15.8</td>
<td>9.8</td>
<td>3.0</td>
</tr>
<tr>
<td>Binge Alcohol Use</td>
<td>10.3</td>
<td>5.1</td>
<td>2.5</td>
</tr>
<tr>
<td>Cigarettes</td>
<td>24.3</td>
<td>23.3</td>
<td>11.6</td>
</tr>
</tbody>
</table>

Source: SAMHSA NSDUH, 2007
Illicit Drug Usage in Pregnant Women

- 5.1% pregnant women used illicit drugs in the past month
  - 9.8% non-pregnant

- Average rate of current illicit drug use was 5.1 percent
  - no significantly change from 2005-2006 (4.0 percent) and was similar to the rate observed in 2003-2004 (4.6 percent).

- Among women aged 15 to 17 those who were pregnant had a higher rate of use than those who were not pregnant (21.6 vs. 12.9 percent)
2008 Alcohol by Gender, age 12 to 20
Pregnant Women (15-44 yo)

- Current alcohol usage: 10.6%
- Binge drinking: 4.5%
- Heavy drinking: 0.8%
  - Non-pregnant rates: 54.0, 24.2, and 5.5 percent, respectively.

Note: The 2007-2008 estimate for first-trimester binge drinking is higher than in 2005-2006, when it was 4.6 percent.
Prevalence of Fetal Alcohol Spectrum Disorders

• CDC studies have documented FAS prevalence rates ranging from 0.2 to 1.5/1,000 live births

• Classic medical education states FASD inclusive may be as high as 1 per 100 live births (40,000 infants per year in the US)
Fetal alcohol syndrome (FAS)

- Term first used in 1973 by Drs. Smith and Jones at the University of Washington
- One of the diagnoses used to describe birth defects caused by alcohol use while pregnant
- A medical diagnosis (760.71) in the International Classification of Diseases (ICD)
- Umbrella term describing the range of effects that can occur in an individual whose mother drank alcohol during pregnancy

- May include physical, mental, behavioral, and/or learning disabilities with possible lifelong implications

- Not a diagnosis
• All alcoholic beverages are harmful
• Binge drinking is especially harmful
• There is no proven safe amount of alcohol use during pregnancy
Normal brain of baby 6 wks old

Brain of baby same age with FAS

Photo courtesy of Sterling Clarren MD
# Cigarettes vs Cocaine in Pregnancy

**Perinatal Risks:**

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- Long Term Effects of Cigarettes:
  - Respiratory Problems
  - SIDS (increased RR 2.0 – 7.2)
  - Increased Behavioral Problems:
    - GIRLS: Increase in substance abuse in adolescents
    - BOYS: Increase in Oppositional Defiant Disorder (ODD)*

2008, Age 12 and older, new initiates

2.9 Million Initiates of Illicit Drugs

- Marijuana (56.6%)
- Pain Relievers (22.5%)
- Inhalants (9.7%)
- Tranquilizers (3.2%)
- Hallucinogens (3.2%)
- Stimulants (3.0%)
- Cocaine (0.8%)
- Sedatives (0.8%)
- Heroin (0.1%)
Past Year Initiates for Specific Illicit Drugs among Persons Aged 12 or Older: 2008

http://oas.samhsa.gov/NSDUH/2k7NSDUH/2k7results.cfm#Ch2
Dependence on or Abuse of Specific Illicit Drugs in the Past Year among Persons Aged 12 or Older: 2007

- Marijuana: 3,932
- Pain Relievers: 1,707
- Cocaine: 1,598
- Tranquilizers: 443
- Stimulants: 406
- Hallucinogens: 368
- Heroin: 213
- Inhalants: 164
- Sedatives: 154

http://oas.samhsa.gov/NSDUH/2k7NSDUH/2k7results.cfm#Ch2
A Closer Look at Opiate Addiction in Pregnancy
Addiction in Pregnancy

- Opiate dependence (especially pills) is a significant and growing problem in the US.
- Long term prescription opiate use in young (and pregnant) women warrants assessment for addiction to opiates.
- Opiate addiction is a treatable condition.
Opiates and Pregnancy

- Difficult to Screen – If only using softer Signs/Symptoms
  - Late entry to care
  - Missed appointments
  - Past Ob history
  - History of children with problems or CPS
  - History of other drug or alcohol problems

