Prevention of Tobacco Use and Secondhand Smoke Exposure Before, During, and After Pregnancy

June 19, 2008

The Science and Practice of Perinatal Tobacco Use Cessation

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Agenda

- Effects of Smoking on Maternal and Child Health
- The Best-Practice Intervention
- Pharmacotherapy During Pregnancy
- Using the 5As in Clinical Practice

Effects of Smoking on Maternal and Child Health

Smoking Prevalence Among Women in the United States

- 29.5% of non-pregnant women between 15 and 44 years old smoked cigarettes*
- 16.5% of pregnant women between 15 and 44 years old smoked cigarettes*
- In 2005, between 10.7% (unrevised birth certificate data) and 12.4% (revised data) women who had a live birth reported smoking during pregnancy**

Tobacco Use During Pregnancy: Maternal Harm

Causal association
- Premature rupture of the membranes
- Placenta previa
- Placental abruption

Probable causal association
- Ectopic pregnancy
- Spontaneous abortion
- Preterm delivery


Tobacco Use During Pregnancy: Infant Harm

Causal association
- Preterm delivery
- Small for gestational age
- Low birthweight
- Stillbirth
- Sudden Infant Death Syndrome (SIDS)


Tobacco Use During Infancy and Early Childhood

Causal association
- Otitis media
- New and exacerbated cases of asthma
- Bronchitis and pneumonia
- Wheezing and lower respiratory illness

Smoking During Pregnancy: How Do We Close the Gap?

- Effective interventions exist to help pregnant smokers quit
  But...
- Only 59% of prenatal care providers assist patients in developing a quit plan
- Only 38% of prenatal care providers give self-help materials


The Best-Practice Intervention: The 5 As

ASK the patient about her smoking status

ADVISE her to quit smoking with personalized messages for pregnant women

ASSESS her willingness to quit in next 30 days

ASSIST with self-help materials & social support

ARRANGE to follow-up during subsequent visits
The 5 As: Standing the Test of Time

- Since the Public Health Service Guidelines were published in 2000, conclusions have been validated in additional trials
- For light to moderate smokers, extended or augmented counseling increases the likelihood of cessation
- Many enhancements have been tested but none have produced results compelling enough to change current recommendations

Conclusions from Behavioral Intervention Studies

- Pregnancy is a good time to intervene
- Brief counseling works better than simple advice to quit
- Counseling with self-help materials offered by a trained clinician can improve cessation rates by 30% to 70%
- Intervention works best for moderate (<20 cigarettes/day) smokers

Cost Benefit of Prenatal Smoking Cessation

- Cost of counseling intervention ranges from $24 to $34 per individual*
- For every dollar invested, $3 are saved in downstream health-related costs**

"Existing analyses suggest that the return on investment will far outweigh the costs for this critical population"
Pharmacotherapy During Pregnancy

FDA-Approved Pharmacotherapies for Adults

Nicotine Replacement Products
(all Pregnancy Category D)
• Nicotine Patch
• Nicotine Gum
• Lozenge
• Nicotine Nasal Spray
• Nicotine Inhaler

Non-Nicotine Prescription Medications
• Bupropion SR (Zyban) (Pregnancy Category B)
• Varenicline (Chantix) (Pregnancy Category C)

Public Health Service Guidelines
• Behavioral intervention is first-line treatment in pregnant women
• Pharmacotherapy has not been sufficiently tested for efficacy or safety in pregnant patients
• May be necessary for heavy smokers

“Pharmacotherapy should be considered when a pregnant woman is otherwise unable to quit, and when the likelihood of quitting, with its potential benefits, outweighs the risks of the pharmacotherapy and potential continued smoking.” USPHS, 2000
The Controversy

- Lack of safety and efficacy studies
- Safety of nicotine on fetal development?
- Efficacy of NRT for pregnant women?
- Lack of specific guidelines
- Decision-making on an individual level

One End of the Spectrum

“The main concerns are its fetotoxicity and neuroteratogenicity that can cause cognitive, affective and behavioral disorders in children born to mothers exposed to nicotine during pregnancy. The use of nicotine…must be strictly avoided in pregnancy, breastfeeding, childhood and adolescence.”


