

Substance Use in Pregnancy

A Clinician's Toolkit for Screening,
Counseling, Referral and Care



*Presented by:
The Regional Perinatal Advisory Group (RPAG)
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The toolkit online: www.baltimorecountymd.gov/go/perinatal



RPAG
Substance Use in Pregnancy
A Clinician’s Toolkit for Screening, Counseling, Referral and Care
For Maryland Prenatal Care Providers and Substance Use Disorder Treatment Providers

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ACOG - Maryland Section Chair

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Dear Colleague:

As the epidemic of drug and alcohol abuse continues unabated in the United States, the magnitude of impact on the health of the women we serve, as well as their infants, has also grown. This increase has largely been due to the explosion in misuse of legal opioid drugs as well as illicit opioids. Opioid overdose is now the leading cause of accidental death among adults, surpassing motor vehicle accidents, and approaching the number of HIV/AIDS-related deaths that occurred at the height of the HIV/AIDS epidemic. In addition, a 2012 JAMA study estimated that every hour, a baby is born in the United States with evidence of withdrawal from opiates (~13,500 infants per year). Unfortunately, Maryland statistics reflect these national trends.

More than ever, women rely on us for generalized medical care beyond their gynecological and obstetric needs. Adequate screening for threats to the well-being of these women and their offspring has become an integral part of good care. Over the past several years, there have been significant changes in our recommendations for patient screening for depression, HIV, intimate partner violence, and substance misuse.

In an effort to increase knowledge and improve practices among those providing obstetric care, as well as those providing substance abuse treatment to pregnant women, the Regional Perinatal Advisory Group (RPAG) has created Substance Use in Pregnancy: A Clinician's Toolkit for Screening, Counseling, Referral, and Care. This toolkit will be distributed statewide to all sites/providers providing prenatal care and/or substance use disorder treatment, health departments, and hospitals providing obstetrical care.

To provide comprehensive obstetric care, it is up to us to screen all of our patients for substance use and take appropriate actions, based on the results, in an unbiased manner. Indeed, we can make a difference in preventing or mitigating the harmful effects of substance use on our patients and their infants. I trust you will find this toolkit helpful and that it will encourage you to expand your screening for substance use to all your patients, as there is evidence that substance use disorder crosses all socio-economic borders. The Maryland Chapter of the American Congress of Obstetricians and Gynecologists is committed to increasing the available information and tools regarding the problem of substance use in pregnancy in order for our members to continue to provide excellent care for their patients and families.

Sincerely,

A handwritten signature in black ink that reads "Jessica L. Bienstock". The signature is written in a cursive, flowing style.

Jessica L. Bienstock, MD MPH
Chair - Maryland Section
ACOG

Introduction

This toolkit was created for obstetric care providers and substance use disorder treatment providers in order to:

- Provide key information about the impact of legal and illegal substances on a woman's pregnancy and on the unborn child.
- Help professionals take better care of the pregnant woman who has been using or abusing substances.
- Improve the collaboration between obstetric and substance use disorder treatment providers in the care of pregnant women who are misusing drugs or other substances.

Use of legal and illegal substances occurs in all racial, ethnic and socio-economic groups. The use of tobacco and alcohol, misuse of prescription medications, as well as the use of illegal drugs contribute substantially to maternal, fetal, and neonatal morbidity and mortality. In addition, there is increasing evidence that use of some of these substances during pregnancy can have long-term impact on the child's development and behavior. Pregnant women misusing substances are at greater risk for HIV infection and domestic violence than the general population.

Misuse of legal and illegal drugs, alcohol, and tobacco often is not disclosed without specific questioning. Skillful screening for use, counseling about the risks associated with use, referral for treatment, and continuing collaboration between those offering treatment and those caring for the woman's pregnancy are critical to providing optimum care. In order to give their infants the best chance in life, pregnant women are often more open to behavior change. They may be motivated to address substance use issues in an effort to protect their unborn infant. We hope this toolkit will help address the important problem of substance misuse and give you direction as you care for the pregnant woman and her unborn child.

Scope of the Problem

Tobacco Use

Nationally

- Cigarette smoking rates are lower in pregnant women aged 18 to 44 than their non-pregnant counterparts, but 22.7% of pregnant women aged 18 to 25 and 11.8% of pregnant women aged 26 to 44 continue to smoke throughout pregnancy.¹
- Tobacco use during pregnancy is associated with preterm labor, lower birth weights, fetal deaths, and a variety of other pregnancy complications.²
- Tobacco use rates are especially high in adults who also abuse other drugs. Among adults in treatment for substance abuse, studies report as many as 80-98% also use tobacco.³
- Maternal smoking during pregnancy and after birth is estimated to account for one third of the Sudden Infant Death Syndrome deaths in the U.S.⁴
- Maternal smoking during pregnancy has also been associated with a substantial increase in the risk of Attention Deficit Hyperactivity Disorder (ADHD) and other behavior disorders.⁵

In Maryland

- About 7% of Maryland women continue to smoke during pregnancy.⁶

Alcohol Use

Nationally

- An estimated 10.8% of pregnant women report current alcohol use, 3.7% report binge drinking and 1.0% report heavy drinking. Of special concern, 10.1% of women 15 to 44 years old report binge drinking during the first trimester of pregnancy, often before they knew they were pregnant.¹
- An estimated 1 - 2 infants per 1,000 live births has Fetal Alcohol Syndrome (FAS). Fetal Alcohol Effects Syndrome (FAES) is estimated to occur in 3 - 6 infants per 1,000 live births.
- Fetal Alcohol Syndrome is one of the most common known etiologies of intellectual disability. Children with fetal alcohol syndrome often have severe ADHD and complex learning and behavior problems in addition to the physical and global intellectual problems associated with the disorder.

In Maryland

- 9% of pregnant women in Maryland continue to consume some alcohol, 1% still binge drink while pregnant.⁶
- Nearly one out of three women in Maryland report not receiving information about the effects of alcohol on the pregnancy or the developing fetus.⁷
- Women who most frequently report alcohol use during pregnancy (white college educated women over age 35) were the same group that reported the lowest levels of alcohol screening and counseling.⁷

Illicit Drugs and Non-Medical Use of Prescription Drugs

Nationally

- 16.2% of pregnant teens and 7.4% of pregnant women ages 18 to 25 are using illicit drugs according to the 2010 National Survey on Drug Use and Health from the Substance Abuse and Mental Health Administration. Overall, 4.4% of pregnant women were active illicit drug users.¹
- Rates of neonatal abstinence syndrome (NAS), drug withdrawal in the newborn, have almost tripled between 2000 and 2009.⁸
- 18.1% of 18 to 25 year olds report illicit drug use and 5.9% report the non medical use of prescription drugs.¹

In Maryland

- Maryland Pregnancy Risk Assessment Monitoring System (PRAMS) does not ask questions about drug use during pregnancy but rates are presumed to be similar to national data.
- Maryland PRAMS states that only 60-70% of women report being counseled about the risks of alcohol use, smoking or illicit drug use during pregnancy while 90% were counseled about medications that are safe during pregnancy.⁶

Notes

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3. Baca CT, Yahne CE. Smoking Cessation During Substance Abuse Treatment: What You Need to Know. *J Subst Abuse Treat*. 2009; 36 (2): 205-219. doi: 10.1016/j.jsat.2008.06.003.
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6. Prevention and Health Promotion Administration, Vital Statistics Administration, and Pregnancy Risk Assessment Monitoring System Team. *Maryland PRAMS Report: 2011 Births*. Baltimore: Department of Health and Mental Hygiene, Maternal and Child Health Bureau, March 2013.
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Screening, Counseling and Intervention

Screening is important to identify factors which can be modified or which would affect your care of the pregnant woman. The goal is to identify most of the people who might have a risk factor and then further assess to determine who truly has the condition or risk factor. Counseling about the risk factors, even if the screening is negative, is important since the first screen may not pick up everyone. Counseling also provides education to prevent onset of new risks. Early intervention involves discussing your concerns with the patient and beginning the process of further evaluation and/or treatment if appropriate.

Screening

Screening for drug use, both legal and illegal substances, as well as alcohol and tobacco use is crucial and should occur at the initial visit, at least once every trimester, and at the postpartum visit for **every** pregnant woman. Several examples of standardized questions and/or questionnaires for conducting this screening are included in this section.

Initial Visit:

- Screen Everyone - Providers should be aware that they will miss many cases if they screen based on their personal perception of risk (physical appearance, socio-economic status, age, race or ethnicity).
See Toolkit Section One - Scope of the Problem on pages 1.2 – 1.3 for data.
- Conduct Screening in Private:
 - It is important to screen in a private place and with the person alone.
 - This protects the individual's right to privacy.
 - Screening her alone is important as she may be unwilling to confess to alcohol or substance use/abuse (or domestic violence) in the presence of a partner or a friend.
- Conduct an extensive inquiry about drug, alcohol and tobacco use:
 - Legal drugs – including prescriptions written by a different provider
 - Illegal substances
 - Alcohol
See chart for standard size drink equivalent on page 2.18.
 - Tobacco products including smokeless products
- Consider inquiring about the person's use in three time periods:
 - Ever
 - During the three months prior to getting pregnant
 - During the interval after conception but prior to this first visit
- Select a process for screening:
 - Completed standardized questionnaire (print version, computer version, or administered by a staff member)
 - Asked by clinician as part of history
 - Included by clinician or nurse in a “review of systems”

At Follow-Up Visits:

- For those who **screened positive** at the initial visit, include questions about any alcohol, tobacco product, or drug (legal or illegal, prescribed or not) since the last visit at each visit.
- For those who **screened negative** at the initial visit, re-screen each trimester.

This re-screening is important because new use may be uncovered and also because the patient may disclose more as she gets more comfortable with the clinical staff over time.

We also recommend screening for depression and for intimate partner violence, using the same screening schedule – first visit, each trimester, and at the postpartum visit.

See Toolkit Section 10 – Addenda - Depression on pages 10.2 - 10.3 and Intimate Partner Violence on page 10.12 for screening tools.

Tools for substance use screening and details about these tools are included in this section on pages 2.3 through 2.12.

Tools to Use for Screening

Several sample tools are included in this section. Some can be given to the patient to complete in writing while she is waiting for her obstetric provider, while others are a set of questions to be asked. You should choose the one that best fits your practice and your patient flow.

It is important to document the tool you used for screening, any positive results, and any intervention that you did. Billing for screening and early intervention requires using “structured screening” as well as carrying out early intervention.

Any of the following tools would be considered acceptable as “structured screening.” Copies of each follow with descriptions, information about how to administer and some of the characteristics of each.

TAD (Tobacco, Alcohol and Drug) Questionnaire

This was developed by the Regional Perinatal Advisory Group in order to address a wide range of exposures that might affect the woman's pregnancy and the development of the fetus. It can be completed by the patient while waiting for the provider or the questions could be asked and answers recorded by your office staff. Be careful about asking the patient to complete this in the waiting room, as that may not afford adequate privacy for answering truthfully.

- If the patient reports never using in a category, it is unlikely that they are using during their pregnancy or will start during the pregnancy. These would be low risk patients.
- If the patient reported use prior to getting pregnant but not since, most truly stopped. However, the clinician should use judgment about how often to ask these questions again as some will restart.
- If the person reports any use during pregnancy, further questions should be asked to delineate extent of use and counseling should be provided about the dangers of tobacco, alcohol and drug use during pregnancy, including use of over the counter and prescribed drugs not specifically approved by the obstetric care provider.
- If the patient feels they may be unable to stop use without assistance, they should be referred to a substance use disorder treatment program for further evaluation and intervention.

TAD Questionnaire*

Name: _____ Date: _____

Please check the appropriate box for any of the following that you have ever used, used prior to getting pregnant and/or used within the last month (even once).

Your answers will help your health care provider work with you to make your pregnancy as safe as possible and to protect the health of your baby.

	Ever used	Used during the three months before getting pregnant	Used even once during last month
Vitamins other than a daily multivitamin			
Herbal products			
Tobacco products (cigarettes, cigars, chewing tobacco, snuff, etc.)			
Alcohol (including beer, wine, wine coolers, as well as hard alcohol such as gin, vodka, scotch, etc.)			
Prescription drugs other than ones prescribed by the doctor or nurse practitioner caring for you during your pregnancy			
Illegal drugs (taken by mouth, snorted, inhaled, or injected)			

**Developed by the Regional Perinatal Advisory Group*

4 Ps Patient Questionnaire

This tool was described by H. Ewing from the Born Free Project in Martinez, California. It can be given to the patient to complete and then the clinician should follow up on any positive responses with further questions or the clinician can just ask these questions and document the response. Of concern is that it does not cover tobacco. See below for one possible solution to this.

4 Ps Plus T Questionnaire

The Regional Perinatal Advisory Group adapted the 4Ps by adding tobacco since recent evidence suggests that this has substantial impact on the pregnancy as well as impact on the developing fetus. This tool can be given to the client to complete. Alternatively, either the support staff, once the patient is in the exam room, or the obstetric provider can ask these questions and document the answer. The clinician should follow up any positive responses with additional questions to clarify use and answers should be documented in writing. Again, the patient admitting to substance use (tobacco, alcohol or drugs) during the pregnancy warrants counseling (brief intervention) and possible referral for further assessment and/or formal substance use treatment. If the patient reports parental or partner misuse or personal use prior to getting pregnant, a question about current use should be asked again at subsequent visits.

4 Ps Patient Questionnaire

Name _____ Date _____

Please answer each question below.

Yes No

Have you ever used drugs or alcohol during this pregnancy?

Have you had a problem with drugs or alcohol in the past?

Does your partner have a problem with drugs or alcohol?

Do you consider one of your parents to be an addict or an alcoholic?

4 Ps Plus T Questionnaire*

Name _____ Date _____

Please answer each question below.

Yes No

Have you ever used drugs, alcohol or tobacco during this pregnancy?

Have you had a problem with drugs, alcohol or tobacco in the past?

Does your partner have a problem with drugs, alcohol or tobacco?

Do you consider one of your parents to be an addict, an alcoholic, or unable to stop smoking?

**Adapted by the Regional Perinatal Advisory Group from the 4Ps Questionnaire described by H. Ewing of the Born Free Project, Martinez, CA*

CAGE-AID Questionnaire

This questionnaire was developed by Dr. Richard Brown and asks questions in a structured format about alcohol and drug use. It was developed to identify those addicted to alcohol or drugs, not merely those who use them and does not address tobacco use at all. It also may not identify those misusing prescription drugs. Any positive answer warrants further questions. A single positive answer has a sensitivity of 0.79 and a specificity of 0.77 for identifying those addicted. Two or more positive answers make it highly likely that the person is addicted and needs formal treatment to stop. This questionnaire would need to be supplemented with questions about prescription drug use and tobacco use for optimal care of the pregnant woman.

CAGE-AID QUESTIONNAIRE

Name _____ Date _____

Please answer each question below.

When thinking about drug use, include illegal drugs and the use of any prescription drugs other than prescribed.

Questions:	Yes	No
1. Have you ever felt that you ought to cut down on your drinking or drug use?	<input type="checkbox"/>	<input type="checkbox"/>
2. Have people annoyed you by criticizing your drinking or drug use?	<input type="checkbox"/>	<input type="checkbox"/>
3. Have you ever felt bad or guilty about your drinking or drug use?	<input type="checkbox"/>	<input type="checkbox"/>
4. Have you ever had a drink or used drugs first thing in the morning to steady your nerves or to get rid of a hangover?	<input type="checkbox"/>	<input type="checkbox"/>

Permission for use granted by Richard Brown, M.D.

DHMH Client Assessment Screening Form

This was developed by the Bureau of Maternal and Child Health at the Maryland State Department of Health and Mental Hygiene. It is an easy to read questionnaire that can be completed by a woman in the exam room while she is waiting to be seen. Alternatively, a staff member can read the questions and record her responses to them.

It was intended for use with women during regular health care. When used with pregnant women, it may miss those who have been misusing drugs that were originally supplied for a legitimate use as well as people who may be causing harm to their babies by tobacco use or alcohol use below the level of abuse. Both of these groups need counseling about their drug use as well. Any positive response warrants further questions and counseling.

MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE
CLIENT ASSESSMENT SCREENING FORM

Last Name	First Name	Phone Number () -	Date
Tobacco			
Tobacco Use: current former never			
If you checked "current," are you willing to quit at this time? yes no			
Depression			
1. Over the past two weeks, have you ever felt down, depressed, or hopeless? yes no			
2. Over the past two weeks, have you felt little interest or pleasure in doing things? yes no			
Alcohol Use			
1. How many times in the past year have you had 4 or more drinks in a day? _____ One drink is a 12 ounce can or glass of beer or cooler, a 5 ounce glass of wine, or a drink containing 1 shot of liquor			
Drug Use			
1. How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons? _____			
Relationship Safety			
1. Has your current or former partner ever threatened you or made you feel afraid? (stalked you, insulted you, threatened you with a weapon, threatened to hurt you or your children if you did or didn't do something, controlled whom you talk to/where you go/how you spend money) yes no			
2. Has your partner hit, strangled, or physically hurt you? ("hurt" includes being hit, slapped, kicked, "choked" [or strangled], bitten, shoved) yes no			
3. Has your partner made you have sex when you didn't want to? yes no			
Other			
Are there any other issues you would like to discuss with your provider? _____ _____ _____			

Counseling and Intervention

When Screening Is Negative

Counseling about the risks of alcohol, tobacco and drug use outside of what has specifically been approved by the clinician should occur following screening, even when the person denies use.

Potential script if screening is negative:

- I am glad to see that you are not using alcohol, tobacco or medications and drugs except those cleared by me.
- This is important because these substances can cause increased risks to you during your pregnancy.
- They also may cause long-term damage to your unborn baby.
- Please continue to avoid alcohol, tobacco, and drugs.
- And check with me before taking any medications not prescribed by me.

When Screening Is Positive

When screening is positive, ask further questions to confirm and delineate on-going tobacco, alcohol, or drug use, and provide intervention.

When use is disclosed, more questions are necessary to define the problem including details about what drugs, when, how often and how much. This further assessment might be done by the obstetric care provider and/or by an addictions specialist. However, the obstetric care provider will need to ask enough questions to determine whether this is an on-going problem and whether it is something that the person could easily stop doing or is likely to require professional help to stop. Counseling then needs to be specific to the identified issue and then intervention should be directed at helping the patient recognize the risks of her substance use and facilitating her getting treatment, if warranted. Further details are provided in the next section.

There are a variety of models for brief intervention. While they are called different names (SBIRT for screening, brief intervention, referral and treatment; SART for screening, assessment, referral, treatment; or motivational interviewing), they all use a similar language for the early intervention and have similar goals of indicating your concerns, providing information about why you are concerned, encouraging the person to address the problem, and providing help in seeking treatment.

On the next page is a potential script for your intervention.

Brief Intervention

1. I am concerned about your use of _____ because of the risks to your health and to your baby's health.

(insert some details if appropriate – see below or see chart for key impacts)

See Toolkit Section 4 on pages 4.3 through 4.23 for Table of Substances and Their Effects

- **alcohol** – major risks for the baby – most common preventable cause of mental retardation, risks of major learning and behavior problems, congenital anomalies
- **opioids/narcotics** – drug withdrawal for the baby and difficulty with self regulation for months afterwards
- **cocaine, stimulants, methamphetamine, hallucinogens** - risks of stroke for mother or baby, premature delivery, too small a baby, difficulty focusing on caring for yourself and for the baby, neglect of the baby, etc.
- **tobacco and marijuana** – risks of premature delivery, too small a baby, respiratory problems for the baby, SIDS, and hyperactivity risks in the child

2. Is this something you are concerned about too?

3. Do you think this is something that you can change?

4. These (drugs, smoking, drinking) can be hard for many people just to give up. Do you need some help with addressing this problem?
What kind of help would you like?

5. Are you ready to tackle this now or do you want to give it some thought over the next week?

- If now, let's develop a plan together.
- If not now, we'll schedule a time for you to come back in a week so we can develop a plan together.

Documentation of Screening and Brief Intervention

Make sure you document the screening tool or questions used in the patient chart as well as any positive responses. Also document the brief intervention done for any positive responses – both for the purpose of good documentation and care, and to support billing.

See next page on billing

Examples:

- Patient screened using 4 P's plus alcohol questions. No positive responses.
- Patient screened using RPAG TAD screen. Only positive result was to tobacco use. Counseled to stop tobacco use and gave list of places where she can get assistance in quitting smoking.
- Patient screened using DHMH screen. Also asked additional questions about any tobacco or alcohol use. Positive for depressive symptoms. On further questioning, has long-standing history of depression but stopped depression meds prior to trying to get pregnant. Referred for additional psychiatric assessment and counseled about the benefits and risks of antidepressants during pregnancy.

Billing

Billing for Screening and Brief Intervention

Many insurance companies provide a mechanism for billing for this screening and intervention since it is crucial to providing appropriate care for your pregnant patient. Addressing these kinds of problems has the potential to substantially reduce the costs both for obstetric care and for care of the newborn after birth.

Use the codes below when the screening is positive and you have provided the appropriate assessment, brief intervention, and/or referral.

Billing for Care Provided for a High Risk Pregnancy

If the substance misuse is such that referral for treatment is necessary or the patient already is in on-going treatment, the pregnancy may well require closer monitoring because of the increased risk factors to the mother and her fetus, and your care may qualify for billing as a high risk pregnancy.

Billing Codes and Reimbursement Rates for Screening and Brief Intervention

from SAMHSA (as of 06/27/2014) – see website for details –
<http://www.samhsa.gov/prevention/sbirt/coding.aspx>

Payer	Code	Description	Fee Schedule
Commercial Insurance	CPT 99408	Alcohol and/or substance abuse structured screening and brief intervention services; 15-30 minutes	\$33.41
Commercial Insurance	CPT 99409	Alcohol and/or substance abuse structured screening and brief intervention services; greater than 30 minutes	\$65.51
Medicare	G0396	Alcohol and/or substance abuse structured screening and brief intervention services; 15-30 minutes	\$29.42
Medicare	G0397	Alcohol and/or substance abuse structured screening and brief intervention services; greater than 30 minutes	\$57.69
Medicaid	H0049	Alcohol and/or drug screening	\$24.00
	H0050	Alcohol and/or drug service, brief intervention; per 15 minutes	\$48.00



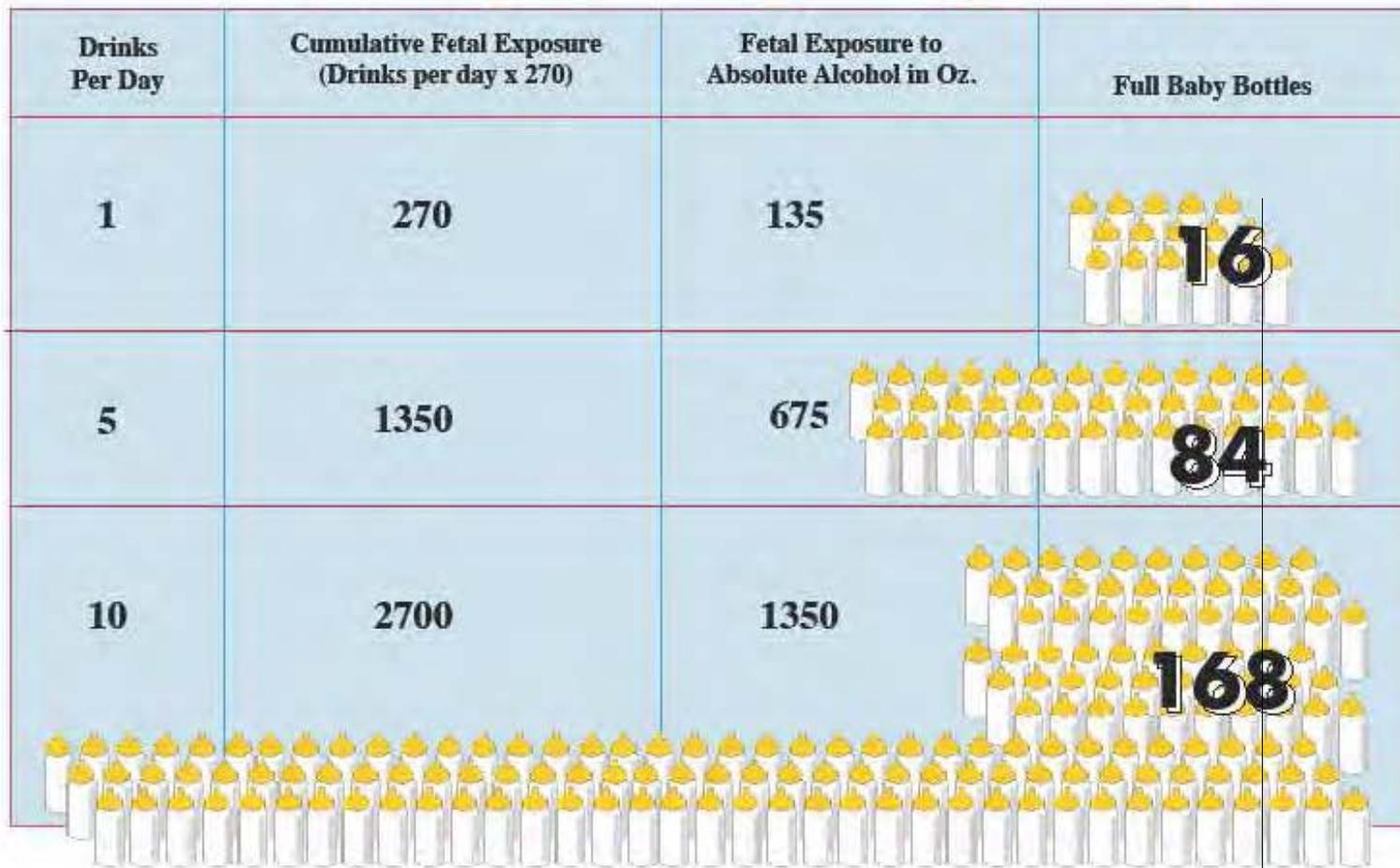
WHAT IS AT RISK ALCOHOL USE FOR WOMEN

- **Any drinking during pregnancy** or when medically contraindicated
- Greater than 3 drinks/occasion
- Greater than 7 drinks/week

STANDARD DRINK EQUIVALENT (1 SDE = 15cc absolute alcohol)

- Beer or Cooler – 12 oz
- Table Wine – 5 oz (750 ml bottle = 5 drinks)
- Malt liquor – 8-9 oz (12 oz can = 1.5 drinks)
- 80 proof spirits – 1.5 oz (a mixed drink may contain 1 to 3 or more SDEs)

Drinking During Pregnancy



Created by: Larry Burd, Ph.D. | Fetal Alcohol Syndrome Center
 1.888.8CJ.SIDS | www.cjsids.org



Smoking During Pregnancy

Cigarettes Per Day	Cumulative Fetal Exposure (Cigarettes per day x 270)	Full Packs of Cigarettes
1	270	13 
5	1350	67 
10	2700	135 

Created by: Larry Burd, Ph.D. | Fetal Alcohol Syndrome Center
 1.888.8CJ.SIDS | www.cjsids.org



Referring a Patient for Substance Use Disorder Evaluation and Treatment

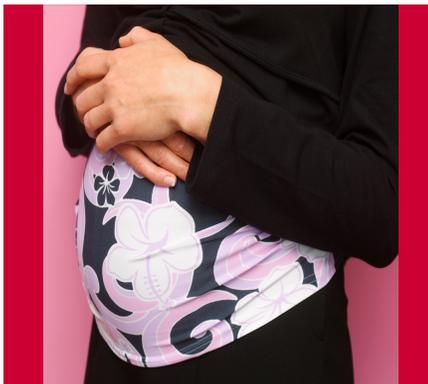
If you determine that a pregnant patient needs further evaluation or treatment for substance use, the next step is finding a treatment provider. Finding a provider is based on what kind of health insurance, if any, the woman has. It may be helpful to have a member of your staff assist the patient in making phone calls. Ideally, she should not leave your office until she has an appointment scheduled. **Any treatment provider in Maryland that accepts state funds (Medical Assistance or grant funds) is mandated to see a pregnant woman within 24 hours of initial contact.** See below for direction in finding a treatment provider:

- **Private insurance** – You or your office can contact the company for information on benefits and covered providers. A covered provider will do a substance use evaluation and, based on the findings, refer the patient to the proper level of treatment.
- **Medical Assistance** – For information on patient benefits and covered providers you or your office can contact ValueOptions at 1-800-888-1965. They can assist you with finding a substance use disorder treatment provider in your area. The provider will do a substance use evaluation to determine the proper level of treatment and refer the patient to the appropriate care.
- **Uninsured** – You or your office can contact the local health department Local Addictions Authority for information on available resources for uninsured pregnant women. Some health departments provide treatment, others contract out and purchase treatment services through community providers. Either way, treatment should be available on a sliding fee scale to anyone who does not have health insurance.

If you need additional help, guidance, or consultation about a specific case, please contact the Local Addictions Authority at your local health department for assistance. A list of these in each county can be found at the Maryland Alcohol and Drug Abuse Administration website.

http://bha.dhmdh.maryland.gov/Documents/QUICK_LINKS/LocalAddictionsAuthority_LAA.pdf

Alcohol and Drug Use in Pregnancy



Alcoholics Anonymous
www.aa.org

Narcotics Anonymous
Free State Region Hotline
1-800-317-3222
www.freestatena.org

Maryland Alcohol and Drug Abuse Administration
Treatment Coordinators
by county
www.adaa.dhmh.maryland.gov (Quick Links)



Using alcohol, illegal drugs or misusing prescription drugs while pregnant can harm your unborn child. Getting into treatment is important for a healthy baby.

Addiction is a complex condition. Do not be embarrassed to ask for help. Taking steps to recover from alcohol or drug use will reduce the health risks for you and your baby.

You may need medically supervised detoxification or be referred for opioid maintenance treatment. Withdrawal

should not be attempted without your physician's approval, as it may result in serious harm to you or your baby. If you are in a treatment program already, tell them you are pregnant.

Outpatient and inpatient treatment for drug and alcohol problems is available. You may need to make some phone calls or get an approval from your insurance company to get an evaluation for treatment.

Pregnant women are given priority for assessment and treatment.

Steps to Finding a Treatment Provider

1. If you have **private insurance**:
 - a) Call your insurance company to ask about your benefits and eligibility requirements for substance abuse treatment.
 - b) Ask for names of "in-plan" or "in-network" providers.
2. If you have **Maryland Medical Assistance (MA)**:
Call ValueOptions at 1-800-888-1965 to ask for a treatment provider in your area.
3. If you **have no health insurance**:
 - a) Call the Health Department in the county where you live.
 - b) Ask about treatment for someone without insurance—**make sure to inform them you are pregnant!**
4. Make an appointment for an evaluation. An evaluation by a substance abuse treatment provider will help determine the kind of treatment that you need. The evaluator should be able to assist you in finding an appropriate provider.
5. While you are trying to arrange for treatment, begin attending a support group such as Alcoholics Anonymous or Narcotics Anonymous.

Substance Use Disorder Treatment in Pregnancy

It is well known that substance misuse during pregnancy may be harmful to the pregnant woman, the fetus and the neonate. Pregnancy is an opportune time to help women engage in treatment for substance use disorders as recovery is associated with healthier short and long term outcomes for both the mother and her child. The ideal would be to eliminate all harmful substance use during pregnancy. However this is often not feasible and the rapid removal from some substances can cause severe withdrawal in the pregnant woman with the potential for adverse fetal effects.

Substance Use Terms

Addiction is a compulsive drive to take a drug despite adverse consequences. Some of the resulting behaviors of addiction may include:

- Substance use in larger amounts or over a longer period than intended
- Persistent desire for the drug or unsuccessful efforts to cut down or control use of the drug
- Craving, or a strong desire or urge to use the substance
- Failure to fulfill major role obligations at work, school, or home
- Continuance despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance

Substance Use Disorder is a cluster of cognitive, behavioral, and physiological symptoms indicating the continued use of a substance, despite significant substance-related problems. Overall, the diagnosis of a substance use disorder is based on a pathological pattern of behaviors related to the use of a substance. Substance use disorder is the umbrella term for the misuse of tobacco, alcohol, and legal and illicit drugs. It encompasses everything from a mild misuse to a severe state of chronically relapsing, compulsive drug taking. The substance use disorder diagnosis covers a broader range of misuse than addiction alone.

Physical Dependence occurs when abruptly stopping the drug leads to withdrawal symptoms. Physical dependence often occurs with medications being misused, but it also can occur with medications taken in a prescribed way for a medical condition.

Tolerance is the physiological need for a higher drug dose to attain the same effect. It is common in addiction and dependence.

Withdrawal is the presence of discomfort, distress, and intense craving for a substance when use of the substance is abruptly stopped. These symptoms occur because the body has become physiologically adapted to the substance. The withdrawal symptoms can range from mild discomfort resembling the flu to severe withdrawal that can be life threatening. While withdrawal can occur with many substances, the most pronounced withdrawal syndromes occur with opioids, benzodiazepines, and alcohol. Withdrawal symptoms are varied and can include gastrointestinal, integumentary, musculoskeletal, neurologic, and respiratory problems. Effective medications exist for many substances to safely manage withdrawal in the short and long term, and to prevent relapse to unhealthy substance use.

Withdrawal Management/Detoxification is the procedure by which one attempts to eliminate the substance entirely from the body. Detoxification may take place in an inpatient setting or in a closely supervised outpatient setting, and should only be attempted under medical supervision by specially trained personnel. The patient must be medically evaluated to participate. Many patients have prolonged withdrawal symptoms even after detoxification has been achieved. Because of this and because of the risk of resumption of drug use, detoxification should be followed by structured substance use disorder treatment or long term supportive therapy.

Maintenance Therapy is the regular administration of an opioid agonist medication (methadone or buprenorphine) to treat opioid addiction or dependence. The medication is administered at a steady dose sufficient to suppress withdrawal symptoms and drug cravings, but allows alertness and active participation in activities of daily living.

Recovery from substance use disorder is the process of change through which individuals improve their health and wellness, live self directed lives, and try to reach their potential.

Referral for Treatment

Referral to an alcohol and drug professional counselor may be made through a patient's medical insurance, a hospital social worker or the local health department substance abuse coordinator. The American Society of Addiction Medicine (ASAM) has set standards for patient placement into the various levels of care. In order to determine what kind of treatment is best, an alcohol and drug professional counselor performs a complete evaluation using these standards to make the appropriate recommendation and referral.

See this section of Toolkit, page 3.1 for more referral information.

Levels of Care

A brief description of the most common levels of care follows, starting from less intensive to most intensive treatment for any substance use disorder. Medications used in the treatment of specific substance use disorders may be included at any level of care. In Maryland, all levels of care are covered either by insurance or through state and federal grant funds with pregnant women classified as a priority group.

Level 1 – Outpatient Treatment:

- Usually includes individual, group, and family counseling and education.
- Usually includes one or two sessions weekly (no more than nine hours of services per week).
- Sometimes includes medical and/or psychiatric assessments, referrals and/or interventions.
- Usually includes some case management.

Level 2 – Intensive Outpatient Treatment:

- Usually includes individual, group, and family counseling and education.
- Defined as nine or more hours of services weekly.
- Often includes psychiatric assessment and interventions.
- Usually includes case management including referrals to other services such as medical care.
- May include withdrawal management with a medication taper.

Level 3.1–Low Intensity Residential Rehabilitation (Halfway House):

- Defined as at least 5 hours of services weekly.
- Provides a residential setting with 24 hour non-medical recovery environment.
- May provide some case management.

Level 3.3 –Medium Intensity Residential Rehabilitation:

- Provides a residential setting with 24 hour counseling support.
- Provides a structured therapeutic community that includes individual, group, and family counseling.
- Includes psychiatric interventions and referrals to other services such as medical care.

Level 3.7 – Medically Monitored Intensive Inpatient Treatment:

- Provides a residential setting with 24 hour medically monitored care.
- Includes individual, group, and family counseling and education in a highly structured setting.
- Includes psychiatric interventions and referrals to ancillary services.
- May include medically monitored withdrawal management and detoxification.

Medication Assisted Treatment for Opiate Dependence:

- Provides methadone maintenance under the supervision of a physician and dispensed by nursing staff.
- Requires daily attendance until the patient is stabilized.
- Provides individual, group, and family counseling and education.
- May include psychiatric interventions and referrals to ancillary services.
- Must be provided at a state licensed clinic.

Substance Use Disorders Treatment with Medication

Alcohol

Withdrawal management/detoxification is usually managed with thiamine replacement and a pharmacologic taper. Benzodiazepine is the medication taper that is usually used during pregnancy. Adjuvant counseling should also be provided. In the **post partum** period three other medications are available as part of the treatment of alcohol use disorder. They are disulfiram (Antabuse), acamprosate (Campral), and injectable or oral naltrexone (Vivitrol or Revia).

Benzodiazepine and Other Sedatives

Currently, no effective maintenance medications exist to help patients stabilize and manage sedative use disorder, so withdrawal management/detoxification is the main treatment option. Because of the risk of benzodiazepine withdrawal seizures, withdrawal management/detoxification is most safely conducted in a medically monitored setting. Benzodiazepine detoxification is a difficult process with a very high failure rate. Many patients have prolonged withdrawal symptoms, including severe anxiety. Because of this, detoxification should be followed by long term therapy, including substance use disorder treatment and mental health care.

Cannabis, Cocaine, Club Drugs, Hallucinogens and Stimulants

Unfortunately, no specific medications are available for the treatment of these disorders. Management of withdrawal symptoms coupled with counseling is the standard of care.

Opioids

Opioid detoxification is controversial in pregnancy due to concern about potentially harmful effects on the fetus. Because there are significant changes to the central nervous system that occur with chronic opioid use, many patients have prolonged withdrawal symptoms. Opioid detoxification treatment also has a very high failure rate. For these reasons, detoxification in pregnancy should be followed by long term therapy, including substance use disorder treatment and mental health care.

Maintenance analog therapy has been associated with the most successful outcomes, often through prolonged treatment over years or a lifetime. Methadone and buprenorphine are the two maintenance medications that are currently used in the United States in the treatment of opioid disorder during pregnancy. Both methadone and buprenorphine allow for stabilization of dysfunctional brain physiology and disordered neurocircuitry. The two medications are different in their pharmacology and in their delivery systems.

The goals of treatment with either methadone or buprenorphine during pregnancy:

- Elimination of opioid seeking behaviors
- Cessation of illicit opioid use
- Stabilization of intrauterine environment
- Stabilization of patient's environment
- Increased compliance with prenatal care
- Enhanced pregnancy outcomes
- Ability to live a self directed life and to try to reach one's potential

Methadone Maintenance Therapy

Methadone maintenance therapy has been used in the treatment of opioid addiction since the 1960s. It has been the “gold standard” for treating opioid addiction in pregnant women since the 1970s. Methadone is a synthetic, full opioid agonist that acts on the opioid receptor system in a manner similar to morphine, but the half-life is longer at 24 to 36 hours.

When methadone is used as part of the treatment for opioid addiction, it must be done through a certified opioid treatment program (OTP). Because of strict federal regulations, methadone for maintenance therapy cannot be initiated during a hospital stay unless done in cooperation with a certified opioid treatment program which can continue treatment after hospital discharge. Physicians are prohibited from prescribing methadone for maintenance outside of a certified methadone program.

All opioid treatment programs (OTPs) are required to provide counseling and comprehensive urine toxicology testing in addition to medication. Patients are required to report every day to receive their oral dose of medication until they are stable enough to be given some doses to self-administer. Progress in treatment is measured by regular attendance at the clinic (not missing days/doses), regular attendance at counseling sessions, and cessation of illicit drug use (negative urine toxicology reports).

Although methadone treats opioid withdrawal symptoms, prevents future withdrawal symptoms, and reduces cravings for opioids, it has no direct effect on other substances. As with all opioids, patients develop physical dependence on methadone so abrupt cessation or large decreases in a maintenance dose will cause withdrawal.

Methadone Dosing During Pregnancy

The average daily dose of methadone ranges from 30 - 140 mg to eliminate opioid withdrawal symptoms and reduce cravings for opioids. Dosing is individualized to the patient’s needs. There are, however, no established guidelines for methadone dosing during pregnancy.

In several studies, the severity of Neonatal Abstinence Syndrome (NAS) has not been found to be dose dependent when the maintenance dose is in the 30 - 140 mg range. About 60% of infants born to mothers maintained on methadone will require medication for NAS.

Generally, methadone doses do not have to be increased during pregnancy unless there is evidence of ongoing or new withdrawal symptoms. Decreasing or tapering the dose of an established methadone maintenance patient is not recommended during pregnancy, unless the patient appears overly sedated. Despite this, there may be instances where the benefits of tapering outweigh the risks. In these cases, in a closely monitored setting, the dose of methadone can be slowly reduced as tolerated by the patient.

If a woman presents to the hospital and reports missing a dose of methadone, the amount and date of the last dose must be confirmed with her treatment program before prescribing a replacement dose. The standard used in determining how much to replace is as follows:

- If 1 day has been missed, prescribe 1 full dose.
- If 2 days have been missed, prescribe a ½ dose.
- If 3 days have been missed, do not prescribe medication without consulting with the medical director of the patient’s opioid treatment program.

Buprenorphine Maintenance Therapy

Buprenorphine has been approved for treatment of opioid addiction since 2002. It is a semi-synthetic, partial opioid agonist. The pharmacologic half-life for buprenorphine is 24 to 60 hours so there is a long-duration of action. It is usually given on a daily basis, but can be given several times per week, due to this property. It is given sublingually and reaches plasma concentrations within 90 minutes.

Buprenorphine alone (trade name Subutex), rather than the combination drug, buprenorphine and naloxone (Suboxone), is used to treat opioid addiction during pregnancy. According to the Drug Addiction Treatment Act of 2000 (DATA 2000), specially qualified physicians may prescribe buprenorphine for the treatment of opioid addiction in office-based settings. Counseling is strongly encouraged with buprenorphine therapy. For more information on DATA 2000 and buprenorphine, please visit the Substance Abuse and Mental Health Services Administration website at <http://buprenorphine.samhsa.gov/index.html>.

At lower doses, buprenorphine acts pharmacologically in a similar way to morphine and methadone. However, as the dosage increases, the effect of buprenorphine reaches a maximum level and does not increase further. This is a “ceiling effect” and is due to the partial agonist properties of buprenorphine. The ceiling effect applies to all effects of the drug, including analgesia, euphoria, and respiratory depression. As higher doses are reached, the drug can act like an antagonist by occupying receptors, but not fully activating them. This property of buprenorphine results in a safer clinical profile. Buprenorphine may be associated with a lower level of physical dependence than methadone and other opioids. Also, the withdrawal syndrome associated with buprenorphine discontinuation or taper may be milder in intensity.

The National Institute of Drug Abuse (NIDA) multi-centered trial of 2002 supported buprenorphine’s effectiveness and safety in short term withdrawal management (at doses of 8-12 mg/day) and in long term maintenance (at doses of 4-32 mg/day). Other research on buprenorphine in pregnancy has shown that the effects on infants were similar to in utero methadone exposure. The 2012 multicenter study, Maternal Opioid Treatment: Human Experimental Research (*MOTHER*), compared methadone to buprenorphine maintenance in pregnancy. It demonstrated that buprenorphine was at least as safe as methadone and may have some advantages. While this one study showed potential advantages of buprenorphine maintenance in pregnancy regarding NAS treatment for exposed infants, additional investigation is ongoing.

Pain management of pregnant women on buprenorphine maintenance therapy is challenging. Opiate therapy for severe pain may be ineffective in the presence of buprenorphine. Since non steroidal anti-inflammatory drugs (NSAIDs) are contraindicated in pregnancy, buprenorphine may need to be switched to methadone or discontinued during time of acute pain management. Coordination with the buprenorphine provider may be necessary to provide adequate pain relief while treating the opioid addiction. Postpartum pain management is not as difficult since ketorolac (Toradol) and other NSAIDs can be used together with narcotic drugs, including buprenorphine, to relieve post-operative pain.

Hospital Based Treatment of Opioid Withdrawal Symptoms

Protocols are in place for those pregnant women who are not currently enrolled in medication assisted therapy when they present to hospitals with withdrawal symptoms. The protocols for buprenorphine or clonidine use are listed below.

Buprenorphine is administered either IM or SQ. The side effects may include mild withdrawal symptoms, constipation, and sedation. The doses and schedule are as follows:

- 0.6 mg every 8 hours for 3 doses
- then 0.6 mg every 12 hours for 2 doses
- then 0.3 mg every 8 hours for 3 doses
- then 0.3 mg every 12 hours for 2 doses
- then a single dose on day 5

Clonidine is administered orally. The side effects may include hypotension and sedation. The dose is 0.1 mg. The dosing schedule is as follows:

- every 4 hours for 6 doses
- then every 6 hours for 4 doses
- then every 8 hours for 3 doses
- then every 12 hours for 2 doses
- then a single dose on day 5

To achieve and maintain recovery, all patients with substance use disorder should participate in structured substance use disorder treatment or long term supportive therapy.