- NCal Early Start: Universal Screening with questionnaire and toxicology (with consent)
Opiates and Pregnancy

- Neonatal Outcomes
  - Withdrawal Syndrome (NAS – Neonatal Abstinence Syndrome)
  - Prematurity
  - Microcephaly
  - Neurobehavioral Deficits
  - SIDS
Opiates and Pregnancy

- **Treatment Options for Addiction**
  - Methadone Programs
    - Remains National Standard of Care
  - Detoxification
    - Prefer second trimester, generally inpatient
    - Motivated patient
  - Buprenorphine
    - Consider continuing treatment if already on med
    - No new starts yet (multicenter trials results pending)
    - May require inpatient detox for new starts
Buprenorphine and Babies: Do they mix?
Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
Buprenorphine passes into the breast milk of lactating women at a plasma-to-milk ratio of approximately 1.

- Very poor oral bioavailability
- Infant will be exposed to only 1/5–1/10 of the total amount of buprenorphine available.
Breast Feeding While on Buprenorphine Treatment

- The literature reports on approximately 40 to 50 women who were maintained on buprenorphine and who breastfed.
  (Johnson et al. 2003a; Lejeune et al. 2001; Loustauneau et al. 2002; Marquet et al. 1997).

- Buprenorphine present in breast milk does not appear to suppress NAS.

- NAS has not been observed after the cessation of breastfeeding by women who were maintained on buprenorphine
  (Loustauneau et al. 2002).
Breast Feeding While on Buprenorphine Treatment

- Subutex® and Suboxone® package inserts state that breastfeeding is not advised.
- It is the consensus of the panel that any effects of these medications on the breastfed infant would be minimal and that breastfeeding is not contraindicated.
- Given the limited literature in this subject area, physicians are advised to use their judgment in their recommendations.
A pessimist sees the difficulty in every opportunity; an optimist sees the opportunity in every difficulty.

--Sir Winston Churchill
We believe that every woman deserves a non-punitive health care environment, such that she have access to services and support to have an alcohol, tobacco and drug free pregnancy, allowing the delivery of a healthy baby.
Early Start Innovation

- Place a licensed mental health provider in the department of Ob/Gyn
- Link Early Start appointments with routine prenatal care
- Universal screening
- Educate all women and providers
2009 Early Start Data

- 38,216 questionnaires: 10,430 (27%) positive
- 8817 (84.5%) were assessed
  - Negative assessment: 4513 (51.19%)
  - Smoker Only: 1141 (12.94%)
  - “At Risk” Diagnosis: 1800 (20.42%)
  - Substance Abuse: 807 (9.15%)
  - Chemical Dependency: 460 (5.22%)
“Substance Abuse Treatment Linked with Prenatal Visits Improves Perinatal Outcomes: A New Standard”

Nancy Goler MD, Mary Anne Armstrong MA, Cosette J Taillac LCSW, and Veronica M Osejo BS

Journal of Perinatology
June 26, 2008
METHODS

Study Members

- 49,985 female KP members
- Completed ES Prenatal Substance Abuse Screening Questionnaires 01/99 - 6/03
- Urine toxicology screening test
- Live birth or Intrauterine Fetal Demise at a KP NCal Hospital
Definition of Study Groups:

- SAT (2073): Screened pos, assessed pos, follow-up
- SA (1203): Screened pos, assessed pos, but no follow-up
- S (156): Screened pos (including toxicology), no follow-up
- C (46,553): Screened negative
"I thought I liked babies, but, as it turned out, I mainly like baby clothes."
### Self-Reported Substance Use on Screening Questionnaires

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>% in group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SAT</td>
</tr>
<tr>
<td>Alcohol weekly/daily since preg</td>
<td>6.6</td>
</tr>
<tr>
<td>Meth weekly/daily since preg</td>
<td>1.3</td>
</tr>
<tr>
<td>THC weekly/daily since preg</td>
<td>14.7</td>
</tr>
<tr>
<td>Alcohol weekly/daily before preg</td>
<td>32.9</td>
</tr>
<tr>
<td>Meth weekly/daily before preg</td>
<td>5.7</td>
</tr>
<tr>
<td>THC weekly/daily before preg</td>
<td>34.1</td>
</tr>
<tr>
<td>Smoked cigarettes during preg</td>
<td>26.6</td>
</tr>
</tbody>
</table>
Rate of delivery before 37 weeks gestational age by study group:

- **SAT**: 8.1%
- **SA**: 9.7%
- **S**: 17.4%
- **Controls**: 6.8%
RATE OF NEONATAL ASSISTED VENTILATION BY STUDY GROUP

- SAT: 3.2%
- SA: 4.2%
- S: 6.9%
- Controls: 2.2%
RATE OF LOW BIRTHWEIGHT (<2500 GRAMS) BY STUDY GROUP

- SAT: 6.5%
- SA: 7.7%
- S: 12.4%
- Controls: 4.7%
RATE OF PLACENTAL ABRUPTION BY STUDY GROUP

- SAT: 0.9%
- SA: 1.1%
- S: 6.5%
- Controls: 0.9%
RATE OF INTRAUTERINE FETAL DEMISE BY STUDY GROUP

- SAT: 0.5%
- SA: 0.8%
- S: 7.1%
- Controls: 0.6%
What could have been for the “S” group (156)?

- 15 more term babies
- 6 more babies breathing without a ventilator
- 9 more babies born at a normal birth weight
- 9 more women not experiencing an abruption
- 10 more babies alive
RESULTS of COST BENEFIT ANALYSIS

Using 2000 Cost Data
30% Estimated Simple Return on Investment

Using 2004 Cost Data
53% Estimated Simple Return on Investment (Projections matched actuals in retrospect)
"Before I came to Early Start, I thought I was never going to get off the drugs. But coming here and talking about my feelings was very helpful. I had to face my drug use so that I was doing everything in my power to give my baby the best chance for proper development."

- Early Start Client

Kaiser Permanente’s confidential Early Start program helps women who are at risk for smoking, drinking alcohol or using drugs to have healthy pregnancies so they can have healthy babies.

Services Offered

Early Start gives you the support you need to make healthy choices regarding cigarettes, alcohol and drugs while you are pregnant and after your baby is born.

Learn more>>>

Mission

The Early Start Program is designed to reduce negative maternal and neonatal outcomes associated with prenatal substance use by making education and early intervention accessible to pregnant women. The key is the integration of substance abuse services with routine prenatal care by adding a licensed counselor, the Early Start Specialist, to the prenatal care team.

Is Early Start for Me?

Dear Expecting Mother:
You are ready to love and care for the new baby growing inside of you. That's a good reason to stop smoking, drinking alcohol and taking drugs today.

Take the quiz>>>

For more information visit the Early Start Web Site http://www.kp.org/earlystart
Appendix Slides

- FDA Drug Classification in Pregnancy
- Fetal Alcohol Spectrum Disorders
- Other drugs
  - Caffeine
  - Cigarettes/Cocaine
  - Methamphetamine
<table>
<thead>
<tr>
<th>Pregnancy Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category A</strong></td>
<td>Adequate and well-controlled human studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters).</td>
</tr>
<tr>
<td><strong>Category B</strong></td>
<td>Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in any trimester.</td>
</tr>
<tr>
<td><strong>Category C</strong></td>
<td>Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.</td>
</tr>
<tr>
<td><strong>Category D</strong></td>
<td>There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.</td>
</tr>
<tr>
<td><strong>Category X</strong></td>
<td>Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.</td>
</tr>
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“We must prevent all injury and illness that is preventable in society, and alcohol-related birth defects are completely preventable.”

Dr. Richard Carmona
U.S. Surgeon General
Prevalence: FAS/FASD

- CDC studies have documented FAS prevalence rates ranging from 0.2 to 1.5/1,000 live births

- Classic medical education states FASD inclusive may be as high as 1 per 100 live births (40,000 infants per year in the US)
Perinatal Effects of Alcohol

- Fetal alcohol syndrome (FAS)
  - Term first used in 1973 by Drs. Smith and Jones at the University of Washington
  - One of the diagnoses used to describe birth defects caused by alcohol use while pregnant
  - A medical diagnosis (760.71) in the International Classification of Diseases (ICD)
Fetal Alcohol Spectrum Disorders (FASD)

- Umbrella term describing the range of effects that can occur in an individual whose mother drank alcohol during pregnancy

- May include physical, mental, behavioral, and/or learning disabilities with possible lifelong implications

- Not a diagnosis
FASD, continued

- All alcoholic beverages are harmful.