The Other End of the Spectrum

“Although the use of nicotine replacement products may not be completely without risk, the risk is certainly much less than that of cigarette smoke. It is reasonable to consider the use of nicotine replacement therapies…in pregnant women who cannot quit smoking with behavioral treatment alone.”

**Bupropion: Similar Debate**

- No randomized controlled trials of bupropion for smoking cessation among pregnant women
- Five studies had mixed results regarding safety
  - Fetal anomalies?
  - Spontaneous abortion?
- One small non-randomized trial demonstrated effectiveness

Coleman T, CNS Drugs. 2007;21(12):983-993

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**Using the 5 As in Clinical Practice**

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**PHS Guidelines: Systems Level Approaches**

- Implement a tobacco-user identification system in every clinic
- Provide education, resources, and feedback to promote provider interventions
- Dedicate staff to provide tobacco dependence treatment

PHS Guidelines: Systems Level Approaches

- Promote policies that support and provide tobacco dependence services.
- Include effective tobacco dependence treatments as paid or covered services in all health plans.
- Reimburse clinicians and specialists for delivery of tobacco treatment.


Smoke Free Families National Dissemination Office

A seven-year grant from The Robert Wood Johnson Foundation to evaluate and promote evidence-based smoking cessation for women & their families.

Goals
1. Assure that all pregnant women are asked about their tobacco use.
2. Assure that all pregnant smokers receive evidence-based interventions (5 As).

Smoke Free Families Prenatal Demonstration Projects

- Maine Prenatal Collaborative
  - Collaborative model focused on tobacco treatment with team learning sessions and on-site technical assistance.
- Oklahoma Smoke-Free Beginnings
  - Physician enhancement assistants conducted academic detailing around the 5 As within practices.
- Oregon Smoke-Free Mothers & Babies
  - Incorporated the 5 As via technical assistance and trainings, team meetings, and infrastructure support within a maternity case management system.
### Smoke Free Families
#### Prenatal Demonstration Projects

- Quality of “real world” data are variable and difficult to interpret, but…
  - documentation of 5 A’s is feasible and content is relatively standardized
- Compared to national data, providers in the demonstration projects were providing more assistance to pregnant clients who smoke
- Proactive fax referral process can lead to substantial increases in pregnant women enrolling in quitline services

### Ohio Partners for Smoke Free Families

- 18 month pilot project funded by the Ohio Department of Health to determine the feasibility of implementing the 5 As in WIC and early intervention settings
  - 4 geographically diverse counties (urban, rural, Appalachian, non-Appalachian)
  - 4 WIC programs
  - 2 Early Intervention Home Visiting programs
- Goals:
  - Reach at-risk pregnant and post-partum women in the WIC and early intervention systems
  - Increase provider efficacy in counseling clients about tobacco use
  - Address barriers to implementation by involving staff in the design and delivery of the project
  - Create continuity of care by addressing cessation in the prenatal and post-partum periods

### Quit for Two – Quit for YOU

- 3 year project funded by the NC Health and Wellness Trust Fund to UNC Center for Maternal and Infant Health and Smoke Free Families
- Seeks to expand the reach of established prevention strategies and cessation programs for pregnant and postpartum women in North Carolina through state-wide outreach, pilot projects in four counties, and a social marketing campaign
- Starts July 2008
Baby & Me – Tobacco Free Program

Prevention of Tobacco Use and Secondhand Smoke Exposure Before, During, and After Pregnancy
Maternal and Child Health Series Webcast
Thursday, June 19, 2008 3:00–4:30 PM (ET)
Laurie Adams Project Director

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“Smoking during pregnancy is one of the nation’s most important public health challenges, but it’s a challenge that we can overcome.”
Dr. David Satcher
Former Surgeon General
GOALS

A. History of program – Current research project
B. 8-Steps to the Baby & Me – Tobacco Free Program
C. During pregnancy - Outline the 4 cessation classes
D. Post partum - Explain the testing and voucher process
E. Researchers update
F. Lessons learned