Communication Between Obstetric Providers and Substance Use Disorder Treatment Providers

It is very important for communication to take place between the OB provider and the substance use disorder treatment provider to ensure optimal care for the patient. Communication can only occur with proper consents, and it is best to obtain consent at the earliest possible opportunity. Alcohol and drug abuse treatment records are protected not only by HIPAA but also by the Code of Federal Regulations (42 CFR Part 2). **General medical consent forms are NOT sufficient for the release of substance use treatment records.** Talk with your patient about the importance of communication with the treatment provider and ask her to sign an appropriate consent form. Fax or send a copy to the provider before calling to discuss your patient's care. If the substance use treatment provider does not have a signed consent form, they will not acknowledge that a patient is enrolled in their program or be able to provide any information about that patient. Similarly, under HIPAA laws, the obstetric provider cannot divulge any patient information without written consent.

To summarize, the federal code on Confidentiality of Alcohol and Drug Abuse Patient Records requires that a program may only disclose information identifying a patient as an alcohol or drug abuser if one or more occur:

- The patient consents in writing (as discussed above).
- The disclosure is allowed by a court order.
- The disclosure is made to medical personnel in a medical emergency.
- The disclosure is made to qualified personnel for research, audit, or program evaluation.

In addition, federal law and regulations do NOT protect any information about:

- A crime committed by a patient at the program, against any person who works for the program, or about any threat to commit such a crime.
- Suspected child abuse or neglect, which must be reported under State law to appropriate State or local authorities.

Substance abuse treatment programs are obligated to follow the federal confidentiality law, and violation of the law by a program is a criminal offense. Suspected violations may be reported to appropriate authorities in accordance with federal regulations.

After consent is obtained, the obstetric provider can request some basic information from the substance abuse treatment provider such as:

- Diagnosis
- Treatment recommendations
- Patient's attendance and participation in treatment
- Drug test results
- Medications that are being prescribed, dosage, and whether patient is compliant with the medication regimen
- Prognosis

With consent, the substance use disorder treatment provider may request information from the obstetric provider such as:

- Additional obstetrical/medical risk factors
- Patient's compliance with appointments and tests
- Other pertinent problems

Please see the following sample consent form that includes all the elements required by federal confidentiality law.

Consent for the Release of Confidential Information

I, _____ authorize _____

to disclose to and obtain from _____

the following information: Any and all clinical information including medications prescribed related to substance abuse treatment and/or obstetrical care. _____

for the purpose of: _____ Continuance and coordination of care _____

I have been informed of the type of information being released; the benefits and disadvantages (if any), and I understand that treatment services are not contingent upon my decision concerning the signing of this release.

I understand that my alcohol and/or drug treatment records are protected under the federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. Pts. 160 and 164 and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it. If not previously revoked, this consent will terminate one year from the date signed.

Printed name of client

Signature of client

Date

Date of birth

Signature of witness

PROHIBITION OF REDISCLOSURE

This information has been disclosed to you from records protected by Federal Confidentiality Regulations (42 C.F.R. Part 2). The federal regulations prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 C.F.R. Part 1. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The federal regulations restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

Impact of Substance Use Disorders on Mother, Fetus, Infant and Child

An Overview

Substance misuse impacts the pregnant woman's health in a wide variety of ways. The table provided on the next several pages details the specific impact of each substance on the mother's health, the fetus's health, and the long-term impact on the child from intrauterine exposure. However, the effects of any single drug or the use of alcohol is confounded by the synergistic effects of other agents. **Simultaneous use or abuse of multiple substances is a common occurrence.** To date, it has been challenging to isolate the effects from a single substance or to provide an accurate assessment of the impact of specific combinations of drugs. Research has generally not taken into account co-existing use of tobacco and/or alcohol that may have a substantial effect on the pregnancy and the infant too. Route of administration of the drug may cause additional complications. Also substance abuse often is associated with poor nutrition, inadequate sleep, and failure to address other medical problems in a timely fashion. All of these may compound the impact of substance misuse on the pregnancy and the health of the mother and baby.

Tobacco Use

In Maryland, 19% of pregnant women reported using tobacco during the three months before they got pregnant and 9% are still smoking during the last trimester of pregnancy (2010 PRAMS Report). Few studies of the effects of drugs on the pregnant woman and the developing fetus take into account tobacco use, despite the fact that tobacco use is increasingly associated with significant pregnancy complications and subsequent problems for the child after birth. Of note, 88 - 93% of those in substance use disorder treatment report continuing to smoke at least some throughout pregnancy.

Smoking cigarettes is linked to an increased risk for placental abruption (relative risk of 2.5) and doubles perinatal mortality risk. Maternal tobacco use decreases birth weight on average by 135 to 300 grams and results in smaller neonatal head size. There is increased risk of fetal growth restriction (relative risk of 1.3 to 10) and an increase in pregnancy loss. Maternal **tobacco use has an additive or synergistic effect on the maternal and fetal effects of both alcohol and substance use.** In utero exposure to tobacco has been linked to increased externalizing behavior problems, especially Attention Deficit Hyperactivity Disorder, and possibly to some increased incidence of learning problems. Often women resume smoking after delivery but exposure to secondhand smoke significantly increases the rates of Sudden Infant Death Syndrome, respiratory infections, and asthma in infants and young children.

Drug Use

Route of drug administration affects the medical risk both in terms of rapidity of drug absorption and in terms of additional medical risks incurred because of the route used. For instance, intravenous use increases the risk of bacteremia, endocarditis, cardiac disease (often due to inadequately treated endocarditis), hepatitis B and C, and HIV/AIDS. Intra-nasal use increases

risk of nasal, sinus, laryngeal, and respiratory infections and malignancy. Increasingly, prescription narcotics are being crushed and either injected or snorted.

Medical Complications

Complications of substance use include spontaneous cellulitis/abscesses (often MRSA positive) at multiple sites and severe dental disease (both a result of chronic substance abuse and neglect). Pre-existing medical conditions often are present and may be in poor control. These medical conditions include diabetes, hypertension and heart disease, seizure disorder, and severe asthma.

Sexually Transmitted Infections (STIs)

Women with substance use disorders have an increased risk for all STIs including HIV/AIDS, hepatitis B and C, gonorrhea, chlamydia, trichomoniasis, genital herpes, and syphilis. These STIs, especially if untreated, may have a very negative impact on the pregnancy, fetus, and/or neonate.

Psychiatric Co-morbidity

Psychiatric problems often exist in the presence of substance abuse in the pregnant woman. Up to 70% of those with substance misuse have significant co-occurring psychiatric illness. Half of these require medication during pregnancy. An estimated 30 - 59% of pregnant women with substance use disorder have post traumatic distress disorder (PTSD), often the result of childhood physical and/or sexual abuse. Appropriate psychiatric intervention is important to address psychiatric disorders for which the woman may have been self-medicating with their substance misuse.

Obstetrical Complications

Preterm delivery (prior to 37 weeks) occurs in up to 30% of substance abusing pregnant women, from a variety of causes including preterm rupture of membranes. Other increased obstetrical complications include fetal growth restriction/low birth weight, abruptio placenta, meconium in utero, chorioamnionitis, maternal hypertension, and fetal non-reassuring status in labor.

Neonatal Abstinence Syndrome (NAS)

NAS is best defined for in utero opioid exposure. However, there is evidence that poly-drug abuse may increase both the severity and duration of NAS. Other drugs of abuse, such as benzodiazepines, may be associated with withdrawal symptoms that are less well defined.

Long-term Sequelae

Some of these observed problems are directly related to the fetal exposure to drugs, tobacco or alcohol. Others are related to the poor nutritional status and/or poor health of the pregnant woman who is abusing the drugs. Still others are related to maternal depression and/or child neglect and abuse that occur more frequently in households with a parent who misuses substances, especially when that parent is the sole parent for the child.

The complications of substance use and abuse contribute to challenges in providing obstetric care for patients. However, careful attention to the details of these potential complications and collaboration among the people providing care often improve outcomes substantially.

Effects of Substance Use and Abuse During Pregnancy

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Alcohol Product and <i>Street Names</i></p> <ul style="list-style-type: none"> • Beer • Cordials • Liquor • Malt beverages • Wine • Wine Coolers • Combination products with caffeine <p><i>Example:</i> <i>4 Loco</i></p>	Information not found	<ul style="list-style-type: none"> ✓ Central nervous system depressant ✓ Withdrawal symptoms with cessation after ≥ 6 drinks per day ✓ With withdrawal, increased risk for tremor, ataxia, sweating, hypertension, tachycardia, GI upset, anxiety, seizures, hallucinations, and arrhythmias 	<ul style="list-style-type: none"> ✓ Increased risk for intrauterine growth restriction ✓ Increased risk for miscarriage ✓ Increased risk for fetal death ✓ Increased risk for Fetal Alcohol Syndrome 	<ul style="list-style-type: none"> ✓ Low birth weight (<2500 g) ✓ Small head and brain ✓ Deformities of face and limbs consistent with Fetal Alcohol Syndrome ✓ Potential for poor habituation and lower levels of arousal ✓ Developmental delays ✓ Behavioral difficulties including Attention Deficit Hyperactivity Disorder and impulse control problems ✓ Increased potential for interference of language development and learning disabilities ✓ In childhood there is potential for increased risk of delinquency, criminal behavior, and substance abuse later in life 	<p>L3</p> <p>Benefit of breastfeeding usually outweighs risk</p> <p>Use while breastfeeding may cause decreased milk production and neuro-behavioral effects on the infant</p>

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Amphetamines Generic and <i>Trade names</i></p> <p>Legal</p> <ul style="list-style-type: none"> • Amphetamine Salt <i>Adderall</i> • Dextro-Amphetamine Sulfate <i>Dexedrine and Dextrostat</i> • Dexmethylphenidate • Lisdexamfetamine Dimesylate <i>Vyvanse</i> • Methylphenidate <i>Concerta, Focalin, Daytrana, Metadate, and Ritalin</i> 	C	<p>Limited data is available but no negative maternal effects seen other than slight increased heart rate or blood pressure for some, when used in the prescribed range for treatment of Attention Deficit Hyperactivity Disorder (ADHD)</p> <p><i>With misuse of legal stimulants, especially with snorting or injection, the results are the same as use of illegal drugs:</i></p> <ul style="list-style-type: none"> ✓ Central nervous system stimulant ✓ Irritability, restlessness, and insomnia 	<p>Limited data available show no adverse fetal effects seen from stimulants, when used in the prescribed range for treatment of Attention Deficit Hyperactivity Disorder (ADHD)</p> <p><i>With misuse of legal stimulants, especially with snorting or injection, the results are the same as use of illegal drugs:</i></p> <ul style="list-style-type: none"> ✓ Increased risk of miscarriage ✓ Increased risk of fetal distress 	<p>Limited data available, but no data showing infant/child effects, when used in the prescribed range for treatment of Attention Deficit Hyperactivity Disorder (ADHD)</p> <p><i>With misuse of legal stimulants, especially with snorting or injection, the results are the same as use of illegal drugs:</i></p> <ul style="list-style-type: none"> ✓ Increased risk for neonatal mortality ✓ Increased risk for premature birth 	<p>L3/L5</p> <p>Risk of breastfeeding usually outweighs benefit</p>

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Amphetamines Drug and <i>Street Names</i></p> <p>Illegal</p> <ul style="list-style-type: none"> • Crystal Meth • Meth-amphetamine <i>Ice, Glass, Crystal, Shake n' Bake, Birch, and P2P</i> • Khat <i>Kat, Chat, Gat, African Salad, Bushman's, and Tea</i> • MDMA <i>Ecstasy</i> 	Information not found	<ul style="list-style-type: none"> ✓ Increased heart rate, respiration, blood pressure, and temperature ✓ Increased risk of arrhythmias ✓ Paranoia ✓ Increased risk for placental abruption ✓ Increased risk of premature rupture of membranes and preterm delivery ✓ Brain damage in overdose ✓ Ecstasy causes inability to regulate temperature leading to liver, kidney, cardio-vascular damage, and potentially death ✓ Ecstasy can cause confusion, depression, and sleep difficulties, anxiety, and panic attacks 	<ul style="list-style-type: none"> ✓ Increased risk of intrauterine growth restriction ✓ Potential for cerebral infarction (stroke) ✓ Slightly increased risk of cardiovascular and genitourinary tract abnormalities ✓ Ecstasy can cause the potential for fetal death due to increase in maternal temperature 	<ul style="list-style-type: none"> ✓ Small for gestational size and low birth weight (<2500 g) ✓ If mother is intoxicated at delivery, neonates may demonstrate irritability, tremors, muscular rigidity, vomiting and diarrhea ✓ Subtle problems with dysregulation in infancy ✓ Some studies have found subtle learning differences 	Information not found

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
Amphetamines Drug and <i>Street Names</i> Synthetic <ul style="list-style-type: none"> • Bath salts <i>Bliss,</i> <i>Cloud Nine,</i> <i>Drone,</i> <i>Purple Wave,</i> <i>Vanilla Sky,</i> <i>White Knight,</i> <i>and</i> <i>White</i> <i>Lightening</i> 	Information not found	<ul style="list-style-type: none"> ✓ Rapid heartbeat which can lead to heart attack and stroke ✓ Chest pain ✓ Nosebleeds ✓ Increased sweating ✓ Nausea and vomiting ✓ Agitation, insomnia, irritability, and panic attacks ✓ Dizziness ✓ Depression, paranoia, delusions, and suicidal thoughts ✓ Seizures 	Information not found	Information not found	Information not found

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
Barbiturates Generic and <i>Trade names</i> <ul style="list-style-type: none"> • Amobarbital • Mephobarbital <i>Mebaral</i> • Pentobarbital • Phenobarbital <i>Nembutal</i> • Secobarbital <i>Seconal</i> 	D	✓ Central nervous system depressant	Information not found	<ul style="list-style-type: none"> ✓ Respiratory problems at birth ✓ Increased risk of birth defects– especially cleft lip and palate, and cardiac and spine defects ✓ Bleeding in newborn ✓ Physical dependence and withdrawal at birth 	L3

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Benzodiazepines Generic and <i>Trade names</i></p> <ul style="list-style-type: none"> • Alprazolam <i>Niravam and Xanax</i> • Chlor-diazepoxide HCL <i>Librium</i> • Clonazepam <i>Klonopin</i> • Clorazepate <i>Tranxene</i> • Diazepam <i>Diasta and Valium</i> • Flurazepam <i>Dalmane</i> • Lorazepam <i>Ativan</i> • Midazolam HCL <i>Versed</i> • Oxazepam • Temazepam <i>Restoril</i> • Triazolam <i>Halcion</i> 	D	<ul style="list-style-type: none"> ✓ Central nervous system depressant ✓ Withdrawal can cause anxiety, panic attacks, insomnia, emotional lability, dysperceptions, depersonalization, and seizures 	<ul style="list-style-type: none"> ✓ Possibly increased risk of cleft lip and/or palate with first trimester use ✓ Preterm Delivery 	<ul style="list-style-type: none"> ✓ Use prior to delivery can cause “floppy baby syndrome” ✓ Low birth weight (<2500 g) ✓ Postnatal withdrawal symptoms include diarrhea, vomiting, muscle weakness, irritability, tremors, and sleep disturbance ✓ Third trimester use is associated with problems with temperature regulation and apnea which may last hours to months after birth 	L3

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
Caffeine <ul style="list-style-type: none"> • Coffee • Tea • Supplements • Energy drinks • Combination products with alcohol • Combination prescription and non-prescription medications 	Information not found	✓ Central nervous system stimulant	✓ Increased chance of miscarriage and fetal death with high dose consumption (>800mg)	✓ At birth: Fast heart rate Tremors Fast respiratory rate with dose consumption of >500 mg	L2

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Cannabis Type and <i>Street Names</i></p> <ul style="list-style-type: none"> • Marijuana <i>Pot, Gange, Weed, Grass, 420, Boom, Aunt Mary, Blunts,, Chronic, Dope, Hash, Joint, Mary Jane, Reefer, Skunk, and Smoke</i> • Legal Medical Marijuana <i>Marinol, Cesamet, and Sativex</i> 	Information not found	<ul style="list-style-type: none"> ✓ Increased heart rate and risk of heart attack ✓ Increased risk of palpitations and arrhythmias ✓ Central nervous system depressant ✓ Sleepiness ✓ Behaviour changes ✓ Distorted perception especially of depth and time ✓ Impaired coordination ✓ Difficulty with thinking, problem solving, learning, and memory ✓ Can lead to addiction and withdrawal ✓ Increased potential (with long term use) for mental illness, including psychosis and schizophrenia 	<ul style="list-style-type: none"> ✓ Increased risk of gastroschisis ✓ Increased risk of cardiac malformations ✓ Increased risk of premature birth 	<ul style="list-style-type: none"> ✓ Low birth weight (<2500 g) ✓ Decreased height and head circumference ✓ Increased risk of neurobehavioral effects such as increase tremor, exaggerated startles, tremors, and sleep disturbances ✓ Increased risk of Attention Deficit Hyperactivity Disorder <p>Child effects:</p> <ul style="list-style-type: none"> ✓ Potential for increased hyperactivity, inattention, short attention span, and impulsivity from age 6 to adolescence ✓ Potential for problems with learning, memory, perceptual problems, and academic underachievement 	<p>L5</p> <p>Risk of breastfeeding usually outweighs benefit</p>

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Cannabis Type and <i>Street Names</i></p> <p>Synthetic</p> <ul style="list-style-type: none"> • K2/Spice <i>Fake pot,</i> <i>Yucatan Fire,</i> <i>Skunk,</i> <i>Moon Rocks,</i> <i>Funky Monkey,</i> <i>Incense,</i> <i>Scooby Snax</i> <i>Kush, Afterlife,</i> <i>Visionary</i> <i>Quest,</i> <i>Jokers Wild,</i> <i>Mad Hatter,</i> <i>Bomb Marley,</i> <i>Bayou Blaster,</i> <i>KLIMAX,</i> <i>Down 2 Earth,</i> <i>Flintstones,</i> <i>and Potpourri</i> 	Information not found	<ul style="list-style-type: none"> ✓ Rapid heart rate ✓ Increased blood pressure ✓ Anxiety and agitation ✓ Hallucinations, delusions, and paranoia ✓ Changes in behavior and perception ✓ Seizures and death 	Information not found	Information not found	Information not found

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
Cocaine <i>Street Names: Coke, Snow, C, Flake, Blow, and Crack</i>	Information not found	<ul style="list-style-type: none"> ✓ Central nervous system stimulant ✓ Constricted blood vessels ✓ Increased heart rate, blood pressure, and temperature ✓ Arrhythmias and increased potential for heart attack ✓ Increased potential for respiratory arrest and subsequent death ✓ Sudden death ✓ Headache, seizures, and coma ✓ Irritability, restlessness, insomnia, anxiety, panic, and paranoia ✓ Potential for bizarre, erratic, and violent behavior 	<ul style="list-style-type: none"> ✓ Increased risk for placental abruption ✓ Increased risk of fetal distress ✓ Increased risk of intrauterine fetal death (cocaine) ✓ Increased risk for miscarriage ✓ Increased risk of intrauterine growth restriction ✓ Potential for cerebral infarction (stroke) ✓ Increased risk for premature birth 	<ul style="list-style-type: none"> ✓ Low birth weight (<2500 g) ✓ Fast heart rate ✓ Poor weight gain and growth disorders ✓ Potential for increased irritability and lability of state, decreased behavioral and autonomic regulation, and poor alertness and orientation ✓ In childhood there is potential for subtle learning disabilities, alteration in language development, alteration in visual-motor ability, attention, and working memory 	<p>L5</p> <p>Risk of breastfeeding usually outweighs benefit</p>

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Hallucinogens Drug and <i>Street Names</i></p> <p>Legal, but non-therapeutic use</p> <ul style="list-style-type: none"> • Coricidin (Chlorpheniramine maleate) <i>Triple C's, Skittles, Candy, Candy Coated Chaos, Red Devils, Little Red Devils, ccc, Robo, Robots, Robo dots, Fry, and Whities,</i> • Dextromethorphan <i>DXM, CCC, Triple C, Skittles, Robo, and Poor Man's PCP</i> • Ketamine (non-hospital use) <i>K, Special K, Kit Kat, Cat Valium, Purple, Jet, and Vitamin K</i> 	Information not found	<ul style="list-style-type: none"> ✓ Dissociative anesthetic with impaired motor function ✓ Agitated, difficult to control behavior, profuse sweating (Coricidin) ✓ Causes sedation, immobility, and amnesia ✓ Distorted perception of reality and hallucinations ✓ Increased heart rate and blood pressure; liver damage; and central nervous system, cardiovascular system, and anticholinergic toxicity (DXM) ✓ Can cause death when used in combination products, with alcohol, or with antidepressants (DXM) ✓ Potentially fatal respiratory distress 	<ul style="list-style-type: none"> ✓ Increased risk of fetal demise ✓ Possible cardiac and skeletal abnormalities (Ecstasy) 	<ul style="list-style-type: none"> ✓ Potential for neuro-developmental damage (Ketamine, GHB, and PCP) ✓ Craniofacial Malformations similar to Fetal Alcohol Syndrome ✓ Increased risk of Attention Deficit Hyperactivity Disorder and/or developmental delays with language problems 	L5

<p>Hallucinogens – cont. Drug and <i>Street Names</i></p> <p>Illegal</p> <ul style="list-style-type: none"> • GHB (Gamma Hydroxybutyrate) • LSD <i>Acid, Battery Acid, Blotter, Window Pane, Microdots, Loony Toons, Sunshine, and Zen</i> 		<p>✓ Increased body temperature and profuse sweating (LSD)</p>			
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Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Hallucinogens – cont. Drug and <i>Street Names</i></p> <p>Illegal – cont.</p> <ul style="list-style-type: none"> • PCP (Phencyclidine) <i>Angel Dust,</i> <i>Embalming</i> <i>Fluid,</i> <i>Killer Weed,</i> <i>Rocket Fuel,</i> <i>Super Grass,</i> <i>Boat, Dipper,</i> <i>Wet Sticks</i> (with <i>Embalming</i> <i>Fluid), and</i> <i>Zoom</i> • Peyote Cactus • Psilocybin Mushrooms <i>Magic</i> <i>Mushrooms</i> • San Pedro Cactus <i>Buttons,</i> <i>Cactus, Mesc,</i> <i>and Peyote</i> • Tryptamines <i>Foxy and</i> <i>Foxy Methoxy</i> 	Information not found	<ul style="list-style-type: none"> ✓ Acts as a hallucinogen, stimulant, depressant, and anesthetic at the same time (PCP) ✓ Seizures and coma (PCP) ✓ Chronic use can lead to physical dependence and withdrawal (PCP) 	Information not found	Information not found	Information not found

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
Inhalants <i>Street Names: Sniffing, Snorting, Bagging, Glue Sniffing, Glading, Hippie Crack, Oz, Pearls, Wippets, Whiteout, and Huffing</i>	Information not found	<ul style="list-style-type: none"> ✓ Central nervous system depressant ✓ Dissociative anesthetic ✓ Distorted perception of reality ✓ Can cause cardiac arrhythmias, heart failure, and death ✓ Risk of asphyxia and aspiration ✓ Risk of kidney, liver, brain, and nervous system damage ✓ Risk of acute encephalopathy ✓ Increased risk of psychosis, delirium, aggression, and trauma 	<ul style="list-style-type: none"> ✓ Increased risk of miscarriage 	<ul style="list-style-type: none"> ✓ Increased risk of prematurity and low birth weight (<2500 g) ✓ Craniofacial malformations similar to Fetal Alcohol Syndrome ✓ Increased risk for neuro-developmental delay 	Information not found

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Nicotine</p> <ul style="list-style-type: none"> • Cigarettes • Cigars • Electronic cigarettes • Pipe Tobacco • Smokeless Tobacco (Chew/spit, Snuff, Snus) • Smoking cessation products: Nicotine gum, lozenges, and patches 	Information not found	<ul style="list-style-type: none"> ✓ Central nervous system stimulant and depressant ✓ Increases blood pressure, respiration, and heart rate ✓ Can cause hyperglycemia due to effect on pancreas ✓ Increased risk of placenta previa, placental abruption, and premature rupture of membranes ✓ May experience withdrawal with abrupt cessation: nausea, salivation, abdominal pain, sweating, headache, and dizziness 	<ul style="list-style-type: none"> ✓ Disrupted oxygen supply to the fetus ✓ Increased risk of intrauterine growth restriction ✓ Increased risk of premature birth ✓ Increased risk of fetal loss ✓ Increased risk of oral facial clefts 	<ul style="list-style-type: none"> ✓ Increased risk of neonatal loss ✓ Increased risk (2x) of low birth weight (<2500 g) ✓ Increased risk of irritability and hypertonia ✓ Increased risk of Sudden Infant Death Syndrome ✓ Increased risk of Attention Deficit Hyperactivity Disorder ✓ Increased risk (20%) of morbidity/mortality due to infections and asthma ✓ Potential for abnormalities in language development, learning, and memory ✓ In childhood: potential for increased risk of delinquency, criminal behavior, and substance abuse later in life <p>Second hand smoke:</p> <ul style="list-style-type: none"> ✓ Increased risk of Sudden Infant Death Syndrome ✓ Increased risk of behavior problems ✓ Increased incidence of bronchitis, pneumonia, otitis media, asthma, and allergies 	<p>L2 (Commercial products)</p> <p>Benefit of breastfeeding usually outweighs risk</p> <p>Use while breastfeeding may cause decreased milk production</p>

Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Opiates Generic and <i>Trade Names</i></p> <p>Legal Many of these products are combined with Aspirin, Caffeine, NSAIDS, and/or Tylenol</p> <ul style="list-style-type: none"> • Alfentanil HCL <i>Alfenta and Alfentanil</i> • Codeine • Dihydrocodeine <i>Synalogs</i> • Fentanyl <i>Duragesic and Sublimaze</i> • Hydrocodone Bitartrate <i>Anexsia, Lorcet, Lortab, Norco, Reprexain, Vicodin, Vicoprofen, and Zydone</i> 	B/C	<ul style="list-style-type: none"> ✓ Overdose is a medical emergency for mother and fetus ✓ Withdrawal can cause physical symptoms including flu-like symptoms, nausea, vomiting, diarrhea, sweating, myalgias, chills, rhinorrhea, and runny eyes ✓ Withdrawal can cause psychological symptoms such as insomnia, anxiety, drug cravings, dysphoria, abdominal cramping, and uterine irritability ✓ Uterine irritability can lead to increased risk of miscarriage, preterm labor, fetal hypoxia, and fetal death 	<ul style="list-style-type: none"> ✓ Fetal distress ✓ Increased risk of fetal demise ✓ Increased risk of intrauterine growth restriction ✓ Abrupt withdrawal of opioids can result in preterm labor, fetal distress or fetal demise 	<ul style="list-style-type: none"> ✓ Low birth weight (<2500 g) ✓ Risk of withdrawal symptoms (Neonatal Abstinence Syndrome) including sweating, irritability, vomiting, watery stools, high-pitched crying, tremors, seizures, abnormal muscle tone, poor weight gain, vasomotor, and respiratory effects ✓ Increased risk of Sudden Infant Death Syndrome ✓ Decreased behavioral, perceptual, and organizational abilities 	<p>L2/L3</p> <p>Risk of breastfeeding usually outweighs benefit</p>

<p>Opiates – cont. Generic and <i>Trade Names</i></p> <ul style="list-style-type: none"> • Hydro-morphone HCL <i>Dilaudid</i> • Merperidine <i>Demerol</i> • Morphine Sulfate <i>Astramorph, Avinza, Duramorph, Infumorph, Kadian, MS Contin, Oramorph, and Roxanol</i> • Oxycodone <i>Combunox, Endocet, Endodan, Oxycontin, Oxyir, Percocet, Percodan, Roxicet, Roxicodone, Roxilox, and Tylox</i> 					
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<p>Opiates – cont. Generic and <i>Trade Names</i></p> <ul style="list-style-type: none"> • Oxymorphone <i>Numorphan and Opana</i> • Remifentanil HCL <i>Ultiva</i> • Sufentanil <i>Sufenta</i> <p>Illegal Drug and Street Names</p> <ul style="list-style-type: none"> • Heroin <i>Smack, H, Tar, Junk, Brown Sugar, Skag, Mud, Dragon, Dope, White China, White, White Nurse, White Lady, White Horse, White Girl, White Boy, Stuff, Black, and Black Tar</i> 	Information not found	<ul style="list-style-type: none"> ✓ Heroin can cause a decrease or absence of pupillary response to light, a rush of pleasurable feelings, cessation of physical pain, lethargy, drowsiness, slurred speech, shallow breathing, sweating, vomiting, a drop in body temperature, sleepiness, and loss of appetite 			Information not found
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<p>Opiates – cont.</p> <ul style="list-style-type: none"> • Heroin – cont. <i>Black Pearl, Black Stuff, Black Eagle, Brown, Brown Crystal, Brown Tape, Brown Rhine, Mexican Brown, Mexican Mud, Mexican Horse, Snow, Snowball, Scat, Sack, Skunk, Number 3, Number 4, and Number 8</i> • Opium <i>Big O, OP, Hop, Midnight Oil, Tar, Dope, Black Stuff, Block, Poppy, Black Block, and Afga</i> 		<ul style="list-style-type: none"> ✓ Increased risk for contracting HIV, Hepatitis C, and other infectious diseases ✓ Opium can cause pinpoint pupils, no response of pupils to light, a rush of pleasurable feelings, lethargy, drowsiness, slurred speech, shallow breathing, sweating, vomiting, a drop in body temperature, sleepiness, loss of appetite, lower heart rate and blood 			
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Opiates – cont.		<p>pressure, and decrease sexual drive</p> <ul style="list-style-type: none"> ✓ Long-term use can cause physical and psychological dependence, addiction, physical tolerance, mood swings, severe constipation, menstrual irregularities, lung damage, skin infections, seizures, unconsciousness, and coma 			
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Classification And Examples	FDA Pregnancy Category*	Potential Maternal Effects	Potential Fetal Effects	Potential Infant/Child Effects	Dr. Hale's Lactation Category**
<p>Opiates Generic and <i>Trade Names</i></p> <p>Synthetic</p> <ul style="list-style-type: none"> • Buprenorphine <i>Buprenex, Subutex, and Suboxone (combination of buprenorphine and naloxone)</i> • Methadone HCL <i>Dolophine and Methadose</i> • Propoxyphene Napsylate <i>Darvocet and Darvon</i> 	C	<ul style="list-style-type: none"> ✓ Methadone can cause dizziness, sweating, nausea, vomiting, headache, agitation, sedation, insomnia, euphoria, and seizures ✓ Methadone can cause arrhythmias, prolonged QT interval, and cardiac arrest ✓ Methadone can cause hypomagnesia, pulmonary edema, respiratory depression, and respiratory arrest ✓ Subutex can cause increased intracranial pressure, confusion, depression, psychosis, and slurred speech ✓ Subutex can cause bradycardia, hypotension, and tachycardia ✓ Visual changes 	Information not found	<ul style="list-style-type: none"> ✓ Methadone may cause increased risk of withdrawal symptoms (Neonatal abstinence syndrome - NAS) that may be more severe than other legal and illegal opiates with symptoms of sweating, irritability, vomiting, watery stools, high-pitched crying, tremors, seizures, abnormal muscle tone, poor weight gain, vasomotor, and respiratory effects ✓ Suboxone and Subutex may cause milder withdrawal symptoms 	<p>Methadone use during breastfeeding is compatible and may have the potential benefit of reducing the symptoms associated with NAS</p> <p>Suboxone and Subutex - L2/L3</p>

Federal Drug Administration's Pregnancy Risk Category*Category A:**

Controlled studies in women fail to demonstrate a risk to the fetus in the first trimester (and there is no evidence of a risk in later trimesters) and the possibility of fetal harm appears remote.

Category B:

Animal-reproduction studies have failed to demonstrate a fetal risk, and there are no adequate and well controlled studies in pregnant women.

Category C:

Either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal, or other) and there are no controlled studies in women, or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Category D:

There is positive evidence of human fetal risk, but the benefits from use in pregnancy may be acceptable despite the risk (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

Category X:

Studies in animals or human beings have demonstrated fetal abnormalities, and/or there is evidence of fetal risk based on human experience, and the risk of the use of the drug in pregnant women clearly outweighs any possible benefit. The drug is contraindicated in women who are or may become pregnant.

Category NR:

Not rated

****Dr. Hale's Lactation Risk Category****L1 Safest:**

Drug which has been taken by a large number of breastfeeding mothers without any observed increase in adverse effects in the infant. Controlled studies in breastfeeding women fail to demonstrate a risk to the infant and the possibility of harm to the breastfeeding infant is remote, or the product is not orally bioavailable in an infant.

L2 Safer:

Drug which has been studied in a limited number of breastfeeding women without an increase in adverse effects in the infant, and/or the evidence of a demonstrated risk which is likely to follow use of this medication in a breastfeeding woman is remote.

L3 Moderately Safe:

There are no controlled studies in breastfeeding women, however, the risk of untoward effects to a breastfed infant is possible, or controlled studies show only minimal non-threatening adverse effects. Drugs should be given only if the potential benefit justifies the potential risk to the infant. (New medications that have absolutely no published data are automatically categorized in this category, regardless of how safe they may be.)

L4 Possibly Hazardous:

There is positive evidence of risk to a breastfed infant or to breast milk production, but the benefits from the use in the breastfeeding mother may be acceptable despite the risk to the infant (e.g., if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective).

L5 Contraindicated:

Studies in breastfeeding mothers have demonstrated that there is significant and documented risk to the infant based on human experience, or it is a medication that has a high risk of causing significant damage to an infant. The risk of using the drug in breastfeeding women clearly outweighs any possible benefit from breastfeeding. The drug is contraindicated in women who are breastfeeding an infant.

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Fetal Alcohol Spectrum Disorder

Consumption of alcohol during pregnancy is the leading preventable cause of intellectual disability in children. Studies attempting to determine whether any degree of alcohol consumption during pregnancy is safe are unclear. Current thinking is that some people have a genetic sensitivity to the effects of alcohol on their fetus and, for them, no amount of alcohol would be safe. For others, a rare drink is probably ok. However, since medical science has not yet developed a method to determine who is especially sensitive to alcohol, the best advice is for the pregnant woman to avoid all alcohol for the duration of her pregnancy (and preferably from the time she begins to try to conceive). Otherwise, her baby is at risk for developing Fetal Alcohol Spectrum Disorder.

Fetal alcohol spectrum disorder (FASD) is a non-diagnostic term. It describes the broad range of adverse sequelae from maternal alcohol consumption during pregnancy that can be seen in prenatally exposed offspring. FASD includes fetal alcohol syndrome (FAS), partial fetal alcohol syndrome (pFAS), alcohol-related birth defects (ARBD), and alcohol-related neurodevelopmental disorder (ARND). These are described below. Note: prenatal alcohol exposure may or may not be confirmed in making the diagnosis.

Fetal Alcohol Syndrome (FAS) is defined by abnormalities in three domains:

- **Poor Prenatal and/or Postnatal Growth** - Growth retardation is defined as confirmed prenatal or postnatal height and/or weight at or below the tenth percentile for age. Poor growth due to intrauterine alcohol exposure tends to continue through infancy and childhood.
- **Central Nervous System (CNS) Abnormalities** - Prenatal exposure to alcohol causes impaired brain growth and/or abnormal development that result in a wide range of neurobehavioral problems including impairment of self-regulation, cognition, and adaptive functioning. Imaging and neurobehavioral studies indicate that there are particular vulnerable regions of the brain including the frontal cortex, corpus callosum, hippocampus, cerebellum, and basal ganglia. These areas control impulse control and judgment, transference of information between the hemispheres, memory and learning, coordination of movement, and behaviors such as the ability to make transitions, work toward goals, and perceive time.
- **Specific Dysmorphic Facial Features** - Abnormalities seen include short palpebral fissures, smooth philtrum, and thin upper lip.

Partial Fetal Alcohol Syndrome (pFAS)

These children have a confirmed history of exposure to significant levels of alcohol during pregnancy but do not meet all of the criteria to qualify for a FAS diagnosis. They have some of the neurobehavioral deficits seen in FAS.

Alcohol-Related Birth Defects (ARBD)

These children have one or more congenital defects associated with prenatal exposure to alcohol that include dysplastic kidneys, ptosis, atrial and ventricular septal defects, and neurosensory loss. For this diagnosis, confirmation of prenatal alcohol exposure is required.

Alcohol-Related Neurodevelopmental Disorder (ARND)

These children have normal growth and lack the facial stigmata of FASD, but display a pattern of behavioral, developmental and/or cognitive problems that are inconsistent with the developmental level of the individual and cannot be explained by the genetic contribution of the biological parents or abnormalities in brain maturation related to toxic environmental factors. For this diagnosis, confirmation of prenatal alcohol exposure is required.

Early diagnosis of children with neurodevelopmental problems related to FASD is essential so that affected children can be placed in appropriate therapies and/or educational programs. Early intervention may ameliorate primary effects such as language problems and emotional dysregulation, and prevent secondary effects such as academic, legal, and psychiatric problems.

Neonatal Abstinence Syndrome

Neonatal abstinence syndrome (NAS) is comprised of the signs and symptoms that occur when prenatal exposure to a substance is interrupted at birth. It is typically used to describe opioid exposures from heroin, methadone, buprenorphine, and opioid containing pain medicine. Other substances such as alcohol and benzodiazepines have also been found to predispose the infant to symptoms of neurobehavioral disorganization after birth. The presentation of NAS in the neonate is widely variable in timing of onset, types of symptoms displayed and severity of symptoms displayed. This variability is poorly understood, but is probably due to a myriad of factors which include:

- Maternal exposures - substances used, concurrent use of prescribed medications (particularly psychotropic drugs), timing of exposures during gestation, poly substance use (including alcohol and nicotine)
- Maternal factors - nutrition, infections, stress, comorbid psychiatric conditions
- Placental opioid metabolism
- Genetics, epigenetics
- Infant factors - preterm birth, comorbid infections and other conditions, medications
- Environmental factors - ability of the handlers to respond to infant cueing appropriately, physical environment (NICU versus newborn nursery versus rooming in)
- Severity of NAS is inconsistently related to the dose of the drug of exposure.

NAS is comprised of symptoms of dysfunction in four domains: state control and attention, motor and tone control, sensory integration, and autonomic functioning. Problems in these domains can lead to a host of signs:

- Difficulties with feeding
- Loose stools
- Failure to thrive
- Trouble sleeping and interacting
- Hypertonicity, tremors, exaggerated primitive reflexes
- Autonomic symptoms such as yawning, sweating, nasal stuffiness, sneezing and tachypnea
- Extreme irritability with high pitched cry

NAS is typically evaluated periodically during the neonatal period in infants exhibiting symptoms using a scoring tool such as the Finnegan NAS scoring system. This tool provides an assessment of the infant's NAS symptoms and is used as a guide for beginning and maintaining pharmacotherapeutic interventions. Pharmacotherapy is begun when the infant reaches a threshold numerical cutoff. Only a subset of infants, approximately 60%, are affected severely enough to receive pharmacotherapy for NAS. Preterm infants present a challenge to the practitioner as no tools for NAS evaluation specific to this population exist. In general, preterm infants have shorter courses of NAS and require less medication.

Pharmacotherapy for NAS is variable between institutions, and there is a general dearth of literature to allow the identification of a superior evaluation or treatment algorithm. Generally, treatment for opioid exposed neonates is with opioid containing preparations such as oral

morphine solution or methadone. Secondary medications are employed when the infant's symptoms are not controlled on monotherapy. Agents typically used as secondary drugs include clonidine and phenobarbital. NAS evaluation and medication should be at intervals no longer than every 4 hours, as lengthier time periods can result in rebound symptoms. Treatment strategies for NAS include weight-based protocols, dosing the infant with medication on a mg/kg basis, and symptom-based protocols, dosing the infant with medication based on the severity of symptoms displayed.

Breastfeeding has been shown to provide some amelioration of NAS severity, but lactation requires a risk/benefit assessment of the substance dependent woman.

See Toolkit Section 6 - Care of the Substance Exposed Infant, pages 6.1 through 6.4 for breastfeeding information.

NAS is not defined by the need for pharmacotherapy, and all substance exposed infants, regardless of the need for medication, should receive non-pharmacologic, supportive care after birth. Supportive care interventions individualize the care of the infant based on behavioral observations, with the goal of promoting organization, physiologic stability and competence. The environment should be modified to support the infant's autonomic, sensory, motor and interactive development based on the infant's demonstrated strengths and weaknesses. Parental involvement should be encouraged to allow the caretaker to understand the newborn's condition, and to develop a care plan to support the infant's developmental requirements after hospital discharge.

See Toolkit Section 6 - Care of the Substance Exposed Infant, pages 6.5 through 6.6 for therapeutic handling techniques.

Early identification of a pediatrician to assume care of the newborn immediately after hospital discharge is important, as a small subset of infants can present with significant NAS symptoms at home as late as day 7 of life.