- Binge drinking is especially harmful.

- There is no proven safe amount of alcohol use during pregnancy.
FAS and the Brain

Normal brain of baby 6 wks old

Brain of baby same age with FAS

Photo courtesy of Sterling Clarren MD
Terminology: Fetal Alcohol Spectrum Disorders (FASD)

- FAS (Fetal Alcohol Syndrome)
- PFAS (Partial Fetal Alcohol Syndrome)
- FAE (Fetal Alcohol Effects)
  - ARND (Alcohol Related Neurodevelopmental Disorder)
  - ARBD (Alcohol Related Birth Defects)
Diagnosis: FASD

- FASD is diagnosed based on the mother's history, the physical appearance of the baby, and development of the child.

- All must be present for pure FAS:
  - Growth Problems (<10th %)
  - Facial Anomalies (thin upper lip, small eye openings, smooth area from lip to nare)
  - CNS Damage (learning/behavioral problems)
Diagnosis: FASD Features

Mental handicap
Abnormal facial features
Growth problems
Birth defects
Problems with the central nervous system
Trouble remembering and/or learning
Vision or hearing problems
Behavior problems
Treatment: Multifaceted approach

- Raising public awareness regarding the dangers of alcohol use during pregnancy

- Educating and training health and social service professionals how to identify and intervene with women at risk for alcohol-exposed pregnancies
Treatment: Multifaceted approach

- Developing effective intervention programs for children affected by prenatal alcohol exposure
- Promoting and supporting basic research to identify the etiology and mechanisms involved in FAS
- Improving the quality of life of affected persons and families
Improving the quality of life of affected persons and families

- There is no cure
- Effects are lessened with earlier intervention
- Referrals to medical specialists as well as behavioral specialists is often needed
- Family support and education
Caffeine in Pregnancy

- Increases rates of SAB in 1st Trimester
- Decreased ability to metabolize methylxanthines: cross placenta
- Neonates and newborns less tolerant
- No long term effects proven

MDs recommend: Avoiding Caffeine (1/day)
Cigarettes and Pregnancy

- Early Start 2005: 21.63% “smoker only”

- Perinatal Risks:
  - Increased SAB (>10cigs) 1.2-3.4
  - Low Birth Weight 1.5-3.5
  - Placental Abruption 1.4-2.5
  - PPROM 1.9-4.2
  - Preterm Delivery 1.3-2.5
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  - Stillborn 1.2-1.4

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Cigarettes and Pregnancy

- **Long Term Effects:**
  - Respiratory Problems
  - SIDS (increased RR 2.0 – 7.2)
  - Increased Behavioral Problems:
    - **GIRLS:** Increase in substance abuse in adolescents
    - **BOYS:** Increase in Oppositional Defiant Disorder (ODD)*
    - Increase in Conduct Disorder
    - Earlier on-set of significant delinquent behavior*

Cigarettes and Pregnancy

- COSTS: 1995 - $2.0 billion (direct costs only)

- Smoking Cessation Programs

- Pharmacology (eg Bupropion – class B)

- Nicotine Patch – class D
Why follow women who say that they quit drinking at onset of pregnancy?

- Past alcohol use (especially in the month before pregnancy) is associated with greater alcohol use in pregnancy
- Heavy alcohol use before pregnancy is highly predictive of continued use in pregnancy
Why follow women who say that they quit drinking at onset of pregnancy?

- Binge drinking and frequent drinking rates in pregnancy (more than 5 drinks on one occasion or 7 or more drinks per week) have not declined in the past 10 years

- A number of women who binge drink in pregnancy are not alcoholic
My daughter tells three of her friends that it is okay to drink in pregnancy after the first trimester.

The number of women with incorrect information grows astronomically.
Methamphetamine and Pregnancy

- Epidemic in Hawaii and growing in the nation
- Speed, meth, chalk, ice crystal, and glass
- Is easily made in home labs

- Increased rates of smoking ("ice"):
  - 1992: 12%
  - 2002: 50% (HI – 97%; CA – 61%)
Methamphetamine and Pregnancy

- Perinatal Outcomes: Similar to effects of cocaine/amphetamines
  - Placental Abruption
  - Preterm Labor
  - Blood Pressure Crisis
  - Growth Retardation
  - Stillborn
  - Neonatal Withdrawal