A. Program History
Research Project

Currently, about 13% of pregnant women in the U.S. smoke during pregnancy. If all pregnant women stopped smoking, there would be an estimated 11% reduction in stillbirths and 5% reduction in newborn deaths in this country. - U.S. Public Health Service, May 2004

In 2004, Chautauqua, Cattaraugus, and Allegany Counties
- 28% Rate of Prenatal Smoking (four hospitals)
In 2005 applied for a NYS Tobacco Control Promising Intervention
- Goal of enrolling 150 per year / 50 per county
In April 2006 – Awarded, research pilot program begins
- Bassett Research Institute, Cooperstown, NY
- Total women enrolled in three counties from April 2006 to March 2008 is 584. Exceeding enrollment goal by 284

B. Baby & Me – Tobacco Free

8 Steps - Program Format

1). Smoking, pregnant mother completes application for the program.

2). Calls and/or mails in the application to one of the three participating agencies in WNY.
3). Agency contacts the woman and enrolls her in the smoking cessation program. Schedules her first class.

4). Pregnant woman agrees to the program rules and requirements, including the necessary testing to prove her smoke-free status.

5). Pregnant woman quits smoking and attends at least four smoking cessation sessions before delivery.

6). After the birth of the baby the mother returns to the agency and takes a breath test (or additional testing, if necessary) to verify her smoke free status.

7). Upon testing smoke-free the mother receives a voucher for free diapers, valued at $20.00. ($25 in some states). She continues to qualify for diaper vouchers once a month, for up to one year.

8). Mother redeems the voucher for any size, brand of diapers at the participating stores.
C. Cessation Classes

Class One:

Congratulations on making a quit attempt

- Complete Application - Baby & Me Brochure
- Complete Registration Form
- Explain Program Protocols – Conduct CO test
- Provide Handouts – Schedule next appointment
- Give assignments

Class Two:

Effects of Secondhand Smoke

- Discuss successes/barriers
- Complete Class 2 registration information
- Conduct CO test
- Provide Handouts – Schedule next appointment

Class Three:

Benefits of not smoking - Stress Management

- Discuss success/barriers
- Complete Class 3 registration information
- Conduct CO test
- Provide Handouts – Schedule next appointment
**Cessation Classes** (cont)

Class Four:
Smoke Free Post Partum

- Discuss program requirements post partum
- Complete Class 4 registration information
- Conduct CO test
- Provide Handouts

**D. Post Partum – Providing vouchers**

**Voucher Program**

- Women call agency after the baby is born
- Provide brief counseling at each visit
- CO test – Complete voucher
- CO test conducted monthly
- Eligible for vouchers for one year

**Measuring the effectiveness of the Baby & Me - Tobacco Free Program**

Anne Gadomski MD MPH
Research Institute
E. Researchers Update

- Four prenatal face-to-face contacts with a cessation specialist who does counseling and carbon monoxide testing.
- Program sites included WIC offices, obstetric and other clinics.
- For 1 year post-partum, mothers are tested for carbon monoxide every 3 to 4 weeks and, if negative, receive a $20 diaper voucher.

Measuring the effectiveness of the Baby & Me – Tobacco Free Program

Two models to compare

- Office based counselors (WIC, clinics)
- Traveling counselor

Voucher receipt used to track quit rates

- Carbon monoxide (CO) testing
- Random saliva cotinine testing

Comparison and drop-out groups included

Demographics of NY State Program Participants:

<table>
<thead>
<tr>
<th>Baseline Characteristics of the Study Groups as of 5/1/08</th>
<th>Baby &amp; Me Program Participants Total = 554</th>
<th>Drop-out Total = 128</th>
<th>Off-Join Comparison Group Total = 50</th>
<th>WIC Comparison Group Total = 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Age</td>
<td>23.3</td>
<td>23.6</td>
<td>23.7</td>
<td>23.4</td>
</tr>
<tr>
<td>Average Years smoking</td>
<td>7.7</td>
<td>4.8</td>
<td>8.8</td>
<td>7.3</td>
</tr>
<tr>
<td>Average Cig per day smoked</td>
<td>5.3</td>
<td>5.5</td>
<td>6.3</td>
<td>5.3</td>
</tr>
<tr>
<td>Average Mins in AM before 1st cigarette</td>
<td>94.4</td>
<td>73.6</td>
<td>64.5</td>
<td>89.0</td>
</tr>
<tr>
<td>Average # of Quit attempts</td>
<td>3.2</td>
<td>2.9</td>
<td>3.2</td>
<td>2.8</td>
</tr>
<tr>
<td>Baseline % in Preparatory SOC</td>
<td>25%</td>
<td>38%</td>
<td>12.5%</td>
<td>8%</td>
</tr>
<tr>
<td>% with spouse/partner smokes</td>
<td>64%</td>
<td>69%</td>
<td>54%</td>
<td>64%</td>
</tr>
<tr>
<td>Average # of children</td>
<td>0.71</td>
<td>0.89</td>
<td>0.96</td>
<td>0.83</td>
</tr>
<tr>
<td>% on Medicaid</td>
<td>80%</td>
<td>82%</td>
<td>100%</td>
<td>80%</td>
</tr>
<tr>
<td>% of Rural Residence</td>
<td>62%</td>
<td>64%</td>
<td>95.8%</td>
<td>83%</td>
</tr>
</tbody>
</table>
Measuring the effectiveness of the Baby & Me – Tobacco Free Program

**PREGNANCY**quit rate = proportion of pregnant women who have a negative carbon monoxide breath test at the 4th class = 69% (273/393).

**PROGRAM RETENTION**
- pregnancy (1st and 4th session) = 60%
- post-partum (4th class and first test one month) = 89%

F. Lesson Learned

- Never underestimate the power of positive reinforcement.
  - "I could’ve never stayed quit without the program"
  - "You gave me the power to realize that if I can quit smoking and stay quit - I can do anything"

- Program Benefits – mom, baby, and family members: Reduced asthma incidences, colds, less sick days from work and school.

Count the Cost

- One year of diapers for $240 or one day in neonatal $77,000*

* March of Dimes 2003 report
Baby & Me- Tobacco Free Program

Contact Information:
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Tomorrow’s Child
Michigan SIDS

• State’s Title V SIDS and Other Infant Death Program

• Resource for *Back to Sleep* and *Infant Safe Sleep*

• Michigan’s central referral site for grief services related to all infant deaths

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We’ve changed.

Everything we thought we knew about ‘SIDS’ has changed.

1994 - 2008

Profound changes in the landscape.

SIDS cases decreasing but other causes of postneonatal death appear to be increasing. Possible diagnostic shift?
Back to Sleep

• >70% decrease in Michigan SIDS rates
• Attributed in part to Back to Sleep
• Changed our understanding of SIDS and sudden infant death

Evolved from Back to Sleep to Infant Safe Sleep

• Based on AAP 2005 Policy Statement
• Sleep practices and smoking are the major modifiable risk factors for SIDS and sudden unexpected infant death (SUID)
• Michigan response was to initiate Infant Safe Sleep efforts
• Message also address smoking

AAP Recommendations
Policy Statement, 2005

• Back sleep for every sleep
• Separate but proximate sleeping environment
• Firm crib mattress, tight fitting sheet, no pillows, soft objects or loose bedding
• Do not smoke during pregnancy
• Avoid overheating
• Pacifier may be protective
• Babies should be placed on backs in hospital
• Encourage “tummy time” when infant is awake and observed

AMERICAN ACADEMY OF PEDIATRICS POLICY STATEMENT
The Changing Concept of Sudden Infant Death Syndrome: Diagnostic Coding Shifts, Controversies Regarding the Sleeping Environment, and New Variables to Consider in Reducing Risk. PEDIATRICS Vol. 116 No. 5 November 2005
AAP 2005 Policy Statement
Smoking and SIDS

Maternal smoking during pregnancy has emerged as a major risk factor in almost every epidemiologic study of SIDS. Smoke in the infant's environment after birth has emerged as a separate risk factor in a few studies, although separating this variable from maternal smoking before birth is problematic. Avoiding an infant's exposure to second-hand smoke is advisable for numerous reasons in addition to SIDS risk.