Infant Self Regulation

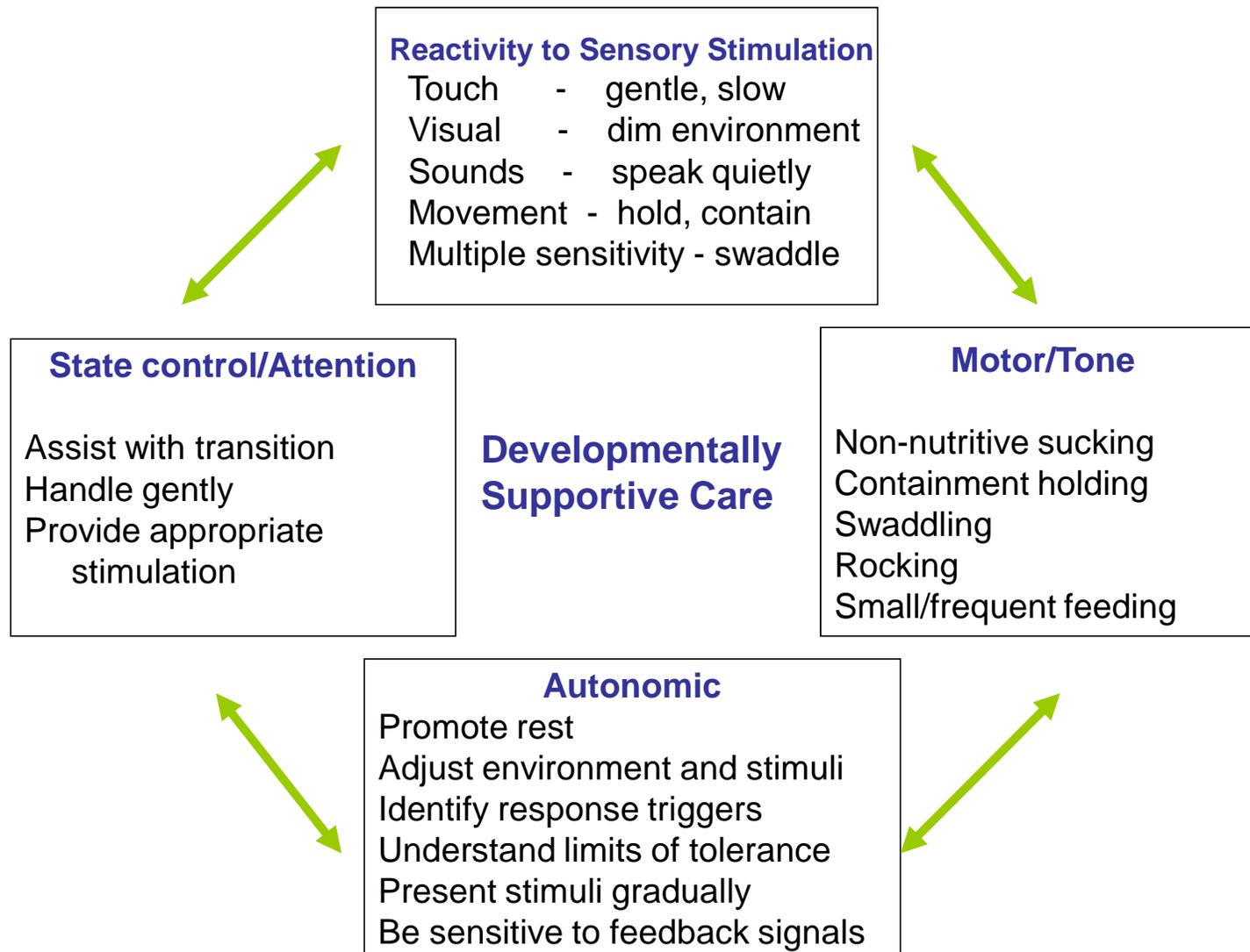
Organized Self Regulation

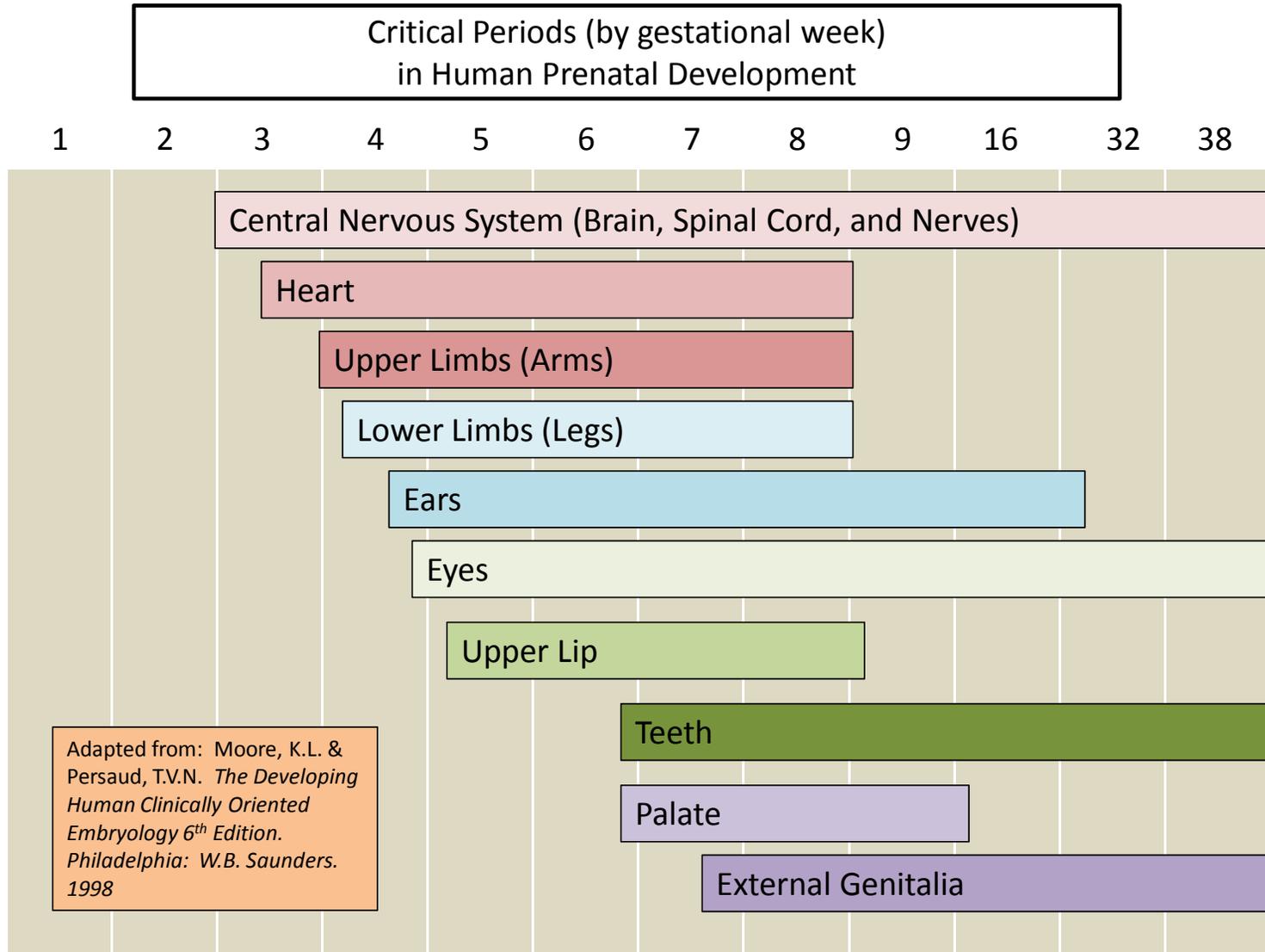
- **Autonomic**
 - Smooth respiration pattern
 - Consistent color
 - Stable digestion
- **Motoric**
 - Smooth, well modulated posture and tone
 - Smooth, synchronus movements
 - Coordinated sucking
 - Hand to mouth activity
- **State**
 - Clarity of states
 - Smoothness of transitions
 - Rhythmicity of sleep–awake cycles
 - Ability to quiet or console self
 - Good attention and orientation
- **Sensory**
 - Typical responses

Disorganized Self Regulation

- **Autonomic**
 - Respiratory pauses or tachypnea
 - Changes in color
 - Gagging
 - Hiccoughs or sneezing
 - Grunting
- **Motoric**
 - Hypertonic or hypotonic
 - Tremors
 - Frantic movements
 - Facial grimacing
- **State**
 - Rapid transition from states
 - Gaze aversion/staring
 - Fussiness or irritability
- **Sensory**
 - Atypical responses

Adapted from Als (1982) and Taquino 1999





Care of the Substance Using Pregnant Woman

The care of women who use alcohol, tobacco, illicit drugs, and/or misuse licit drugs is a challenge for obstetric providers as well as substance abuse treatment providers. Two of the most pervasive myths are that continued drug use is voluntary and that a person's inability to overcome addiction stems solely from character flaws or a lack of willpower. Society accepts that quitting smoking often requires repeated attempts, and the potential for relapse after treatment for alcoholism is generally recognized and accepted. Similarly recovery from other substance misuse is often a long-term effort, requiring multiple episodes of treatment including behavioral therapy. However, recovery is achievable.

The following section will help clarify what common co-occurring problems to look for, how often to see these women for care, when and how to do tests, how to deal with problems identified, and when to seek consultation and/or emergency intervention.

Of paramount importance is the communication between the obstetric provider and the substance abuse treatment provider. Consent from the woman for communication between providers should be obtained at the earliest possible time so that both sets of providers can be aware of the identified problems and care can be coordinated. Communication between providers can allow caregivers to give consistent messages to the patient, facilitate concerns being addressed in a timely fashion, and address questions about treatment. This coordinated care helps everyone involved provide the best possible care for the woman and her unborn baby, improving outcomes for both.

See Toolkit Section 3 Referral and Treatment, pages 3.10 through 3.13 for directions and sample forms.

Special Considerations in Prenatal Care

Care of the substance-using pregnant women should be a multi-disciplinary effort to optimize perinatal outcome. If the substance use/abuse is such that referral for treatment is necessary, or the patient already is in on-going substance abuse treatment, the pregnancy will require closer monitoring because of the increased risk to the mother and her fetus. If this is the case, your care will qualify for **billing as a high risk pregnancy**.

The completion of a full prenatal assessment will likely **require more frequent visits and case coordination** due to the complexities of care for the substance using pregnant women. Key components of the care may include:

- Substance abuse treatment and establishment of care in a substance abuse treatment program
- Nutritional counseling and WIC referral
- Assessment and counseling for tobacco and alcohol use
- Fetal growth assessment - ultrasound assessment at 28 and 34 to 36 weeks
- Social services
- Management of pain
- Assessment of willingness to participate and be referred for treatment
- Evaluation and treatment of common co-morbid conditions
 - Psychiatric disorders
 - Intimate partner violence
 - Medical problems often undertreated and presenting in poor control
 - Diabetes
 - Hypertension
 - Seizure disorders
 - Asthma
 - Cervical cancer test (Pap test) abnormalities
 - Cardiac disorders, valvular disease, and/or endocarditis from IV drug use

Sexual and Blood Borne Infections

Several infections occur more commonly in substance using women because of their transmission via sexual contact, drug paraphernalia, or blood to blood transmission. Suggested protocols for screening and management of these are included below.

Sexually Transmitted Infections (STIs)

Women with substance use problems may engage in high-risk sexual behaviors which put them at increased risk for STIs. Plan to screen for **gonorrhea, chlamydia, and trichomoniasis**:

- At the initial prenatal visit
- After any lapse in care
- With complaint of vaginal discharge
- At 36 weeks gestation

Hepatitis B

Obtain **hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb) and hepatitis B core antibody (HBcAb) tests** at the initial prenatal visit. A positive hepatitis B surface antigen means that the person has either an acute or a chronic hepatitis B infection and can pass the virus to others. The hepatitis B surface antibody test is positive when the person has been vaccinated against hepatitis B or has recovered from a hepatitis B infection. A positive hepatitis B core antibody test means the person is either currently infected or was infected in the past. Proceed as follows:

- If hepatitis B surface antigen and/or hepatitis B core antibody are positive, obtain a hepatitis Be antigen test. A positive hepatitis Be antigen means that the person has high levels of virus in her blood and can easily spread the virus to others including her infant during delivery. You may also want to obtain a viral load and liver function tests as they will be useful in planning potential interventions.
- If liver function tests are elevated, involve a gastroenterologist or a hepatologist in the patient's care to determine a treatment plan and timing of treatment.
- Recognize that treatment carries major risks during pregnancy. No antiviral is approved for use in pregnancy and most agree that no treatment should occur before the third trimester because of risks of teratogenicity to the fetus from the available medications. Even treatment during the third trimester is controversial.
- Consider offering hepatitis B vaccination (3 injections spaced over a 6 month period) if the woman is hepatitis B negative for all markers.
- Counsel the mother that hepatitis B surface antigen positive mothers are at substantial risk of infecting their infants during delivery, regardless of delivery method. Those with acute infection (with positive hepatitis Be antigen) will infect their infant 70 -90% of the time. Those with a chronic infection will infect their infant approximately 5 - 20% of the time during delivery.
- Notify the pediatrician about the mother's hepatitis status, as infants born to HBsAg positive mothers will need to be treated with both hepatitis B vaccine and hepatitis B immunoglobulin within 12 hours of birth. Infants born to mothers with unknown hepatitis B status may also need similar care since the risk of transmission during delivery is so high from both acute and chronic hepatitis B infected mothers.
- Encourage breastfeeding since hepatitis B infected mothers rarely transmit hepatitis B to their infants via breast milk.

Hepatitis C

Evaluate hepatitis C status by obtaining **hepatitis C antibody, qualitative test** at the initial prenatal visit. Further testing and care should proceed as follows:

- Obtain hepatitis C viral load and liver function tests if initial screen is positive.
- Refer for gastroenterology/hepatology consult in the third trimester or postpartum if the patient has an active hepatitis C infection, an elevated viral load, or abnormal liver function tests to develop a plan for treatment as appropriate. In most cases, treatment will be deferred until after delivery.
- Reassure the pregnant woman that transmission to her infant occurs in only 4% of cases.
- Strongly urge the woman to get treatment after delivery since current treatment options can provide a cure. If transmission has occurred, the baby will need treatment as well.

Hepatitis C (cont.)

- Encourage breastfeeding since hepatitis C infected mothers rarely transmit hepatitis C to their infants via breast milk.

Human Immunodeficiency Virus (HIV) and AIDS

Rates of HIV infection are higher among substance using pregnant women compared to other pregnant women. Proceed as follows:

- Screen all women for HIV at the first prenatal visit. Repeat HIV screening in the third trimester because of the high incidence of HIV infection in Maryland.
- Notify the woman that, unless she declines, HIV screening is part of the routine panel of prenatal tests.
See Toolkit Section 10 HIV addendum, pages 10.7 to 10.9 for screening procedures.
- Document any refusal of HIV testing in the medical record.
- Disclose positive tests in person and make arrangements for case management and follow up with a perinatologist, infectious disease specialist, or immunologist for advice about appropriate treatment during pregnancy.

To reduce the risk of HIV transmission to the infant, the CDC recommends the following:

- Begin medication promptly if the pregnant woman is identified with HIV infection and counsel her about the necessity of taking HIV medication daily to protect her infant.
- Perform a rapid HIV test if the pregnant woman arrives to Labor and Delivery and was not screened in the third trimester or if she continues active substance use.
 - Begin treatment in the delivery room if the rapid HIV test is positive in order to reduce the risk of transmission during delivery.
 - Obtain a confirmatory blood test, but do not delay treatment pending the results.
 - Offer a cesarean section, if possible.
- Schedule delivery by cesarean section at 38 weeks (or earlier, if in labor) if the woman's HIV RNA levels are greater than 1,000 copies/ml.
- Perform a cesarean section on an HIV positive woman if delivery is imminent and her HIV RNA levels are unknown.
- Always avoid the placement of fetal scalp electrodes and performance of operative vaginal delivery with forceps or a vacuum extractor.
- Avoid artificial rupture of membranes and episiotomy unless obstetric indications clearly outweigh the increased risk of HIV transmission to the infant.

Additional information:

- See appendix section on HIV for further details about procedures for HIV testing and steps to access care should the testing be positive.
- Check information on the website <http://aidsinfo.nih.gov/guidelines>.
- Call the National Perinatal HIV Hotline – 1-888-448-8765.
- Use the following local resources.
 - Johns Hopkins HIV and Pregnancy(HALO) Clinic - 410-502-3200
 - University of Maryland HIV in Pregnancy Clinic - 410-706-2500
 - University of Maryland HIV Clinic - 410-328-9200

Special Cautions in Methadone and Buprenorphine Treatment

- Pregnant women on methadone maintenance tend to have more nausea, vomiting and constipation than the typical pregnant woman. Generally these symptoms respond to the interventions employed in typical cases. However, **use caution in prescribing promethazine** (Phenergan, Phenadoz, or Promethegan) for these symptoms because its psychoactive properties may be abused to “enhance” the effects of methadone.
- When benzodiazepines are combined with opioids, including buprenorphine, patients may experience reduced oxygen saturation and respiratory depression along with an increased risk of mortality. Whenever possible, benzodiazepines should be avoided in patients who are regularly maintained on opioids.

Pain Control

Patients who have a tolerance to opiate drugs may need **higher than typical doses** of pain medication to address legitimate sources of pain. Carefully titrate all pain medications.

- Methadone treatment is not a substitute for pain management. Methadone is a poor choice to treat pain as the duration of pain relief is very short while the respiratory inhibition from methadone is of long duration.
- Treatment of pain with opioid medications should be limited to the minimum time period necessary, taking into account the expected clinical course of the particular source of pain. Give no more than a 7 day supply prior to a clinical reassessment.
- Treatment of severe pain during pregnancy for patients on buprenorphine is especially challenging because it blocks access to opioid receptor sites.
See Toolkit Section 3 Referral and Treatment, page 3.9 for pain management on buprenorphine.
- Pain management after delivery is most safely accomplished by non-opioid pain medication or post-operative epidural analgesia, when appropriate.
- Narcotic prescriptions for patients complaining of pain after delivery should be limited to no more than a 3-7 day supply, with no refills given prior to an in-person follow-up visit.

Hospitalizations

Hospital personnel need to be non-judgmental and empathetic, but willing to set firm limits. Common patient issues include:

- Short attention span
- Agitation
- Priorities other than the current pregnancy
- Need to smoke because of tobacco addiction
- Requirements for methadone dose adjustment
- Problems with hyperalgesia and allodynia (increased skin and subcutaneous pain perception due to altered dopamine receptors from chronic opioid use)

Special Considerations in Postpartum Care

The postpartum period is a particularly vulnerable time for relapse into substance misuse. Women who have been actively engaged in a substance use disorder program may decrease or stop their attendance. Women who have not been involved in formal treatment, but were able to independently curtail their substance misuse during pregnancy to protect the fetus, often return to substance use after the infant is born.

Some of the contributing factors leading to postpartum relapse include hormonal shifts, stress of caring for the newborn, fatigue, adjustment to new family dynamics, and/or the transition to new providers. Being pregnant is a powerful motivator for abstinence to protect the growing fetus. Once the baby is born that particular motivation disappears and many women eventually return to substance use despite their best intentions to remain abstinent. It may be helpful to point out that continued recovery is essential to help the mother provide the infant with consistent, nurturing care that is sensitive to the child's cues and needs. This is necessary to help the infant develop a sense of trust that his or her needs will be met and fosters optimal growth and development in the infant.

Because of the high risk of relapse, the OB provider should confirm and document ongoing substance use disorder treatment and any mental health treatment upon postpartum discharge from the hospital and at the routine 6-week postpartum visit. The OB provider may consider scheduling an earlier postpartum visit at 4 to 5 weeks postpartum for improved compliance.

Prioritization of pregnant women in receiving treatment for substance use disorder is mandated in Maryland to continue through the first year postpartum. If insurance coverage needs to change after the 6-week postpartum visit, the Affordable Care Act requires all new insurance policies to cover mental health and substance use disorder services including behavioral health treatment. Insurance companies are required to provide continuity in care between insurance companies when coverage changes. There are specialized women and children services in some treatment programs when the woman has custody of her infant. Information about these programs can be obtained through the local department of health.

Rescreening

Because of the stresses on new mothers and the high incidence of relapse, the OB provider should re-screen all women at their postpartum visit for substance use/misuse. Similarly, this is a key time also to screen for depression and intimate partner violence since risks for both of these problems increase during this postpartum time.

Hepatitis B and C

Those women whose prenatal blood tests have indicated a need for treatment should begin this during the postpartum period. Referral to the gastroenterologist or hepatologist should be initiated or confirmed.

Special Considerations in Drug and Alcohol Treatment for The Substance Use Disorder Treatment Provider

The Importance of Prenatal Care

Early enrollment and regular attendance in prenatal care is associated with improved pregnancy outcomes. Assessment of pregnancy progression and close monitoring for maternal and fetal complications is an important part of prenatal care in this high risk population. Prevention and treatment of infections and illnesses, control of existing medical conditions, counseling about diet and healthy habits can lead to healthier pregnant women and infants. The substance abuse treatment provider can be an integral part of this process by strongly encouraging these women to access and to continue prenatal care. Consent should be obtained early in the treatment of the pregnant woman allowing communication and collaboration with the obstetric care provider.

Accessing Prenatal Care

In Maryland, almost all pregnant women are eligible for prenatal and postpartum care either through their own private insurance or through Medical Assistance (MA) / Maryland Children's Health Program (MCHP). In most cases, the local health department receives pregnant women's applications for MA/MCHP and is expected to process these applications within 48 hours. Local departments of social services can also process these applications but are not required to follow the 48 hour timeline. Once approved, MA/MCHP will cover prenatal care (up to three months retroactively) as well as delivery costs and the 6 week post partum visit. This public insurance does not cover elective abortion services.

Characteristics of Prenatal Care

Women should enroll in prenatal care with their provider as soon as they are aware of the pregnancy. Early prenatal care allows interventions to occur that may help the early developing baby. The routine schedule of prenatal visits is the following:

- Every 4 weeks up to 30 weeks of pregnancy
- Every 2 weeks from 30 weeks to 36 weeks of pregnancy
- Every week from 36 weeks until delivery

Maternal weight, blood pressure, urine test for protein and glucose, and assessment of fetal wellbeing are obtained at each visit. When there are complications during the pregnancy, more frequent visits will be scheduled.

Prenatal blood draws routinely occur at the initial prenatal visit and again at 24 to 28 weeks of pregnancy. These include screening for HIV status, syphilis and a complete blood count. Obstetrical ultrasounds are done to determine pregnancy dating, to screen for fetal abnormalities, and to assess fetal growth. All pregnant women are offered screening for genetic problems. Counseling is provided regarding a balanced diet, exercise, smoking, alcohol and drug use and the importance of prenatal vitamins. Medical conditions such as diabetes, asthma, high blood pressure, anemia, HIV, and others are closely monitored.

Pregnancy Characteristics and Needs

The pregnancy is divided into three parts called trimesters, each lasting about 13 weeks. There are major changes to the mother and the fetus during each trimester. A “term” pregnancy is from 37 completed weeks to 42 completed weeks of pregnancy, with deliveries optimally occurring between 39 and 41 weeks. Deliveries before 37 weeks are considered premature.

The First Trimester (0 to 13 weeks pregnant)

During this trimester, the woman’s hormone balance and metabolism shift substantially, which can result in many symptoms and discomforts including nausea, vomiting (morning sickness), excessive tiredness, fatigue, dizziness, breast tenderness, cravings for certain foods, and frequent urination. There are subtle physical changes to the woman as well. Throughout pregnancy there may be mood swings or signs of depression. Note that some symptoms of pregnancy, such as nausea, vomiting, and constipation, can be worse when taking methadone. During this trimester she may need frequent breaks and additional rest. She may find that eating small frequent meals helps with morning sickness, and increased water intake is recommended throughout the pregnancy.

During this phase all of the major systems of the fetus begin to develop including the brain and nervous system, heart, musculoskeletal, and genitourinary systems. The greatest risk of miscarriage occurs during this trimester.

The Second Trimester (13 to 27 weeks pregnant)

Most women feel more energized in this period and begin to put on weight. In many women the symptoms of morning sickness subside. This is less true in the substance using population. Usually around the 20th week fetal movement can be felt by the mother. Typical discomforts are indigestion, fatigue, dizziness, breast soreness, and constipation. The fetal systems continue to develop and grow.

The Third Trimester (27 to 42 weeks pregnant)

Final maternal and fetal weight gain takes place. Fetal movement can become quite strong and be disruptive to the woman. Breathing becomes more difficult as the enlarging abdomen decreases the lung capacity. Near the end of the pregnancy the fetal head descends into the pelvis. This improves breathing, but it also severely reduces bladder capacity, leading to frequent urination. It may be difficult to sleep with the enlarged uterus. Additional discomforts may include leg cramps, ankle swelling, lower backache, continued indigestion, constipation, and mild, irregular (Braxton Hick) contractions. These women will need more rest, and may need to elevate their feet. The fetus continues to grow, and the cardiovascular and respiratory systems are usually fully developed around 40 weeks.

Preventing Mother-To-Child Transmission of HIV

The transmission of HIV from mother to fetus during pregnancy and at delivery is preventable. For untreated HIV positive pregnant women, the risk of transmission to the infant is 25-40%. With diagnosis and daily adherence to HIV drug therapy during pregnancy and infant medication therapy, the risk is decreased to less than 2% transmission to the infant. Active alcohol and substance use is a major obstacle to diagnosis and adherence to treatment for HIV infection during pregnancy.

Obstetrical Problems

Many things can occur during pregnancy that can negatively affect the outcome of the pregnancy. Medical problems can begin or worsen, blood pressure can dramatically increase, and symptoms of potential miscarriages may occur. The woman in your care should call her obstetrical provider if there are any symptoms out of the ordinary. Any of the following can indicate a critical problem:

- Vaginal spotting or bleeding
- Fluid from the vagina
- Pelvic or abdominal pain or contractions
- Constant or severe intermittent lower back pain
- Severe or persistent headache
- Vision problems
- Sudden weight gain (more than 2 pounds in a week)
- Seizures
- Decreased or absent fetal movement
- Fever
- Pain on urination
- Swelling and pain in one leg

Risk of premature birth is markedly increased in the pregnant woman with substance use disorder. The earlier the birth, the chance is greater for medical complications and impaired development of the infant.

Medication Treatment in Pregnancy

The pregnant woman in your program may need medication for headaches, colds, nausea and constipation. The best advice is to have her contact her OB provider.

Opioid Maintenance Medication Management in Pregnancy

Substance use treatment gives the woman and her infant the best chance at a healthy start. It should be timely, of high quality, and appropriate for pregnancy. For opioid dependent patients, methadone or buprenorphine maintenance is usually the best treatment option. Pregnancy in itself is not a reason for increased maintenance doses of methadone or buprenorphine. The doses of maintenance medication should still be optimized based on the elimination of opioid withdrawal symptoms and reduction/elimination of cravings to use opioids. The goal is to use the lowest effective dose possible. In general, the severity of Neonatal Abstinence Syndrome (NAS) has not been found to be dose dependent when the maintenance dose is in the range cited below. About 60% of infants born to mothers maintained on methadone will require medication for NAS. There are no established guidelines for methadone and buprenorphine dosing during pregnancy. The doses that are usually effective and adequate during pregnancy are as follows:

- Methadone 30 - 140 mg daily
- Buprenorphine 4 - 32 mg daily

Pregnancy Friendly Treatment Programs

In order to give their babies the best chance in life, pregnant women are often more receptive to treatment. They may be more motivated to address substance abuse issues in an effort to protect their babies. Pregnancy is a stressful time for all women, and even more so for a woman with a substance use disorder. They may feel stigmatized by other program participants, staff, health care providers, and society. Some women are afraid that participation in a substance use disorder program will increase the risk of Child Protective Services (CPS) involvement. In reality, the consistent participation of a woman in a treatment program is viewed favorably by CPS.

It may be difficult to attract and maintain pregnant women in treatment programs. Consider providing sessions with other pregnant women, parenting classes, and assistance in addressing temporary child care. It is helpful to provide these women with extra support and encouragement with a non judgmental and compassionate approach.

Breastfeeding and Substance Use/Abuse

Breastfeeding is recommended for almost all women by the American Academy of Pediatrics. Breastfeeding conveys substantial health benefits both for the infant and for the mother. Breast fed babies have fewer infections, decreased rates of obesity later in life, improved attachment with their mothers, lower risks for Sudden Infant Death Syndrome, and lower rates of asthma. Mothers who breast feed their babies have improved bonding with their infants, lower food costs for their babies, more rapid recovery following childbirth, and lower rates of breast and ovarian cancer later in life.

However, these benefits must be balanced against the risks of transmitting substances through breast milk when the mother continues to use drugs (both licit and illicit) or other substances. Of note, the American Academy of Pediatrics Clinical Report on this topic specifically mentions that the risks from drug exposure are higher for premature infants and infants under two months of age but are rare to occur for infants over six months of age. (See Toolkit Section 9 – Resources, pages 9.44 through 9.59 for a copy of this report.) Current and comprehensive information about transfer of specific medications by way of breast milk is available through LactMed <http://toxnet.nlm.nih.gov>.

In addition to the risks of transfer of drugs via breast milk, one must consider whether breastfeeding while impaired by drug use also increases other risks – such as the transfer of certain infections (such as HIV) or the likelihood of engaging in other behaviors which may be dangerous for the infant. The latter could include co-sleeping with the infant, burning the infant when smoking while breastfeeding, or exposure to secondhand smoke.

Polydrug use is common for substance using pregnant women, including the use of legal substances such as tobacco and alcohol. Illicit drugs are frequently cut with dangerous adulterants that can pose additional threats to the infant. Drug using populations are at higher risk for infections such as human immunodeficiency virus (HIV) and/or hepatitis B or C, as well as poor nutrition. Psychiatric disorders that require pharmacotherapeutic intervention are more prevalent among this population, making decisions about breastfeeding even more complicated as there is limited information available on the relative safety of breastfeeding with many psychotropic medications.

The decision whether to encourage breastfeeding or not must be based on consideration of both the risks of substances transmitted and the fact that infants of substance-using women are at risk for multiple health and developmental difficulties that might be improved substantially with breastfeeding. This position is described in detail in Jansson, Lauren, M. *ABM Clinical Protocol #21: Guidelines for Breastfeeding and the Drug-Dependent Woman*. The Academy of Breastfeeding Medicine Protocol Committee. 2009 December; 4(4): 225-228.

Overall benefits of breastfeeding:

- Improved infant nutrition
- Decreased risk of infections and allergies in infants and children
- Increased empowerment and self-esteem of the woman
- Lower feeding costs
- Accelerated physical recovery for the woman after delivery
- Increased attachment between the mother and her infant

Risks are reduced when a woman with a history of substance use/abuse:

- Engages in substance use disorder treatment and provides consent for open communication between providers.
- Commits to maintaining abstinence from substance use/abuse.
- Has negative toxicology screens in the third trimester and at delivery (except for substances used to treat addictions and drugs cleared as safe for use when breastfeeding).
- Has been tested for Human Immunodeficiency Virus (HIV) and is negative.
- Has had any additional medications reviewed and determined to be safe or worth the minimal risks.

Discussion of Selected Substances (in alphabetical order)

Alcohol

- Alcohol is transferred into breast milk by passive diffusion within 30 to 60 minutes of ingestion.
- Maternal serum and breast milk levels are equal but, in heavy drinkers, breast milk concentrations are greater than plasma concentrations.
- Alcohol can alter the infant's milk intake and sleep/wake cycles.
- Infants process alcohol in the body at half the rate of adults until the age of 3.

Advice to patients: Women with a history of a substance use disorder or misuse of licit substances should avoid all alcohol while breastfeeding. (Note: this advice is different than the published recommendations for women without a history of substance abuse or misuse – see references.)

Buprenorphine

- Case studies suggest that the amount of buprenorphine in human milk is low and is unlikely to have negative effects on the developing infant.

Advice to patients: Women who are maintained on buprenorphine and abstain from other drugs may safely breastfeed their infants.

Cocaine

- Studies have found large variability in concentrations in breast milk.
- Cocaine has been found in human milk in high concentrations leading to infant intoxication in some cases.

Advice to patients: Women using cocaine should not breastfeed their infants.

Heroin and other Opioids

- Codeine, oxycodone and heroin transmitted in breast milk have substantial risks of CNS depression and possibly even infant death.
- Low dose prescribed opioids for pain control in the postpartum period are compatible with breastfeeding since these doses are much lower than doses that are taken by those misusing these drugs.

Advice to patients: Women using illicit opioids or misusing licit opioids should not breastfeed their infants.

Marijuana

- Breast milk levels of tetrahydrocannabinol (THC) may be higher than maternal serum levels in chronic users.
- THC may cause the short term effects of sedation, weakness, and/or poor feeding in the infant.
- Long term effects are generally unknown but there is one study suggesting that chronic exposure in the first month of life via breast milk may be associated with poorer motor development in children at one year of age than in children not exposed to marijuana.

Advice to patients: Current advice is that women using marijuana should not breastfeed, although studies of its effects on infants are very limited at present.

Methadone

- Methadone has been the treatment of choice for opioid dependent women in the United States.
- Very low concentrations are found in breast milk.
- No apparent short-term or long-term effects have been found on neurodevelopment of infants from methadone transferred in human milk.

Advice to patients: Women on methadone maintenance and abstaining from other substance use/abuse may breastfeed their infants.

Methamphetamine

- Concentration in breast milk is found to be at 3 to 7.5 times the mother's plasma levels.
- Methamphetamine can cause irritability and agitation in the infant.
- Infant death has been reported related to breast milk transfer of methamphetamine.
- Exposure to the production of methamphetamine is extremely dangerous due to the toxic chemicals used.

Advice to patients: Women using methamphetamine should not breastfeed their infants.

Nicotine

- Maternal serum and breast milk levels are equal (measuring cotinine).
- Nicotine use has been associated with low milk supply and poor infant weight gain in some cases.
- Smoking carries injury (burn) danger due to dropped cigarettes and/or ashes.
- Passive inhalation (secondhand smoke) of nicotine and tar is more dangerous to infants than adults due to the infant's increased respiratory rate and rapid absorption via the respiratory route.
- Nicotine patch (21 mg) leads to serum levels equivalent to that of about 17 cigarettes.

Advice to patients: Women who smoke may breastfeed but should take steps to reduce the risks to their infants (decrease smoking and use lowest possible nicotine product, smoke outside and not in the presence of baby, smoke immediately after nursing to provide maximal time for nicotine to be excreted, change clothes after smoking).

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Therapeutic Handling Techniques for use with the Substance Exposed Infant

Adapted from: Barbara Drennen's *Care Givers Guide to Drug Exposed Infants* www.picc.net

Infants suffering from drug withdrawal symptoms benefit from specific handling techniques to help keep them medically safe, manageable, and more comfortable. Caregivers who are trained in reading signs and signals given off by the infant are in a better position to help the infant learn to control their bodies and emotions. In addition, the training assists the caregiver with strategies to not only help the infant, but also help the caregiver to remain calm.

Controlling the Environment

One of the easiest and most effective ways to start is to offer a calm surrounding. Limiting the number of caregivers, decreasing all noise, and turning off overhead lights is the best start. In addition, the caregiver needs to offer a calm and soothing presence. Setting routines for care is important and all speaking should be done very slowly and in a soft voice.

Introduction of Stimuli

All babies need stimulation for healthy development, but stimulation of a drug exposed infant needs to be introduced in small doses and on a schedule dictated by the infant's ability to adjust. Stimuli are best received when the baby is in an active/alert state. The caregiver should introduce one stimulus (light, sound, voice, touch, etc.) at a time and should only move to increase the same stimuli or add another when the infant shows no further signs of stress. This process takes time and patience on the part of the caregiver and requires watching for clues from the baby to assess its tolerance level.

Swaddling

Swaddling is the process of wrapping the baby snugly in a blanket or cloth with its arms and legs bent against its body. This prevents the baby from moving and provides a sense of security and comfort for the baby.

The C-Position

Holding or laying the baby in a "C" position increases the infant's sense of control and ability to relax. This position is accomplished by holding the baby's back firmly and curling the head and legs into a "C" form. If the position is done properly, the chin is resting near the chest, the arms are curled over the chest, the back is slightly rounded, and the legs are bent at the knee. The baby can then be held against the body in this position.

Head-to-Toe Movement

Common techniques like back and forth rocking, a baby swing, and bouncing are not helpful with a drug exposed infant. Instead, a slow, rhythmic swaying following the line from head-to-toe with the baby swaddled and held firmly in the "C" position is calming. It is imperative to keep the movements slow and rhythmic in order to relax and calm the infant.

Vertical Rock

This technique can be used to help soothe a very frantic and very hard to calm infant. Place the baby in a “C” position and face the baby away from you holding it 2 inches away from your body. Slowly and rhythmically move the baby up and down. This movement is soothing to the baby’s neurological system as is holding the baby away from your body without touch.

Clapping

Another technique that can help the baby relax is to hold the swaddled baby upright, facing your body, and clap the diapered and blanketed bottom. By cupping your hand and clapping slowly and rhythmically, you should be able to feel the baby relax. It is important to remember that for some babies, this may actually stimulate them, so it is imperative to read the baby’s clues.

Feeding

Babies withdrawing from drugs may suck frantically and in a disorganized manner when trying to feed. This can lead them to not feed well, not take in an adequate amount of formula, and to have trouble with the suck-swallow-breath routine. The key is to ensure the baby is in a low stimulus environment, swaddled, held in a “C” position, and relaxed prior to each feeding.

How Can Maryland Laws and Mandates Assist in Perinatal Care?

Frequently Asked Questions

The MD General Assembly has a long history of support for maternal and child health issues. The laws governing many of these issues are explained below. There is a segment devoted to each of the following topics:

- resources for prenatal substance use disorder treatment
- newborns who have been substance exposed
- postpartum resources
- health funding resources for mothers and children
- health services required to be paid by insurances
- Affordable Care Act and maternal/child health
- newborn screening

See Toolkit this section, page 7.7 for a Guide to Internet Access to the Maryland Statutes.

Definition of terms:

- Controlled Drug is a controlled dangerous substance included in Schedules I-V under Title 5, Subtitle 4 of the Criminal Law Article.
- Health Care Practitioner is a person who is licensed, certified, or otherwise authorized under this article to provide health care services in the ordinary course of business or practice of a profession. [*Health Occupations §1-301*].
- LDSS is the Local Department of Social Service. The social worker, employed by the hospital or birthing center, is not part of this group.
- Newborn is a child under the age of 30 days who is born or who receives care in the State of Maryland.
- Substance - Exposed Newborn is a newborn who exhibits one or more of the following:
 - Has a positive toxicology screen for a controlled drug as evidenced by any appropriate test after birth.
 - Displays the effects of controlled drug use or symptoms of withdrawal resulting from prenatal controlled drug exposure as determined by medical personnel.
 - Displays the effects of a fetal alcohol spectrum disorder (FASD).
 - Has a mother who had a positive toxicology screen for a controlled drug at the time of delivery.

1. My patient is using alcohol or illegal substances while pregnant. What resources are available for treatment?

Pregnant Women Priority

Maryland law [*Health-General, Alcohol and Drug Abuse Administration, ADAA Programs and Facilities §8-403.1*] allows a pregnant woman to have priority for drug or alcohol treatment:

- Pregnant and postpartum women (up to one year) are given priority in any state funded substance abuse program or treatment facility (outpatient or residential).

- A pregnant woman's application must be addressed within 24 hours.
- Protocols are in place in treatment programs and facilities for referring patients for prenatal care and Medicaid.
- The law does not address pregnancy loss, thus women who have a loss may lose their priority status, and possibly their treatment funding for inpatient treatment.
- The patient's private insurance carrier has a responsibility to direct the patient to an appropriate treatment facility.

See Toolkit Section 3 - Referral and Treatment, page 3.1 for information on referrals

2. A baby has been born exposed to alcohol or controlled drugs. What are my responsibilities as an obstetrician?

Maryland law on Substance-Exposed Newborns [*Family Law §5-704.2*] was passed in 2013 to address the needs of newborns affected by prenatal alcohol or controlled drug exposure and to bring Maryland law into compliance with the federal law [*Child Abuse Prevention and Treatment Act, CAPTA-P.L. 111-320*]. Prenatal use of controlled dangerous substances is not defined as child abuse or neglect in Maryland. State law stipulates that there must be a living child for child abuse or neglect to occur.

Substance-Exposed Newborn Report

Some of the requirements of reporting substance exposed newborns include:

- Health care practitioners involved in the delivery or care of a substance-exposed newborn are required to make an oral report to the Local Department of Social Services (LDSS) as soon as possible and to make a written report (DHR/SSA Form 2079) within 48 hours. A health care practitioner is not required to make a report if the health care practitioner has verified any of the following:
 - The head of an institution, his designee or another individual at that institution has made a report regarding the substance-exposed newborn.
 - The mother at the time of delivery was using a controlled substance as currently prescribed for the mother by a licensed health care practitioner.
 - The presence of the controlled substance at the time of delivery was consistent with a prescribed medical or drug treatment administered to the mother or the newborn.
- Reports made in accordance with this law do not create a presumption that the newborn has been or will be abused or neglected.
- The report is not a referral of child abuse or neglect but a notification to the LDSS of the birth of a substance-exposed newborn in order that the LDSS may take the steps to evaluate needs.

See this section, page 7.8 for the form or go to http://www.dhr.state.md.us/blog/?page_id=3992.

Local Department of Social Services (LDSS) Action

The LDSS is required, within 48 hours of the report to carry out all of the following:

- See the newborn.
- Consult with a health care practitioner with knowledge of the newborn's condition and the effects of the prenatal alcohol or drug exposure.

- Attempt to interview the newborn's mother and any other individual responsible for care of the newborn.
- Assess the safety of, and risk of harm to, the newborn.

If the LDSS determines that further intervention is necessary, the Local Department will:

- Develop a plan of safe care.
- Refer the family for appropriate services, including alcohol or drug treatment.
- Monitor the family's participation in appropriate services

See this section, pages 7.9 and 7.10 for a list of the LDSS departments by jurisdiction.

Based on this new law, health care practitioners may want to review their health care institutions' policies, protocols, and standards of care on this issue.

Proper Care and Attention of Substance-Exposed Newborns

- Maryland law [*Courts and Judicial Proceedings §3-818*] holds both parents equally responsible for providing proper care and attention to their children, including care appropriate to the child's needs and development. Proper care and attention includes but is not limited to providing:
 - appropriate food
 - clothing
 - shelter
 - medical care
 - nurturing
 - activity
 - guardianship and supervision
 - caring and planning for the child's welfare
- Maryland law, passed in 1997, [*Family Law §5-706.3, §5-710 and Courts and Judicial Proceedings §3-818*] is a **pilot program for drug-exposed newborns**. The pilot program continues and is sometimes referred to as SB 512:
 - Addresses only newborns exposed to illegal drugs, and is in effect only in Baltimore City, Prince Georges County, Washington County, Dorchester County, and the Lower Shore counties of Wicomico, Worcester, and Somerset.
 - Requires the health care practitioner to report a newborn at high risk for child abuse or neglect to the Local Department of Social Services (LDSS).
 - Offers the mother substance abuse treatment and provides supportive services to maintain family unity.
 - Stipulates that, if a parent, due to drug abuse, is not willing or able to provide the proper care and attention to a child who was born drug-exposed, and refuses or fails to complete substance abuse treatment, the LDSS caseworker may conclude that, in order to keep the child safe, they must seek court intervention by filing a Child In Need of Assistance Petition (CINA). Maryland law [*Courts and Judicial Proceedings §3-818*] provides a one year time frame for the parent to address the various problems, including substance abuse, that make the child unsafe.
 - Includes some funding for substance abuse treatment for the mother residing in the designated counties.

3. Mother and baby are heading home. What resources are available?

Postpartum Care Pertaining to Substance Use

Maryland, in 1995, [*Insurance, Health Insurance, Private Review Agents §15-10B-09*] passed legislation addressing the early discharge of privately insured patients, requiring hospitals to follow *The Guidelines for Perinatal Care*, co-authored by the American Academy of Pediatrics and the American Congress of Obstetrics and Gynecology. The provision to follow *The Guidelines for Perinatal Care* remains in Maryland law.

These guidelines recommend:

- Babies exposed to opiates stay in the hospital a minimum of 4 days.
- "Concern for parental substance abuse should prompt awareness of the need for increased support after discharge." (p. 375)

48 Hour Discharge and Home Visiting

Maryland, in 1996, [*Insurance, Health Insurance, Required Health Insurance Benefits §15-812*] passed legislation requiring that women be allowed to stay in the hospital for 48 hours (96 hours for a cesarean section delivery). Additionally, private health insurers in Maryland are required to cover:

- A newborn hospital stay for up to 4 days, while the mother is there
- Home visits for the mother and baby:
 - One home visit is covered within 24 hours of discharge for the mother who is discharged before 48 hours plus an additional home visit as prescribed by the attending provider for a medical reason, such as elevated bilirubin, inadequate feeding, weight concerns, or substance withdrawal.
 - One home visit is covered, if prescribed for medical reasons, for the mother and child discharged after 48 hours.
 - Home visit(s) may be prescribed by the attending provider (obstetrician or pediatrician) and coordinated by the hospital social worker or hospital referral system, if substance abuse is suspected.
 - **Maryland insurers may not be accustomed to reimbursing for this home visiting benefit, despite being in Maryland law for many years - the key is the provider prescription to assure coverage.**
 - Medicaid patients are not covered by these private insurance provisions but may have similar benefits under their MCO.

4. What funding resources are available in Maryland for maternal and child health?

Medicaid Coverage for Pregnant Women and Children

[*Health-General, Assistance Programs, §15-103(ii)*]

- Currently, pregnant women in Maryland are covered by Medicaid MA up to 138% of the Federal Poverty Level (FPL) or the Maryland Children's Health Program (MCHP) from 138% to 250% of the FPL.

- Approximately, 40% of deliveries in Maryland are covered by MA/MCHP. This generally includes coverage for prenatal and postpartum care.
- Medicaid applications for pregnant women at local health departments are “accelerated” (ACE - Accelerated Certification of Eligibility). A pregnant woman whose application is not completed within 10 days is presumptively enrolled in Medicaid and provided 90 days of coverage while her application is being processed.
- Illegal immigrants are not eligible for Medicaid, although there is an exception for labor and delivery services.
- At the time of enrollment into Medicaid, pregnant women are screened for and referred to other services:
 - The Special Supplemental Nutrition Program for Women, Infants and Children (WIC)
 - substance abuse services
 - mental health services
 - domestic violence prevention
 - smoking cessation services

Maryland Children's Health Insurance Plan (MCHP)

- In 1998, Maryland implemented MCHP [*Health- General, Assistance Programs, MCHP, §15-301*] with new federal funds made available, expanding Medicaid for children to age 19 to eventually 300% of the Federal Poverty Level (FPL).
- For those children whose family income falls between 200% and 300% of the FPL, premiums are allowed based on family income.

Medicaid Managed Care

- Maryland, in 1997, [*Health-General, Assistance Programs, §15-103*] moved most of their Medicaid recipients to managed care when they created Health Choice and the managed care organizations (MCOs).
- Many Maryland MCOs have personnel devoted to coordination of services for pregnant women and newborns.

Family Planning

- Maryland [*Health-General, Assistance Programs, §15-103(iv)*] for many years has had a Medicaid funded program for family planning, at one time called the “purple and white card.”
- Maryland, as of 2012, provides family planning coverage for uninsured women up to 200% of the Federal Poverty Level (FPL) for office visits, physical exams, lab work, family planning supplies, reproductive education, counseling, referral, and tubal ligation.
- The requirement to have been previously pregnant no longer applies.
- Participants must reapply annually.
- Some local health departments have family planning programs and clinics.

