# The Science and Practice of Perinatal Tobacco Use Cessation

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

June 19, 2008

# 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

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# 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**

*SAMHSA (2007). Results from the 2006 National Survey on Drug Use and Health,
**Martin JA, et al. Births, Final Data for 2005. National Vital Statistics Report;56(6). December 5, 2007

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# 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

The Health Consequences of Smoking: A Report of the Surgeon General, 2004.

# Tobacco Use During Pregnancy: Infant Harm

## Causal association

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

Women and Smoking: A Report of the Surgeon General, 2001

# 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

Women and Smoking: A Report of the Surgeon General, 2001

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# 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

Floyd R. et al. Prenatal and Neonatal Medicine; 2001; 6:201-207

# The Best-Practice Intervention: The 5 As

# 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

Fiore MC, Bailey WC, Cohen SJ, et al. *Treating Tobacco Use and Dependence. Clinical Practice Guideline.* Rockville, MD: US Department of Health and Human Services. Public Health Service. June 2000.
Melvin CL, Dolan-Mullen P, Windsor RA, Whiteside HP Jr, Goldenberg RL. Recommended cessation counseling for pregnant women who smoke: a review of the evidence. *Tob Control* 2000;9(suppl III):iii80–iii84.
Mullen PD. Maternal smoking during pregnancy and evidence-based intervention to promote cessation. *Prim Care* 1999;26:577–589.

# 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"***

*Ayadi MF, et al. Public Health Reports. 2006;121(2):120–126
**Ruger, JP. Value in Health. 2008;11(2):191–198

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# 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)

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# 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."

Ginzel KH, et al. Journal of Health Psychology. 2007;12(2):215-224

# 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."

Benowitz N, Dempsey D. Nicotine and Tobacco Research. 2004;6(Suppl 2):S189-202

# 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

# Using the 5 As in Clinical Practice

# 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

Fiore MC, et al. Treating Tobacco Use and Dependence. 2000; DHHS: Rockville, MD

# 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

Fiore MC, et al. Treating Tobacco Use and Dependence. 2000; DHHS: Rockville, MD

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# 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