Smoking, Pregnancy Loss and Infant Death

Higher Rates of:
- Premature delivery
- Low-birth-weight infants
- Pregnancy complications
- Stillbirth
- SIDS

Smoking and Pregnancy Loss

Influence of maternal smoking habits on the risk of subsequent stillbirth: Is there a causal relation?

The result supports that maternal smoking during pregnancy is causally associated with stillbirth risk. Smoking is a preventable cause of stillbirth, and smoking interventions is an important issue in antenatal care.

Smoking and SIDS Risk

Exposure to tobacco smoke is a major risk factor for the sudden infant death syndrome.


Smoking and SIDS Risk

Maternal cigarette smoking and prenatal nicotine exposure increase the risk for sudden infant death syndrome (SIDS) by 2- to 4-fold, yet despite adverse publicity, nearly one of four pregnant women smoke tobacco.


Smoking Increases Risk

Maternal smoking during pregnancy is associated with a significantly increased risk of SIDS.

Investigated the effect of maternal smoking during pregnancy on the relative risk of sudden infant death syndrome (SIDS) by linking data from Georgia birth and death certificates from 1997 to 2000. We estimated the effect of misclassifying smokers as non-smokers and the effect of being misclassified on SIDS rates, and we calculated the fraction of cases caused by exposure. Of all SIDS cases, 21% were attributable to maternal smoking; among smokers, 61% of SIDS cases were attributable to maternal smoking.

Smoking and SIDS in the Back to Sleep era

Background: Parental smoking and prone sleep positioning are recognized causal features of Sudden Infant Death. This study quantifies the relationship between prenatal smoking and infant death over the time period of the Back to Sleep campaign in the United States, which encouraged parents to use a supine sleeping position for infants.

Conclusions: Due to a decreased overall rate of SIDS likely due to changing infant sleep position, the attributed risk associating maternal smoking and SIDS has increased following the Back to Sleep campaign. Mothers should be informed of the 2-fold increased rate of SIDS associated with maternal cigarette consumption.


Bedsharing and Maternal Smoking

The recognition of prone sleeping and maternal smoking as modifiable risk factors for Sudden Infant Death Syndrome (SIDS), has drastically decreased SIDS incidence. However, during the last years other factors have become necessary to consider to further reduce the risk of SIDS. Side sleeping implies a greater risk than supine sleeping but is still common. Bed sharing may increase the risk of SIDS while use of a pacifier seems to be protective. Replacement of maternal smoking with nicotine substitutes is not harmless.

Conclusion: To further reduce the risk of SIDS, exclusive supine sleeping should be encouraged and side sleeping discouraged. Bed sharing can increase the risk of SIDS if the infant is below 2-3 months of age, especially if the mother is a smoker. Any nicotine use should be avoided during pregnancy and breast-feeding.


Environmental tobacco smoke

The aims of this review are (a) to critically examine the epidemiologic evidence for a possible association between smoking and the sudden infant death syndrome (SIDS), (b) to review the pathology and postulated physiological mechanisms by which smoking might be directly related to SIDS, and (c) to provide recommendations for SIDS prevention in relation to tobacco smoking. Over 60 studies have examined the relation between maternal smoking during pregnancy and risk of SIDS.

Epidemiologically, to distinguish the effect of active maternal smoking during pregnancy from involuntary tobacco smoke by the infants of smoking mothers is difficult. Clear evidence for the causal effect of maternal tobacco smoke exposure can be obtained by examining the risk of SIDS from paternal smoking when the mother is a non-smoker. Seven such studies have been carried out. Consideration of the pathological and physiological effects of tobacco suggests that the predominant effect from maternal smoking comes from the in utero exposure of the fetus to tobacco smoke, while the exposure of the mother is of secondary importance. Further studies are needed to determine the role of maternal smoking in the etiology of SIDS deaths that might have been prevented if all fetuses had not been exposed to maternal smoking in utero.

Researchers have established prenatal maternal smoking as a major preventable risk for SIDS. Evidence indicates that exposure of infants to secondhand smoke from postpartum maternal smoking has a significant additive effect on risk if the mother smoked during pregnancy. In studies that accounted for maternal smoking during pregnancy, evidence indicates that postpartum maternal smoking, particularly proximity to the infant, significantly increases the risk of SIDS. In addition, epidemiologic evidence indicates that potential exposure of infants to secondhand smoke from fathers or other live-in smokers can also contribute to the risk of SIDS. The full range of biologic and epidemiologic data are consistent and indicate that exposure of infants to secondhand smoke causes SIDS.