5. What maternal and child health services are health insurers required to cover in Maryland?

Health insurers are required to cover certain services in Maryland - Maryland's mandated benefits [*Insurance, Health Insurance, Required Health Insurance Benefits §15-subtitle 8.*] The Affordable Care Act requires 10 "Essential Health Benefits." Maryland's Benchmark health insurance plan includes these 10 essential benefits and all of the Maryland mandated benefits. Maryland requires coverage for the following maternal and child health services when a policy is issued or delivered in Maryland:

- 48 hours of hospitalization (96 hours for C-section) following delivery [*§15-812*]
- Pregnancy and childbirth to the same extent as coverage for any other illness [*§15-811*]
- Hospitalization of the newborn as long as the mother is hospitalized [*§15-811*]
- Screening tests for chlamydia and HPV [*§15-829*]
- Routine gynecological care and primary care delivered by an obstetrician/gynecologist without a prior visit to a primary care provider [*§15-816*]
- Standing referral to specialists and standing referral to an obstetrician without a written treatment plan [*§15-830*]
- Continuity of care for pregnancy, mental health conditions and substance use disorders between relinquishing and accepting insurers [*§15-140 effective 1-1-2015*]
- Services to newly born or newly adopted children or dependent grandchildren [*§15-401*]
- Well child care [*§15-817*]
- Mental health and substance abuse services [*§15-802*]
- Medically necessary residential crisis services and intensive mental health service [*§15-840*]
- Screening mammography [*§15-814*]

6. What impact does the Patient Protection and Affordable Care Act have in Maryland and to maternal and child health?

The Patient Protection and Affordable Care Act [*P.L. No. 111-148*] requires states to choose between a Marketplace established by the federal government, or to establish their own Marketplace, a Maryland Health Benefit Exchange (MHBE). In Maryland, the Maryland Health Connection is our Marketplace for small business and individuals to purchase health insurance and the gateway to federal premium tax credits, cost-sharing reductions and expanded Medicaid. Consumers are assisted by 'navigators' and 'connectors' and the Maryland Health Connection began open enrollment in October 2013 for implementation on Jan 1, 2014. Information about the Patient Protection and Affordable Care Act and how it is implemented in Maryland can be found at www.marylandhealthconnection.gov.

The standard for the Essential Health Benefit for individual and small group plans has been established. The benefits available will be those included in the following:

- Maryland's largest small group plan in 2012, Care First Blue Choice HMO HSO *Open Access Plan* is the 'Benchmark' plan.
- All of Maryland's mandated benefits referred to above.
- The federal employee plan's benefits for behavioral health are included.

This Essential Health Benefit covers:

- Maternity and newborn care
- Mental health and substance use disorder services, including behavioral health treatment
- Ambulatory patient services, emergency services, hospitalization, prescription drugs, rehabilitative and habilitative services and devices, lab services, preventive and wellness services, chronic disease management, and pediatric services including oral and vision care
- Tobacco cessation, family planning services, nutrition services, certain sterilization services
- Evidence based preventive services rated “A” or “B” from the United States Preventive Services Task Force

The Affordable Care Act expands Medicaid coverage to basically 138% of the Federal Poverty Level (FPL) for all individuals. A cost calculator at Maryland Health Connection determines who is eligible for reduced premiums and/or cost-sharing subsidies.

Some additional features:

- Exclusion of pre-existing conditions, such as pregnancy, is no longer allowed.
- Health insurance plans sold will be at four levels - bronze, silver, gold and platinum.
- Abortion services are not required to be covered.

7. What are the newborn screening requirements in Maryland?

Maryland requires that newborns be screened for hereditary and genetic disorders [*Health - General §13-111*], and newborn screening for hearing [*Health-General §13-601-605*]. State law does NOT require newborns to be screened for substance abuse exposure. However, new Maryland law does require health care practitioners to report newborns that display a positive toxicology screen after birth, who display the effects of substance exposure, or whose mother had a positive toxicology screen at the time of delivery.

Guide to Accessing Maryland Statutes

Maryland Statutes can be found on the Internet through the Maryland General Assembly web page. Go to <http://mgaleg.maryland.gov>, then to “Statutes” on top bar. Follow one of the two options:

- Option one - in “Statutes,” look up item in the Section or Article of the Code, then the click the arrow at the right.
- Option two - drop down to the bottom of the left hand side of the page to a box, “Related Links.”
 - Choose the bottom entry, “LexisNexis - Unannotated Code of Maryland.”
 - Agree to “Terms and Conditions.”
 - Allow “Plug Ins.”
 - Search for your item of interest in Health-General; Health Occupations; Insurance-Health Insurance; or for issues of child abuse, Family Law, and Courts and Judicial Proceedings.
- Maryland Statute citations are in *Italics* in each section.

NAME OF <u>LOCAL DEPARTMENT</u> BEING NOTIFIED		ADDRESS		ZIP	
NAME OF PERSON MAKING REPORT		POSITION/TITLE		SIGNATURE <i>(Required after printing)</i>	
NAME OF HOSPITAL/BIRTHING CENTER		ADDRESS		ZIP	TELEPHONE
NAME OF NEWBORN		DATE OF BIRTH <i>(The NEWBORN must be less than 30 days old)</i>		WEIGHT <i>(Grams)</i>	GESTATIONAL AGE
ADDRESS WHERE NEWBORN CAN BE SEEN		CITY	STATE	ZIP	GENDER RACE
PARENTS		DOB	ADDRESS		TELEPHONE
MOTHER:					
FATHER OF NEWBORN:					
ALTERNATE CAREGIVER:					
PRENATAL CARE None <i>(select one)</i>	C-SECTION No	NICU No	ESTIMATED LENGTH OF STAY		PLANNED DISCHARGE DATE
MOTHER'S DRUG OF USE			NEWBORN'S DRUG OF EXPOSURE		
Referral Information (All sections must be completed by reporter to the extent known)					
NEWBORN'S MEDICAL CONDITION AND CURRENT AND/OR ONGOING HEALTH CONCERNS:					
SYMPTOMS OF WITHDRAWAL FROM OR EFFECTS OF PRENATAL ALCOHOL OR CONTROLLED DRUG EXPOSURE ON THE NEWBORN:					
IMPACT OF ALCOHOL OR CONTROLLED DRUG USE ON MOTHER'S ABILITY TO PROVIDE PROPER CARE AND ATTENTION TO NEWBORN:					
NATURE AND EXTENT OF MOTHER'S CURRENT DRUG USE AND HISTORY OF PREVIOUS TREATMENT:					
EXTENT TO WHICH MOTHER IS RESPONSIVE TO NEWBORN'S NEEDS AND IS INVOLVED WITH PROVIDING CARE:					
NATURE AND EXTENT OF PARENTS' SOCIAL SUPPORT SYSTEM:					
EXTENT OR HISTORY OF ANY VIOLENCE, MENTAL ILLNESS, OR COGNITIVE LIMITATIONS:					
NATURE AND EXTENT OF RISK OF HARM TO THE NEWBORN:					
PARENTS' LEVEL OF COOPERATION:					
PREPARATIONS FOR NEWBORN:					
ANY OTHER AVAILABLE INFORMATION THAT WOULD ASSIST STAFF IN ASSESSING SAFETY AND RISK AND DEVELOPING PLAN OF CARE:					
INFORMATION ON PREVIOUS INVOLVEMENT WITH THE DEPARTMENT OF SOCIAL SERVICES					
NAME OF LDSS STAFF PERSON TO WHOM REPORT MADE:				DATE / HOUR /	

DHR/SSA 2079 11/15/13 **Original** (Hospital files) Copy (Fax to Local Department within 48 hours)
 The completed document must be printed and faxed to the local department, to the attention of the child Protective Services Screening supervisor, where the child lives with its mother or place where child can be seen. For a complete list of local departments go to www.dhr.state.md.us

Local Maryland Department of Social Services Child Protective Services

Allegany County	Tel: (301) 784-7122 After hours: (301) 759-0362 FAX: (301) 784-7244 Address: One Frederick Street, Cumberland, Maryland 21502
Anne Arundel County	Tel: (410) 421-8400 FAX: (410) 508-2041 Address: 7500 Ritchie Highway, Glen Burnie, Maryland 21061-1787
Baltimore City	Tel: (410) 361-2235 (24 hours) FAX: (443) 423-7003 or 7002 After 3:30 p.m. (443) 423-5950 Address: 1900 N. Howard Street, Baltimore, Maryland 21218
Baltimore County	Tel: (410) 853-3000 (Option 1) After hours: (410) 583-9398 FAX: (410) 853-3698 Address: Drumcastle Government Center 6401 York Road Baltimore, Maryland 21212
Calvert County	Tel: 1-443-550-6900 After hours: (Toll Free: 1-866-898-9848) FAX: (410) 286-7429 Address: 200 Duke Street, Prince Frederick, Maryland 20678
Caroline County	Tel: (410) 819-4500 After hours: (410) 479-2515 Sheriff's Office. FAX: (410) 819-4501 Address: 207 South Third Street, Denton, Maryland 21629
Carroll County	Tel: (410) 386-3434 (24 Hours) FAX: (410) 386-3477 Address: 1232 Tech Drive, Westminster, Maryland 21157
Cecil County	Tel: (410) 996-0100 (Option 3) After hours: (410) 996-5350 FAX: (410) 996-0228 Address: 170 East Main Street, Elkton, Maryland 21922-1160
Charles County	Tel: (301) 392-6739 After hours: (301) 932-2222 Police Dept. FAX: (301) 934-2662 Address: 200 Kent Avenue, LaPlata, Maryland 20646
Dorchester County	Tel: (410) 901-4100 After hours: (410) 228-3333 Police Dept. FAX: (410) 901-1060 Address: P.O. Box 217, 627 Race Street, Cambridge, Maryland 21613
Frederick County	Tel: (301) 600-2464 After hours: (301) 600-2100 Police Dept. FAX: (301) 600-2639 Address: 100 East All Saints Street, Frederick, Maryland 21701
Garrett County	Tel: (301) 533-3005 After hours: (301) 334-1930 Sheriff's Office. FAX: (301) 334-5413 Address: 12578 Garrett Highway, Oakland, Maryland 21550

Harford County	Tel: (410) 836-4713 After hours: (410) 838-6600 Sheriff's Office. FAX: (410) 836-4945 Address: 2 South Bond Street, Bel Air, Maryland 21014
Howard County	Tel: (410) 872-4203 After hours: (410) 313-2929 Police Dept. FAX: (410) 872-4303 Address: 7121 Columbia Gateway Drive, Columbia, Maryland 21046
Kent County	Tel: (410) 810-7600 After hours: (410) 758-1101 State Police FAX: (410) 778-1497 Address: 350 High St, Chestertown, Maryland 21620
Montgomery County	Tel: (240) 777-4417 (24 hours) FAX: (240) 777-4258 Address: The Dept. of Health & Human Services 1301 Piccard Drive, Rockville, Maryland 20850
Prince George's County	Tel: (301) 909-2450 After hours: (301) 699-8605 FAX: (301) 909-2200 Address: 805 Brightseat Road, Landover, Maryland 20785
Queen Anne's County	Tel: (410) 758-8000 (all hours) After hours: (410) 758-0770 Sheriff's Office. FAX: (410) 758-8110 Address: 125 Comet Drive, Centreville, Maryland 21617
St. Mary's County	Tel: (240) 895-7016 After hours: (301) 475-8016 FAX: (240) 895-7099 Address: 23110 Leonard Hall Drive, Leonardtown, Maryland 20650
Somerset County	Tel: (410) 677-4200 After hours: (410) 651-0630 Sheriff's Office Centra, Emergency Services. FAX: (410) 677-4300 Address: P.O. Box 369, 30397 Mt. Vernon Road, Princess Anne, Maryland 21853
Talbot County	Tel: (410) 770-4848 (option#1) After hours: (410) 822-3101 MD State Police FAX: (410) 820-7067 Address: 301 Bay Street, Easton, Maryland 21601
Washington County	Tel: (240) 420-2222 (24 hours) FAX: (240) 420-2549 Address: 122 North Potomac Street, Hagerstown, Maryland 21741-1419
Wicomico County	Tel: (410) 713-3900 (option#4) After hours: (410) 548-4890 FAX: (410) 713-3910 Address: 201 Baptist Street, Salisbury, Maryland 21802-2298
Worcester County	Tel: (410) 641-0097 After hours: (410) 632-1111 (option#2) Sheriff's Office. FAX: (410) 641-0935 Address: 299 Commerce Street, Snow Hill, Maryland 21863

Center for Addiction and Pregnancy (CAP)

The **Center for Addiction and Pregnancy (CAP)** started in 1991 as a cooperative venture between the Maryland State Alcohol and Drug Abuse Administration (ADAA) and Johns Hopkins Bayview Medical Center. This collaborative, inter-departmental program among Departments of Obstetrics & Gynecology, Pediatrics, and Psychiatry was developed as a “**one-stop shopping**” **model of care** to provide integrated care in order to optimize perinatal outcomes. It includes substance use disorder treatment (including methadone maintenance), mental health consultation, obstetrical evaluation and management, pediatric health care, residential services, inter-departmental outreach services, assistance with medical insurance enrollment, housing, and referral for other medical care.

Eligibility Criteria

A woman must be pregnant and have a history of recent or current use of alcohol, illegal drugs and/or prescription medications. She may already be on methadone or buprenorphine maintenance. She must be willing to be treated and agree to abide by the regulations of CAP. Many medical insurances as well as state medical assistance are accepted. The woman can self refer to CAP by phone or request this through her insurance company.

Enrollment

The patient may be enrolled any time prior to delivery. An initial phone screening assessment is done by the intake worker to determine eligibility. The enrollment appointment is usually scheduled to occur within 48 hours of the phone assessment. Any patient with a recent psychiatric, obstetric, or medical hospitalization is reviewed by the psychiatrist or perinatologist to determine CAP eligibility prior to patient enrollment.

The enrollment intake is a three to four hour process. Assessment for substance abuse treatment includes a psychosocial interview that assesses the severity of addiction, prior treatment experiences, and patient functioning in major life domains. Special attention is devoted to issues that are often affected by substance use such as medical problems, employment issues, pending legal actions, psychological functioning, and relationships with family members and others. A substance use disorder treatment plan might include opioid detoxification with methadone or buprenorphine, methadone or buprenorphine maintenance, benzodiazepine detoxification, alcohol detoxification, and/or abstinence from other abused substances.

A thorough obstetric and medical evaluation with complete medical history and physical exam by a nurse practitioner, midwife or obstetrician/gynecologist (OB/GYN) takes place following the substance use disorder assessment. Testing for STIs, pregnancy, toxicology, prenatal labs, and ultrasound are completed. Consents for release of prior medical and obstetric care are obtained, as needed. Medical clearance for admission for detoxification, if needed, is also determined at this time.

Once enrolled in CAP, patients may continue for up to 8 weeks postpartum or 4 weeks post-pregnancy loss. CAP staff assist patients in transitioning to the appropriate level of subsequent care following completion of the program at CAP.

CAP Program Components

There are various divisions of the CAP program involving counseling and treatment within which a women is placed according to her needs. These can include referral to the inpatient unit, temporary housing, intensive outpatient services, and standard outpatient services.

The Chemical Dependency Unit (CDU)

This inpatient department of Johns Hopkins Bayview Medical Center has a collaborative agreement with CAP to provide detoxification for pregnant patients. The CAP OB clinic provides medical and obstetric clearance for admisssion of the pregnant woman to the CDU, and these patients are scheduled for admission through the CAP intake office. Detoxification can be provided for opioids, benzodiazepines, and alcohol, and involves a short inpatient stay. Following completion of this inpatient detoxification program, additional time is highly recommended in the CAP Housing Unit in order to stabilize the patient during her intitial abstinence period.

The CAP Housing Unit (CHU)

The goal of the CAP Housing Unit is to provide stabilization from alcohol or drug abuse and/or address homelessness or domestic violence by providing short term overnight housing in a drug free environment. This unit is located in the same building as CAP. It is open from 4:30 p.m. to 8 a.m. daily and staffed by resident assistants. The unit can provide housing for up to16 women. Criteria for admission to this unit include enrollment in CAP, agreement to adhere to the CHU regulations, and attendance at a specified number of sessions in the Intensive Outpatient Program during the day.

Intensive Outpatient Program (IOP)

The IOP is the primary mechanism by which outpatient services are provided in the CAP program and provides services for 60-90 women. The intensity of services varies depending on the severity of symptoms and the needs of the patient. As a woman progresses in her treatment and recovery, services are modified and she moves to less intensive levels of service. Patients who require the most intensive services may attend up to 7 days per week.

Enrolled patients receive individual counseling as well as group counseling. Some of these core group sessions cover the following topics: Relapse Prevention, 12 Step Recovery Plan, OB Group Education, Drug Education, Smoking Cessation, Mastery Therapy Group, Parenting, Life Skills, and Mental Health.

Standard Outpatient Services

This program is for patients who require less intensive services. These standard services are available one to two days each week.

Obstetric Services

The CAP OB clinic is staffed by a perinatologist (2 days per week), a general OB/GYN, a certified nurse midwife, a registered nurse, a medical technician, and a secretary. It is open Monday through Friday. Nursing services are available for CAP patients every day from 7:30 a.m. until 8 p.m.

All admissions to CAP, and most admissions of pregnant women to the CDU, are evaluated by both nursing and OB providers. Due to complexity of medical problems, patients typically are seen every 1 to 3 weeks for prenatal care.

Johns Hopkins Bayview Medical Center Labor and Delivery is the designated delivery site for CAP patients. For specific obstetrical or fetal complications, patients may be referred to Johns Hopkins Hospital for delivery. Occasionally a patient attending CAP Intensive Outpatient Program will be approved for continuing prenatal care with her established community OB provider.

Psychiatric Services

All patients admitted to CAP are offered a psychiatric evaluation, which is usually completed within 2 weeks of admission. The CAP intake nurse assesses each admission for psychiatric issues that require a more urgent evaluation. Psychiatrists at CAP can provide ongoing treatment, including medications, for the duration of the patient's stay in CAP.

Pediatric Services

The CAP Pediatric Clinic is adjacent to the CAP program for pregnant women, and provides care to children of current or previous CAP patients. The CAP pediatric clinic provides personal, ongoing, general pediatric care for children and adolescents, birth to 21 years of age. Limited insurances are accepted.

Johns Hopkins Bayview Medical Center
Mason Lord Building East Tower
4940 Eastern Avenue
Baltimore, Maryland 21224
410-550-3020 (Administration)
410-550-3032 (OB Clinic)
410-550-3066 (Intake)

Model Programs in Maryland

SART

(Screening, Assessment, Referral, and Treatment)

In Carroll County, Maryland

In 2007 and 2008, Carroll County Fetal/Infant Mortality Review Board and several local obstetricians noticed a sharp increase in the number of substance misusing pregnant women. This prompted an organized **Community Response**. Our first step was to host a Community Forum in May 2008 which was attended by 50 stakeholders and community members. Work began with our local obstetric providers, the Carroll County Health Department, Carroll Hospital Center, and the Alcohol and Drug Abuse Administration at the Department of Health and Mental Hygiene to address practitioner concerns about methadone dosing and substance use during pregnancy.

We determined that the goal of our Community Response was to assist women in achieving better pregnancy outcomes, prevent substance exposed infants, and save health care dollars. In the beginning of 2009, the Carroll County Local Management Board was approached with a request for funding to bring Dr. Ira Chasnoff of the Children's Research Triangle in Chicago to hold educational forums. In May, a provider dinner attended by 17 local OB providers was followed by a community education day attended by 24 providers and 165 stakeholders and community members. As a follow-up, National Organization on Fetal Alcohol Syndrome (NOFAS) was invited to offer training in September 2009 which offered CEUs and CMEs.

The **Carroll County Leadership Team** was subsequently formed and representatives traveled to Chicago for a week-long training in November 2009. The Leadership Team includes various individuals from departments and agencies in our community, each of which have the potential to impact the health of a pregnant woman and her baby. The following agencies are currently part of our Leadership Team. Membership varies as issues are identified.

- Carroll County Advocacy and Investigation Center
- Carroll County Department of Social Services
- Carroll County District Court
- Carroll County Health Department (Bureaus of Community Health Nursing, Prevention, Wellness, and Recovery, and the Cigarette Restitution Program)
- Carroll County Local Management Board
- Carroll County Youth Service Bureau
- Carroll Hospital Center
- Citizens Services and Human Services of Carroll County
- Family and Children's Services of Central Maryland
- Genesis Treatment Program
- Local OB/GYN providers
- Local pediatricians
- Parents of affected children
- State of Maryland Department of Human Resources
- State of Maryland Department of Health and Mental Hygiene

During the training in Chicago, it was discussed that there are currently two basic models for identification and assistance of women who are using substances (drugs, alcohol, and tobacco): **SART – screening, assessment, referral, and treatment**; and **SBIRT – screening, brief intervention, referral, and treatment**. Both models are based on the same premise and are implemented in essentially the same manner. One of the hallmarks in both of these models is the ability to **normalize behavioral screening** questions. It is impossible to predict which women may have a behavioral health problem during pregnancy, hence it is imperative to screen all women. This supports the ACOG recommended universal screening and prevents profiling. In preparation for screening, the following should be considered:

- Training staff in cultural and behavioral sensitivity in order to ensure a non-judgmental environment
- Providing a confidential environment
- Writing procedures that require the patient is seen alone, without additional family members, friends, etc
- Training staff in non-directional interviewing (open-ended questions)
- Integrating all behavioral health assessment questions into the established health history

Upon return from Chicago, the Team chose to use 4 P’s Plus© as part of a SART model that contained training, resources, program support, and data evaluation. Our screening tool is based on validated questions regarding drug, alcohol, and tobacco use before and during pregnancy. In addition, the team added questions about depression and domestic violence. Since inception, the tool has been modified in response to data analysis and provider input. A copy of the form is attached at the end of this section. **This form is under license and may not be reproduced without the permission of NTI Upstream, Chicago, IL.**

Screening Screen all pregnant women who seek OB care by a Carroll County OB/GYN provider for substance use, depression, and domestic violence at the first prenatal visit.

Screening asks the question: “Who might be at risk?”

Assessment Assess those women who screen positive via the use of a validated field assessment for substance use, depression, and/or domestic violence.

Assessment asks the question: “Who is affected?”

Referral Refer all women who are determined to be using substances, experiencing depression, or are a victim of domestic violence.

Referral ensures all affected women are passed on to the next level of care. It is imperative that all referral sources are identified and partnered with prior to implementation of a screening program to ensure seamless transition. They must agree to accept any and all of the identified patients.

Treatment Treat all women who are referred.

Treatment gives the woman and her baby the best chance at a healthy start. It should be timely, of high quality, specific for women, and appropriate for pregnancy.

Step by Step SART in Carroll County, MD

- Office staff screens all OB patients seeking care from any Carroll County OB/GYN provider at the first prenatal care visit using the Carroll County version of the 4 P's Plus questionnaire. This screening is performed by office staff and embedded in the normal health/medical history.
- The provider (physician/clinician) performs a brief intervention for all positive 4 P's Plus screens. The "I am concerned..." format is used and, if indicated, the patient is informed she is being referred for further assessment.
- Office staff forwards all completed screens to the Carroll County SART Specialist for review and flags all positive screens for expedient action.
 - Positive substance abuse screens are assessed using the Treatment Assignment Protocol (TAP) in the Maryland data system.
 - Positive depression screens are assessed using an Edinburgh Post-Partum Depression Screen (which is validated for prenatal use).
See Toolkit Section 10 – Addenda, pages 10.2 and 10.3 for this screen.
 - Positive domestic violence screens are assessed using the Maryland Lethality Assessment Protocol (LAP).
- The SART Specialist discusses the results with the patient, the impact of the behavior on her pregnancy, and encourages appropriate referral and treatment. All referral and treatment is voluntary. The SART Specialist assesses readiness for change and arranges a follow-up intervention if the patient is not ready for treatment at this time.
- The SART Specialist refers all patients to previously identified and collaborative sources. It is imperative that all referrals are made using a "warm hand-off" and that care for the patient is expedited.
 - Referrals for positive substance abuse assessments are made to:
 - Carroll County Health Department, Bureau of Prevention, Wellness, and Recovery
 - Local outpatient and inpatient treatment providers based on the patient's insurance status
 - Referrals for positive tobacco assessments are forwarded to:
 - Carroll County Cigarette Restitution Program
 - Referrals for positive depression assessments are made to:
 - Local providers based on the patient's insurance status
 - Carroll County Health Department, Bureau of Prevention, Wellness, and Recovery
 - Referrals for positive domestic violence assessments are made to:
 - Family and Children's Services of Central Maryland
- The SART Specialist case manages the patient via phone and in person. In addition, the Carroll County Bureau of Prevention, Wellness, and Recovery employs an Addictions Peer Counselor who can be helpful in engaging the woman.
- Carroll Hospital Center (CHC) Family Birth Place staff administers a toxicology screen to all women being admitted for labor and delivery.
- Carroll Hospital Center refers any positive toxicology screen to the CHC OB Navigator, SART Specialist, and Peer Counselor for assessment and care coordination. In addition, in compliance with Family Law §5-704.2, women with a positive toxicology screen or newborns exhibiting substance exposure are referred to the Carroll County Department of Social Services for assessment.

Carroll County Maryland Plan for Perinatal SART (Screening, Assessment, Referral, and Treatment)

Vision

It is our vision to:

- Identify pregnant women who use substances or who are at risk for depression and domestic violence through uniform screening.
- Refer at-risk women to programs that will provide treatment and support.
- Ensure all children are brought home to a safe and nurturing environment with ongoing supportive services.

Foundational Beliefs

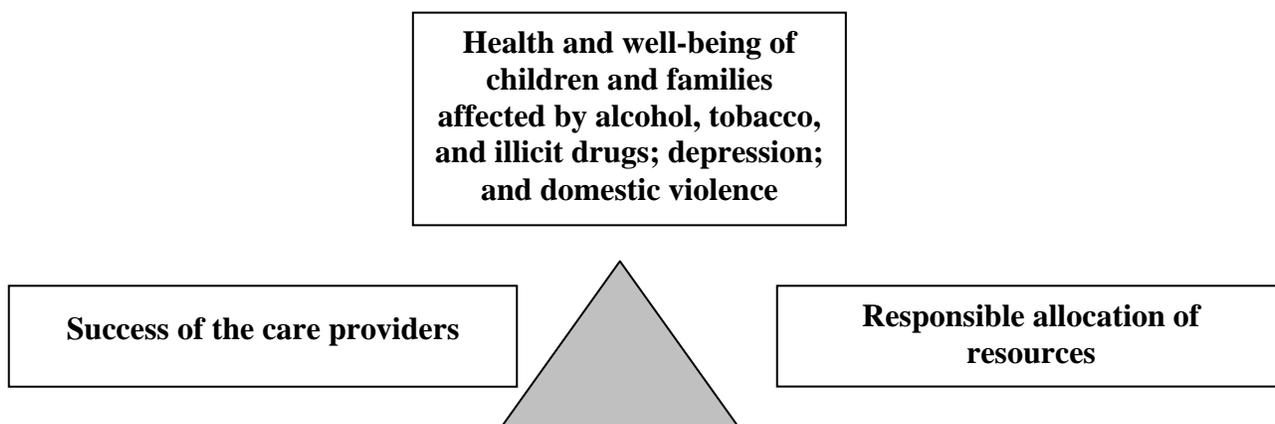
This plan is based on the following research-based knowledge:

- No amount of alcohol, tobacco, or illicit drug use in pregnancy is safe.
- Parents who are healthy, nurturing, and free from substance use and violence can provide the type of home that a child needs for healthy growth and development.
- Quality health and human services are effective if they are well matched to the needs of the person; i.e., gender-specific and culturally appropriate.
- Prevention and early intervention services save lives and save money.
- The health of our community depends on our ability to work together across organizational boundaries.

Three Guiding Concerns

This plan depends on a dynamic balance of three guiding concerns:

- The health and well-being of children and families affected by alcohol, tobacco, and illicit drugs; depression; and domestic violence
- The success of the care providers
- The responsible allocation of resources



Provider Site: _____ Date Screened: _____ DOB: _____
 Patient Name: _____ Zip Code: _____ ID #: _____ EDC: _____ Age: _____

Ethnicity: White Hispanic Latino American Indian Alaska Native Asian Black/African American Other
 Native Hawaiian Pacific Islander

Payer Source: Self MA Insurance Best Beginnings Other _____

		DV Ref	S/A Education	Provide tobacco or S/A assessment	MH Referral
Parents	Did either of your parents have any problem with drugs or alcohol?	<input type="checkbox"/> Yes <input type="checkbox"/> No			
	Does your partner have any problem with drugs or alcohol?	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
Partner	Is your partner's temper ever a problem for you?	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
	Have you ever felt out of control or helpless?	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
	Does your partner threaten to hurt or punish you?	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
Past	Have you ever had any beer/wine/liquor?	<input type="checkbox"/> No	<input type="checkbox"/> Yes		
	In the past two weeks, have you ever felt down, depressed or hopeless?	<input type="checkbox"/> No			<input type="checkbox"/> Yes
	In the past two weeks, have you lost interest in doing the things that used to be fun to you?	<input type="checkbox"/> No			<input type="checkbox"/> Yes
Pregnancy	In the month before you knew you were pregnant, how many cigarettes did you smoke?	<input type="checkbox"/> None		<input type="checkbox"/> Any	
	In the month before you knew you were pregnant, how much beer/wine/liquor did you drink?	<input type="checkbox"/> None		<input type="checkbox"/> Any	
	In the month before you knew you were pregnant, how much marijuana did you smoke?	<input type="checkbox"/> None		<input type="checkbox"/> Any	

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If Any, complete the follow-up questions

Follow-up Questions to the 4P's Plus

1. Sometimes women feel depressed, nervous or stressed out. When this happens to you, do any of the following help you feel better to relax?

- a. Talk things over with friends or relatives? No Yes
- b. Smoke cigarettes? No Yes
- c. Smoke marijuana or pot? No Yes
- d. Have a drink of beer, wine, or other liquor? No Yes
- e. Take some type of pill or medication? No Yes

2a. And last month, about how many days a week did you usually drink beer/wine/liquor?

- Did not drink Every Day 3 to 6 days a week 1 or 2 days a week Less than 1 day a week

2b. And last month, about how many days a week did you usually smoke a cigarette?

- Did not smoke Every day 3 to 6 days a week 1 or 2 days a week Less than 1 day a week

3. And last month, about how many days a week did you usually use marijuana?

- Did not smoke Every day 3 to 6 days a week 1 or 2 days a week Less than 1 day a week

4a. During the month before you knew you were pregnant, about how many days a week did you usually use any drug such as methamphetamine, cocaine or heroin, methadone, or other narcotic (pain relievers)?

- Did not use any drug Every day 3 to 6 days a week 1 or 2 days a week Less than 1 day a week

Refer for further evaluation

Intervention and Referrals: Completed by Practitioner

"I Am Concerned..." Brief Intervention

 Practitioner Signature Date

Practitioners, please check interventions:

Tobacco Cessation _____	Offered	Accepted	Declined
Substance Abuse Treatment _____	Offered	Accepted	Declined
Mental Health Evaluation _____	Offered	Accepted	Declined
Domestic Violence Referral _____	Offered	Accepted	Declined
Maternal Child Health Nursing _____	Offered	Accepted	Declined
Other, specify: _____			

SART Specialist Signature: _____ Date: _____

Revised 9.27.11

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Reaffirmed 2013

The American College of Obstetricians and Gynecologists
Women's Health Care Physicians

COMMITTEE OPINION

Number 496 • August 2011

Committee on Health Care for Underserved Women

This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

At-Risk Drinking and Alcohol Dependence: Obstetric and Gynecologic Implications

ABSTRACT: Compared with men, at-risk alcohol use by women has a disproportionate effect on their health and lives, including reproductive function and pregnancy outcomes. Obstetrician–gynecologists have a key role in screening and providing brief intervention, patient education, and treatment referral for their patients who drink alcohol at risk levels. For women who are not physically addicted to alcohol, tools such as brief intervention and motivational interviewing can be used effectively by the clinician and incorporated into an office visit. For pregnant women and those at risk of pregnancy, it is important for the obstetrician–gynecologist to give compelling and clear advice to avoid alcohol use, provide assistance for achieving abstinence, or provide effective contraception to women who require help. Health care providers should advise women that low-level consumption of alcohol in early pregnancy is not an indication for pregnancy termination.

The National Institute on Alcohol Abuse and Alcoholism defines *at-risk alcohol use* for healthy women as more than three drinks per occasion or more than seven drinks per week and any amount of drinking for women who are pregnant or at risk of pregnancy. *Binge drinking* is defined as more than three drinks per occasion. Almost 50% of binge drinking occurs among otherwise moderate drinkers (1). *Moderate drinking* is defined as one drink per day (2). When evaluating a patient's drinking habits, it is important to verify the description of "a drink" to determine the actual amount of alcohol consumed (Box 1).

National surveys indicate that American Indian and Alaska Native women (13.7%) were the most likely race to have an alcohol use disorder. This is compared with

white non-Hispanic women (5.6%), black non-Hispanic women (3.5%), and Hispanic or Latino women (3.8%) (3). In 2009, 25.6% of individuals aged 18–24 years reported binge drinking (4). Of those individuals, the majority were white non-Hispanic, college graduates who had an average household income greater than \$50,000 per year (4). Among women aged 18–34 years who binge drink, approximately one third (31.4%) report drinking eight or more drinks per occasion (5). In 2008, 61% of full-time college students were current drinkers and 40.5% reported binge drinking (3). Binge drinking is associated with a sudden peak in the level of alcohol in the blood, resulting in unsafe behavior and the risk of more reproductive and organ damage than sustained high levels of alcohol consumption (6).

For many people, alcohol use can be a pleasant experience as a method of relaxation and social connection. It also offers some beneficial cardiovascular effects (7). However, women are particularly vulnerable to the physical and psychosocial health risks of at-risk alcohol use. Alcohol-related mortality represents the third leading cause of preventable death for women in the United States (8). As indicated in Box 2, at-risk alcohol use results in multiple adverse health effects. Of note, data indicate that women who drink between two and five drinks

Box 1. What Is a Drink?

One standard drink is equal to 15 mL of pure ethanol

- Beer or wine cooler – 12 oz
- Table wine – 5 oz (25-oz bottle = 5 drinks)
- Malt liquor – 8–9 oz (12-oz can = 1.5 drink)
- 80-Proof spirits – 1.5 oz (a mixed drink may contain 1–3 or more drinks)

per day have up to a 41% increased incidence of breast cancer, and the risk increases linearly with consumption throughout this range (9, 10).

Box 2. At-Risk Alcohol Use: Secondary Consequences Affecting Women

Increased medical and physical risks

- Unplanned pregnancy
- Sexually transmitted diseases*
- Altered fertility^{†,‡}
- Menstrual disorders[§]
- Injuries
- Seizures[§]
- Malnutrition^{§,||}
- Cardiomyopathies[¶]
- Cancer of the breast, liver, rectum, mouth, throat, and esophagus^{§,*,**}

Increased risk of psychosocial problems

- Loss of primary relationships
- Sexual assault
- Loss of income
- Child neglect or abuse and loss of child custody
- Domestic violence
- Driving under the influence
- Altered judgement
- Bartering sex for drugs
- Depression and suicide

*Nicoletti A. The STD/alcohol connection. *J Pediatr Adolesc Gynecol* 2010;23:53–4.

†Rossi BV, Berry KF, Hornstein MD, Cramer DW, Ehrlich S, Missmer SA. Effect of alcohol consumption on in vitro fertilization. *Obstet Gynecol* 2011;117:136–42.

‡Grodstein F, Goldman MB, Cramer DW. Infertility in women and moderate alcohol use. *Am J Public Health* 1994;84:1429–32.

§Corrao G, Bagnardi V, Zambon A, La Vecchia C. A meta-analysis of alcohol consumption and the risk of 15 diseases. *Prev Med* 2004;38:613–9.

||National Institute on Alcohol Abuse and Alcoholism. Alcohol and nutrition. Alcohol Alert No. 22 PH 346. Bethesda (MD): NIAAA; 1993. Available at: <http://pubs.niaaa.nih.gov/publications/aa22.htm>. Retrieved April 18, 2011.

¶Urbano-Marquez A, Estruch R, Fernandez-Sola J, Nicolas JM, Pare JC, Rubin E. The greater risk of alcoholic cardiomyopathy and myopathy in women compared with men. *JAMA* 1995;274:149–54.

*Ferrari P, Jenab M, Norat T, Moskal A, Slimani N, Olsen A, et al. Lifetime and baseline alcohol intake and risk of colon and rectal cancers in the European prospective investigation into cancer and nutrition (EPIC). *Int J Cancer* 2007;121:2065–72.

**Kuper H, Tzonou A, Kakkamani E, Hsieh CC, Lagiou P, Adami HO, et al. Tobacco smoking, alcohol consumption and their interaction in the causation of hepatocellular carcinoma. *Int J Cancer* 2000;85:498–502.

Obstetrician–gynecologists have important opportunities for at-risk alcohol use intervention in three key areas: 1) identifying women who drink at risk levels, 2) encouraging healthy behaviors through brief intervention and education, and 3) referring patients who are alcohol dependent for professional treatment.

Identification of At-Risk Drinking

The U.S. Preventive Services Task Force recommends that all adult patients in a primary care setting be screened for alcohol misuse and provided counseling for identified risky or harmful drinking. Referral for specialist treatment may be appropriate for those with alcohol abuse or dependence (11). All women seeking obstetric–gynecologic care should be screened for alcohol use at least yearly and within the first trimester of pregnancy. It should be noted that women who drink at risk levels are less likely to maintain routine annual visits, and screening should be considered for episodic visits if not completed within the past 12 months. Screening can be accomplished using a variety of simple validated tools, like TACE with additional questions about the quantity and frequency of alcohol use, within the context of the routine visit (Box 3). Although the CAGE mnemonic screening tool has been taught in most medical schools and residency programs, it has not proved to be sensitive for women and minorities (12). Using a validated screening tool decreases false-positive and false-negative responses. Women may fear disclosure of their alcohol use will result in the loss of employment, their children, or their relationships. Therefore, it is crucial that the clinician assure the patient before screening that the information disclosed is privileged and confidential. Seeking obstetric–gynecologic care should not expose a woman to criminal or civil penalties or the loss of custody of her children (13).

Women who develop alcohol or substance use dependence are often more likely than men to deny that they have a problem and to minimize the problems associated with their use. However, when they do seek help for the problem, it often is from their primary care providers (14). Importantly, most women who use alcohol at risk levels have no signs on physical examination. A detailed medical history obtained by a trusted clinician remains the most sensitive means of detecting alcohol abuse (15).

Encouraging Healthy Behaviors and Early Intervention Strategies

Many women may be surprised to learn that their drinking exceeds a safe level of alcohol consumption. They may live or associate with others who drink similar amounts of alcohol and consider their alcohol use as “normal.” Offering compassionate education, exploring practical strategies to reduce use, and requesting a follow-up appointment is a successful strategy for many women

Box 3. Alcohol Use Screening Tools

TACE

- **T** – Tolerance
How many drinks does it take to make you feel high?
(More than 2 drinks = 2 points)
- **A** – Annoyed
Have people annoyed you by criticizing your drinking?
(Yes = 1 point)
- **C** – Cut down
Have you ever felt you ought to cut down on your drinking?
(Yes = 1 point)
- **E** – Eye-opener
Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover?
(Yes = 1 point)

A total score of 2 points or more indicates a positive screening for at-risk drinking

Alcohol Quantity and Drinking Frequency Questions

- In a typical week, how many drinks do you have that contain alcohol?
(Positive for at-risk drinking if more than 7 drinks)
- In the past 90 days, how many times have you had more than 3 drinks on any one occasion?
(Positive for at-risk drinking if more than one time)

Data from Sokol RJ, Martier SS, Ager JW. The T-ACE questions: practical prenatal detection of risk-drinking. *Am J Obstet Gynecol* 1989;160:863–8; discussion 868–70 and National Institute on Alcohol Abuse and Alcoholism. Helping patients who drink too much: a clinician's guide. Updated 2005 edition. Bethesda (MD): NIAAA; 2005. Available at: http://pubs.niaaa.nih.gov/publications/practitioner/CliniciansGuide2005/Guide_Slideshow.htm. Retrieved April 18, 2011.

who are not physically or psychologically dependent on alcohol. There are effective alcohol educational materials available for patients that are free or offered at a very low cost (see Resources).

Brief, motivation-enhancing interventions are associated with a sustained reduction in alcohol consumption (16–18). Following is an example of a brief intervention:

“You indicated that you are drinking five or six drinks one evening a week and that you often do not feel drunk when you drink that amount. This is considered at-risk drinking. What do you think about that?”

(Wait for her response.)

“As your obstetrician–gynecologist, I am concerned that your menstrual irregularities or other clinical findings may be associated with your drinking. This level of drinking also puts you at risk of unplanned pregnancy and injuries. Are you willing to try and reduce your drinking? I can offer you resources to help.”

(Wait for her response.)

“Getting pregnant at this time could be very harmful for you and your baby. I want you to consider using a more effective contraception method while you are working on reducing your alcohol intake.”

(Wait for her response.)

At the conclusion of the brief intervention, it is important to assist the patient in setting a goal (eg, “I will not have more than three drinks at the Friday happy hour”), record the goal, and let her know that there will be a follow-up discussion at the next visit. If she does not consistently meet her goal, restate the advice to quit or cut back on drinking, review her plan, and encourage her to seek additional support. A failed attempt is a motivating moment toward seeking help.

Referral

Women who continue to drink or use alcohol at risk levels and women who exhibit signs of alcohol dependence require referral to a substance abuse specialist. This referral is best made while the patient is in the clinician's office so that she is involved in making the appointment with the encouragement of her health care provider. Local substance abuse treatment programs can be found through the Substance Abuse and Mental Health Services Administration treatment locator (19). If the patient refuses treatment, the health care provider should respect her decision, make a short-term follow-up appointment with her, and assure her that she will be welcomed back in the clinician's office. It may take a number of offers before the patient is ready to accept a treatment referral. The patient's trust in her medical provider may be key in taking the step toward treatment.

Alcohol Use and Pregnancy and Breastfeeding

Alcohol is a teratogen. Fetal alcohol syndrome is the most severe result of prenatal drinking. Fetal alcohol syndrome is associated with central nervous system abnormalities, growth defects, and facial dysmorphism. However, for every child born with fetal alcohol syndrome, many more are born with neurobehavioral defects caused by prenatal alcohol exposure. Alcohol-related birth defects include growth deformities, facial abnormalities, central nervous system impairment, behavioral disorders, and impaired intellectual development. Alcohol can affect a fetus at any

stage of pregnancy, and the cognitive defects and behavioral problems that result from prenatal alcohol exposure are lifelong. In early pregnancy during organogenesis and perhaps before the patient's recognition of pregnancy, the fetus may be particularly vulnerable to maternal binge or heavy alcohol use. Alcohol-related birth defects are completely preventable (20). Even moderate alcohol consumption during pregnancy may alter psychomotor development, contribute to cognitive defects, and produce emotional and behavioral problems in children, although patient denial and underreporting make it difficult to quantify these effects (21). There is evidence of varying susceptibility to alcohol's effect on the developing fetus. Although alcohol consumption may have negative consequences for any pregnant woman, the effects of alcohol may be more potent in mothers who are older, in poor health, or who also smoke or use drugs (22).

The U.S. Surgeon General advises that pregnant women should not drink any alcohol. Women who have already consumed alcohol during a current pregnancy should stop in order to minimize further risk, and those who are considering becoming pregnant should abstain from drinking alcohol. Recognizing that nearly one half of all births in the United States are unintended, women of childbearing age should discuss with their clinicians steps to reduce the possibility of prenatal alcohol exposure (20). Health care providers should advise women that low-level consumption of alcohol in early pregnancy is not an indication for pregnancy termination.

A recent study indicated that the highest prevalence of late-pregnancy alcohol use was reported by women who were white non-Hispanic, college graduates, and aged 35 years or older (23). However, these same women were those who reported the least screening and counseling for alcohol use by their health care providers. There is strong evidence that brief behavioral counseling interventions with women who engage in at-risk drinking reduce the incidence of alcohol-exposed pregnancy (24, 25). Pregnant women are generally motivated to change their drinking behavior, and alcohol dependence is relatively rare (24). In one multicenter project, nearly 70% of women who were drinking at risky levels and not using effective contraception reduced their risk of alcohol-exposed pregnancy 6 months after a brief intervention because they stopped or reduced their drinking below risky levels or they started using effective contraception (26). Randomized studies report significant reductions in alcohol use and improved newborn outcomes after interventions with women who are already pregnant. Women who are alcohol dependent need intense specialized counseling and medical support during the process of withdrawal. They should be given priority access to withdrawal management and treatment (24). If a woman continues to use alcohol during pregnancy, harm reduction strategies should be encouraged (24). Postpartum, many women who were abstinent during pregnancy rapidly resume at-risk levels of alcohol use and should

be monitored at the postpartum and follow-up visits (27). It is important to educate the at-risk patient about pregnancy prevention and offer and provide effective, long-term reversible contraception until at-risk alcohol use has been curtailed.

Contrary to cultural folklore, alcohol consumption does not enhance lactational performance. There is consistent evidence showing that when lactating mothers consume alcohol, there is reduced milk consumption by the infant (28). Alcohol consumption during lactation is associated with altered postnatal growth, sleep patterns, and psychomotor patterns of the offspring (29). After breastfeeding is well established, a mother should be encouraged by her health care provider to wait 3–4 hours after a single drink before breastfeeding her infant. By doing so, the infant's exposure to alcohol would be negligible (30).

Coding for Screening and Assessment and Brief Intervention

There are two *Current Procedural Terminology* codes to report for alcohol abuse structured screening and brief intervention services. Report *Current Procedural Terminology* codes 99408 (alcohol abuse structured screening and brief intervention services; 15 to 30 minutes) and 99409 (greater than 30 minutes) for screening and brief intervention services for patients without Medicare. These codes are only reportable for structured screening using a validated screening tool, such as TACE, and brief intervention. They are not reportable when physicians ask patients about their alcohol use as part of a comprehensive medical history. The services under these new codes may be conducted as part of a periodic, scheduled, preventive care office visit or in an acute setting.

Resources

American College of Obstetricians and Gynecologists. Alcohol, tobacco, and other substance use and abuse. *Guidelines for Adolescent Health Care* [CD-ROM]. 2nd ed. Washington, DC: ACOG; 2011.

National Institute on Alcohol Abuse and Alcoholism (NIAAA), has free brochures on women and alcohol as well as pregnancy and drinking available in English, Spanish and for American Indians. They also have videotaped screening and brief intervention interviews to guide physician–patient interaction.

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At-risk drinking and alcohol dependence: obstetric and gynecologic implications. Committee Opinion No. 496. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2011;118:383–8.



The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

9.7

COMMITTEE OPINION

Number 538 • October 2012

Committee on Health Care for Underserved Women

This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Nonmedical Use of Prescription Drugs

ABSTRACT: The nonmedical use of prescription drugs, particularly opioids, sedatives, and stimulants, has been cited as epidemic in the United States, accounting for increasing numbers of emergency department visits and deaths from reactions and overdoses. The prevalence of prescription drug abuse is similar among men and women. Those who abuse prescription drugs most often obtain them from friends and family either through sharing or theft. Physicians should screen all patients annually and early in prenatal care with a validated questionnaire for the nonmedical use of prescription drugs. They should provide preventive education for all patients and referral for treatment, when psychologic or physical drug dependence is identified. Physicians should also educate patients in the proper use, storage, and disposal of prescription drugs.

The nonmedical use of prescription drugs is a significant problem in the United States. The purpose of this Committee Opinion is to guide obstetrician–gynecologists in their role in prescribing drugs of potential abuse and working with women who abuse or are dependent on prescription drugs.

The National Survey on Drug Use and Health assesses the nonmedical use of illicit and prescription drugs, alcohol, and tobacco products among civilian, noninstitutionalized individuals aged 12 years and older in the United States (1). Over-the-counter drugs and legitimate use of prescribed medication are not included in the study. The 2010 National Survey on Drug Use and Health report indicated that 2.4 million individuals used psychotherapeutic drugs (pain relievers, tranquilizers, stimulants, or sedatives) for nonmedical reasons for the first time within the past year, or approximately 6,600 individuals per day, and 7.0 million individuals used a prescription psychotherapeutic drug in the month before the survey without a medical indication (1). Nonmedical use of prescription drugs is the third most common drug category of abuse after marijuana and tobacco (1). The percentage of individuals in the population who abuse psychotherapeutics has remained stable since 2002; however, the rate of death from unintentional overdose increased to approximately 27,000 deaths in 2007 (2). Among the 3 million individuals who used illicit drugs for the first time in 2010, 26.2% started with psychotherapeutics, predominantly pain relievers (1).

Prescription drug abuse is defined as the intentional use of a medication without a prescription, in a way other than as prescribed, or for the experience or feeling that it causes (3). Drug addiction is characterized by an inability to consistently abstain from drug use, impairment in behavior control, a craving or increased need for drugs, a diminished recognition of significant problems with one's behavior and interpersonal relationships, and a dysfunctional emotional response (4). Physical dependence occurs because of normal adaptations to chronic exposure to a drug. Those who are physically drug dependent usually experience withdrawal symptoms when the drug is abruptly discontinued. They often develop a tolerance to the drug and require higher doses for the same effect (3). Drug dependency is not a synonym for drug addiction or drug abuse.

Although men are more likely to engage in substance abuse, the rate of prescription drug abuse among women is similar to men. Adolescent girls and women older than 35 years have significantly greater rates of abuse and dependence on psychotherapeutic drugs than men (5, 6). In older populations, changes in drug metabolism and the potential for drug interactions increase the health dangers of prescription drug misuse and abuse (3). Individuals who report nonmedical use of prescription drugs often report concurrent use of other drugs and alcohol.

Sources of Misused Prescription Drugs

The majority of individuals who misused prescription pain relievers (55%) received them for free from a friend

or relative, 17.3% obtained them as prescribed from one physician, 4.4% bought them from a drug dealer, and 0.4% ordered them online (1). Adolescents who misuse prescription drugs often acquire medications prescribed to other family members, taking the medications without the knowledge or permission of the person to whom they were prescribed (7). Alternatively, a visitor or worker in the home may steal the medication from an unsecured cabinet.

Issues Specific to Women

Although there are known risk factors for drug abuse, (eg, living in a community where drugs are easily available, tobacco use, and a family history of substance use), patients who are not suspected also may be misusing prescription drugs. Prescription drug abuse can lead to adverse social consequences, such as poor judgment and impaired decision making; increased unprotected sex; and arguments, fights, and domestic violence, including child abuse. The neurobehavioral effects of prescription drug abuse, especially when mixed with alcohol, have been cited as precipitating factors in injuries and deaths caused by the individual engaging in drug misuse.

Prescription drug misuse does not by itself guarantee child neglect or prove inadequate parenting (8). Paradoxically, a woman who pursues assistance for a substance abuse problem may become involved with legal and child welfare agencies, potentially leading to the loss of custody of her children. Substance abuse treatment that supports the family as a unit has been proved to be effective for maintaining maternal sobriety and child well-being (9). A woman must not be unnecessarily separated from her family in order to receive appropriate treatment.

Prescription Drugs of Abuse

Prescription drugs that are abused are most often available in tablet or capsule form. To enhance psychoactive effects, they can be crushed or dissolved and inhaled, injected, or used as enemas or suppositories.

Opioids

According to the 2010 National Survey on Drug Use and Health, opioid pain relievers are the most frequently abused prescription drugs (1). The number of individuals who received treatment for nonmedical pain reliever abuse more than doubled between 2004 and 2009, accounting for 1,244,679 medical treatment visits in 2009, which far exceeded medical treatment visits for other drugs of abuse (10). White women are more likely to abuse prescription pain relievers than women of any other race or ethnicity (1). The 2010 National Survey on Drug Use and Health report indicated that 23% of women aged 18 years to 34 years reported ever having used prescription pain relievers not prescribed to them or taking them to experience the effect. When abused, opioids produce varying degrees of euphoria depend-

ing on the drug's affinity for micro-opioid receptor binding and the ability to cross the blood-brain barrier. Prescription opioids available in the United States include morphine, methadone, codeine, hydrocodone, oxycodone, propoxyphene, fentanyl, tramadol, hydromorphone, and buprenorphine.

Overdose of opioids may lead to oversedation, aspiration of stomach contents, respiratory depression, and death. Acute opioid overdose is treated with naloxone and respiratory support. Chronic exposure to opioids may trigger a deregulation of the endogenous opioid receptor system, resulting in biologic or psychologic dependence. Withdrawal from opioid dependence is uncomfortable, but not life-threatening for a woman who is not pregnant. However, for pregnant women who are opioid-dependent, abrupt withdrawal from opioids can be life-threatening to the fetus (11). Withdrawal symptoms in opioid-dependent individuals include agitation, anxiety, muscle aches, and gastrointestinal distress. Prescription opioids are often coformulated with acetaminophen, aspirin, or ibuprofen. Use of acetaminophen at doses exceeding 4 g/d is associated with liver damage and may lead to liver failure and death (12). Aspirin and ibuprofen may precipitate gastrointestinal bleeding and are usually contraindicated during pregnancy. Individuals may unknowingly consume dangerous amounts of the coformulated drug.

Sedatives and Tranquilizers

Sedatives (barbiturates) and tranquilizers (benzodiazepines) are used as anxiolytics, sleep aids, and to treat psychologic and neurologic conditions. Data from the 2010 National Survey on Drug Use and Health report indicated that 7.6% of women reported ever having used tranquilizers and 2.4% reported ever having used sedatives not prescribed to them or taking them to experience the effect (1). White women abused sedatives and tranquilizers significantly more frequently than women of any other race or ethnicity. Women older than 35 years are more likely to abuse sedatives and those aged 18 years to 50 years are more likely to abuse tranquilizers (1). Abuse of sedatives often occurs in conjunction with other substances or medications. The combination of sedatives with opioids can potentiate the effect of an opioid and can increase the risk of an overdose. Long-term use and abuse of sedatives and tranquilizers can produce dependence and addiction. Abrupt withdrawal from these drugs, particularly from benzodiazepines and barbiturates, can be severe and life-threatening, and includes seizures, acute heart conditions, and acute psychiatric conditions (13).

Stimulants

Drugs such as amphetamines, methamphetamines, and methylphenidate increase alertness and are used for treatment of narcolepsy or attention-deficit/hyperactivity disorder. They are also prescribed for short-term management of weight loss. Stimulants are misused to achieve anorexic effects, heightened attention and wakefulness

for academic enhancement, hallucinations, euphoria, and altered perception. Nonmedical use of stimulants is most common among students and women younger than 50 years. The 2010 National Survey on Drug Use and Health report indicated that 6.7% of women reported ever having used stimulants not prescribed to them (1). White women were two to four times more likely to abuse stimulants than women of any other race or ethnicity (1). These drugs can be ingested or crushed for inhalation or injection. Adverse effects of stimulants include hypertension, tachycardia, arrhythmia, and psychologic or neurologic dysfunction. Prolonged abuse of stimulants can result in addiction. Withdrawal symptoms include fatigue, depression, and sleep disturbances.

Anesthetics

Ketamine, a dissociative anesthetic, is the most commonly abused anesthetic. It is a “club drug,” a psychoactive substance abused by adolescents and young adults at bars, nightclubs, concerts, and parties. Ketamine is often diverted from veterinary practices, and is usually snorted or injected intramuscularly (13). Acute side effects include central nervous system depression, psychomotor agitation, rhabdomyolysis, abdominal pain, and urinary tract symptoms. Chronic abuse can lead to psychosis, cognitive impairment, and dependence.

Management of the Patient Misusing Prescription Drugs

All women should be screened annually for substance abuse, including prescription drug abuse, using a validated questionnaire such as the 4 P’s (Box 1) (14). Other screening tools more specific to prescription drug misuse are in development. Laboratory drug testing for prescription drugs is not appropriate for routine well-women care. A standard urine testing panel does not detect synthetic opioids and does not detect some stimulants

Box 1. The 4 P’s

Parents: Did any of your parents have a problem with alcohol or other drug use?

Partner: Does your partner have a problem with alcohol or drug use?

Past: In the past, have you had difficulties in your life due to alcohol or other drugs, including prescription medications?

Present: In the past month have you drunk any alcohol or used other drugs?

Scoring: Any “yes” should trigger further questions.

Ewing H. A practical guide to intervention in health and social services with pregnant and postpartum addicts and alcoholics: theoretical framework, brief screening tool, key interview questions, and strategies for referral to recovery resources. Martinez (CA): The Born Free Project, Contra Costa County Department of Health Services; 1990.

and benzodiazepines (15). However, when combined with a thorough medical history, physical examination, and screening questionnaire, biophysical drug testing can help the clinician provide appropriate interventions to the patient (16). If prescription drug abuse is identified, the health care provider should follow with a brief motivational intervention as described in the American College of Obstetricians and Gynecologists’ Committee Opinion Number 423, *Motivational Interviewing: A Tool for Behavior Change* (17). Given the potential consequences of prescription drug misuse during pregnancy, counseling on the use of effective contraception methods should be included in the intervention. If drug dependence is revealed, the patient should be referred to a substance abuse treatment specialist (see Resources). The problem of substance abuse is not only one of physiologic dependence to a drug, but also of strong emotional and psychologic dependence and habituation. Physical withdrawal symptoms and psychologic cravings following abrupt discontinuation of opioids, sedatives, and stimulants often result in a return to drug use. Women with a substance abuse disorder should be managed by physicians trained in the appropriate methods to safely withdraw medications or regulate maintenance therapy. Underlying medical or psychologic conditions that contribute to the substance abuse should be evaluated and treated appropriately.

Unless there are specific indications, two drugs, methadone and buprenorphine, can be legally used for opioid withdrawal and maintenance treatment (18). When used within a treatment program, methadone and buprenorphine reduce criminal behavior and morbidity related to opioid addiction and reduce disease transmission related to intravenous drug use (19). For opioid maintenance, methadone is dispensed on a limited dose basis within state-licensed opioid treatment programs. Specially trained and licensed physicians can dispense buprenorphine from their offices. The advantage of buprenorphine over methadone is the ability to receive multiple doses of the drug from a local primary care physician, negating frequent visits to a drug treatment program. However, diversion of buprenorphine is an emerging epidemic. *Diversion* is defined as obtaining medication with the intent to redistribute it to others (20). In some areas, buprenorphine and methadone are as readily available on the street as marijuana (21).

Overdose from methadone can lead to respiratory depression and arrhythmias such as torsade de pointes. The use of methadone as a prescribed pain reliever, not as part of a drug treatment program, is discouraged because of the high rate of drug diversion and the morbidity and mortality associated with its use.

Prescription Drug Abuse in Pregnancy

All women should be screened early during pregnancy for substance use, including prescription drug abuse, with a validated questionnaire such as, but not limited to, The

4 P's (Box 1) (14). If biophysical testing for evidence of substance use is indicated as a result of clinical observation or to comply with state law, the health care provider should be aware of the potential for false-positive and false-negative results of urine toxicology for drug use, the typical urine drug metabolite detection times, and the legal and social consequences of a positive test result. It is incumbent on the health care provider, as part of the procedure in obtaining consent before testing, to provide information about the nature and purpose of the test to the patient and how the results will guide management (22). The American College of Obstetricians and Gynecologists' Committee Opinion Number 524, *Opioid Use, Dependence, and Addiction in Pregnancy*, contains detailed information for the prenatal health care provider on managing a patient using opioids during pregnancy (23). There are excellent programs that provide nonjudgmental integrated prenatal care, education, and substance abuse treatment for pregnant women who misuse prescription drugs. One such program is Kaiser Permanente's *Early Start* (24). Up-to-date information concerning individual state policies on substance abuse during pregnancy can be found in the monthly Guttmacher Institute's *State Policies in Brief* (see Resources).

Emergency Department Visits and Overdose

In 2009, more than 1.2 million emergency department visits occurred because of the misuse or abuse of prescription drugs. During the same period, 974,000 emergency department visits occurred because of the abuse of illegal drugs (10). Unintentional opioid analgesic overdose deaths have dramatically increased since 1999, reaching 11,500 deaths in the United States in 2007—more than the number of deaths from heroin and cocaine combined (25). Women in the postpartum period who abused prescription drugs during pregnancy and are not involved in substance abuse treatment are particularly at risk of overdose because their physiologic drug requirement decreases as their blood volume and body mass decreases (26). In addition, women who were abstinent from drug use during pregnancy often resume drug use postpartum, but without the tolerance to their prepregnancy drug doses, leaving them susceptible to overdose.

Pain Management

Patients who are prescribed opioid medications for legitimate pain control are unlikely to abuse them (27). However, education on the medications prescribed, including interactions and potential for overdose, should be stressed to help avoid emergency department visits and overdose deaths. Physicians also should be aware of individuals who try to exploit practitioner sensitivity to patient pain. Use of patient pain contracts and drug testing may help to reduce this exploitation. Referral to a pain management expert should be considered for patients with intractable pain.

Regulatory policies vary by state, and physicians should be aware of the laws and regulations in their states. With appropriate documentation of pain levels and patient management, a physician should not fear disciplinary action from regulatory agencies. More information on specific state policies and laws are available at the Office of National Drug Control Policy web site (see Resources).

Avoiding Diversion

Patient education is central in preventing intentional and unintentional drug diversion. When prescribing medications that may be misused, physicians should educate their patients on proper use, storage, and disposal of medications:

- Patients should be instructed to take the medication only as it is prescribed to them. They should be cautioned to not share the medication with anyone else, including friends and relatives who may feel that taking the patient's medication may help them.
- Medication that may be abused should be stored in secure places to prevent misuse by others, particularly youth who may obtain them without anyone knowing.
- Unused medications should be taken to a pharmacy for proper disposal, or thrown away mixed in coffee grounds or kitty litter to discourage recovery of the medications by someone intending to misuse the drug.

Regulations to Prevent Nonmedical Use of Prescription Drugs

Various attempts at the state and national levels have been made to regulate the distribution and use of prescription drugs in order to reduce misuse and overdose. In 2002, the U.S. General Accountability Office concluded that prescription drug monitoring programs helped reduce drug diversion (28). Prescription drug monitoring programs usually require pharmacists to enter information pertaining to prescriptions for controlled substances into a state database to allow monitoring of prescribing and filling practices. Data include the prescriber, the patient, the drug, the dosage, and the amount dispensed. The 2005 National All Schedules Prescription Electronic Reporting Act was reauthorized in 2010, which funds federal grants to states for the establishment or improvement of prescription drug monitoring programs (29, 30). As of January 2012, 48 states had enacted prescription drug monitoring programs (31). Access to the prescription monitoring program's database varies from state to state.

Methods to help reduce both prescription drug abuse and diversion include tamper-resistant packaging, prescribing only the amount of medication that would typically be used for a particular condition or procedure, not offering prescription refills without a consultation, and using special prescription forms for prescribing con-

trolled medications. Health care providers should be aware of the requirements for their states.

Summary

All women should be screened annually and early in pregnancy for nonmedical use of prescription drugs and should be counseled when abuse is suspected or identified. In the case of drug dependence, physicians should offer referrals for treatment to mitigate withdrawal symptoms and address drug-seeking behavior. Women's health care providers should

- follow suggestions on prescribing to reduce drug abuse and diversion.
- educate patients who have been prescribed medications to be the sole user of the drug.
- give instructions for safe medication storage and disposal.
- consider referral to a pain management expert for women with chronic pain.
- be aware of state laws addressing the prescribing of opioids and other potential drugs of addiction.

Resources ↩

American College of Obstetricians and Gynecologists

At-risk drinking and illicit drug use: ethical issues in obstetric and gynecologic practice. ACOG Committee Opinion No. 422. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2008;112:1449–60. [PubMed] [*Obstetrics & Gynecology*]

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Other Resources

The following list is for information purposes only. Referral to these sources and web sites does not imply the endorsement of the American College of Obstetricians and Gynecologists. This list is not meant to be comprehensive. The exclusion of a source or web site does not reflect the quality of that source or web site. Please note that web sites are subject to change without notice.

Federation of State Medical Boards. Pain policy resource center. Available at: http://www.fsmb.org/grpol_links.html. Retrieved June 14, 2012.

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WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

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Committee on Health Care for Underserved Women
and the American Society of Addiction Medicine

This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Opioid Abuse, Dependence, and Addiction in Pregnancy

ABSTRACT: Opioid use in pregnancy is not uncommon, and the use of illicit opioids during pregnancy is associated with an increased risk of adverse outcomes. The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone, but emerging evidence suggests that buprenorphine also should be considered. Medically supervised tapered doses of opioids during pregnancy often result in relapse to former use. Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal demise. During the intrapartum and postpartum period, special considerations are needed for women who are opioid dependent to ensure appropriate pain management, to prevent postpartum relapse and a risk of overdose, and to ensure adequate contraception to prevent unintended pregnancies. Patient stabilization with opioid-assisted therapy is compatible with breastfeeding. Neonatal abstinence syndrome is an expected and treatable condition that follows prenatal exposure to opioid agonists.

Opioid abuse in pregnancy includes the use of heroin and the misuse of prescription opioid analgesic medications. According to the 2010 National Survey on Drug Use and Health, an estimated 4.4% of pregnant women reported illicit drug use in the past 30 days (1). A second study showed that whereas 0.1% of pregnant women were estimated to have used heroin in the past 30 days, 1% of pregnant women reported nonmedical use of opioid-containing pain medication (2). In this study, the rates of use varied by setting and by mode of assessment. The urine screening of pregnant women in an urban teaching hospital resulted in a detection rate for opioids of 2.6% (2). The prevalence of opioid abuse during pregnancy requires that practicing obstetrician–gynecologists be aware of the implications of opioid abuse by pregnant women and of appropriate management strategies.

Pharmacology and Physiology of Opioid Addiction

Opioid addiction may develop with repetitive use of either prescription opioid analgesics or heroin. Heroin is the most rapidly acting of the opioids and is highly addictive (3). Heroin may be injected, smoked, or nasally inhaled. Heroin has a short half-life, and a heroin user may need to take multiple doses daily to maintain the

drug's effects. Prescribed opioids that may be abused include codeine, fentanyl, morphine, opium, methadone, oxycodone, meperidine, hydromorphone, hydrocodone, propoxyphene, and buprenorphine (the partial agonist). These products may variously be swallowed, injected, nasally inhaled, smoked, chewed, or used as suppositories (4). The onset and intensity of euphoria will vary based on how the drug was taken and the formulation; however, all have the potential for overdose, physical dependence, abuse, and addiction. Injection of opioids also carries the risk of cellulitis and abscess formation at the injection site, sepsis, endocarditis, osteomyelitis, hepatitis B, hepatitis C, and human immunodeficiency virus (HIV) infection.

Opioids bind to opioid receptors in the brain and produce a pleasurable sensation (3). Opioids also depress respiration, potentially resulting in respiratory arrest and death. Opioid addiction is associated with compulsive drug-seeking behavior, physical dependence, and tolerance that lead to the need for ever higher doses (4). Once physical dependence to an opioid has developed, a withdrawal syndrome occurs if use is discontinued. With short-acting opioids, such as heroin, withdrawal symptoms may develop within 4–6 hours of use, may progress up to 72 hours, and usually subside within a week. For long-acting opioids, such as methadone, withdrawal

symptoms are usually experienced between 24 hours and 36 hours of use and may last for several weeks. Obsessive thinking and drug cravings may persist for years, thus leading to relapse. Although heroin withdrawal is not fatal to healthy adults, fetal death is a risk in pregnant women who are not treated for opioid addiction because their offspring experience acute opioid abstinence syndrome (5).

Effects on Pregnancy and Pregnancy Outcome

An association between first-trimester use of codeine and congenital heart defects has been found in three of four case-control studies (6–9). Previous reports have not shown an increase in risks of birth defects after prenatal exposure to oxycodone, propoxyphene, or meperidine (10, 11). The authors of one retrospective study observed an increased risk of some birth defects with the use of prescribed opioids by women in the month before or during the first trimester of pregnancy (12). However, methodological problems with this study exist, and such an association has not been previously reported. The observed birth defects remain rare with a minute increase in absolute risk. Although none of these studies investigated methadone or buprenorphine specifically, concern about a potential small increased risk of birth defects associated with opioid-assisted therapy during pregnancy must be weighed against the clear risks associated with the ongoing use of illicit opioids by a pregnant woman.

During pregnancy, chronic untreated heroin use is associated with an increased risk of fetal growth restriction, abruptio placentae, fetal death, preterm labor, and intrauterine passage of meconium (13). These effects may be related to the repeated exposure of the fetus to opioid withdrawal as well as the effects of withdrawal on placental function. Additionally, the lifestyle issues associated with illicit drug use put the pregnant woman at risk of engaging in activities, such as prostitution, theft, and violence, to support herself or her addiction. Such activities expose women to sexually transmitted infections, becoming victims of violence, and legal consequences, including loss of child custody, criminal proceedings, or incarceration.

Screening for Opioid Use, Abuse, and Addiction

Screening for substance abuse is a part of complete obstetric care and should be done in partnership with the pregnant woman. Both before pregnancy and in early pregnancy, all women should be routinely asked about their use of alcohol and drugs, including prescription opioids and other medications used for nonmedical reasons. To begin the conversation, the patient should be informed that these questions are asked of all pregnant women to ensure they receive the care they require for themselves and their fetuses and that the informa-

tion will be kept confidential. Maintaining a caring and nonjudgmental approach is important and will yield the most inclusive disclosure. Routine screening should rely on validated screening tools, such as questionnaires including 4P's and CRAFFT (for women aged 26 years or younger) (Box 1) (14, 15).

In addition to the use of screening tools, certain signs and symptoms may suggest a substance use disorder in a

Box 1. Clinical Screening Tools for Prenatal Substance Use and Abuse ←

4 P's

Parents: Did any of your parents have a problem with alcohol or other drug use?

Partner: Does your partner have a problem with alcohol or drug use?

Past: In the past, have you had difficulties in your life because of alcohol or other drugs, including prescription medications?

Present: In the past month have you drunk any alcohol or used other drugs?

Scoring: Any "yes" should trigger further questions.

Ewing H. A practical guide to intervention in health and social services with pregnant and postpartum addicts and alcoholics: theoretical framework, brief screening tool, key interview questions, and strategies for referral to recovery resources. Martinez (CA): The Born Free Project, Contra Costa County Department of Health Services; 1990.

CRAFFT—Substance Abuse Screen for Adolescents and Young Adults

C Have you ever ridden in a CAR driven by someone (including yourself) who was high or had been using alcohol or drugs?

R Do you ever use alcohol or drugs to RELAX, feel better about yourself, or fit in?

A Do you ever use alcohol or drugs while you are by yourself or ALONE?

F Do you ever FORGET things you did while using alcohol or drugs?

F Do your FAMILY or friends ever tell you that you should cut down on your drinking or drug use?

T Have you ever gotten in TROUBLE while you were using alcohol or drugs?

Scoring: Two or more positive items indicate the need for further assessment.

Center for Adolescent Substance Abuse Research, Children's Hospital Boston. The CRAFFT screening interview. Boston (MA): CeASAR; 2009. Available at: http://www.ceasar.org/CRAFFT/pdf/CRAFFT_English.pdf. Retrieved February 10, 2012.

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pregnant woman. Pregnant women with opioid addiction often seek prenatal care late in pregnancy; exhibit poor adherence to their appointments; experience poor weight gain; or exhibit sedation, intoxication, withdrawal, or erratic behavior. On physical examination, some signs of drug use may be present, such as track marks from intravenous injection, lesions from interdermal injections or “skin popping,” abscesses, or cellulitis. Positive results of serologic tests for HIV, hepatitis B, or hepatitis C also may indicate substance abuse. Urine drug testing is an adjunct to detect or confirm suspected substance use, but should be performed only with the patient’s consent and in compliance with state laws. Pregnant women must be informed of the potential ramifications of a positive test result, including any mandatory reporting requirements (16). Laboratory testing for HIV, hepatitis B, and hepatitis C should be repeated in the third trimester, if indicated (17).

The use of an antagonist, such as naloxone, to diagnose opioid dependence in pregnant women is contraindicated because induced withdrawal may precipitate preterm labor or fetal distress (13). Naloxone should be used only in the case of maternal overdose to save the woman’s life.

Treatment

Since the 1970s, maintenance therapy with methadone has been the standard treatment of heroin addiction during pregnancy (13). Recently, this treatment also has been used for nonheroin opioid addiction (13) although the benefits are less well documented than for the treatment of heroin dependence.

The rationale for opioid-assisted therapy during pregnancy is to prevent complications of illicit opioid use and narcotic withdrawal, encourage prenatal care and drug treatment, reduce criminal activity, and avoid risks to the patient of associating with a drug culture. Comprehensive opioid-assisted therapy that includes prenatal care reduces the risk of obstetric complications (13). Neonatal abstinence syndrome is an expected and treatable condition that follows prenatal exposure to opioid agonists and requires collaboration with the pediatric care team. Methadone has significant pharmacokinetic interactions with many other drugs, including antiretroviral agents.

Methadone maintenance, as prescribed and dispensed on a daily basis by a registered substance abuse treatment program, is part of a comprehensive package of prenatal care, chemical dependency counseling, family therapy, nutritional education, and other medical and psychosocial services as indicated for pregnant women with opioid dependence. Perinatal methadone dosages are managed by addiction treatment specialists within registered methadone treatment programs. A list of local treatment programs for opioid addiction can be found at the Substance Abuse and Mental Health Services Administration’s web site (<http://dpt2.samhsa.gov/treatment/>

[directory.aspx](#)). Obstetricians should communicate with the addiction treatment program whenever there are concerns about the patient’s care and methadone dosage. The dosage should be adjusted throughout the pregnancy to avoid withdrawal symptoms, which include drug cravings, abdominal cramps, nausea, insomnia, irritability, and anxiety. If a woman is treated with a stable methadone dosage before pregnancy, pharmacokinetic changes may require dosage adjustments, especially in the third trimester (18). Some women develop rapid metabolism to the extent that it becomes difficult to control withdrawal symptoms for 24 hours on a single daily dose; in these cases, split dosages may be optimal. Not all women require dose increases during pregnancy and any dosage adjustments should be made on clinical grounds by the addiction specialist. Methadone dosages usually are initiated at 10–30 mg/d (13). If a woman begins treatment with methadone while pregnant, her dosage should be titrated until she is asymptomatic in accordance with safe induction protocols. An inadequate maternal methadone dosage may result in mild to moderate opioid withdrawal signs and symptoms and cause fetal stress and increased likelihood for the maternal use of illicit drugs. Separate studies examined the extent to which the maternal methadone dosage is related to the severity of neonatal abstinence syndrome. The results are inconclusive and conflicting (19, 20). One systematic literature review and meta-analysis concluded that the severity of neonatal abstinence syndrome does not appear to differ based on the maternal dosage of methadone treatment (21). These maternal, fetal, and neonatal findings all underscore the need to provide pregnant women with an adequate methadone dosage that relieves and prevents opioid withdrawal signs and symptoms and also blocks the euphoric effect of misused opioids.

In most situations, it is advisable for pregnant women to initiate methadone induction in a licensed outpatient methadone program. In situations when a pregnant woman requires hospitalization for initiation of methadone treatment, an arrangement must be made before discharge for next day admission to an outpatient program. With the exception of buprenorphine, it is illegal for a physician to write a prescription for any other opioid for the treatment of opioid dependence, including methadone, outside of a licensed treatment program (22). Buprenorphine, when prescribed by accredited physicians who have undergone specific credentialing, is the only opioid approved for the treatment of opioid dependence in an office-based setting (23). Physicians should be familiar with federal and state regulations regarding prescribing of medications for the treatment of opioid dependence.

Emerging evidence supports the use of buprenorphine for opioid-assisted treatment during pregnancy. Buprenorphine acts on the same receptors as heroin and morphine (24). With appropriate informed consent, including disclosure of the lack of evidence from long-

term neurodevelopmental studies, buprenorphine also may be offered to patients in need of opioid-assisted therapy during pregnancy (25). The advantages of buprenorphine over methadone include a lower risk of overdose, fewer drug interactions, the ability to be treated on an outpatient basis without the need for daily visits to a licensed treatment program, and evidence of less severe neonatal abstinence syndrome (25). The disadvantages compared with methadone include reports of hepatic dysfunction, the lack of long-term data on infant and child effects, a clinically important patient dropout rate due to dissatisfaction with the drug, a more difficult induction with the potential risk of precipitated withdrawal, and an increased risk of diversion (ie, sharing or sale) of prescribed buprenorphine (25). Buprenorphine is available as a single-agent product or in a combined formulation with naloxone, an opioid antagonist used to reduce diversion. Buprenorphine with naloxone is formulated to prevent injected use because naloxone causes severe withdrawal symptoms when injected. However, because of poor naloxone absorption, the formulation has rare adverse effects when used sublingually as directed (24). The single-agent product is recommended during pregnancy to avoid any potential prenatal exposure to naloxone, especially if injected (25). The single-agent buprenorphine product has a higher potential to lead to abuse as well as a higher street value than the combination product. Thus, all patients should be monitored for the risk of diversion of their medication, especially if the single product is prescribed. Unlike methadone, which may be administered only through very tightly controlled programs, buprenorphine may be prescribed by trained and approved physicians in a medical office setting, which potentially increases the availability of treatment and decreases the stigma (24). The Substance Abuse and Mental Health Services Administration publishes a directory of physicians licensed to dispense buprenorphine (http://buprenorphine.samhsa.gov/bwns_locator). Patients considered for using buprenorphine need to be able to self-administer the drug safely and maintain adherence with their treatment regimen. Compared with methadone clinics, the less stringent structure of buprenorphine treatment may make it inappropriate for some patients who require more intensive structure and supervision (17).

Until recently, data on use of buprenorphine in pregnancy were relatively limited (25). A 2010 multicenter, randomized clinical trial compared the neonatal effects of buprenorphine and methadone in 175 opioid-dependent gravid women (26). In that study, the buprenorphine-exposed neonates required, on average, 89% less morphine to treat neonatal abstinence syndrome, a 43% shorter hospital stay, and a 58% shorter duration of medical treatment for neonatal abstinence syndrome (26). These results support the use of buprenorphine as a potential first-line medication for pregnant opioid-dependent women who are new to treatment. It is

important to understand that buprenorphine will not be effective for all patients.

Women who become pregnant while already undergoing a treatment with a stable co-formulated buprenorphine dosage generally are advised to continue the same dosage but to transition to the single-agent product. The indications for the use of buprenorphine during pregnancy are in flux currently. Previous recommendations have limited use of buprenorphine to women who have refused to use methadone, have been unable to take methadone, or those for whom methadone treatment was unavailable. The current trend is moving toward considering a patient as a potential candidate for buprenorphine if she prefers buprenorphine to methadone, gives informed consent after a thorough discussion of relative risks and benefits, and is capable of adherence and safe self-administration of the medication. If the pregnant woman is receiving methadone therapy, she should not consider transitioning to buprenorphine because of the significant risk of precipitated withdrawal. The potential risk of unrecognized adverse long-term outcomes, which is inherent with widespread use of relatively new medications during pregnancy, should always be taken into consideration.

Medically supervised withdrawal from opioids in opioid-dependent women is not recommended during pregnancy because the withdrawal is associated with high relapse rates (27). However, if methadone maintenance is unavailable or if women refuse to undergo methadone or buprenorphine maintenance, medically supervised withdrawal should ideally be undertaken during the second trimester and under the supervision of a physician experienced in perinatal addiction treatment (13). If the alternative to medically supervised withdrawal is continued illicit drug use, then a medically supervised withdrawal in the first trimester is preferable to waiting until the second trimester.

It is important that frequent communication be maintained between the patient's obstetric care provider and the addiction medicine provider to coordinate care. The federal confidentiality law 42 CFR Part 2 applies to addiction treatment providers. Patient information release forms with specific language regarding substance use are required (28).

Intrapartum and Postpartum Management

Women receiving opioid-assisted therapy who are undergoing labor should receive pain relief as if they were not taking opioids because the maintenance dosage does not provide adequate analgesia for labor (29, 30). Epidural or spinal anesthesia should be offered where appropriate for management of pain in labor or for delivery. Narcotic agonist-antagonist drugs, such as butorphanol, nalbuphine, and pentazocine, should be avoided because they may precipitate acute withdrawal. Buprenorphine should not be administered to a patient who takes methadone.

Pediatric staff should be notified of all narcotic-exposed infants.

In general, patients undergoing opioid maintenance treatment will require higher doses of opioids to achieve analgesia than other patients. One study showed that after cesarean delivery, women who used buprenorphine required 47% more opioid analgesic than women who did not use buprenorphine treatment, but adequate pain relief was achieved with short-acting opioids and anti-inflammatory medication (31). Injectable nonsteroidal antiinflammatory agents, such as ketorolac, also are highly effective in postpartum and postcesarean delivery pain control. Daily doses of methadone or buprenorphine should be maintained during labor to prevent withdrawal, and patients should be reassured of this plan in order to reduce anxiety. Dividing the usual daily maintenance dose of buprenorphine or methadone into three or four doses every 6–8 hours may provide partial pain relief; however, additional analgesia will be required (29).

Women should be counseled that minimal levels of methadone and buprenorphine are found in breast milk regardless of the maternal dose. Breastfeeding should be encouraged in patients without HIV who are not using additional drugs and who have no other contraindications (32). The current buprenorphine package insert advises against breastfeeding; however, a consensus panel stated that the effects on the breastfed infant are likely to be minimal and that breastfeeding is not contraindicated (33). Swaddling associated with breastfeeding may reduce neonatal abstinence syndrome symptoms, and breastfeeding contributes to bonding between mother and infant as well as providing immunity to the infant.

Although most pregnant women who receive methadone will experience dosage increases during pregnancy, and a need for dosage reduction might be expected, one study demonstrated little need for immediate postpartum methadone dosage reduction (34). Most women who undergo buprenorphine maintenance therapy will not experience large dosage adjustments during their pregnancies and may continue the same dosages after delivery (34). However, the postpartum patient who receives opioid therapy should be closely monitored for symptoms of oversedation with dosages titrated as indicated. Women should continue in their treatment and addiction support postpartum. Discussions of contraceptive options should begin during pregnancy and contraception, including long-acting reversible contraceptive methods, should be provided or prescribed before hospital discharge. Access to adequate postpartum psychosocial support services, including chemical dependency treatment and relapse prevention programs, should be ensured (33).

Neonatal Abstinence Syndrome

Although maternal methadone or buprenorphine therapy improves pregnancy outcomes and reduces risky behavior, its use puts the neonate at risk of neonatal abstinence syndrome, which is characterized by hyperactivity of the

central and autonomic nervous systems (13). Infants with neonatal abstinence syndrome may have uncoordinated sucking reflexes leading to poor feeding, become irritable, and produce a high-pitched cry. In infants exposed to methadone, symptoms of withdrawal may begin at anytime in the first 2 weeks of life, but usually appear within 72 hours of birth and may last several days to weeks (13). Infants exposed to buprenorphine who develop neonatal abstinence syndrome generally develop symptoms within 12–48 hours of birth that peak at 72–96 hours and resolve by 7 days (35). Close communication between the obstetrician and pediatrician is necessary for optimal management of the neonate.

All infants born to women who use opioids during pregnancy should be monitored for neonatal abstinence syndrome and treated if indicated (13). Treatment is adequate if the infant has rhythmic feeding and sleep cycles and optimal weight gain (13).

Long-Term Infant Outcome

Recent data on long-term outcomes of infants with in utero opioid exposure are limited. For the most part, earlier studies have not found significant differences in cognitive development between children up to 5 years of age exposed to methadone in utero and control groups matched for age, race, and socioeconomic status, although scores were often lower in both groups compared with population data (36). Preventive interventions that focus on enriching the early experiences of such children and improving the quality of the home environment are likely to be beneficial (37).

Summary

Early identification of opioid-dependent pregnant women improves maternal and infant outcomes. Contraceptive counseling should be a routine part of substance use treatment among women of reproductive age to minimize the risk of unplanned pregnancy. Pregnancy in the opioid-dependent woman should be co-managed by the obstetrician–gynecologist and addiction medicine specialist with appropriate 42 CFR Part 2-compliant release of information forms. This collaboration is particularly important when the woman receives opioid maintenance treatment or is at high risk of relapse. When opioid maintenance treatment is available, medically supervised withdrawal should be discouraged during pregnancy. It is essential for hospitalized pregnant women who initiated opioid-assisted therapy to make a next-day appointment with a treatment program before discharge. Infants born to women who used opioids during pregnancy should be closely monitored for neonatal abstinence syndrome and other effects of opioid use by a pediatric health care provider.

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Women's Health Care Physicians

COMMITTEE OPINION

Number 471 • November 2010

(Replaces No. 316, October 2005)

Committee on Health Care for Underserved Women
Committee on Obstetric Practice

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Smoking Cessation During Pregnancy

ABSTRACT: Smoking is the one of the most important modifiable causes of poor pregnancy outcomes in the United States, and is associated with maternal, fetal, and infant morbidity and mortality. The physical and psychologic addiction to cigarettes is powerful; however, the compassionate intervention of the obstetrician-gynecologist can be the critical element in prenatal smoking cessation. An office-based protocol that systematically identifies pregnant women who smoke and offers treatment or referral has been proved to increase quit rates. A short counseling session with pregnancy-specific educational materials and a referral to the smokers' quit line is an effective smoking cessation strategy. The 5A's is an office-based intervention developed to be used under the guidance of trained practitioners to help pregnant women quit smoking. Knowledge of the use of the 5A's, health care support systems, and pharmacotherapy add to the techniques providers can use to support perinatal smoking cessation.

Epidemiology

Increased public education measures and public health campaigns in the United States have led to a decrease in smoking by pregnant women and nonpregnant women of reproductive age (1). Pregnancy appears to motivate women to stop smoking; 46% of prepregnancy smokers quit smoking directly before or during pregnancy (1). Although the rate of reported smoking during pregnancy has decreased from 18.4% in 1990 to 13.2% overall in 2006, for some populations, such as adolescent females and less educated non-Hispanic white and American Indian women, the decrease was less dramatic (2, 3). Smoking during pregnancy is a public health problem because of the many adverse effects associated with it. These include intrauterine growth restriction, placenta previa, abruptio placentae, decreased maternal thyroid function (4, 5), preterm premature rupture of membranes (6, 7), low birth weight, perinatal mortality (4), and ectopic pregnancy (4). An estimated 5–8% of preterm deliveries, 13–19% of term deliveries of infants with low birth weight, 23–34% cases of sudden infant death syndrome (SIDS), and 5–7% of preterm-related infant deaths can be attributed to prenatal maternal smoking (8). The risks of smoking during pregnancy extend beyond pregnancy-related complications. Children born to mothers who smoke during pregnancy are at an increased risk of asthma, infantile colic, and childhood obesity (9–11). Researchers report that infants born to

women who use smokeless tobacco during pregnancy have a high level of nicotine exposure, low birth weight, and shortened gestational age as to mothers who smoke during pregnancy (12, 13). Secondhand prenatal exposure to tobacco smoke also increases the risk of having an infant with low birth weight by as much as 20% (14).

Intervention

Cessation of tobacco use, prevention of secondhand smoke exposure and prevention of relapse to smoking are key clinical intervention strategies during pregnancy. Inquiry into tobacco use and smoke exposure should be a routine part of the prenatal visit. The U.S. Preventive Services Task Force (USPSTF) recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke (15). The U.S. Public Health Service recommends that clinicians offer effective tobacco dependence interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy (16).

Addiction to and dependence on cigarettes is both physiologic and psychologic, and cessation techniques have included counseling, cognitive and behavioral therapy, hypnosis, acupuncture, and pharmacologic therapy. Women who indicate that they are not ready to quit smoking can benefit from consistent motivational approaches by their health care providers as outlined in Committee Opinion No. 423, "Motivational Interview-

ing” published by the American College of Obstetricians and Gynecologists (17). Patients who are willing to try to quit smoking benefit from a brief counseling session, such as the 5A’s intervention (Box 1), which has been proved to be effective when initiated by health care providers (16). With appropriate training, obstetrician–gynecologists, other clinicians, or auxiliary health care providers can perform these five steps with pregnant women who smoke (16). Referral to a smoker’s quit line may further benefit the patient. Quit lines offer information, direct support, and ongoing counseling, and have been very successful in helping pregnant smokers quit and remain smoke free (18). Most states offer pregnancy-specific services, focusing on the pregnant woman’s motivation to quit and providing postpartum follow-up to prevent relapse to smoking. By dialing the national quit line network (1-800-QUIT NOW) a caller is immediately routed to her state’s smokers’ quit line. Many states offer fax referral access to their quit lines for prenatal health care providers. Health care providers can call the national quit line to learn about the services offered within their states. Examples of effective smoking cessation interventions delivered by a health care provider are listed in Box 2.