The evidence is sufficient to infer a causal relationship between exposure to secondhand smoke and sudden infant death syndrome.

Various risk factors have been postulated to be related to sudden infant death syndrome (SIDS). Despite its reduction, thanks to the “Back to Sleep” campaign, SIDS is still a major cause of infant mortality in the first year of life. The purpose of this study was to correlate the different risk factors with the autopsy results and thus to determine if one or more of those variables is really specific for SIDS. We collected 728 sudden infant death victims with clinical diagnosis of SIDS and performed a complete autopsy with in-depth histology on serial sections, particularly of the brainstem, in accordance with our necropsy protocol. Histopathologic and immunohistochemical examination of the central autonomic nervous system revealed, in 78 cases of the SIDS group, the following anomalies: hypodevelopment of the arcuate nucleus, somatostatin positive hypoglossus nucleus, tyrosine hydroxylase negativity in the locus coeruleus, gliosis, and hypoplasia of the hypoglossus nucleus. A significant relation was found between maternal smoke and brainstem alterations.


"Since the advocacy of 'back to sleep position,' smoking during pregnancy has become the principal risk factor for SIDS."

The study suggests that exposure to cigarette smoke in the womb causes altered respiratory responses in early infancy to thermal stress (primarily overheating from too high temperatures or too much clothing) and hypoxia (low oxygen), which can occur when infants are put to sleep belly down, thus raising the risk of SIDS.

So what are the implications for risk reduction strategies?

To assess the change of risk factors that are specific to sudden infant death syndrome (SIDS) after the initialization of a campaign to reduce the risk (RTR) of SIDS compared to non-SIDS postneonatal deaths.

Conclusions: Maternal smoking during pregnancy remains the most important modifiable risk factor for SIDS in the post-campaign period in comparison with non-SIDS postneonatal deaths. Other than putting babies in a supine sleeping position, maternal smoking should be the next most important issue to be considered...


Partnership and Collaboration

Incorporating the safe sleep and no smoking messages across systems

- Private and public sector
- SIDS/SUID programs
- Infant mortality initiatives
- Tobacco cessation
- Women’s health
- Others

National SIDS/ID Centers

Funded by MCHB

Four National Centers are your resource:

- National Sudden Infant Death Resource Center
- National SIDS/ID Project IMPACT
- National SIDS/ID Program Support Center
- National SIDS/ID Center for Cultural Competence
**National Sudden Infant Death Resource Center**

The National Sudden Infant Death Resource Center (NSIDRC) serves as a central source of information on sudden infant death and on promoting healthy outcomes for infants from the prenatal period through the first year of life and beyond.

Website: [www.sidscenter.org](http://www.sidscenter.org)

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**National SIDS & Infant Death Project IMPACT**

*IMPACT = Infant Mortality Policy and Communication Tools*

The National SIDS & Infant Death Project IMPACT supports state and local infant death programs through sharing information, promoting policy and legislative changes, building upon resources, and fostering partnerships and communication.

Website: [www.sidsprojectimpact.com](http://www.sidsprojectimpact.com)

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**National SIDS & Infant Death Program Support Center**

Promotes development of community-based services for bereavement support and risk reduction and provides a bilingual crisis counseling helpline for families.

Website: [www.firstcandle.org](http://www.firstcandle.org)
National SIDS/ID Center for Cultural Competence

Increase the capacity of SIDS/ID programs and organizations to incorporate cultural and linguistic competence into their services and supports, materials and training efforts and community engagement.

Website: www11.georgetown.edu/research/gucchd/nccc/projects/sids

Tomorrow’s Child/Michigan SIDS

Contact Information:

Website: www.tomrowschildmi.org or www.tcmisids.org
Email: sfrank@tcmisids.org
Phone: 1-800-331-7437

Questions???
Thank you for your participation!

Please take a moment to submit the online evaluation form for this session. Click on the “Evaluation” link to the left of the slide.