Although counseling and pregnancy-specific materials are effective cessation aids for many pregnant women, some women continue to smoke (15). These smokers often are heavily addicted to nicotine and should be encouraged at every follow-up visit to seek help to stop smoking. They also may benefit from screening and intervention for alcohol use and other drug use because continued smoking during pregnancy increases the likelihood of other substance use (19). Clinicians also may consider referring patients for additional psychosocial treatment (16). There is insufficient evidence to support the use of meditation, hypnosis, and acupuncture for smoking cessation (16). Although quitting smoking before 15 weeks of gestation yields the greatest benefits for the pregnant woman and fetus, quitting at any point can be beneficial (20). Successful smoking cessation before the third trimester can eliminate much of the reduction in birth weight caused by maternal smoking (20). The benefits of reduced cigarette smoking are difficult to measure or verify. The effort of women who reduce the amount they smoke should be lauded, but these women also should be reminded that quitting entirely brings the best results for their health, the health of their fetuses, and ultimately that of their infants (21). Pregnant women who are exposed to the smoking of family members or coworkers should be given advice on how to address these smokers or avoid exposure.

Approximately 50–60% of women who quit smoking during pregnancy return to smoking within 1 year postpartum, putting at risk their health, that of their infants, and the outcomes of future pregnancies (1). Determining a woman’s intention to return to smoking during the third trimester has proved useful at targeting smoking relapse interventions (22). Most pregnant former smokers

Box 1. Five A’s of Smoking Cessation

1. **ASK** the patient about smoking status at the first prenatal visit and follow-up with her at subsequent visits. The patient should choose the statement that best describes her smoking status:
 - A. I have NEVER smoked or have smoked LESS THAN 100 cigarettes in my lifetime.
 - B. I stopped smoking BEFORE I found out I was pregnant, and I am not smoking now.
 - C. I stopped smoking AFTER I found out I was pregnant, and I am not smoking now.
 - D. I smoke some now, but I have cut down on the number of cigarettes I smoke SINCE I found out I was pregnant.
 - E. I smoke regularly now, about the same as BEFORE I found out I was pregnant.

If the patient stopped smoking before or after she found out she was pregnant (B or C), reinforce her decision to quit, congratulate her on success in quitting, and encourage her to stay smoke free throughout pregnancy and postpartum. If the patient is still smoking (D or E), document smoking status in her medical record, and proceed to Advise, Assess, Assist, and Arrange.

2. **ADVISE** the patient who smokes to stop by providing advice to quit with information about the risks of continued smoking to the woman, fetus, and newborn.
3. **ASSESS** the patient’s willingness to attempt to quit smoking at the time. Quitting advice, assessment, and motivational assistance should be offered at subsequent prenatal care visits.
4. **ASSIST** the patient who is interested in quitting by providing pregnancy-specific, self-help smoking cessation materials. Support the importance of having smoke-free space at home and seeking out a “quitting buddy,” such as a former smoker or nonsmoker. Encourage the patient to talk about the process of quitting. Offer a direct referral to the smoker’s quit line (1-800-QUIT NOW) to provide ongoing counseling and support.
5. **ARRANGE** follow-up visits to track the progress of the patient’s attempt to quit smoking. For current and former smokers, smoking status should be monitored and recorded throughout pregnancy, providing opportunities to congratulate and support success, reinforce steps taken towards quitting, and advise those still considering a cessation attempt.

Modified from Fiore MC, Jaen CR, Baker TB, Bailey WC, Benowitz NL, Curry SJ, et al. Treating tobacco use and dependence: 2008 update. Clinical Practice Guideline. Rockville (MD): U.S. Department of Health and Human Services, Public Health Service; 2008. Available at: http://www.surgeongeneral.gov/tobacco/treating_tobacco_use08.pdf. Retrieved July 6, 2010.

indicate that they do not intend to smoke. To strengthen their resolve for continued smoking abstinence, a review of tobacco use prevention strategies and identification of

Box 2. Examples of Effective Smoking Cessation Interventions With Pregnant Patients

- Physician advice regarding smoking related risks (2–3 minutes)
- Video tape with information on risks, barriers, and tips for quitting; provider counseling in one 10-minute session; self-help manual; and follow-up letters
- Pregnancy-specific self-help guide and one 10-minute counseling session with a health educator.
- Provide counseling in one 90-minute session plus twice monthly telephone follow-up calls during pregnancy and monthly telephone calls after delivery

social support systems to remain smoke free in the third trimester and postpartum is encouraged (22).

Pharmacotherapy

The U.S. Preventive Services Task Force has concluded that the use of nicotine replacement products or other pharmaceuticals for smoking cessation aids during pregnancy and lactation have not been sufficiently evaluated to determine their efficacy or safety (15). There is conflicting evidence as to whether or not nicotine replacement therapy increases abstinence rates in pregnant smokers, and it does not appear to increase the likelihood of permanent smoking cessation during postpartum follow-up of these patients (23, 24). Trials studying the use of nicotine replacement therapy in pregnancy have been attempted, yet all of those conducted in the United States have been stopped by data and safety monitoring committees for either demonstration of adverse pregnancy effects or failure to demonstrate effectiveness (15, 25, 26). Therefore, the use of nicotine replacement therapy should be undertaken with close supervision and after careful consideration and discussion with the patient of the known risks of continued smoking and the possible risks of nicotine replacement therapy. If nicotine replacement is used, it should be with the clear resolve of the patient to quit smoking.

Alternative smoking cessation agents used in the non-pregnant population include varenicline and bupropion. Varenicline is a drug that acts on brain nicotine receptors, but there is no knowledge as to the safety of varenicline use in pregnancy (27). Bupropion is an antidepressant with only limited data, but there is no known risk of fetal anomalies or adverse pregnancy effects (28). However, both of these medications have recently added product warnings mandated by the U.S. Food and Drug Administration about the risk of psychiatric symptoms and suicide associated with their use (29, 30). Both bupropion and varenicline are transmitted to breast milk. There is insufficient evidence to evaluate the safety and efficacy of these treatments in pregnancy and lactation (16). Furthermore, in

a population at risk of depression, medications that can cause an increased risk of psychiatric symptoms and suicide should be used with caution and considered in consultation with experienced prescribers only.

Coding

Office visits specifically addressing smoking cessation may be billed, but not all payers reimburse for counseling outside of the global pregnancy care package and some do not cover preventive services at all. Under the health care reform, physicians will be reimbursed for the provision of smoking cessation counseling to pregnant women in Medicaid and in new health plans with no cost sharing for the patient. Health care providers are encouraged to consult coding manuals regarding billing and be aware that reimbursements will vary by insurance carrier.

Resources

The American College of Obstetricians and Gynecologists Resources

American College of Obstetricians and Gynecologists. Smoking cessation during pregnancy: a clinician's guide to helping pregnant women quit smoking. Washington, DC: ACOG; 2002. The guide, pocket reminder card, and slide lecture can be ordered by writing to smoking@acog.org.

American College of Obstetricians and Gynecologists. Need help putting out that cigarette? Washington, DC: ACOG; 2008. This pregnancy-specific smoking cessation workbook for patients is available in English and Spanish from the ACOG bookstore at <http://www.acog.org/bookstore>.

Other Resources

Dartmouth Medical School. Smoking cessation for pregnancy and beyond: learn proven strategies to help your patients quit. Available at: <http://iml.dartmouth.edu/education/cme/Smoking>. Retrieved July 6, 2010.

National Alliance for Tobacco Cessation. BecomeAnEX.org: if you're pregnant, start here. Available at: <http://www.becomeanex.org/pregnant-smokers.php>. Retrieved July 6, 2010. All states offer free smoking cessation telephone quit line services. Dialing 1-800-QUIT NOW will connect the caller to their state quit line.

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Women's Health Care Physicians

COMMITTEE OPINION

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Committee on Health Care for Underserved Women

This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Substance Abuse Reporting and Pregnancy: The Role of the Obstetrician–Gynecologist

Abstract: Drug enforcement policies that deter women from seeking prenatal care are contrary to the welfare of the mother and fetus. Incarceration and the threat of incarceration have proved to be ineffective in reducing the incidence of alcohol or drug abuse. Obstetrician–gynecologists should be aware of the reporting requirements related to alcohol and drug abuse within their states. They are encouraged to work with state legislators to retract legislation that punishes women for substance abuse during pregnancy.

A disturbing trend in legal actions and policies is the criminalization of substance abuse during pregnancy when it is believed to be associated with fetal harm or adverse perinatal outcomes. Although no state specifically criminalizes drug abuse during pregnancy, prosecutors have relied on a host of established criminal laws to punish a woman for prenatal substance abuse (1). As of September 1, 2010, fifteen states consider substance abuse during pregnancy to be child abuse under civil child-welfare statutes, and three consider it grounds for involuntary commitment to a mental health or substance abuse treatment facility (1). States vary in their requirements for the evidence of drug exposure to the fetus or newborn in order to report a case to the child welfare system. Examples of the differences include the following: South Carolina relies on a single positive drug test result, Florida mandates reporting newborns that are “demonstrably adversely affected” by prenatal drug exposure, and in Texas, an infant must be “addicted” to an illegal substance at birth. Most states focus only on the abuse of some illegal drugs as cause for legal action. For instance, in Maryland, the use of drugs such as methamphetamines or marijuana may not be cause for reporting the pregnant woman to authorities (2). Some states also include evidence of alcohol use by a pregnant woman in their definitions of child neglect.

Although legal action against women who abuse drugs prenatally is taken with the intent to produce healthy birth outcomes, negative results are frequently cited. Incarceration and the threat of incarceration have

proved to be ineffective in reducing the incidence of alcohol or drug abuse (3–5). Legally mandated testing and reporting puts the therapeutic relationship between the obstetrician–gynecologist and the patient at risk, potentially placing the physician in an adversarial relationship with the patient (6, 7). In one study, women who abused drugs did not trust health care providers to protect them from the social and legal consequences of identification and avoided or emotionally disengaged from prenatal care (8). Studies indicate that prenatal care greatly reduces the negative effects of substance abuse during pregnancy, including decreased risks of low birth weight and prematurity (9). Drug enforcement policies that deter women from seeking prenatal care are contrary to the welfare of the mother and fetus.

Seeking obstetric–gynecologic care should not expose a woman to criminal or civil penalties, such as incarceration, involuntary commitment, loss of custody of her children, or loss of housing (6). These approaches treat addiction as a moral failing. Addiction is a chronic, relapsing biological and behavioral disorder with genetic components. The disease of substance addiction is subject to medical and behavioral management in the same fashion as hypertension and diabetes. Substance abuse reporting during pregnancy may dissuade women from seeking prenatal care and may unjustly single out the most vulnerable, particularly women with low incomes and women of color (10). Although the type of drug may differ, individuals from all races and socioeconomic strata have similar rates of substance abuse and addiction (11).

Pregnant women who do not receive treatment for drug dependence cannot be assumed to have rejected treatment (12). The few drug treatment facilities in the United States accepting pregnant women often do not provide child care, account for the woman's family responsibilities, or provide treatment that is affordable. As of 2010, only 19 states have drug treatment programs for pregnant women, and only nine give priority access to pregnant women (1).

Obstetrician-gynecologists have important opportunities for substance abuse intervention. Three of the key areas in which they can have an effect are 1) adhering to safe prescribing practices, 2) encouraging healthy behaviors by providing appropriate information and education, and 3) identifying and referring patients already abusing drugs to addiction treatment professionals (13). Substance abuse treatment programs integrated with prenatal care have proved to be effective in reducing maternal and fetal pregnancy complications and costs (14).

The use of the legal system to address perinatal alcohol and substance abuse is inappropriate. Obstetrician-gynecologists should be aware of the reporting requirements related to alcohol and drug abuse within their states. In states that mandate reporting, policy makers, legislators, and physicians should work together to retract punitive legislation and identify and implement evidence-based strategies outside the legal system to address the needs of women with addictions. These approaches should include the development of safe, affordable, available, efficacious, and comprehensive alcohol and drug treatment services for all women, especially pregnant women, and their families.

Resource

Guttmacher Institute. Substance abuse during pregnancy. State Policies in Brief. New York (NY): GI; 2010. Available at: http://www.guttmacher.org/statecenter/spibs/spib_SADP.pdf. Retrieved September 10, 2010.

This report lists policies regarding prosecution for substance abuse during pregnancy and drug abuse treatment options for pregnant women for each state. It is updated monthly.

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COMMITTEE ON FETUS AND NEWBORN
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TECHNICAL REPORT

Prenatal Substance Abuse: Short- and Long-term Effects on the Exposed Fetus

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KEY WORDS

prenatal drug exposure, alcohol, nicotine, marijuana, cocaine, methamphetamine, growth and development

ABBREVIATIONS

AAP—American Academy of Pediatrics
THC—tetrahydrocannabinol

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Abstract

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Prenatal substance abuse continues to be a significant problem in this country and poses important health risks for the developing fetus. The primary care pediatrician's role in addressing prenatal substance exposure includes prevention, identification of exposure, recognition of medical issues for the exposed newborn infant, protection of the infant, and follow-up of the exposed infant. This report will provide information for the most common drugs involved in prenatal exposure: nicotine, alcohol, marijuana, opiates, cocaine, and methamphetamine. *Pediatrics* 2013;131:e1009–e1024

Substance abuse has been a worldwide problem at all levels of society since ancient times. Attention has been directed toward the use of legal and illegal substances by pregnant women over the past several decades. Almost all drugs are known to cross the placenta and have some effect on the fetus. The effects on the human fetus of prenatal cigarette use have been identified and studied since the 1960s,¹ the effects of alcohol and opiate use have been studied since the 1970s,^{2–4} and the effects a variety of other illicit drugs have been studied since the 1980s.^{5–7} This report reviews data regarding the prevalence of exposure and available technologies for identifying exposure as well as current information regarding short- and long-term outcomes of exposed infants, with the aim of facilitating pediatricians in fulfilling their role in the promotion and maintenance of infant and child health.

PREVALENCE

Prevalence estimates for prenatal substance use vary widely and have been difficult to establish. Differences are likely attributable to such things as the use of different sampling methods and drug-detection methods, screening women in different settings, and obtaining data at different points in time. For example, prevalence will vary depending on whether history or testing of biological specimens is used; whether the biological specimen is hair, urine, or meconium; and whether the specimens are merely screened for drugs or screened and confirmed with additional testing. There also will be differences depending on whether the sample being investigated is a community sample or a targeted sample, such as women who are in drug treatment or are incarcerated. Lastly, prevalence must be interpreted in light of the fact

that the use of specific drugs waxes and wanes over time nationwide as the popularity of certain substances changes.

Although a variety of prevalence studies have been conducted over the past 2 decades, there is 1 national survey that regularly provides information on trends in substance abuse among pregnant women. The National Survey on Drug Use and Health (formerly called the National Household Survey on Drug Abuse), sponsored by the Substance Abuse and Mental Health Services Administration (<http://www.oas.samhsa.gov/nhsda.htm>), is an annual survey providing national and state level information on the use of alcohol, tobacco, and illicit drugs in a sample of more than 67 000 noninstitutionalized people older than 12 years. Data are combined into 2-year epochs and include reported drug use for pregnant women between the ages of 15 and 44 years. Current illegal drug use among pregnant women remained relatively stable from 2007–2008 (5.1%) to 2009–2010 (4.4%). These average prevalence rates are significantly lower than reported current illicit drug use rates for nonpregnant women (10.9%). Importantly, the rate of current drug use among the youngest and possibly the most vulnerable pregnant women was highest (16.2% for 15- to 17-year-olds, compared with 7.4% among 18- to 25-year-olds and 1.9% among 26- to 44-year-olds). Table 1 summarizes these data along with information regarding current alcohol use, binge drinking,

and cigarette use by pregnant and nonpregnant women. An additional important finding from this survey was that the rate of cigarette smoking for those 15 to 17 years of age actually was higher for pregnant women than for nonpregnant women (22.7% vs 13.4%, respectively). This report details many sociodemographic variables related to drug use in the American population, and the reader is referred to the Substance Abuse and Mental Health Services Administration Web site for the full report (<http://www.oas.samhsa.gov/nhsda.htm>).

IDENTIFICATION OF PRENATAL EXPOSURE

Two basic methods are used to identify drug users: self-report or biological specimens. Although no single approach can accurately determine the presence or amount of drug used during pregnancy, it is more likely that fetal exposure will be identified if a biological specimen is collected along with a structured interview.⁸

Self-reported history is an inexpensive and practical method for identifying prenatal drug exposure and is the only method available in which information can be obtained regarding the timing of the drug use during pregnancy and the amount used. Unfortunately, self-report suffers from problems with the veracity of the informant and recall accuracy.^{9,10} Histories obtained by trusted, nonjudgmental individuals or via computerized survey forms; questions referring back to the previous trimester or prepregnancy usage, not current use; and pregnancy calendars used to assist recollection each improve the accuracy of the information obtained.^{11–13}

Several biological specimens can be used to screen for drug exposure. Each specimen has its own individual variations with regard to the window of detection, the specific drug metabolites

used for identification, methods of adulteration of the sample, and analytical techniques, thus altering the sensitivity and specificity for each drug of interest. The most common analytical method used for screening biological specimens is an immunoassay designed to screen out drug-free samples. Threshold values generally are set high to minimize false-positive test results but may be too high to detect low-dose or remote exposure. Because immunoassay is a relatively nonspecific test, positive results require confirmation by using gas chromatography/mass spectrometry. In addition, confirmation of the presence of a drug is not always associated with drug abuse. Alternative explanations include passive exposure to the drug, ingestion of other products contaminated with the drug, or use of prescription medications that either contain the drug or are metabolized to the drug.¹⁴ Thus, careful patient histories remain essential to the process of identification.

The 3 most commonly used specimens to establish drug exposure during the prenatal and perinatal period are urine, meconium, and hair; however, none is accepted as a “gold standard.” Urine has been the most frequently tested biological specimen because of its ease of collection. Urine testing identifies only recent drug use, because threshold levels of drug metabolites generally can be detected in urine only for several days. A notable exception to this is marijuana, the metabolites of which can be excreted for as long as 10 days in the urine of regular users¹⁵ or up to 30 days in chronic, heavy users. Urine is a good medium as well for the detection of nicotine, opiate, cocaine, and amphetamine exposure.^{16,17}

Meconium is also easy to collect noninvasively. It is hypothesized that drugs accumulate in meconium throughout pregnancy, and thus, meconium is

TABLE 1 Comparison of Drug Use Among Women 15 to 44 Years of Age by Pregnancy Status: 2009–2010

	Pregnant Women, %	Nonpregnant Women, %
Illicit drug use	4.4	10.9
Alcohol use	10.8	54.7
Binge drinking	3.7	24.6
Cigarette use	16.3	26.7

thought to reflect exposure during the second and third trimester of pregnancy when meconium forms. However, use of meconium to determine the timing or extent of exposure during pregnancy is controversial¹⁸ because of a lack of studies regarding the effects of the timing and quantity of the postpartum specimen collection as well as the effects of urine or transitional stool contamination of the meconium samples.¹⁹ Meconium has been used for the detection of nicotine, alcohol, marijuana, opiate, cocaine, and amphetamine exposure.^{16,20}

Hair is easy to collect, although some people decline this sampling method because of cosmetic concerns and societal taboos. Drugs become trapped within the hair and, thus, can reflect drug use over a long period of time. Unfortunately, using hair to determine timing and quantity of exposure also is controversial. In addition, environmental contamination, natural hair colors and textures, cosmetic hair processing, and volume of the hair sample available all affect the rational interpretation of the results.^{21–24} Hair is useful for the detection of nicotine, opiate, cocaine, and amphetamine exposure.^{16,25}

Other biological specimens have been studied for use in the detection of in utero drug exposure but are not commonly used in the clinical setting. These include such specimens as cord blood, human milk, amniotic fluid, and umbilical cord tissue.^{8,19,26} In the case of umbilical cord tissue, drug class-specific immunoassays for amphetamines, opiates, cocaine, and cannabinoids appear to be as reliable as meconium testing, with the additional benefit of availability of the tissue at the time of birth.²⁷

Beginning in the early 1980s, states began to enact legislation in response to the increasingly popular use of “crack” cocaine in our society. Such

laws required the reporting of women who used drugs during pregnancy to the legal system through states’ child abuse statutes. In 2003, the Keeping Children and Families Safe Act (Public Law 108-36) was passed by Congress, requiring physicians to notify their state child protective services agency of any infant identified as affected by illegal substances at birth or experiencing drug withdrawal. Currently, issues of whether to use biological specimens to screen for drug abuse; whether to screen the mother, her infant, or both; and which women and infants to screen are issues complicated by legal, ethical, social, and scientific concerns. Each of these concerns must be taken into account as obstetricians, neonatologists, and pediatricians work to develop protocols for identifying prenatal drug exposure. For example, there is no biological specimen that, when obtained randomly, identifies prenatal drug use with 100% accuracy; hence, a negative drug screening result does not ensure that the pregnancy was drug free. Targeted screening of high-risk women is problematic, because it can be biased toward women of racial or ethnic minorities and those who are economically disadvantaged or socially disenfranchised. Universal screening of pregnant women is impractical and not cost-effective.^{28–30} Finally, testing of biological specimens when the maternal history is positive for drug use increases medical costs and does not necessarily provide information that guides the medical care of the infant.³¹

MECHANISMS OF ACTION OF DRUGS ON THE FETUS

Drugs can affect the fetus in multiple ways. Early in gestation, during the embryonic stage, drugs can have significant teratogenic effects. However, during the fetal period, after

major structural development is complete, drugs have more subtle effects, including abnormal growth and/or maturation, alterations in neurotransmitters and their receptors, and brain organization. These are considered to be the direct effects of drugs. However, drugs also can exert a pharmacologic effect on the mother and, thus, indirectly affect the fetus. For example, nicotine acts on nicotinic cholinergic receptors within the mesolimbic pathway, and neuropathways activated by alcohol enhance inhibitory γ -aminobutyric acid (GABA) receptors and reduce glutamate receptor activity. Drugs of abuse mimic naturally occurring neurotransmitters, such that marijuana acts as anandamides, opiates act as endorphins, and cocaine and stimulants act within the mesolimbic dopaminergic pathways to increase dopamine and serotonin within the synapses.³² Other indirect effects of drugs of abuse on the fetus include altered delivery of substrate to the fetus for nutritional purposes, either because of placental insufficiency or altered maternal health behaviors attributable to the mother’s addiction. These altered behaviors, which include poor nutrition, decreased access/compliance with health care, increased exposure to violence, and increased risk of mental illness and infection, may place the fetus at risk.³³

Nicotine concentrations are higher in the fetal compartment (placenta, amniotic fluid, fetal serum) compared with maternal serum concentrations.^{34–36} Nicotine is only 1 of more than 4000 compounds to which the fetus is exposed through maternal smoking. Of these, ~30 compounds have been associated with adverse health outcomes. Although the exact mechanisms by which nicotine produces adverse fetal effects are unknown, it is likely that hypoxia, undernourishment of

the fetus, and direct vasoconstrictor effects on the placental and umbilical vessels all play a role.^{37,38} Nicotine also has been shown to have significant deleterious effects on brain development, including alterations in brain metabolism and neurotransmitter systems and abnormal brain development.³⁹⁻⁴³ Additional toxicity from compounds in smoke, such as cyanide and cadmium, contribute to toxicity.⁴⁴⁻⁴⁸ Ethanol easily crosses the placenta into the fetus, with a significant concentration of the drug identified in the amniotic fluid as well as in maternal and fetal blood.^{49,50} A variety of mechanisms explaining the effects of alcohol on the fetus have been hypothesized. These include direct teratogenic effects during the embryonic and fetal stage of development as well as toxic effects of alcohol on the placenta, altered prostaglandin and protein synthesis, hormonal alterations, nutritional effects, altered neurotransmitter levels in the brain, altered brain morphology and neuronal development, and hypoxia (thought to be attributable to decreased placental blood flow and alterations in vascular tone in the umbilical vessels).⁵¹⁻⁶⁹

Although the main chemical compound in marijuana, δ -9-tetrahydrocannabinol (THC), crosses the placenta rapidly, its major metabolite, 11-nor-9-carboxy-THC, does not.⁷⁰ Unlike other drugs, the placenta appears to limit fetal exposure to marijuana, as fetal THC concentrations have been documented to be lower than maternal concentrations in studies of various animal species.^{15,70-72} The deleterious effects of marijuana on the fetus are thought to be attributable to complex pharmacologic actions on developing biological systems, altered uterine blood flow, and altered maternal health behaviors.⁷³⁻⁷⁵ Similar to other drugs, marijuana has been shown to alter brain neurotransmitters as well

as brain biochemistry, resulting in decreased protein, nucleic acid, and lipid synthesis.^{74,76-79} Marijuana can remain in the body for up to 30 days, thus prolonging fetal exposure. In addition, smoking marijuana produces as much as 5 times the amount of carbon monoxide as does cigarette smoking, perhaps altering fetal oxygenation.⁸⁰

In humans, opiates rapidly cross the placenta, with drug equilibration between the mother and the fetus.⁸¹ Opiates have been shown to decrease brain growth and cell development in animals, but studies of their effects on neurotransmitter levels and opioid receptors have produced mixed results.⁸²⁻⁸⁹

Pharmacologic studies of cocaine in animal models using a variety of species have demonstrated that cocaine easily crosses both the placenta and the blood-brain barrier and can have significant teratogenic effects on the developing fetus, directly and indirectly.⁹⁰ Cocaine's teratogenic effects most likely result from interference with the neurotrophic roles of monoaminergic transmitters during brain development,⁹¹⁻⁹⁴ which can significantly affect cortical neuronal development and may lead to morphologic abnormalities in several brain structures, including the frontal cingulate cortex.⁹⁴ It also appears that the development of areas of the brain that regulate attention and executive functioning are particularly vulnerable to cocaine. Thus, functions such as arousal, attention, and memory may be adversely affected by prenatal cocaine exposure.^{89,91,95-97} Furthermore, insults to the nervous system during neurogenesis, before homeostatic regulatory mechanisms are fully developed, differ from those on mature systems. Thus, cocaine exposure occurring during development of the nervous system might be expected to

result in permanent changes in brain structure and function, which can produce altered responsiveness to environmental or pharmacologic challenges later in life.⁹⁸

Methamphetamine is a member of a group of sympathomimetic drugs that stimulate the central nervous system. It readily passes through the placenta and the blood-brain barrier and can have significant effects on the fetus.⁹⁹⁻¹⁰¹ After a single dose of methamphetamine to pregnant mice, levels of substance in the fetal brain were found to be similar to those found in human infants after prenatal methamphetamine exposure, with accumulation and distribution of the drug most likely dependent on the monoaminergic transport system. It is possible that the mechanism of action of methamphetamine is an interaction with and alteration of these neurotransmitter systems in the developing fetal brain¹⁰⁰ as well as alterations in brain morphogenesis.¹⁰²

MEDICAL ISSUES IN THE NEWBORN PERIOD

Fetal Growth

Fetal tobacco exposure has been a known risk factor for low birth weight and intrauterine growth restriction for more than 50 years,¹⁰³ with decreasing birth weight shown to be related to the number of cigarettes smoked.¹⁰⁴⁻¹⁰⁷ Importantly, by 24 months of age, most studies no longer demonstrate an effect of fetal tobacco exposure on somatic growth parameters of prenatally exposed infants.¹⁰⁸⁻¹¹⁴ Growth restriction is 1 of the hallmarks of prenatal alcohol exposure and must be present to establish a diagnosis of fetal alcohol syndrome.^{3,115} However, even moderate amounts of alcohol use during pregnancy is associated with a decrease in size at birth.¹¹⁶⁻¹¹⁹ In general, marijuana has

not been associated with fetal growth restriction, particularly after controlling for other prenatal drug exposures.^{109,120-122} Fetal growth effects are reported in studies of prenatal opiate exposure; however, confounding variables known to be associated with poor growth, such as multiple drug use and low socioeconomic status, were not well controlled in many of the studies.¹²³ Using data from the Maternal Lifestyle Study, Bada et al¹²⁴ reported lower birth weight in opiate-exposed newborn infants born at ≥ 33 weeks' gestation, independent of use of other drugs, prenatal care, or other medical risk factors. An independent effect of prenatal cocaine exposure on intrauterine growth has been the most consistent finding across studies of prenatally exposed infants.^{122,125-130} Early studies on prenatal methamphetamine exposure¹³¹ as well as recent studies¹³² reveal independent effects of the drug on fetal growth. However, the literature available is limited at this time. Several reviews on the effects of prenatal drug exposure on growth contain additional details.¹³³⁻¹³⁵

Congenital Anomalies

Nicotine has been associated with oral facial clefts in exposed newborn infants,¹³⁶⁻¹⁴⁰ although the data are relatively weak. There is a vast literature on the teratogenic effects of prenatal alcohol exposure after the first description of fetal alcohol syndrome in 1973.³ The American Academy of Pediatrics (AAP) policy statement "Fetal Alcohol Syndrome and Alcohol-Related Neurodevelopmental Disorders" contains more information.¹⁴¹ No clear teratogenic effect of marijuana or opiates is documented in exposed newborn infants.¹⁴² Original reports regarding cocaine teratogenicity have not been further documented.^{133,143} Studies of fetal methamphetamine exposure in humans are

limited. However, Little et al¹³¹ reported no increase in the frequency of major anomalies in a small sample of exposed infants when compared with non-exposed infants.

Withdrawal

No convincing studies are available that document a neonatal withdrawal syndrome for prenatal nicotine exposure. Although several authors describe abnormal newborn behavior of exposed infants immediately after delivery, the findings are more consistent with drug toxicity, which steadily improves over time,^{144,145} as opposed to an abstinence syndrome, in which clinical signs would escalate over time as the drug is metabolized and eliminated from the body. There is 1 report of withdrawal from prenatal alcohol exposure in infants with fetal alcohol syndrome born to mothers who drank heavily during pregnancy,¹⁴⁶ but withdrawal symptoms have not been reported in longitudinal studies available in the extant literature. Neonatal abstinence symptoms have not been observed in marijuana-exposed infants, although abnormal newborn behavior has been reported with some similarities to that associated with narcotic exposure.¹⁴⁷ An opiate withdrawal syndrome was first described by Finnegan et al¹⁴⁸ in 1975. Neonatal abstinence syndrome includes a combination of physiologic and neurobehavioral signs that include such things as sweating, irritability, increased muscle tone and activity, feeding problems, diarrhea, and seizures. Infants with neonatal abstinence syndrome often require prolonged hospitalization and treatment with medication. Methadone exposure has been associated with more severe withdrawal than has exposure to heroin.¹⁴⁹ Early reports regarding buprenorphine, a more recent alternative to methadone, suggest minimal to mild withdrawal in exposed

neonates. A large multicenter trial evaluating buprenorphine's effect on exposed infants documented decreased morphine dose, hospital length of stay, and length of treatment.¹⁵⁰⁻¹⁵² There has been no substantiation of early reports regarding cocaine withdrawal.¹⁵³ Currently, no prospective studies of withdrawal in methamphetamine-exposed infants are available. A retrospective study by Smith et al¹⁵⁴ reported withdrawal symptoms in 49% of their sample of 294 methamphetamine-exposed newborn infants. However, only 4% required pharmacologic intervention. The AAP clinical report on neonatal drug withdrawal contains in-depth information on neonatal drug withdrawal, including treatment options.¹⁵⁵

Neurobehavior

Abnormalities of newborn neurobehavior, including impaired orientation and autonomic regulation¹⁵⁶ and abnormalities of muscle tone,^{144,147,157} have been identified in a number of prenatal nicotine exposure studies. Poor habituation and low levels of arousal along with motor abnormalities have been identified in women who drank alcohol heavily during their pregnancy.^{80,158} Prenatal marijuana exposure is associated with increased startles and tremors in the newborn.¹²⁰ Abnormal neurobehavior in opiate-exposed newborn infants is related to neonatal abstinence (see earlier section on Withdrawal). Using the Brazelton Newborn Behavioral Assessment Scale,¹⁵⁹ reported effects of prenatal cocaine exposure on infants have included irritability and lability of state, decreased behavioral and autonomic regulation, and poor alertness and orientation.¹⁶⁰ Recent data from the Infant Development, Environment, and Lifestyle multicenter study on the effects of prenatal methamphetamine exposure documented abnormal

neurobehavioral patterns in exposed newborn infants consisting of poor movement quality, decreased arousal, and increased stress.¹⁶¹

Breastfeeding

Few sources are available documenting the prevalence of drug use during breastfeeding. Lacking recent data, the 1988 National Maternal and Infant Health Survey (<http://www.cdc.gov/nchs/about/major/nmihs/abnmihs.htm>) revealed that the prevalence of drug use during pregnancy was comparable to the prevalence of use among women who breastfed their infants. Women who used various amounts of alcohol or marijuana and moderate amounts of cocaine during their pregnancy were not deterred from breastfeeding their infants. Thus, the pediatrician is faced with weighing the risks of exposing an infant to drugs during breastfeeding against the many known benefits of breastfeeding.¹⁶² For women who are abstinent at the time of delivery or who are participating in a supervised treatment program and choose to breastfeed, close postpartum follow-up of the mother and infant are essential.

For most street drugs, including marijuana, opiates, cocaine, and methamphetamine, the risks to the infant of ongoing, active use by the mother outweigh the benefits of breastfeeding, because most street drugs have been shown to have some effect on the breastfeeding infant.¹⁶³⁻¹⁶⁶ In addition, the dose of drug being used and the contaminants within the drug are unknown for most street drugs. Nicotine is secreted into human milk^{167,168} and has been associated with decreased milk production, decreased weight gain of the infant, and exposure of the infant to environmental tobacco smoke.¹⁶⁹⁻¹⁷¹ Alcohol is concentrated in human milk. Heavy alcohol use has been shown to be associated with decreased milk

supply and neurobehavioral effects on the infant.¹⁷²⁻¹⁷⁴ However, for nicotine and alcohol, the benefits of breastfeeding in the face of limited use of these drugs outweigh the potential risks. Marijuana has an affinity for lipids and accumulates in human milk,¹⁷⁵ as can cocaine²⁶ and amphetamines.^{101,165} Although the AAP considers the use of marijuana, opiates, cocaine, and methamphetamine to be a contraindication to breastfeeding, supervised methadone use not only is considered to be compatible with breastfeeding, with no effect on the infant or on lactation, but also is a potential benefit in reducing the symptoms associated with neonatal abstinence syndrome. Several available reviews provide more detailed information with regard to breastfeeding and substance abuse.^{162,176} The reader is also referred to the AAP policy statement "Breastfeeding and the Use of Human Milk."¹⁷⁷

LONG-TERM EFFECTS RELATED TO PRENATAL DRUG EXPOSURE

Growth

The effects of prenatal tobacco exposure on long-term growth are not clear-cut. Reports in the literature of effects on height and weight¹⁷⁸⁻¹⁸¹ have not been substantiated by research teams able to control for other drug use in the sample.^{109,117,182,183} Recent studies, some of which include adolescents, have suggested that the effect on growth might be attributable to a disproportionate weight for height, such that prenatally exposed children were more likely to be obese as evidenced by a higher BMI, increased Ponderal index, and increased skinfold thickness.^{113,183,184} A robust and extensive literature is available documenting the effects of prenatal alcohol exposure on long-term growth. Although poor growth is 1 of the hallmarks of fetal alcohol

syndrome, it is the least sensitive of the diagnostic criteria.¹⁸⁵ No independent effect of prenatal marijuana exposure on growth has been documented throughout early childhood and adolescence.^{109,182,184} Long-term effects on growth have not been documented in the opiate-exposed child.¹⁸⁶ The available literature on the effect of prenatal cocaine exposure on growth throughout childhood is not conclusive. Although several studies document the negative effects of prenatal cocaine exposure on postnatal growth,¹⁸⁷⁻¹⁸⁹ others do not.^{126,190,191} No studies are available linking prenatal methamphetamine exposure to postnatal growth problems. However, 1 study of unspecified amphetamine use suggests that in utero exposure may be associated with poor growth throughout early childhood.¹⁹²

Behavior

After controlling for a variety of potentially confounding socioeconomic, psychosocial, family, and health variables, a number of studies have identified independent effects of prenatal tobacco exposure on long-term behavioral outcomes extending from early childhood into adulthood. For example, impulsivity and attention problems have been identified in children prenatally exposed to nicotine.¹⁹³⁻¹⁹⁵ In addition, prenatal tobacco exposure has been associated with hyperactivity¹⁹⁶ and negative¹⁹⁷ and externalizing behaviors in children,¹⁹⁸⁻²⁰⁰ which appear to continue through adolescence and into adulthood in the form of higher rates of delinquency, criminal behavior, and substance abuse.²⁰¹⁻²⁰⁶ Prenatal alcohol exposure is linked with significant attention problems in offspring²⁰⁷⁻²¹⁰ as well as adaptive behavior problems spanning early childhood to adulthood.²¹¹ Problems identified included disrupted school experiences, delinquent

and criminal behavior, and substance abuse. Kelly et al²¹² published an in-depth review of the effects of prenatal alcohol exposure on social behavior. Inattention and impulsivity at 10 years of age have been associated with prenatal marijuana exposure.²¹³ Hyperactivity and short attention span have been noted in toddlers prenatally exposed to opiates,²¹⁴ and older exposed children have demonstrated memory and perceptual problems.²¹⁵ Caregiver reports of child behavior problems in preschool-aged²¹⁶ and elementary school-aged children^{217,218} have not been related to cocaine exposure, except in combination with other risk factors.^{219–221} However, in longitudinal modeling of caregiver reports at 3, 5, and 7 years of age, the multisite Maternal Lifestyles Study revealed that prenatal cocaine exposure had an independent negative effect on trajectories of behavior problems.²²² There have been teacher reports of behavior problems in prenatally exposed children,²²³ although again, findings have not been consistent across studies,¹⁹⁰ and some have been moderated by other risks.²²⁴ There also have been reports in this age group of deficits in attention processing¹⁹⁰ and an increase in symptoms of attention-deficit/hyperactivity disorder and oppositional defiant disorder self-reported by the exposed children.^{217,218} To date, no studies are available that link prenatal methamphetamine exposure with long-term behavioral problems. However, 1 study of unspecified amphetamine use during pregnancy suggests a possible association with externalizing behaviors and peer problems.^{225,226}

Cognition/Executive Functioning

The link between prenatal nicotine exposure and impaired cognition is not nearly as strong as the link with

behavioral problems. However, studies of both young and older children prenatally exposed to nicotine have revealed abnormalities in learning and memory^{227,228} and slightly lower IQ scores.^{201,229–231} Prenatal alcohol exposure frequently is cited as the most common, preventable cause of non-genetic intellectual disability. Although IQ scores are lower in alcohol-exposed offspring,^{207,232} they can be variable. Additionally, prenatal alcohol exposure has been associated with poorer memory and executive functioning skills.²³³ Marijuana has not been shown to affect general IQ, but it has been associated with deficits in problem-solving skills that require sustained attention and visual memory, analysis, and integration.^{230,231,234–236} and with subtle deficits in learning and memory.²³⁷ Longitudinal studies of prenatal opiate exposure have not produced consistent findings with regard to developmental sequelae. Although developmental scores tend to be lower in exposed infants, these differences no longer exist when appropriate medical and environmental controls are included in the analyses.^{238–240} With little exception,²⁴¹ prenatal cocaine exposure has not predicted overall development, IQ, or school readiness among toddlers, elementary school-aged children, or middle school-aged children.^{190,242–250} However, several studies have revealed alterations in various aspects of executive functioning,^{221,241} including visual-motor ability,²⁴⁴ attention,^{251–253} and working memory.²⁵⁴ To date, limited data are available revealing an association between prenatal methamphetamine exposure and IQ.²⁵⁵

Language

Poor language development in early childhood after prenatal nicotine exposure has been reported,^{227,256,257} as have poor language and reading abilities in 9- to 12-year-olds.²⁵⁸ Prenatal

alcohol exposure has been shown to interfere with the development and use of language,²⁵⁹ possibly leading to long-term problems in social interaction.²⁶⁰ No effect of prenatal marijuana exposure on language development has been identified in children through 12 years of age.^{227,258} Subtle language delays have been associated with prenatal cocaine exposure.^{256,261,262} Currently, no data are available relating the prenatal use of opiates or methamphetamine to language development in exposed offspring.

Achievement

The literature available evaluating academic achievement is limited. In nicotine-exposed children, Batstra et al²⁰⁰ identified poorer performance on arithmetic and spelling tasks that were part of standardized Dutch achievement tests. Howell et al²³² reported poorer performance in mathematics on achievement tests in adolescents who had been exposed prenatally to alcohol. Streissguth et al²⁶³ describe a variety of significant academic and school problems related to prenatal alcohol exposure, primarily associated with deficits in reading and math skills throughout the school years.^{263–266} Prenatal marijuana exposure has been associated with academic underachievement, particularly in the areas of reading and spelling.²⁶⁷ School achievement is not an area that has been studied adequately with regard to prenatal opiate exposure. Reported effects of cocaine exposure on school achievement are variable. In the longitudinal Maternal Lifestyle Study, 7-year-old children with prenatal cocaine exposure had a 79% increased odds of having an individualized educational plan (adjusted for IQ),²⁶⁸ and Morrow et al²⁴⁹ found 2.8 times the risk of learning disabilities among children with prenatal cocaine exposure

compared with their peers who were not exposed to drugs prenatally. However, other studies do not support significant cocaine effects on school achievement.^{190,269} No data are available for the effects of methamphetamine on school achievement. Cernerud et al²⁷⁰ reported on 65 children prenatally exposed to amphetamines. At 14 to 15 years of age, the children in their cohort scored significantly lower on mathematics tests than did their classmates who were not exposed to amphetamines prenatally and had a higher rate of grade retention than the Swedish norm.

Predisposed to Own Drug Use

A limited number of studies are available that have investigated the association between prenatal substance exposure and subsequent drug abuse in exposed offspring. These studies did not document cause and effect, and it remains to be determined how much of the association can be linked to prenatal exposure versus socioeconomic, environmental, and genetic influences. Studies available for prenatal nicotine exposure suggest an increased risk of early experimentation²⁷¹ and abuse of nicotine in exposed offspring.^{272,273} Brennan et al²⁷⁴ reported an association of prenatal nicotine exposure with higher rates of hospitalization for substance abuse in adult offspring.

Mounting clinical data support an increased risk of ethanol abuse later in life after prenatal exposure.^{275,277} Prenatal marijuana exposure has been associated with an increased risk for marijuana and cigarette use in exposed offspring.²⁷³ Insufficient data are available to draw any conclusions relative to the affects of prenatal opiate, cocaine, or methamphetamine exposure on the risk for tobacco, problem alcohol, or illicit drug use later in life.

SUMMARY

Although methodologic differences between studies and limited data in the extant literature make generalization of the results for several of the drugs difficult, some summary statements can be made by using the current knowledge base (Table 2).

The negative effect of prenatal nicotine exposure on fetal growth has been known for decades; however, longitudinal studies do not reveal a consistent effect on long-term growth. Clinical studies have failed to reach a consensus regarding congenital anomalies, and there is no evidence of a withdrawal syndrome in the newborn infant. Recent studies document a negative effect of prenatal exposure on infant neurobehavior as well as on long-term behavior, cognition, language, and achievement.

Alcohol remains the most widely studied prenatal drug of abuse, and the evidence is strong for fetal growth problems, congenital anomalies, and abnormal infant neurobehavior. There has been no convincing evidence of a neonatal withdrawal syndrome. Ongoing longitudinal studies continue to document long-term effects on growth, behavior, cognition, language, and achievement, and alcohol is the most common identifiable teratogen associated with intellectual disability.

Although there have been studies revealing subtle abnormalities in infant neurobehavior related to prenatal marijuana exposure, there have been no significant effects documented for fetal growth, congenital anomalies, or withdrawal. Long-term studies reveal effects of prenatal exposure on behavior, cognition, and achievement but not on language or growth.

The most significant effect of prenatal opiate exposure is neonatal abstinence syndrome. There have been documented effects on fetal growth (but not on long-term growth) and infant neurobehavior as well as long-term effects on behavior. There is not a consensus as to the effects of prenatal opiate exposure on cognition, and few data are available regarding language and achievement.

TABLE 2 Summary of Effects of Prenatal Drug Exposure

	Nicotine	Alcohol	Marijuana	Opiates	Cocaine	Methamphetamine
Short-term effects/birth outcome						
Fetal growth	Effect	Strong effect	No effect	Effect	Effect	Effect
Anomalies	No consensus on effect	Strong effect	No effect	No effect	No effect	No effect
Withdrawal	No effect	No effect	No effect	Strong effect	No effect	*
Neurobehavior	Effect	Effect	Effect	Effect	Effect	Effect
Long-term effects						
Growth	No consensus on effect	Strong effect	No effect	No effect	No consensus on effect	*
Behavior	Effect	Strong effect	Effect	Effect	Effect	*
Cognition	Effect	Strong effect	Effect	No consensus on effect	Effect	*
Language	Effect	Effect	No effect	*	Effect	*
Achievement	Effect	Strong effect	Effect	*	No consensus on effect	*

* Limited or no data available.

Prenatal cocaine exposure has a negative effect on fetal growth and subtle effects on infant neurobehavior. However, there is little evidence to support an association with congenital anomalies or withdrawal. There is not a consensus regarding the effects of prenatal cocaine exposure on either long-term growth or achievement; however, there are documented long-term effects on behavior and subtle effects on language. Although there is little evidence to support an effect on overall cognition, a number of studies have documented effects on specific areas of executive function.

Studies on prenatal methamphetamine exposure are still in their infancy. Early studies have documented an effect of prenatal exposure on fetal growth and infant neurobehavior but no association with congenital anomalies and no data regarding infant withdrawal or any long-term effects.

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Prenatal Substance Abuse: Short- and Long-term Effects on the Exposed Fetus
 Marylou Behnke, Vincent C. Smith, COMMITTEE ON SUBSTANCE ABUSE and
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The Transfer of Drugs and Therapeutics Into Human Breast Milk: An Update on Selected Topics

Hari Cheryl Sachs and COMMITTEE ON DRUGS
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CLINICAL REPORT

The Transfer of Drugs and Therapeutics Into Human Breast Milk: An Update on Selected Topics

Abstract

FREE

Many mothers are inappropriately advised to discontinue breastfeeding or avoid taking essential medications because of fears of adverse effects on their infants. This cautious approach may be unnecessary in many cases, because only a small proportion of medications are contraindicated in breastfeeding mothers or associated with adverse effects on their infants. Information to inform physicians about the extent of excretion for a particular drug into human milk is needed but may not be available. Previous statements on this topic from the American Academy of Pediatrics provided physicians with data concerning the known excretion of specific medications into breast milk. More current and comprehensive information is now available on the Internet, as well as an application for mobile devices, at LactMed (<http://toxnet.nlm.nih.gov>). Therefore, with the exception of radioactive compounds requiring temporary cessation of breastfeeding, the reader will be referred to LactMed to obtain the most current data on an individual medication. This report discusses several topics of interest surrounding lactation, such as the use of psychotropic therapies, drugs to treat substance abuse, narcotics, galactagogues, and herbal products, as well as immunization of breastfeeding women. A discussion regarding the global implications of maternal medications and lactation in the developing world is beyond the scope of this report. The World Health Organization offers several programs and resources that address the importance of breastfeeding (see <http://www.who.int/topics/breastfeeding/en/>). *Pediatrics* 2013;132:e796–e809

INTRODUCTION

Lactating women can be exposed to medications or other therapeutics, either on a limited or long-term basis, depending on the need to treat acute or chronic conditions. Many women are advised to discontinue nursing or avoid taking necessary medications because of concerns about possible adverse effects in their infants.¹ Such advice is often not based on evidence, because information about the extent of drug excretion into human milk may be unavailable, and for many drugs, information is limited to data from animal studies, which may not correlate with human experience. In addition, not all drugs are excreted in clinically significant amounts into human milk, and the presence of a drug in human milk may not pose a risk for the infant. To weigh the risks and benefits of breastfeeding, physicians need to consider multiple factors. These factors include the need for the drug by the mother, the potential effects of

Hari Cheryl Sachs, MD, FAAP* and COMMITTEE ON DRUGS

KEY WORD

human milk

ABBREVIATIONS

AAP—American Academy of Pediatrics
 FDA—Food and Drug Administration
 HBV—hepatitis B vaccine
 HPV—human papillomavirus vaccine
 NSAID—nonsteroidal antiinflammatory drug

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

*The recommendations in this review are those of the authors and do not represent the views of the US Food and Drug Administration.

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the drug on milk production, the amount of the drug excreted into human milk, the extent of oral absorption by the breastfeeding infant, and potential adverse effects on the breastfeeding infant. The age of the infant is also an important factor in the decision-making process, because adverse events associated with drug exposure via lactation occur most often in neonates younger than 2 months and rarely in infants older than 6 months.² In the near future, pharmacogenetics may also provide important guidance for individualized decisions.

In large part because of efforts by Cheston Berlin, Jr, MD, a statement by the American Academy of Pediatrics

(AAP) on the transfer of drugs and chemicals into human milk was first published in 1983³ and underwent several subsequent revisions,^{4,5} the most recent of which was published in 2001.⁶ Previous editions were intended to list drugs potentially used during lactation and to describe possible effects on the infant and/or on lactation. Revisions for the statement can no longer keep pace with the rapidly changing information available via the Internet, published studies, and new drug approvals. A more comprehensive and current database is available at LactMed (<http://toxnet.nlm.nih.gov>). LactMed includes up-to-date information on drug levels in

human milk and infant serum, possible adverse effects on breastfeeding infants, potential effects on lactation, and recommendations for possible alternative drugs to consider. Common herbal products are also included. For this reason, with the exception of radioactive compounds that require temporary or permanent cessation of breastfeeding, the reader will be referred to LactMed to obtain the most current data on an individual medication.

This statement reviews proposed changes in US Food and Drug Administration (FDA) labeling that are designed to provide useful information to the physician and to outline general

LactMed is part of the National Library of Medicine's Toxicology Data Network (TOXNET)

Each record includes the following information:

- Generic name: refers to US-adopted name of active portion of the drug
- Scientific name: genus and species of botanical products (when applicable)
- Summary of use during lactation (includes discussion of conflicting recommendations and citations)
- Drug levels
 - Maternal levels: based on studies that measure concentration in breast milk; includes relative infant dose (weight-adjusted percentage of maternal dose) when possible
 - Infant levels: serum or urine concentrations from the literature
- Effects in breastfed infants: adverse events with Naranjo* assessment of causality (definite, probably, possibly, unlikely)
- Possible effects on lactation: if known, including effects on infants that may interfere with nursing (eg, sedation)
- Alternative drugs to consider: may not be comprehensive
- References
- Chemical Abstracts Service Registry Number
- Drug class
- LactMed record number
- Last revision date

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* The Naranjo probability scale is a method used to estimate the probability that an adverse event is caused by a drug.⁷

considerations for individual risk/benefit counseling. An update regarding the use of antidepressants, anxiolytics, and antipsychotics in the lactating woman is also provided, because the use of psychotropic agents during lactation is still debated. Since publication of the last statement, numerous questions have been raised regarding the use of methadone in the lactating woman. For this reason, therapies for substance abuse and smoking cessation are discussed. Given the finding that codeine use may be associated with toxicity in patients, including neonates with ultrarapid metabolism, a brief review of alternative agents to treat pain in the lactating woman is provided. The use of galactagogues is also reviewed because more women now endeavor to breastfeed adopted infants or preterm neonates. The increasing use of herbal products has invited a discussion of the merits of these alternative therapies in the nursing woman. Finally, immunization of breastfeeding women and their infants will be reviewed to assist pediatricians in encouraging immunization when needed in lactating women and addressing parental reluctance to immunize breastfed infants.

GENERAL CONSIDERATIONS

Several factors should be considered when advising a woman regarding a decision to breastfeed her infant while she is on drug therapy. The benefits of breastfeeding for both the infant and mother need to be weighed against the risks of drug exposure to the infant (or to the mother, in the case of agents intended to induce lactation). Many factors affect the individual risk/benefit decision, including specific information about chemical and pharmacologic properties of the drug, which may be available from resources such as LactMed and in product labeling. In

general, chemical properties of a drug, such as lack of ionization, small molecular weight, low volume of distribution, low maternal serum protein binding, and high lipid solubility, facilitate drug excretion into human milk. Drugs with long half-lives are more likely to accumulate in human milk, and drugs with high oral bioavailability are more easily absorbed by the infant.⁸ The adverse event profile of the drug is another property that affects the individual risk/benefit ratio. Use of a drug with a significant adverse effect in a lactating woman (such as an arrhythmia) may be acceptable to treat a serious illness in the mother; however, use of the same drug to increase milk production would not be acceptable. For drugs with an adverse event profile that correlates with increasing dosage, higher maternal doses may be associated with greater neonatal toxicity. In addition, the timing of exposure and the duration of therapy are other important considerations. A decision to breastfeed when continuing treatment with an agent for which in utero exposure also has occurred differs from a decision to initiate a novel therapy in the early postpartum period. Similarly, the risks of a single-dose therapy or short-term treatment may differ from those of a chronic therapy.

In addition to pharmacokinetic or chemical properties of the drug, the infant's expected drug exposure is influenced by infant and maternal factors beyond basic known pharmacokinetic and chemical properties of the drug itself. For example, the risk of adverse reactions in a preterm infant or an infant with underlying chronic medical conditions may be higher than that for a more mature or healthier infant. Certain drugs may accumulate in the breastfed infant because of reduced clearance or immaturity of metabolic pathways. However, for other

drugs (eg, acetaminophen), the immaturity of these same pathways may protect an infant from toxic drug metabolites. Similarly, patients with specific genotypes may experience drug toxicity, as evidenced by fatalities observed in individuals who demonstrate ultrarapid metabolism of codeine.⁹ Finally, certain infant conditions, such as metabolic diseases, and maternal health conditions may preclude nursing (eg, HIV) or require multiple therapies that are particularly toxic (eg, cancer treatment).

CHANGES IN DRUG LABELING

In the past, the lactation section in FDA-approved labeling was often limited to statements that advise caution or contain an admonition to discontinue breastfeeding or discontinue therapy, depending on the importance to the mother. In 2008, the FDA published a proposed revision to the regulations, which affects the pregnancy and lactation sections of labeling. The agency is currently working on the final rule, which is intended to provide a clinically oriented framework for placement of pregnancy and lactation information into drug labeling and to permit the patient and physician to explore the risk/benefit on the basis of the best available data. Under the proposed rule, the current Nursing Mothers section is replaced by a section called Lactation. The Lactation section of labeling will contain 3 subsections: Risk Summary, Clinical Considerations, and Data. The Risk Summary section will include a summary of what is known about the excretion of the drug into human milk and potential effects on the breastfed infant, as well as maternal milk production. The Clinical Considerations section will include methods to minimize exposure of the breastfed infant to the drug when applicable, as well as information about monitoring for

expected adverse drug effects on the infant. The Data component will provide a detailed overview of the existing data that forms the evidence base for the other 2 sections.

In addition to the proposed rule, the FDA published "Guidance for Industry: Clinical Lactation Studies: Study Design, Data Analysis, and Recommendations for Labeling."¹⁰

Along with outlining recommendations regarding lactation study design as well as the timing and indications for these studies, this draft guidance includes advice on parameters (several of which are used in LactMed) that can be used to inform physicians about the extent of drug exposure. Using these parameters, drug exposure to the infant may be measured directly in infant serum or estimated on the basis of pharmacokinetic parameters. These estimates of infant exposure (for example, relative infant dose) can be expressed as a percent of weight-adjusted maternal or, when known, weight-adjusted pediatric dose.

ESTIMATES OF DRUG EXPOSURE

Daily Infant Dosage (mg/day)=

$$\sum (\text{drug concentration in each milk collection} \times \text{expressed volume in each milk collection})$$

OR

$$C_{\text{milk}} [\text{average drug concentration in milk (mg/mL)}] \times V_{\text{milk}} (\text{volume in mL of milk ingested in 24 hours})$$

Note: V_{milk} is typically estimated to be 150 mL/kg/day

Relative Infant Dose

$$\% \text{ Maternal Dose} = \left[\frac{\text{Daily Infant Dosage (mg/kg/day)}}{\text{Maternal Dose (mg/kg/day)}} \right] \times 100$$

$$\% \text{ Infant or Pediatric Dose} = \left[\frac{\text{Daily Infant Dosage (mg/kg/day)}}{\text{Infant or Pediatric dose (mg/kg/day)}} \right] \times 100$$

ANTIDEPRESSANTS, ANXIOLYTICS, AND ANTIPSYCHOTICS

Previous statements from the AAP categorized the effect of psychoactive drugs on the nursing infant as "unknown but may be of concern." Although new data have been published since 2001, information on the long-term effects of these compounds is still limited. Most publications regarding psychoactive drugs describe the pharmacokinetics in small numbers of lactating women with short-term observational studies of their infants. In addition, interpretation of the effects on the infant from the small number of longer-term studies is confounded by prenatal treatment or exposure to multiple therapies. For these reasons, the long-term effect on the developing infant is still largely unknown.^{11,12}

Many antianxiety drugs, antidepressants, and mood stabilizers appear in low concentrations in human milk, with estimated relative infant doses less than 2% of weight-adjusted maternal dose and/or milk-plasma ratios less than 1.¹³ However, the percentage of maternal doses that approach clinically significant levels (10% or more) have been reported for bupropion,¹⁴ diazepam,¹⁵ fluoxetine,¹⁵ citalopram,¹⁶ lithium,¹⁷ lamotrigine,¹⁸ and venlafaxine.¹⁹ Data on drug excretion in human milk are not available for up to one-third of psychoactive therapies.¹³

Because of the long half-life of some of these compounds and/or their metabolites, coupled with an infant's immature hepatic and renal function, nursing infants may have measurable amounts of the drug or its metabolites in plasma and potentially in neural tissue. Infant plasma concentrations that exceed 10% of therapeutic maternal plasma concentrations have been reported for a number of selective serotonin reuptake inhibitors,

TABLE 1 Psychoactive Drugs With Infant Serum Concentrations Exceeding 10% of Maternal Plasma Concentrations^a

Agent	Reference
Citalopram	Weissman 2004 ²⁰
Clomipramine	Schimmell 1991 ²¹
Diazepam	Wesson 1985 ²²
Doxepin	Moretti 2009 ¹⁵
Fluoxetine	Weissman 2004, ²⁰ product labeling
Fluvoxamine	Weissman 2004 ²⁰
Lamotrigine	Newport 2008, ¹⁸ Fotopoulou 2009 ²³
Lithium	Viguerra 2007, ²⁴ Grandjean 2009, ²⁵ Bogen 2012 ²⁶
Mirtazapine	Tonn 2009 ²⁷
Nortriptyline	Weissman 2004 ²⁰
Olanzapine	Whitworth 2008 ²⁸
Sertraline	Hendrick 2001, ²⁹ Stowe 2003 ³⁰
Venlafaxine	Newport 2009 ¹⁹

^a Based on individual maternal-infant pair(s); may include active metabolites.

antipsychotics, anxiolytics, and mood stabilizers (see Table 1).

Mothers who desire to breastfeed their infant(s) while taking these agents should be counseled about the benefits of breastfeeding as well as the potential risk that the infant may be exposed to clinically significant levels and that the long-term effects of this exposure are unknown. Consideration should be given to monitoring growth and neurodevelopment of the infant.

DRUGS FOR SMOKING CESSATION OR TO TREAT SUBSTANCE ABUSE/ALCOHOL DEPENDENCE

Although many women are appropriately advised to refrain from smoking, drinking, and using recreational drugs during and after pregnancy, in part because of adverse effects on their infants (see Table 2), some are unable to do so and may seek assistance after delivery. Maternal smoking is not an absolute contraindication to breastfeeding.³¹ Nonetheless, for multiple reasons, including the association of sudden infant death syndrome with

TABLE 2 Drugs of Abuse for Which Adverse Effects on the Breastfeeding Infant Have Been Reported^a

Drug	Reported Effect or Reason for Concern	Reference
Alcohol	Impaired motor development or postnatal growth, decreased milk consumption, sleep disturbances. Note: Although binge drinking should be avoided, occasional, limited ingestion (0.5 g of alcohol/kg/d; equivalent to 8 oz wine or 2 cans of beer per day) may be acceptable.	Koren 2002, ³⁴ Backstrand 2004, ³⁵ Mennella 2007 ³⁶ National Academy of Sciences 1991 ³⁷
Amphetamines	Hypertension, tachycardia, and seizures. In animal studies of postnatal exposure, long-term behavioral effects, including learning and memory deficits and altered locomotor activity, were observed.	Product labeling
Benzodiazepines	Accumulation of metabolite, prolonged half-life in neonate or preterm infant is noted; chronic use not recommended.	Jain 2005, ³⁸ Malone 2004 ³⁹
Cocaine	Apnea, cyanosis, withdrawal, sedation, cyanosis, and seizures. Intoxication, seizures, irritability, vomiting, diarrhea, tremulousness.	Chasnoff 1987, ⁴⁰ Winecker 2001 ⁴¹
Heroin	Withdrawal symptoms, tremors, restlessness, vomiting, poor feeding.	vandeVelde 2007 ⁴²
LSD	Potent hallucinogen.	
Methamphetamine	Fatality, persists in breast milk for 48 h.	Ariagno 1995, ⁴³ Bartu 2009 ⁴⁴
Methylene dioxymethamphetamine (ecstasy)	Closely related products (amphetamines) are concentrated in human milk.	
Marijuana (cannabis)	Neurodevelopmental effects, delayed motor development at 1 y, lethargy, less frequent and shorter feedings, high milk-plasma ratios in heavy users.	Djulus 2005, ⁴⁵ Campolongo 2009, ⁴⁶ Garry 2010 ⁴⁷
Phencyclidine	Potent hallucinogen, infant intoxication.	AAP 2001, ⁶ Academy of Breastfeeding Medicine ⁴⁸

^a Effect on maternal judgment or mood may affect ability to care for infant.

tobacco exposure,^{32,33} lactating women should be strongly encouraged to stop smoking and to minimize secondhand exposure. Exposure to alcohol or recreational drugs may impair a mother's judgment and interfere with her care of the infant and can cause toxicity to the breastfeeding infant (see Table 2).

Limited information is available regarding the use of medications in lactating women to treat substance abuse or alcohol dependence or for smoking cessation. However, the presence of behaviors, such as continued ingestion of illicit drugs or alcohol, and underlying conditions, such as HIV infection, are not compatible with breastfeeding.^{49,50} Patients also require ongoing psychosocial support to maintain abstinence.⁴⁸

Methadone, buprenorphine, and naltrexone are 3 agents approved by the FDA for use in the treatment of opioid dependence. Continued breastfeeding by women undergoing such treatment presumes that the patient remains abstinent, is HIV negative, and is en-

rolled in and closely monitored by an appropriate drug treatment program with significant social support.^{48,51}

Potential adverse effects on breastfeeding infants from methadone (according to product labeling) and buprenorphine include lethargy, respiratory difficulty, and poor weight gain.⁵² The long-term effects of methadone in humans are unknown. Nonetheless, methadone levels in human milk are low, with calculated infant exposures less than 3% of the maternal weight-adjusted dose.^{53,54} Plasma concentrations in infants are also low (less than 3% of maternal trough concentrations) during the neonatal period and up to 6 months postpartum.^{55,56} For these reasons, guidelines from the Academy of Breastfeeding Medicine encourage breastfeeding for women treated with methadone who are enrolled in methadone-maintenance programs.⁴⁸

Buprenorphine is excreted into human milk and achieves a level similar to that in maternal plasma.⁵⁷ Infant exposure

appears to be up to 2.4% of the maternal weight-adjusted dose.^{55,56,58} However, buprenorphine can be abused, and although the significance in humans is unknown, labeling for buprenorphine and buprenorphine/naloxone combinations states that use is not advised by lactating women, because animal lactation studies have shown decreased milk production and viability of the offspring. FDA labeling also advises caution for use of naltrexone in nursing infants of opioid-dependent women. Of note, published information on naltrexone is limited to 1 case report that estimates infant exposure to be low (7 µg/kg/d, or 0.86% of the maternal weight-adjusted dose).⁵⁹

Transferred amounts of methadone or buprenorphine are insufficient to prevent symptoms of neonatal abstinence syndrome.^{49,60} Neonatal abstinence syndrome can occur after abrupt discontinuation of methadone.^{51,61} Thus, breastfeeding should not be stopped abruptly, and gradual

weaning is advised if a decision is made to discontinue breastfeeding.

Limited information is available for disulfiram and naltrexone, agents that are used to treat alcohol dependence. As noted previously, a low relative infant dose (<1%) was observed in a single case report of naltrexone exposure in a 6-week-old breastfed infant.⁵⁹ FDA labeling discourages use of disulfiram and both the injectable and oral form of naltrexone in lactating women.

Only one-third of women successfully discontinue smoking without pharmacologic aids.⁶² Nicotine replacement therapy, bupropion, and varenicline are agents indicated for use as aids to smoking cessation treatment. Nicotine replacement therapy is compatible with breastfeeding as long as the dose (assuming a cigarette delivers ~1 mg of nicotine) is less than the number of cigarettes typically smoked, because nicotine passes freely into human milk and is orally absorbed as nicotine. Cotinine concentrations are lower than those related to tobacco use. Short-acting products (eg, gum or lozenges) are recommended.⁶² Infant exposure decreases proportionally with maternal patch doses.⁶³

In contrast, bupropion is excreted into human milk with exposures that may exceed 10% (range, 1.4%–10.6%) of the maternal dose.¹⁴ Although infant levels were not measured, there is a case report of a seizure in a 6-month-old breastfed infant potentially related to bupropion.⁶⁴ Limited published information is available for varenicline, but the varenicline label includes a boxed warning for serious neuropsychiatric adverse events, including suicidal ideation or behavior. FDA labeling discourages use of both these agents in lactating women.

PAIN MEDICATIONS

Rarely, normal doses of codeine given to lactating women may result in

dangerously high levels of its active metabolite morphine in breastfeeding infants. A fatality has been noted in an infant of a mother with ultrarapid metabolism.⁶⁵ In this infant, the post-mortem level of morphine (87 ng/mL) greatly exceeded a typical level in a breastfeeding infant (2.2 ng/mL), as well as the therapeutic range for neonates (10–12 ng/mL). In addition, unexplained apnea, bradycardia, cyanosis, and sedation have been reported in nursing infants of mothers receiving codeine.^{2,66} Hydrocodone is also metabolized via the CYP2D6 pathway. On the basis of pharmacokinetic data, infants exposed to hydrocodone through human milk may receive up to 9% of the relative maternal dose.⁶⁷ Given the reduced clearance of hydrocodone in neonates and the adverse events observed in ultrarapid metabolizers of codeine, caution is advised for use of codeine and hydrocodone in both the mother and nursing infant. Close monitoring for signs and symptoms of neonatal as well as maternal toxicity is recommended. A commercial test to identify ultrarapid metabolizers is not yet widely available. The incidence of this specific CYP2D6 genotype varies with racial and ethnic group as follows: Chinese, Japanese, or Hispanic, 0.5% to 1.0%; Caucasian, 1.0% to 10.0%; African American, 3.0%; and North African, Ethiopian, and Saudi Arabian, 16.0% to 28.0%.⁶⁸

For these reasons, when narcotic agents are needed to treat pain in the breastfeeding woman, agents other than codeine (eg, butorphanol, morphine, or hydromorphone) are preferred. Clinically insignificant levels of butorphanol are excreted into human milk. Morphine appears to be tolerated by the breastfeeding infant, although there is 1 case report of an infant with plasma concentrations within the therapeutic range.⁶⁹ Clear-

ance of morphine is decreased in infants younger than 1 month and approaches 80% of adult values by 6 months of age.⁷⁰ Limited data suggest that use of hydromorphone for brief periods may be compatible with breastfeeding^{71,72}; however, FDA labeling discourages use. Regardless of the choice of therapy, to minimize adverse events for both the mother and her nursing infant, the lowest dose and shortest duration of therapy should be prescribed. Drug delivery via patient-controlled anesthesia or administration by the epidural route may also minimize infant exposure.

Other narcotic agents, such as oxycodone, pentazocine, propoxyphene, and meperidine, are not recommended in the lactating mother. Relatively high amounts of oxycodone are excreted into human milk, and therapeutic concentrations have been detected in the plasma of a nursing infant.⁷³ Central nervous system depression was noted in 20% of infants exposed to oxycodone during breastfeeding.⁷⁴ Thus, use of oxycodone should be discouraged. Limited published data are available about pentazocine. However, respiratory depression and apnea occur frequently in infants, particularly in neonates or in preterm infants, who are treated with pentazocine. Propoxyphene has been associated with unexplained apnea, bradycardia, and cyanosis, as well as hypotonia in nursing infants.^{75,76} Moreover, propoxyphene was withdrawn from the market because significant QT prolongation occurred at therapeutic doses.⁷⁷ Meperidine use is associated with decreased alertness of the infant and is likely to interfere with breastfeeding.⁷¹ Although estimates of meperidine exposure are low (approximately 2% to 3% of the maternal weight-adjusted dose), the half-life of the active metabolite for meperidine is prolonged, and it may accumulate in infant blood or tissue.^{71,72}

When narcotics are not required to relieve mild to moderate pain, other analgesic agents can be used. Presuming that pain relief is adequate, short-acting agents, such as ibuprofen and acetaminophen, are acceptable.⁷⁸ Although the half-life of ibuprofen may be prolonged in neonates, particularly in preterm infants (according to product labeling), minimal amounts of ibuprofen are excreted into human milk.⁷² Despite reduced clearance of acetaminophen,⁷⁹ hepatotoxicity is less common in neonates than in older infants, in part because of low levels of certain cytochrome P-450 enzymes, which convert acetaminophen into toxic metabolites.⁸⁰ Acetaminophen is available for both oral and intravenous administration.

Although all nonsteroidal antiinflammatory drugs (NSAIDs) carry a boxed warning regarding gastrointestinal bleeding and potential long-term cardiac toxicity, according to their product labeling and Gardiner et al,⁸¹ celecoxib, flurbiprofen, and naproxen are considered to be compatible with breastfeeding, because less than 1% is excreted into human milk. In addition, a breastfeeding infant would receive less than 1% of the relative pediatric dose of celecoxib prescribed for a 2-year-old (according to product labeling). However, long-term use of naproxen is not recommended because of the drug's long half-life and case reports of gastrointestinal tract bleeding and emesis. Avoiding NSAIDs in breastfeeding infants with ductal-dependent cardiac lesions may be prudent.

Limited published data on other NSAIDs (etodolac, fenoprofen, meloxicam, oxaprozin, piroxicam, sulindac, and tolmetin) are available, and FDA labeling discourages their use for a variety of reasons. Although the implications for humans are unknown, meloxicam concentrations in milk of lactating animals exceed plasma con-

centrations. Diflunisal has a long half-life and is not recommended because of potential adverse events, including cataracts and fatality, in neonatal animals. Similarly, mefenamic acid has a prolonged half-life in preterm infants. Injectable and oral forms of ketorolac are contraindicated in nursing women, according to product labeling, because of potential adverse effects related to closure of the ductus arteriosus in neonates. Less than 1% of ketorolac nasal spray is excreted into human milk, and unlike the oral and intravenous forms of ketorolac, use is not contraindicated (product labeling).

Carisoprodol and its active metabolite, meprobamate, are concentrated in human milk (2–4 times maternal plasma concentrations). Impaired milk production has been observed, and animal studies suggest maternal use may lead to less effective infant feeding (because of sedation) and/or decreased milk production (according to product labeling).

Low doses (75–162 mg/d) of aspirin may be acceptable⁸²; however, use of high-dose aspirin therapy during breastfeeding is not advised, because the serum concentration of salicylate in breastfeeding infants has been reported to reach approximately 40% of therapeutic concentrations. Adverse events, such as rash, platelet abnormalities, bleeding, and metabolic acidosis have also been reported.⁷¹

GALACTAGOGUES

Galactagogues, or agents to stimulate lactation, are often used to facilitate lactation, particularly for mothers of preterm infants. They also may be used to induce lactation in an adoptive mother. However, evidence to support these agents, including use of dopamine antagonists, such as domperidone and metoclopramide; herbal treatments; and hormonal manipulation, is lacking.⁸³

Although a placebo-controlled study ($n = 42$) suggested that domperidone may increase milk volume in mothers of preterm infants,⁸⁴ maternal safety has not been established. The FDA issued a warning in June 2004 regarding use of domperidone in breastfeeding women because of safety concerns based on published reports of arrhythmia, cardiac arrest, and sudden death associated with intravenous therapy. Furthermore, treatment with oral domperidone is associated with QT prolongation in children and infants.^{85,86} Domperidone is not an approved product in the United States, and labeling for oral formulations marketed outside the United States do not recommend use during lactation.

Several small trials (each with fewer than 25 subjects) published before 1990 suggested that metoclopramide increases prolactin concentrations and/or milk production in mothers of both term and preterm infants.⁸⁷ However, more recent controlled studies do not replicate this finding.^{88,89} Human milk concentrations of metoclopramide are similar to therapeutic concentrations in adult plasma,⁸⁸ and measurable amounts can be detected in breastfeeding infants.⁹⁰ Clearance of metoclopramide in neonates is prolonged, which may result in excessive serum concentrations and the risk of conditions associated with overdose, such as methemoglobinemia. Of concern, prolactin concentrations were increased in 4 of 7 infants exposed to metoclopramide via human milk.⁹⁰ The safety profile for metoclopramide includes adverse reactions, such as dystonia, depression, suicidal ideation, and gastrointestinal tract disturbances, as well as a boxed warning about the risk of tardive dyskinesia. These risks to the mother limit the usefulness of this therapy.

Although a pilot study in 8 lactating women performed decades ago suggested that oxytocin nasal spray

increased human milk production, a larger placebo-controlled trial in 51 women has not confirmed that observation.⁹¹ Oxytocin nasal spray is no longer marketed in the United States. Similarly, anecdotal reports supporting the use of the herb fenugreek to facilitate lactation have not been confirmed by controlled studies.^{92,93} Fenugreek contains coumarin, which may interact with NSAIDs.⁹⁴ Use of fenugreek in lactating women also is associated with maple-syrup odor in infants.⁹⁵ Available data do not support the routine use of other herbal products, such as fennel, to facilitate lactation.⁹⁶

In summary, galactagogues have a limited role in facilitating lactation and have not been subject to full assessments of safety for the nursing infant. Nursing mothers should seek consultation with a lactation specialist and use non-pharmacologic measures to increase milk supply, such as ensuring proper technique, using massage therapy, increasing the frequency of milk expression, prolonging the duration of pumping, and maximizing emotional support.

COMMONLY USED HERBAL PRODUCTS

Despite the frequent use of herbal products in breastfeeding women (up to 43% of lactating mothers in a 2004 survey),⁹⁷ reliable information on the safety of many herbal products is lacking. Herbal products are not subject to the same standards for manufacturing and proven effectiveness and safety as are drug products before they are marketed.⁹⁸ In fact, the use of several herbal products may be harmful, including kava and yohimbe. For example, the FDA has issued a warning that links kava supplementation to severe liver damage.⁹⁹ Breastfeeding mothers should not use yohimbe because of reports of associated fatalities in children.¹⁰⁰ In addition, from 2008 through 2010, the

FDA recalled 10 or more dietary supplements each year because of the presence of potentially toxic undeclared ingredients in the supplement.¹⁰¹ Similarly, the US Government Accountability Office found that 16 of 40 common herbal dietary supplements obtained from retail stores contained pesticide residues.¹⁰²

Safety data are lacking for many herbs commonly used during breastfeeding, such as chamomile,¹⁰³ black cohosh,¹⁰⁴ blue cohosh,¹⁰⁵ chastetree,¹⁰⁶ echinacea,¹⁰⁷ ginseng,¹⁰⁸ ginkgo,¹⁰⁹ *Hypericum* (St John's wort),^{110,111} and valerian.¹¹² Adverse events have been reported in both breastfeeding infants and mothers. For example, St John's wort may cause colic, drowsiness, or lethargy in the breastfed infant even though milk production and infant weight do not appear to be adversely affected¹¹⁰ and relative maternal dose and infant plasma concentrations are low.¹¹³ Prolonged use of fenugreek may require monitoring of coagulation status and serum glucose concentrations.¹¹⁴ For these reasons, these aforementioned herbal products are not recommended for use by nursing women.

Although supplementation of nursing mothers with iron and vitamins is safe as long as recommended daily allowances are not exceeded, the use of other nutritional supplements may not be. For instance, L-tryptophan has been associated with eosinophilic myositis.¹¹⁵ Therefore, physicians should inquire about the use of herbal products and dietary supplements in lactating women and discuss the need for caution because of the paucity of data available.

DIAGNOSTIC IMAGING

When feasible, elective imaging procedures should be delayed until a woman is no longer breastfeeding. For most radiopharmaceuticals, breastfeeding should be interrupted for a time period based on the rate of de-

cline of the agent and dosimetry to avoid infant exposures greater than 1 mSv (100 mrem). For agents that may be concentrated in breast tissue, close contact of the mother with the infant and, consequently, nursing may need to be avoided for a period of time, although expressed milk that has been refrigerated until the radioactivity has decayed may be safe. General guidelines based on Nuclear Regulatory Commission regulations and International Commission on Radiologic Protection guidelines¹¹⁶ are cited in Tables 3 and 4. However, because there is considerable variability in milk radioactivity, and close contact with an infant may result in additional exposure, consultation with a radiologist should be sought. If deemed necessary, individualized testing of expressed milk may be performed to ensure that radioactivity has reached background levels before breastfeeding is resumed.¹¹⁷

Notably, because radiolabeled iodinated products are concentrated in the developing thyroid and radioactivity persists after imaging with most ¹³¹I and ¹²⁵I radiopharmaceuticals (with the exception of ¹²⁵I-hippurate), breastfeeding should be interrupted for a minimum of 3 weeks. Similarly, ²²Na and ⁶⁷Ga (gallium) administration also require a prolonged (3-week) interruption in breastfeeding. Because the lactating breast has a greater ¹³¹I affinity than does the nonlactating breast, women should cease breastfeeding at least 4 weeks before whole-body procedures with ¹³¹I and should discontinue breastfeeding thereafter. Doing so will reduce the radiation dose and potential cancer risk to maternal breast tissue.

Traditionally, lactating women receiving intravascular gadolinium or iodinated contrast (as opposed to radiolabeled iodine) are advised to discontinue nursing for 24 hours. However, a minimal amount (0.04%) of the intravenous dose reaches human milk, and, of that, less than 1% to

TABLE 3 Radioactive Compounds That May Require Temporary Cessation of Breastfeeding: Recommendations of the International Commission on Radiologic Protection

Compound	Examples	Example of Procedures	Recommended Time for Cessation of Breastfeeding	Comments
¹⁴ C-labeled	Triolein, glycocholic acid, urea	<i>Helicobacter pylori</i> breath test	None	No approved US products
^{99m} Tc-labeled	DMSA, DTPA, phosphonates (MDP), PYP, tetrofosmin	Multiple: imaging of kidney, bone, lung, heart, tumors	0 to 4 h, as long as no free pertechnetate	Consider discarding at least 1 meal after procedure
	Microspheres, pertechnetate, WBC		12–24 h	Range depends on dose
I-labeled	Sulfur-colloids, RBC in vivo		6 h	
	¹²⁵ I, ¹²⁵ I or ¹³¹ I-iodo hippurate	Thyroid imaging	12 h	Note: whole-body irradiation with ¹³¹ I requires prolonged cessation
Others	¹¹ C- ¹¹ N or ¹¹ O-labeled	PET scans	None	Short physical half-life
	⁵⁷ Co-labeled vitamin B ₁₂	Schilling test	24 h	Pomeroy 2005 ¹¹⁹
	¹⁸ F-FDG	PET scans	None, first feeding should be expressed breast milk to avoid direct contact ¹²⁰	Use alternatives for 10 half-lives (10×109 min= 18 h) ^a
	⁵¹ Cr-EDTA	Renal imaging	None	
	^{81m} Kr-gas	Pulmonary imaging	None	No approved US products
	⁸² Rb chloride	PET scan of myocardium	May resume 1 h after last infusion	Half-life 75 s ^a
	¹¹¹ In-octreotide	SPECT, neuroendocrine tumors	None	
	¹¹¹ In -WBC		1 wk	Depends on dose
	¹³⁵ Xe	Cardiac, pulmonary, and cerebral imaging	None	Half-life 5 d ^a

DMSA, dimercaptosuccinic acid; DTPA, diethylenetriaminepentaacetate; EDTA, ethylenediaminetetraacetic acid; FDG, fludeoxyglucose; PET, positron emission tomography; PYP, pyrophosphate; RBC, red blood cell; SPECT, single-photon emission computed tomography; WBC, white blood cell.

^a FDA-approved drug labeling.

TABLE 4 Radioactive Compounds Requiring Prolonged Cessation of Breastfeeding

Compound	Examples	Example of Procedures	Recommended Time for Cessation of Breastfeeding	Comments
I-labeled	¹²⁵ I- BMIPP, -HSA, -IPPA, -MIBG, -Nal, or -HSA	Imaging of tumors	Greater than 3 wk	Essentially need to stop breastfeeding
	¹³¹ I-MIBG or -Nal			
Others	²⁰¹ Tl-chloride	Cardiac imaging	48 h to 2 wk	Half-life 73 h ^a
	⁶⁷ Ga-citrate	Imaging of tumors	1 wk to 1 mo	Depends on dose
	²² Na, ⁷⁵ Se		Greater than 3 wk	Essentially need to stop breastfeeding

Use of expressed human milk recommended because of exposure via direct contact.¹²⁰ BMIPP, β-methyl-p-iodophenyl-pentadecanoic acid; HSA, human serum albumin; IPPA, iodophenylpentadecanoic; MIBG, metaiodobenzylguanidine; Nal, sodium iodide.

^a FDA-approved drug labeling.

2% is absorbed by the infant. Therefore, breastfeeding can be continued without interruption after the use of iodinated contrast or gadolinium.¹¹⁸

BREASTFEEDING AND VACCINES

With rare exceptions, maternal immunization does not create any problems for breastfeeding infants, although questions concerning 2 topics often arise regarding lactation and immunization: the effect of lactation on the infant's immune response to a vaccine and a potential adverse effect on the infant from maternal immunization. Breastfeeding does not interfere with

the infant's immune response to most routine immunizations (eg, diphtheria and tetanus toxoids and acellular pertussis vaccine, inactivated poliovirus vaccine, and hepatitis B vaccine [HBV]),¹²¹ despite the presence of maternal antibodies in human milk. Seroconversion rates are also similar between breastfed and formula-fed infants receiving rotavirus vaccine; however, vaccine efficacy for severe rotavirus gastroenteritis appears to be higher in formula-fed infants compared with exclusively breastfed infants, particularly during the second season (98% vs 88%) when breastfeeding has been discontinued.¹²² Nonetheless, protection

during the first year is similar. Moreover, breastfeeding enhances the antibody response to pneumococcal and *Haemophilus influenzae* type b vaccines.¹²³ Breastfeeding may also decrease the incidence of fever after infant immunization.¹²⁴ Therefore, the timing of infant feeding (including human milk) relative to immunization is not restricted, even for live vaccines, such as rotavirus.

Lactating women may need to be immunized. Inactivated vaccines (such as tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine; inactivated poliovirus vaccine; influenza; hepatitis A vaccine; HBV; or human papillomavirus vaccine [HPV]) given to

a nursing mother do not pose a risk to the breastfeeding infant. Several vaccines, such as tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine and influenza vaccine, are recommended for the mother during the postpartum period to protect the infant as well as the mother. Other routine or catch-up vaccines, such as HPV, hepatitis A vaccine, and HBV, can be given to the lactating mother. HPV immunization is recommended for women younger than 27 years. The incidence of adverse reactions in nursing infants within 30 days of maternal immunization with HPV was similar to nursing infants of women receiving the control except for acute respiratory illness (according to Gardasil labeling). Hence, caution is warranted when immunizing mothers of infants who are vulnerable to respiratory illnesses (eg, preterm infants, infants with congenital heart disease or chronic respiratory problems).

Most live vaccines are not associated with virus secretion in human milk. For example, despite maternal seroconversion, neither the varicella virus nor antibody to varicella DNA has been detected in breastfeeding infants.¹²⁵ Although attenuated rubella can be secreted into human milk and transmitted to breastfed infants, infections are usually asymptomatic or mild. Consequently, postpartum immunization with measles-mumps-rubella vaccine is recommended for women who lack immunity, especially to rubella.¹²⁶ In contrast, infants are considered to be at high risk of developing vaccinia

after exposure to smallpox vaccine or encephalitis after yellow fever vaccine. Two cases of meningoenitis in nursing infants whose mothers had been immunized against yellow fever are documented in the literature.^{127,128} Therefore, most vaccines, with the exception of smallpox or yellow-fever vaccine, which are contraindicated in nonemergency situations, may be administered during lactation.

SUMMARY

The benefits of breastfeeding outweigh the risk of exposure to most therapeutic agents via human milk. Although most drugs and therapeutic agents do not pose a risk to the mother or nursing infant, careful consideration of the individual risk/benefit ratio is necessary for certain agents, particularly those that are concentrated in human milk or result in exposures in the infant that may be clinically significant on the basis of relative infant dose or detectable serum concentrations. Caution is also advised for drugs and agents with unproven benefits, with long half-lives that may lead to drug accumulation, or with known toxicity to the mother or infant. In addition, specific infants may be more vulnerable to adverse events because of immature organ function (eg, preterm infants or neonates) or underlying medical conditions. Several excellent resources are available for the pediatrician, including product labeling and the peer-reviewed database, LactMed. Consultation with a specialist may be indicated, particularly when the

use of radiopharmaceuticals, oncologic drugs, or other therapies not addressed by LactMed is contemplated. Additional information about topics outside the scope of this report, such as environmental agents, can be obtained from the third edition of the AAP textbook *Pediatric Environmental Health*.¹²⁹

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**The Transfer of Drugs and Therapeutics Into Human Breast Milk: An Update
on Selected Topics**

Hari Cheryl Sachs and COMMITTEE ON DRUGS
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Patient Materials

Frequently Asked Questions

How Can I Help My Pregnant Patient With a Substance Use Disorder?

1. What if my patient discloses substance use?

Complete a more detailed assessment for the amount, frequency, duration, and type of substance(s) used. Use of more than one substance is common.

2. Is there anything I can do in my office?

Show your concern and provide information about the impact of the substance(s) on the pregnancy. Encourage your patient to stop or reduce substance use and inform her that help is available. Some useful brief interventions include SBIRT (screening, brief intervention, referral treatment), SART (screening, assessment, referral, treatment), and motivational interviewing.

3. Where can I find a substance abuse treatment program for a pregnant patient?

The substance use disorder treatment programs that a patient uses are based upon her health insurance coverage.

- **Private insurance** – contact the insurance company for covered providers.
- **Medical Assistance** - Contact the MA or the managed care organization for in-network providers. Any treatment provider in Maryland that accepts state funds (Medical Assistance or grant funds) is ***mandated to see a pregnant woman within 24 hours of initial contact***. They will evaluate the patient and refer to the appropriate level of care.
- **Uninsured** - Treatment is usually available on a sliding fee scale to anyone without health insurance. Contact the local Alcohol and Drug Abuse Treatment Coordinator.

Each of Maryland's 24 jurisdictions has an identified **substance abuse treatment coordinator** (*website listed on back of page*). They can help identify alcohol and drug abuse treatment needs and services, and coordinate the delivery of publicly funded treatments.

4. How can I obtain records from the substance use disorder treatment center?

The patient needs to sign a special form for release of confidential information. **General medical consent forms are NOT sufficient for release of substance use treatment records.** See *Toolkit Section 3 - Referral and Treatment, page 3.14* for an appropriate form.

5. Is there any special medical record documentation?

Document responses to the validated screening tool, concerns identified, interventions completed, and plan of care. This will help to keep other health professionals informed about your patient. It will also help in reimbursement for your care of this high risk pregnancy.

6. What non obstetrical conditions are commonly seen with substance use during pregnancy?

Conditions associated with substance use include depression, PTSD, intimate partner violence, sexually transmitted infections, HIV, hepatitis B and C, and abnormal cervical cancer screens. Medical disorders such as diabetes, hypertension, seizures, asthma, heart disease, and endocarditis often are undertreated with the patient presenting in poor control.

For Care Consultation Call:

Hopkins - Center for Addiction and Pregnancy (CAP)

410-550-3020

University of Maryland – Outpatient Addictions Treatment Services

410-328-6600

For Detailed Information See:

Substance Use in Pregnancy

A Clinician's Toolkit for Counseling, Screening, Referral and Care

or go to:

www.baltimorecountymd.gov/go/perinatal

For Smoking Cessation Go To:

1-800-QUITNOW

www.quitnow.net/maryland

For Alcohol and Drug Abuse Treatment Coordinators by Jurisdiction

www.adaa.dhmh.maryland.gov go to Quick Links Treatment Coordinators



Prepared by

Regional Perinatal Advisory Group (RPAG)

Information and Resources



Talk to your
health care
provider.

Get free help to quit smoking.

1-800-QUITNOW

www.quitnow.net/maryland

Centers for Disease Control & Prevention

www.cdc.gov/tobacco

**U.S. Department of Health
& Human Services**

www.smokefree.gov



Get help to quit alcohol
or drug use.

Alcoholics Anonymous

www.aa.org

Baltimore Area Narcotics Anonymous

www.baltoareana.org

Centers for Disease Control & Prevention

Fetal Alcohol Spectrum Disorders

www.cdc.gov/fasd

Maryland Alcohol & Drug Abuse Administration

www.maryland-adaa.org | 410-402-8600

U.S. Substance Abuse & Mental Health

Services Administration

www.samhsa.gov | 1-800-662-4357



**This brochure is produced by
The Regional Perinatal Advisory Group
(RPAG)**

The Baltimore Regional Perinatal Advisory Group (RPAG) was established in 2002. The RPAG's goal is to optimize the health of pregnant women and newborn infants in the Baltimore region through education, advocacy and information sharing. RPAG members are public and private sector clinicians and administrators, public health officials, and advocates from Anne Arundel County, Baltimore County, Baltimore City, Carroll County, Frederick County, Harford County, Howard County and Prince George's County. Specifically, RPAG members represent hospital departments of obstetrics, neonatology, nursing, and infection control; community health centers; Medicaid managed care organizations; officials from the eight local health departments and the Maryland Department of Health and Mental Hygiene; MedChi, the Maryland State Medical Society; and other national and state-level professional and advocacy associations.

Download this brochure online at

www.baltimorecountymd.gov/go/perinatal

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Three Ways to Prevent Harm for Mothers & Babies



1. Stop Tobacco Use

*When you smoke,
your baby smokes too!*



Women who smoke are more likely to have:

- Bleeding in pregnancy
- Miscarriage (pregnancy loss)
- Premature delivery (baby born too soon)
- Breathing problems
- Cancer

Babies born of women who smoke are more likely to have:

- Prematurity (born too soon)
- Low birth weight
- Breathing problems (such as asthma)
- Sudden Infant Death (SIDS)
- Infections (especially ear infections and pneumonia)
- Behavior problems (such as hyperactivity)

2. Stop Alcohol Use

*When you drink alcohol,
your baby drinks too!*



Even a small amount of alcohol while pregnant might harm the baby.

Women who drink alcohol are more likely to have:

- Miscarriage (pregnancy loss)
- Premature delivery (baby born too soon)

Babies of women who drink alcohol are more likely to have:

- Prematurity (born too soon)
- Low birth weight
- Brain damage
- Learning and behavior problems
- Poor growth
- Fetal Alcohol Syndrome

3. Stop Drug Use

*Babies can be harmed
by many drugs!*



Check with your doctor before you take ANY drug or medicine.

Women who misuse legal or illegal drugs are more likely to have:

- Miscarriage (pregnancy loss)
- Premature delivery (baby born too soon)

Babies of women who use drugs are more likely to have:

- Prematurity (born too soon)
- Low birth weight
- Addiction withdrawal symptoms
- Feeding problems

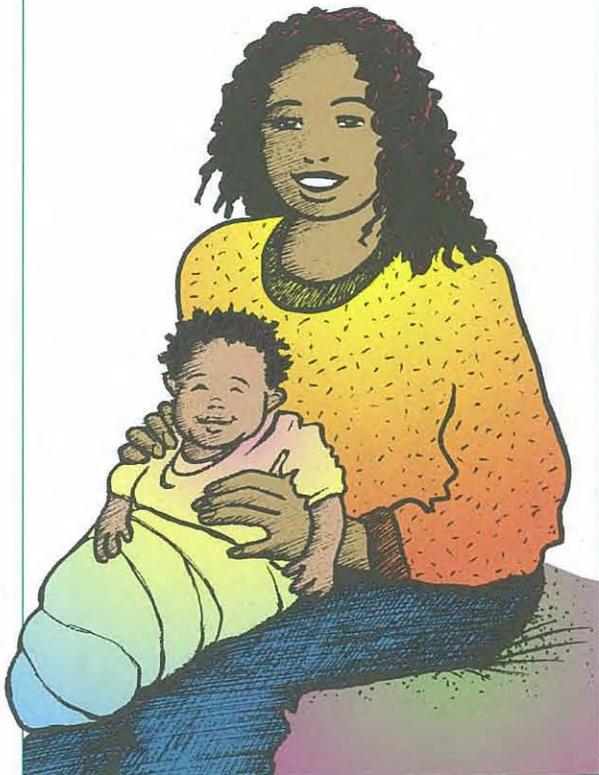
9. If you are using alcohol or other drugs and cannot stop, get help.

- ✓ You may have an addiction. Go to a health care provider or clinic and ask for help.

10. Your health and your baby's health are worth it!

- ✓ Staying away from alcohol and other drugs gives your baby a good chance of being born strong and healthy.

Give your baby the best chance of being born healthy.



If you are pregnant and take drugs, your baby could be born with serious problems. Even drugs or medication that are OK for adults could hurt your baby.

For more information or a referral to a program in your area, visit www.drugabuse.gov on the Internet or call the National Institute on Drug Abuse at 1-800-662-4357.

This pamphlet is not a substitute for professional medical care. If you have questions or concerns, please talk with a health care provider.

Written by Mardi Richmond.

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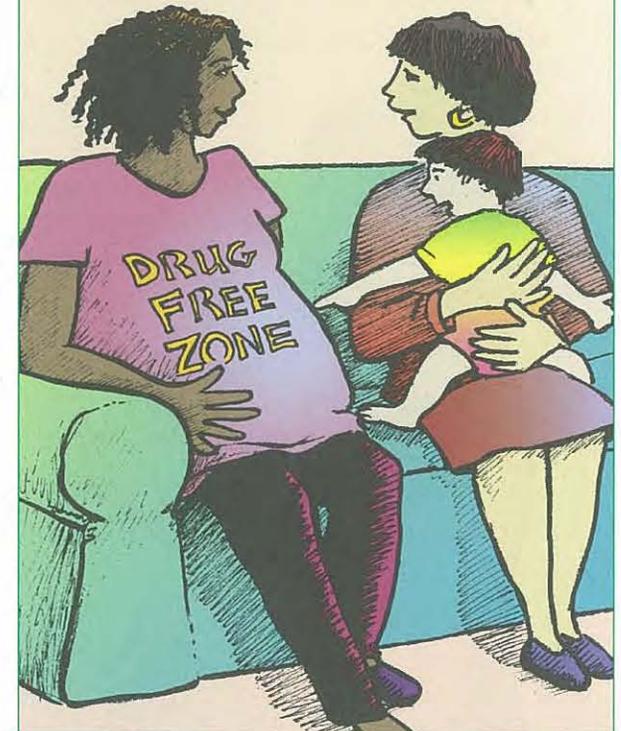
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A HEALTHY PREGNANCY

Drug Use and Pregnancy

Ten Things You Should Know

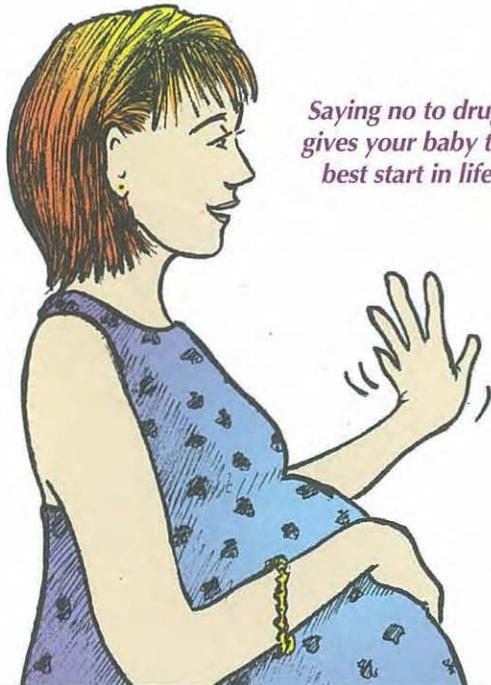


FOR YOU AND YOUR BABY

DRUG USE AND PREGNANCY

If you are pregnant, using drugs or taking certain medications can hurt you and your baby. Here's what you need to know to give your baby the best chance for a healthy life.

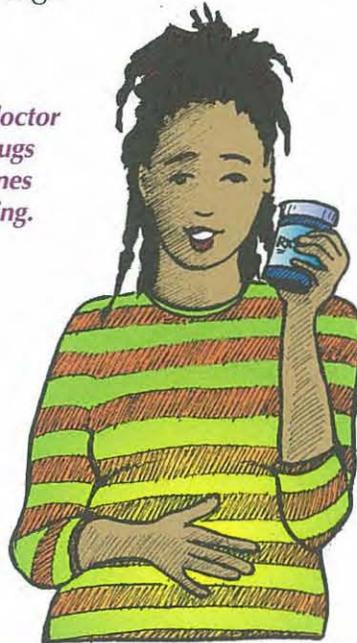
- 1. Babies whose mothers take drugs while pregnant can be born very sick.**
 - ✓ Your baby could be born with a low birthweight or with birth defects.
 - ✓ You may lose your baby (miscarriage).
- 2. Some problems don't show up until later on.**
 - ✓ Your child may have trouble sitting still and learning new things.
 - ✓ Some problems might not show up until your child starts school.



Saying no to drugs gives your baby the best start in life.

- 3. Tell your health care provider about all drugs that you are taking.**
 - ✓ If you use illegal drugs, it may be scary to tell your doctor. But you and your baby's health depend on it.
 - ✓ Tell your doctor about everything – including over-the-counter medicines, prescriptions, cigarettes, alcohol, and illegal drugs.

Talk to your doctor about all drugs and medicines you are taking.



- 4. If you get sick, talk to your health care provider before taking any medicine.**
 - ✓ Some medicines that can help you may hurt your baby.
- 5. Talk to your health care provider before taking over-the-counter medications.**
 - ✓ Medicine that you can buy at the store, like aspirin or cough syrup, may also be harmful.

- 6. Drugs like marijuana and cocaine can hurt your baby.**
 - ✓ Your baby could be born addicted.
 - ✓ He or she may have physical and emotional problems that don't go away.
- 7. Drinking alcohol during pregnancy is the leading cause of preventable birth defects.**
 - ✓ Even small amounts of alcohol may cause birth defects and learning problems.
- 8. Smoking cigarettes can cause your baby to be born early or too small.**
 - ✓ Smoking may also cause stillbirth and sudden infant death syndrome (SIDS).

If you can't stop using drugs, ask for help.



5. What if I am pregnant and have been drinking?

If you drank alcohol before you knew you were pregnant, stop drinking now. You will feel better, and your baby will have a good chance to be born healthy. If you want to get pregnant, do not drink alcohol. You may not know you are pregnant right away. Alcohol can hurt a baby even when you are only 1 or 2 months pregnant.

6. How can I stop drinking?

There are many ways to help yourself stop drinking. You do not have to drink when other people drink. If someone gives you a drink, it is OK to say no. Stay away from people or places that make you drink. Do not keep alcohol at home.

If you cannot stop drinking, GET HELP. You may have a disease called **alcoholism**. There are programs that can help you stop drinking. They are called **alcohol treatment programs**. Your doctor or nurse can find a program to help you. Even if you have been through a treatment program before, try it again. There are programs just for women.



For help and information

You can get help from a doctor, nurse, social worker, pastor, or clinics and programs near you.

For confidential information, you can contact:

Alcoholics Anonymous (AA)

check your local phone book for listings in your area
Internet address: <http://www.aa.org>

National Council on Alcoholism and Drug Dependence (NCADD)

22 Cortlandt Street, Suite 801
New York, NY 10007-3128
Phone: (212) 269-7797; Fax: (212) 269-7510
HOPE LINE: (800) NCA-CALL (24-hour Affiliate referral)
Email: national@ncadd.org
Internet address: <http://www.ncadd.org>

National Institute on Alcohol Abuse and Alcoholism

5635 Fishers Lane, MSC 9304
Bethesda, MD 20892-9304
(301) 443-3860; Fax: (301) 480-1726
Internet address: <http://www.niaaa.nih.gov>

National Organization on Fetal Alcohol Syndrome

900 17th Street, NW, Suite 910
Washington, DC 20006
(800) 66-NOFAS; Fax: (202) 466-6456
Internet address: <http://www.nofas.org>

Substance Abuse and Mental Health Services Administration (SAMHSA) Treatment Facility Locator

(800) 662-HELP
Internet address:
<http://www.findtreatment.samhsa.gov>

Drinking and Your Pregnancy



U.S. Department of Health and Human Services
National Institutes of Health
National Institute on Alcohol Abuse and Alcoholism
NIH...Turning Discovery Into Health

In cooperation with
The National Organization on Fetal Alcohol Syndrome

When you are pregnant

Drinking Can Hurt Your Baby

When you are pregnant, your baby grows inside you.

Everything you eat and drink while you are pregnant affects your baby. If you drink **alcohol**, it can hurt your baby's growth. Your baby may have physical and behavioral problems that can last for the rest of his or her life. Children born with the most serious problems caused by alcohol have **fetal alcohol syndrome**.



Children with fetal alcohol syndrome may:

- Be born small.
- Have problems eating and sleeping.
- Have problems seeing and hearing.
- Have trouble following directions and learning how to do simple things.
- Have trouble paying attention and learning in school.
- Need special teachers and schools.
- Have trouble getting along with others and controlling their behavior.
- Need medical care all their lives.



Here are some questions you may have about alcohol and drinking while you are pregnant.



1. Can I drink alcohol if I am pregnant?

No. Do not drink alcohol when you are pregnant. Why?

Because when you drink alcohol, so does your baby. Think about it. Everything you drink, your baby also drinks.

2. Is any kind of alcohol safe to drink during pregnancy?

No. Drinking any kind of alcohol when you are pregnant can hurt your baby. Alcoholic drinks are beer, wine, wine coolers, liquor, or mixed drinks. A glass of wine, a can of beer, and a mixed drink all have about the same amount of alcohol.



3. What if I drank during my last pregnancy and my baby was fine?

Every pregnancy is different. Drinking alcohol may hurt one baby more than another. You could have one child that is born healthy and another child that is born with problems.

4. Will these problems go away?

No. These problems will last for a child's whole life. People with severe problems may not be able to take care of themselves as adults. They may never be able to work.

Jurisdiction Resources

Depression Screening and Mental Health Referral

Pregnant women may experience mental health issues during and/or after their pregnancy. Pregnant and post partum women should, at a minimum, be screened for depression. The Edinburgh Postnatal Depression Scale (EPDS) has been used extensively with both pregnant and postpartum women and is a reliable instrument for screening. It is easy to administer and score and may be reproduced without permission as long as the authors' names, titles and source of the paper are included. A copy along with scoring directions is attached. If a woman scores positive on the EPDS or has current symptoms suggesting a mental health disorder, she should be referred for a mental health evaluation.

Finding a provider is based on what kind of health insurance, if any, the woman has. It may be helpful to have a member of your staff assist the patient in making phone calls. Ideally, she should not leave your office until she has an appointment scheduled.

Types of insurance coverage:

- **Private insurance** – You or your office should contact the insurance company for information on benefits and covered providers. A covered provider should provide a mental health evaluation and treatment.
- **Medical Assistance** – Anyone who has Medical Assistance in Maryland is eligible to be in the state's "Public Mental Health System". You or your office can obtain information on where to refer patients by contacting the Core Service Agency (CSA) in your jurisdiction. Every jurisdiction has a CSA and a listing of these agencies is attached. The list can be found at <http://dhmh.maryland.gov/mha/csa.html>. The CSA is charged with linking patients to public mental health services in their jurisdiction.
- **Uninsured** – You or your office can contact the local Core Service Agency (CSA) for information on available resources for uninsured pregnant women.

If you need additional help, guidance, or consultation about a specific case, please contact the Core Service Agency (CSA) in your jurisdiction.

See this section of Toolkit, page 10.4 for a list of Core Service Agencies by jurisdiction.

Name _____ Today's Date _____

Please circle the answer which comes closest to how you have felt in the past 7 days

- | | |
|---|---|
| <p>1. I have been able to laugh and see the funny side of things</p> <p>0 As much as I always could</p> <p>1 Not quite so much now</p> <p>2 Not so much now</p> <p>3 Not at all</p> | <p>6. Things have been too much for me</p> <p>3 Yes, most of the time I haven't been able to cope at all</p> <p>2 Yes, sometimes I haven't been coping as well as usual</p> <p>1 No, most of the time I have coped well</p> <p>0 No, I have been coping as well as ever</p> |
| <p>2. I have looked forward with enjoyment to things</p> <p>0 As much as I ever did</p> <p>1 Somewhat less than I used to</p> <p>2 A lot less than I used to</p> <p>3 Hardly at all</p> | <p>7. I have been so unhappy that I have had difficulty sleeping</p> <p>3 Yes, most of the time</p> <p>2 Yes, sometimes</p> <p>1 Not very often</p> <p>0 No, not at all</p> |
| <p>3. I have blamed myself unnecessarily when things went wrong</p> <p>0 No, not at all</p> <p>1 Hardly ever</p> <p>2 Yes, sometimes</p> <p>3 Yes, very often</p> | <p>8. I have felt sad or miserable</p> <p>3 Yes, most of the time</p> <p>2 Yes, quite often</p> <p>1 Not very often</p> <p>0 No, not at all</p> |
| <p>4. I have been anxious or worried for no good reason</p> <p>3 Yes, often</p> <p>2 Yes, sometimes</p> <p>1 No, not much</p> <p>0 No, not at all</p> | <p>9. I have been so unhappy that I have been crying</p> <p>3 Yes, most of the time</p> <p>2 Yes, quite often</p> <p>1 Only occasionally</p> <p>0 No, never</p> |
| <p>5. I have felt scared or panicky for no good reason</p> <p>3 Yes, often</p> <p>2 Yes, sometimes</p> <p>1 No, not much</p> <p>0 No, not at all</p> | <p>10. The thought of harming myself has occurred to me</p> <p>3 Yes, quite often</p> <p>2 Sometimes</p> <p>1 Hardly ever</p> <p>0 Never</p> |

TOTAL SCORE: _____

Edinburgh Postnatal Depression Scale (EPDS) (J.L. Cox, J.M. Holden, R. Safovsky, Department of Psychiatry, University of Edinburgh)

Edinburgh Postnatal Depression Scale Instructions

1. The mother is asked to circle the response which comes closest to how she has been feeling in the **previous 7 days**.
2. All ten items must be completed.
3. Care should be taken to avoid the possibility of the mother discussing her answers with others.
4. The mother should complete the scale herself, unless she has limited English proficiency or has difficulty with reading.

Scoring

A score of 10 may require assessment, as depression symptoms *may* be present.

A score of 12 indicates that depression is likely and further assessment by a trained healthcare provider is recommended.

If any number other than “0” is circled for item number 10, further assessment and possible referral is required immediately.

The EPDS is an assessment tool and should not override clinical judgment. A comprehensive clinical assessment should confirm the diagnosis.

Mental Health Core Service Agencies in Maryland		
Jurisdiction	Agency Name	Phone number
Allegany County	Allegany Co. Mental Health System's Office	301-759-5070
Anne Arundel County	Anne Arundel Co. Mental Health Agency	410-222-7858
Baltimore City	Baltimore Mental Health Systems, Inc.	410-837-2647
Baltimore County	Bureau of Behavioral Health of Baltimore County Health Department	410-887-3828
Calvert County	Calvert County Core Service Agency	410-535-5400
Carroll County	Carroll County Core Service Agency	410-876-4440
Cecil County	Cecil County Core Service Agency	410-996-5112
Charles County	Dept. of Health Core Service Agency	301-609-5757
Frederick County	Mental Health Mgmt. Agency of Frederick County	301-682-6017
Garrett County	Garrett County Core Service Agency	301-334-7440
Harford County	Office of Mental Health of Harford County	410-803-8726
Howard County	Howard County Mental Health Authority	410-313-7350
Mid-Shore Counties (Caroline, Dorchester, Kent, Queen Anne, Talbot)	Mid-Shore Mental Health Systems, Inc.	410-770-4801
Montgomery County	Dept. of Health and Human Services	240-777-1400
Prince George's County	Prince George's County Core Service Agency	301-265-8400
St. Mary's County	St. Mary's County Dept. of Aging and Human Services	301-475-4200 x 1682
Washington County	Washington County Mental Health Authority	301-739-2490
Wicomico/Somerset Counties	Wicomico Somerset Behavioral Health Authority	410-543-6981
Worcester County	Worcester County Core Service Agency	410-632-1100

**Maryland Department of Health and Mental Hygiene**

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein M.D., Secretary

Prevention and Health Promotion Administration

Michelle Spencer, MS, Director – Donna Gugel, MHS, Deputy Director

Ilise D. Marrazzo, RN, BSN, MPH, Director, Maternal and Child Health Bureau

Deborah B. McGruder, MPH, PMP, Director, Infectious Disease Bureau

Clifford S. Mitchell, MS, MD, MPH, Director, Environmental Health Bureau

Donald Shell, MD, MA, Director, Cancer and Chronic Disease Bureau

Date: July 31, 2013 -REVISED

To: Counseling, Testing, and Referral Sites
Health Care Providers and Facilities

From: Deborah B. McGruder, MPH, PMP
Director, Infectious Disease
Bureau

Subject: Practice Advisory for the HIV Testing Process in Maryland

The Department of Health and Mental Hygiene's Prevention and Health Promotion Administration (DHMH-PHPA) has developed this Practice Advisory to present best practices for the HIV testing process in the areas of:

- Obtaining Informed Consent for an HIV test;
- Providing Pre-Test Counseling;
- Providing Test Results and Referrals (Post-Test Session);
- Notifying Sexual and Needle Sharing Partners; and
- Working with Pregnant Women.

The DHMH-PHPA recommends that practitioners in all health care settings (e.g. hospitals, urgent care or emergency departments, inpatient services, community health centers and clinics, correctional healthcare facilities, and primary care settings) offer diagnostic HIV testing and HIV screening as part of routine clinical care for individuals ages 13 to 65. In non-health care settings (e.g. community-based organizations, outreach settings, or mobile vans), targeted HIV testing continues to be the recommended practice.

USEFUL DEFINITIONS

Diagnostic testing: Performing an HIV test for persons with clinical signs or symptoms consistent with HIV infection. Diagnostic testing should be conducted when an individual exhibits symptoms or one of the opportunistic infections commonly associated with HIV infection.

Screening: Performing an HIV test for all persons in a defined population. Screening should be performed routinely for all individuals aged 13 to 64 years at least one time in his or her lifetime unless prevalence of undiagnosed HIV infection in the patient population has been documented to be less than 0.1%. If an individual may be at high risk for HIV he or she should be tested at least annually. Examples of individuals who may be at high risk include: persons who themselves or whose partners have had more than one sex partner since their most recent HIV test, injection-drug users, men who have sex with men, persons who exchange sex for money/drugs, and sex/needle sharing partners of HIV infected persons.

Targeted testing: Performing an HIV test for subpopulations of persons based on risk, typically defined on the basis of behavior, clinical, or demographic characteristics. Targeted testing should be conducted in settings where risk-based HIV testing is more cost effective and where individuals with positive results are more likely to be identified (e.g., non-clinical settings like community-based organizations, outreach settings, or mobile vans).

201 W. Preston Street, Baltimore, Maryland 21201
410-767-6742 Fax 410-333-5995
Toll Free 1-877-4MD-DHMH TTY for Disabled
Maryland Relay Service 1-800-735-2258

500 N. Calvert Street, 5th Fl, Baltimore, Maryland 21202
410-767-5227 • Fax 410-333-6333 • TDD for Disabled 410-333-4800
Toll Free 1-800-358-9001 • TTY for Disabled
Maryland Relay Service 1-800-735-2258

PROVIDING PRE-TEST COUNSELING

The purpose of the pre-test counseling session is to provide the individual with adequate information so that an informed decision can be made about having an HIV test. Maryland State law specifies that **pre-test counseling can be provided in writing, verbally, or by video** based on the informational needs and testing history of the person to be tested.

NOTE: If the individual is pregnant, refer to the section entitled, “The HIV Testing Process for Pregnant Women.” Pre-test counseling should include:

- Information that the individual will be tested for human immunodeficiency virus (HIV) infection.
- An explanation that the results of this test, like all medical records, are confidential, which means an individual’s information will only be available to those authorized to have access.
- A description of how HIV is transmitted, including the following:
 - Unprotected sexual contact with an infected partner (e.g., vaginal, oral or anal sex);
 - Blood to blood contact (e.g., sharing needles or other injection drug equipment, transplant recipients, blood transfusions, etc.); and
 - From an infected mother to her baby during pregnancy, delivery or breastfeeding.
- A brief explanation of the potential results for the test being provided.

Possible Results for Conventional Blood Drawn Tests

- A negative test result means that HIV infection has not been found at the time of the test.
- A positive HIV test result means that a person is infected with HIV, but DOES NOT mean a diagnosis of AIDS. Other tests will be needed to make that determination.
- An indeterminate test result means that the test is inconclusive and further testing will need to be conducted.

Possible Results for Rapid Tests

- A negative test result means that HIV infection has not been found at the time of the test.
- A preliminary positive result means that in all probability the individual is infected with HIV. Further tests will be needed to confirm this test result.
- An invalid test result means that the test device has failed and another test should be conducted.
- A description of what will happen if the test result is positive, including the following:
 - Services or referrals for appropriate treatment and support will be provided, including services for pregnant women to reduce the risk of transmission to the fetus or newborn; and
 - The individual will be offered assistance in notifying and referring partners for services.

OBTAINING INFORMED CONSENT

Informed consent is a legal condition whereby a person can be said to have given consent based upon an understanding of the facts and implications of an action. The individual needs to be in possession of relevant facts and also be capable of providing informed consent, e.g. without and impairment of judgment at the time of consenting.

Maryland State law specifies:

- A person must provide informed consent before a test for the presence of HIV can be conducted.
- Informed consent must include information that the individual can refuse the HIV test without penalty.
- Informed consent must be documented in the medical record, however, in health care settings, a separate written form is not required.

All providers should:

- Provide pre-test counseling (see above for details) to the individual prior to obtaining informed consent.
- Determine whether or not the individual is capable of consenting to the test.
- Tell the individual that they have the right to refuse this test without jeopardizing their medical care.

In health care settings, healthcare providers should:

- Document in the individual's medical record (i.e. medical chart) that the individual received pretest counseling and provided informed consent. Individuals do not need to sign a separate written form.
- Document consent on the provider's or facility's General Consent to health care, on a separate written form, or in the medical record progress notes.

In non-health care settings, HIV counselors/providers should:

- Continue using the uniform HIV informed consent form developed and provided by the Department.
- Ensure the uniform HIV informed consent form is distinct and separate from all other consent forms.

PROVIDING TEST RESULTS AND REFERRALS (POST-TEST SESSION)

The purpose of the post-test session is to provide the individual with test results and, when appropriate, connect the individual to treatment and supportive services.

Maryland State law specifies:

- The health care provider must notify an individual of the test result regardless of the result.
- When an individual receives a positive test result, a physician or physician's designee must refer the individual to treatment (i.e., HIV medical care) and supportive services (i.e., partner services and case management).
- Local Health Departments will make information available to health care providers on referral resources, including counseling, treatment, and support services for HIV positive individuals.

The provider should:

- Ensure that their facility has updated referral resources from the Local Health Department, including counseling, treatment, and support services for HIV positive individuals.
- Ensure the post-test session is conducted in a manner that protects the individual's confidentiality, including identity verification, either by telephone (for negative test results ONLY) or in person.
- Tell the individual the result and meaning of his or her HIV test and answer any questions the individual may have about the testing event.

Possible Results for Conventional Blood Drawn Tests:

- A negative test result means that HIV infection has not been found at the time of the test.
- A positive HIV test result means that a person is infected with HIV, but DOES NOT mean a diagnosis of AIDS. Other tests will be needed to make that determination.
- An indeterminate test result means that the test is inconclusive and further testing will need to be conducted.

Possible Results for Rapid Tests:

- A negative test result means that HIV infection has not been found at the time of the test.
- A preliminary positive result means that in all probability the individual is infected with HIV. Further tests will be needed to confirm this test result.
- An invalid test result means that the test device has failed and another test should be taken.
- For individuals who receive a positive HIV test result, deliver the result of the test in the presence of the individual tested and refer the individual to:
 - A specialized HIV/infectious disease practitioner,
 - The local health department for partner services,
 - HIV case management, and
 - Other services as appropriate (i.e., substance abuse treatment, mental health services, STI screening, etc.).
- Discuss precautions that may be taken to prevent infection, re-infection or transmission to others, including the following:
 - Abstinence or safer sex techniques and the use of condoms for all sexual encounters.
 - Never sharing needles or other injection equipment.
 - Never donate blood, plasma, tissue, organs or sperm.
 - Do not share items that could become contaminated with blood.
 - Pregnancy planning and prenatal care to reduce mother-to-child HIV transmission if the individual is of childbearing age.

NOTIFYING SEXUAL AND NEEDLE SHARING PARTNERS

Maryland State law specifies:

- If an individual's test result is positive, the physician or physician's designee must counsel the individual to inform all sexual and needle-sharing partners that they may have been exposed to HIV.
- The physician or physician's designee must offer to assist in notifying sexual and needle-sharing partners or refer the individual to the appropriate local health department for assistance.

Providers should:

- Discuss the importance of partner notification with every HIV positive individual, and
 - Offer to assist the HIV positive individual in notifying and referring partners for services, or
 - Refer the individual to the local health department to assist with partner notification by:
 - Contacting the local health department directly, or
 - Utilizing the Maryland Confidential Morbidity Report (DHMH 1140 at <http://phpa.dhmh.maryland.gov/OIDEOR/CHSE/SitePages/reporting-material.aspx>) form to indicate that the physician requests local health department assistance with partner services.
- Determine if the HIV positive individual is at risk for domestic violence and make appropriate referrals.
- Cooperate with the local health officer's designee if partner notification assistance is requested.
- Inform the local health officer if the individual refuses to notify his or her partners.

HIV TESTING PROCESS FOR PREGNANT WOMEN

Maryland State law specifies that providers:

- Notify the pregnant individual that an HIV test will be administered.
- Include information that the pregnant individual can refuse the HIV test without penalty.
- Deliver pre-test counseling in writing, verbally, or by video based on the needs and testing history of the pregnant individual.
- Obtain informed consent before a test for the presence of HIV is conducted.
- Document in the medical record the declination of an HIV test by the pregnant individual.
- Offer an HIV test in the third trimester to the pregnant individual.
- Explain the risk of fetal transmission and the effect of pharmaceuticals during pregnancy.
- In labor and delivery, offer:
 - A rapid test to a pregnant individual with unknown or undocumented HIV status, and
 - Antiretroviral prophylaxis prior to receiving the results of a confirmatory test if the rapid HIV test is preliminary positive.
- Notify a pregnant individual of the test result regardless of the result.
- For individuals who receive a positive HIV test result, deliver the result of the test in the presence of the individual tested and refer the individual to:
 - A specialized HIV/infectious disease practitioner who specializes in the treatment of HIV positive pregnant individual,
 - The local health department for partner services,
 - HIV case management, and
 - Other services as appropriate (i.e., substance abuse treatment, mental health services, STI screening, etc.).

Providers should:

- Follow Maryland law as outlined above.
- Consult with an infectious disease specialist and/or an OB experienced in prenatal HIV management.
- Discuss actions recommended to prevent transmission to the fetus, including antiretroviral medication and delivery methods, and the risks of breast-feeding once the infant is born.
- Make every effort to ensure HIV-positive pregnant women remain engaged in prenatal care throughout their pregnancy and receive care from a specialized HIV/infectious disease practitioner.
- Request assistance from the local health department with reengagement in care for HIV-positive pregnant women who have fallen out of prenatal care and/or HIV medical care.

HIV REPORTING

Maryland State law specifies that:

- A physician caring for a patient that the physician knows is infected with HIV or is AIDS defined must report the individual to the to the health officer of the county where the physician provides care to the patient within 48 hours of diagnosis or of entry into their care.
- A physician shall report an infant born to a woman who tested positive for HIV to the Secretary of the Department of Health and Mental Hygiene within 48 hours of the infant's birth.
- The physician report must be on a form approved by the Secretary of the Department of Health and Mental Hygiene.
- The report shall identify the disease, state the name, race, sex, and residence address of the patient and be signed by the physician.
- A physician and healthcare facility reporting HIV/AIDS cases shall cooperate with staff of the Department of Health and Mental Hygiene in completing the case report.

Providers should:

- Not use electronic means (e.g., fax, e-mail, etc.) to submit HIV/AIDS reports.
- Complete all information on the Maryland Confidential Morbidity Report (DHMH 1140 at <http://phpa.dhmh.maryland.gov/OIDEOR/CHSE/SitePages/reporting-material.aspx>) including the request for Partner Services as follows:
 - Mark the 'Yes' checkbox on the DHMH 1140 to request local health department assistance with partner services if the provider has not assisted their patient with notifying sexual and needle sharing partners of possible exposure.
 - Submit the completed DHMH 1140 with a request for partner services assistance directly to the local health department to ensure timely provision of partner services.
- Maintain a policy that provides for records access by Department of Health and Mental Hygiene staff.

QUESTIONS AND/OR TECHNICAL ASSISTANCE

Contact the Maryland Department of Health and Mental Hygiene - Prevention and Health Promotion Administration with any questions or for technical assistance at 410-767-5227.

Intimate Partner Violence: Associated with Substance Abuse

Women who have experienced intimate partner violence (IPV) are more likely to abuse alcohol and drugs than women who have not been abused. Two out of every three women in substance abuse treatment reported IPV victimization in the pretreatment year.¹ Therefore, signs of substance abuse (as well as signs of mental health problems, or new or recurrent STIs) should prompt an assessment for IPV. The American Congress of Obstetricians and Gynecologists (ACOG) recommends that screening be done at the first prenatal visit, at least once per trimester, and at the postpartum checkup.²

Definitions

Intimate partner violence encompasses subjection of a partner to physical abuse, psychological abuse, sexual violence, and reproductive coercion:

- **Physical Abuse** - Physical violence can include throwing objects, pushing, kicking, biting, slapping, strangling, hitting, beating, threatening with any form of weapon, or using a weapon.
- **Psychological Abuse** - Psychological abuse erodes a woman's sense of self-worth and can include harassment, verbal abuse (such as name calling, degradation, blaming), threats, stalking, and isolation. Often the abuser progressively isolates the woman from family and friends and may deprive her of food, money, transportation, and access to health care.
- **Sexual Violence** - Sexual violence includes a continuum of sexual activity that covers unwanted kissing, touching, or fondling, sexual coercion, and rape.
- **Reproductive Coercion** - Reproductive coercion involves behaviors that a partner uses to maintain power and control in a relationship related to reproductive health. It is commonly associated with IPV. A partner may sabotage efforts at contraception, refuse to practice safe sex, intentionally expose a partner to STI/HIV, or forbid sterilization, abortion, or access to other reproductive health services. Nearly 20% of women seeking care in family planning clinics who had a history of abuse also experienced pregnancy coercion and 15% reported birth control sabotage.^{3,4}

IPV Assessment

The key component of IPV assessment is the opportunity to provide resources and education about IPV including its impact on medical or behavioral conditions, healthy relationships, and family safety. In a private setting, assess for IPV during new patient visits, annual exams, initial prenatal visits, each trimester of pregnancy, and the postpartum checkup. Assessments may be done in the office in person, by completing a questionnaire or by computer. Unlike child abuse, it is not mandatory by law to report IPV. Under Maryland law, exceptions are in cases of abuse of vulnerable adults, children less than 18 years of age by a guardian/caregiver, or treating certain injuries such as gunshot wounds.⁵ For an abused child or vulnerable adult Child Protective Services or Adult Protective Services should be called.

The Maryland DHMH web site at www.dhmh.maryland.gov/ipv has information to help providers assess for IPV. A sample one-page IPV assessment tool with resource listing is on the following page and can be photocopied for use in your clinical practice. It can also be downloaded from the DHMH webpage.

Notes

1. Lipsky S, Krupski A, Roy-Byrne P, Lucenko B, Mancuso D, Huber A. Effect of Co-Occurring Disorders and Intimate Partner Violence on Substance Abuse Treatment Outcomes. *J Subst Abuse Treat.* 2010; 38 (3): 231-244. doi: 10.1016/j.jsat.2009.12.005.
2. American College of Obstetricians and Gynecologists: Committee on Healthcare for Underserved Women. ACOG Committee Opinion No. 518: Intimate Partner Violence. *ACOG.* 2012; 119 (2): 412-417. doi: 10.1097/AOG.0b013e318249ff74.
3. American College of Obstetricians and Gynecologists: Committee on Healthcare for Underserved Women. ACOG Committee Opinion No. 554: Reproductive and Sexual Coercion. *ACOG.* 2013; 121 (2): 411-415. doi: 10.1097/01.AOG.0000426427.79586.3b.
4. Miller E, Decker M, McCauley H, et. al. Pregnancy Coercion, Intimate Partner Violence, and Unintended Pregnancy. *Contraception.* 2010; 81 (4): 316-322. doi: 10.1016/j.contraception.2009.12.004.
5. Maryland Health Care Coalition Against Domestic Violence. Confidentiality and Reporting Requirements in Maryland: Responding to Abuse and Neglect of Children, Intimate Partners and Vulnerable Adults. Baltimore, MD: n.p., n.d. http://healthymaryland.org/wp-content/uploads/2011/05/66090_DomVio_D_Confid.pdf.

Sample Intimate Partner Violence Assessment¹ – assess privately, without family/friends; use interpreter (not family/friend) if needed; Assess **females**, ages 15-50, at every **new, interval comprehensive, or urgent care** health visit – as part of routine health history. Assess **obstetric patients** each trimester and postpartum. Ask directly or have patient self-administer the questions by computer or paper. Assess **anyone** when signs and symptoms raise concerns about violence (injuries, drug/alcohol use, STIs, psych disorders). or at provider discretion.

Introductory statements:

- "Because violence is so common and help is available, I now ask every patient if they are being hurt by a current or former partner."
- "I won't tell anyone else about what is said unless you give me permission."

[Exceptions for Maryland: abuse of vulnerable adults, children <18 years of age by a guardian, or certain injuries, e.g. inflicted by gun or moving vessel]³

Sample questions²:

1. "Has your current or former partner threatened you or made you feel afraid?"
(stalked you, insulted you, threatened you with a weapon, threatened to hurt you or your children if you did or didn't do something, controlled to whom you talk/where you go/how you spend money)
2. "Has your partner hit, strangled or physically hurt you?"
(“hurt” includes being hit, slapped, kicked, “choked” [or strangled], bitten, shoved)
3. "Has your partner made you have sex when you didn't want to?"

No

Yes (to any of above 3 questions)

"It is not your fault. You are not alone. Help is available. I'm concerned about your safety (and safety of your children). Abuse tends to increase in frequency/intensity and it can impact your health"

Option for on-site safety assessment

Sample questions to quickly assess: Is it safe to go home?⁴

- a. Has the physical violence increased over the past 6 months?
- b. Has your partner used a weapon or threatened you with a weapon?
- c. Do you believe your partner is capable of killing you?
- d. Have you been beaten while pregnant?
- e. Is your partner violently and constantly jealous of you?

Drug or alcohol use intensifies all situations
Note: Patient maybe a danger to herself. Assess for depression/suicidality

"Yes" to ≥3 out of 5 questions** or concern for safety - "From what you've told me, you are at high risk for severe injury or even being killed by your abuser. Let's make a call to help you decide some safe options for you and your family." (Remember that the goal may not be leaving at once but discussing safety with a DV expert. Document if help is declined but respect patient autonomy for making decision.)

Offer to call National Hotline 800-799-SAFE or the local DV Program (see back) for safety assessment/planning, counseling, legal advice, shelter. Make other referrals (mental health) as needed; Schedule a follow up visit Emphasize the need to keep information private and away from abuser. A safety planning fact sheet is available at www.ndvh.org/wp-content/uploads/2008/10/Safety-Planning-2.pdf

- Educate and counsel as needed; discuss healthy relationships and give out safety cards ¹women's health resource list (with local DV *contact* information)
- By providing brochures, cards, resources and information to all women or for their "friends or family who may be dealing with violence" women can receive important information without disclosure.

¹Intimate Partner Violence: A guide for Health Care Providers", available at www.dhmm.maryland.gov/ipv/ has more information about IPV assessment, documentation, reporting requirements, special populations, resources and how to order safety cards
²Confidentiality and Reporting Requirements in Maryland, http://healthymaryland.org/wp-content/uploads/2011/05/66090_DomVio_Confid.pdf
³Other IPV assessment tools such as "HITS" may be found at www.cdc.gov/ncipc/pub-res/images/ipvandsvscreening.pdf
⁴Adapted from Academic Emergency Medicine 2009; 16:1208–1216

Maryland Domestic Violence/ Intimate Partner Violence (IPV)/Sexual Assault Service Programs		
County	Program	Daytime Number
Allegany	Family Crisis Resource Center	301-759-9246
Anne Arundel	YWCA Domestic Violence Services	410-626-7800
Baltimore City	House of Ruth MD	410-889-0840
	TurnAround, Inc.	410-837-8111
Baltimore County	Family and Children's Services of Central MD	410-281-1334
	Family Crisis Center of Baltimore County, Inc.	410-285-4357
	TurnAround, Inc.	410-377-8111
Calvert	Crisis Intervention Center	410-535-1121
Carroll	Family and Children's Services of Central MD	410-876-1233
Caroline	Mid-Shore Council on Family Violence	410-479-1149
Cecil	Cecil Co. Domestic Violence/Rape Crisis Center	410-996-0333
Charles	Center for Abused Persons	301-645-8994
Dorchester	Mid-Shore Council on Family Violence	410-479-1149
Frederick	HeartlyHouse	301-662-8800
Garrett	The Dove Center	301-334-6255
Harford	Sexual Assault/Spouse Abuse Resource Center	410-836-8431
Howard	Hope Works	410-997-0304
Kent	Mid-Shore Council on Family Violence	410-479-1149
Montgomery	Abused Persons Program	240-777-4195
	Family Crisis Center, Inc.	301-779-2100
Prince George's	House of Ruth MD (legal, counseling services)	240-450-3270
	Mid-Shore Council on Family Violence	410-479-1149
Queen Anne's	Walden/Sierra, Inc.	301-863-6661
St. Mary's	Life Crisis Center	410-749-0771
Somerset	Mid-Shore Council on Family Violence	410-479-1149
Talbot	CASA (Citizens Assisting and Sheltering the Abused)	301-739-4990
Washington	Life Crisis Center	410-749-0771
Wicomico	Life Crisis Center	410-749-0771
Worcester	Life Crisis Center	410-749-0771

Resources

Hotlines: 24/7

National Domestic Violence Hotline

1-800-799-SAFE (7233)

1-800-787-3224 TTY

(interpreters for 170 languages and links to local DV hotline)

National Teen Dating Abuse

1-866-331-9474

On-line chat

www.loveisrespect.org

Rape, Abuse & Incest National Network (RAINN) Hotline

1-800-656-HOPE (4673)

Asian/Pacific Islander Domestic Violence Resource Project
202-464-4477

Adelante Familia—Baltimore, MD
410- 732-2176

Chana - Jewish Community
410-234-0023

Futures Without Violence - excellent resource for patients and providers, **brochures, safety cards, fact sheets**
www.FuturesWithoutViolence.org

House of Ruth Maryland - information and resources for patients

www.hruth.org, 410-889-7884 (hotline), 410-889-0840 (administrative office)

Look to End Abuse Permanently - information for health care providers on IPV assessment <http://www.leapsf.org>

Maryland Coalition Against Sexual Assault (MCASA) www.mcasa.org, 410-974-4507

Maryland Department of Health and Mental Hygiene (DHMH)

– information to help health care providers assess for IPV www.dhmh.maryland.gov/ipv

Maryland Health Care Coalition Against Domestic Violence (educational materials, reporting requirements)

<http://healthymaryland.org/public-health/domestic-violence> 410-539-0872

Maryland Network Against Domestic Violence – information for patients, brochures, safety cards, fact sheets, data

www.mnadv.org 800-634-3577

Women's Law Center of Maryland, Inc. - information about protective orders and other legal matters

www.wlcmd.org 410-321-8761



**This toolkit is presented by:
The Regional Perinatal Advisory Group (RPAG)**

The Regional Perinatal Advisory Group (RPAG) was established in 2002. The RPAG's goal is to optimize the health of pregnant women and newborn infants in the Baltimore region through education, advocacy and information sharing. RPAG members are public and private sector clinicians and administrators, public health officials, and advocates from Anne Arundel County, Baltimore County, Baltimore City, Carroll County, Frederick County, Harford County, Howard County and Prince George's County. Specifically, RPAG members represent hospital Departments of Obstetrics, Neonatology, Nursing, and Infection Control; community health centers; Medicaid managed care organizations; officials from the eight local health departments and the state health department; MedChi, the Maryland State Medical Society; and other national- and state-level professional and advocacy associations.

Many of the materials in this toolkit can be found at: www.baltimorecountymd.gov/go/perinatal

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