

Task Force on Research Specific to Pregnant and Lactating Women

Michael F. Greene M.D. FACOG Harvard Medical School August 22, 2017



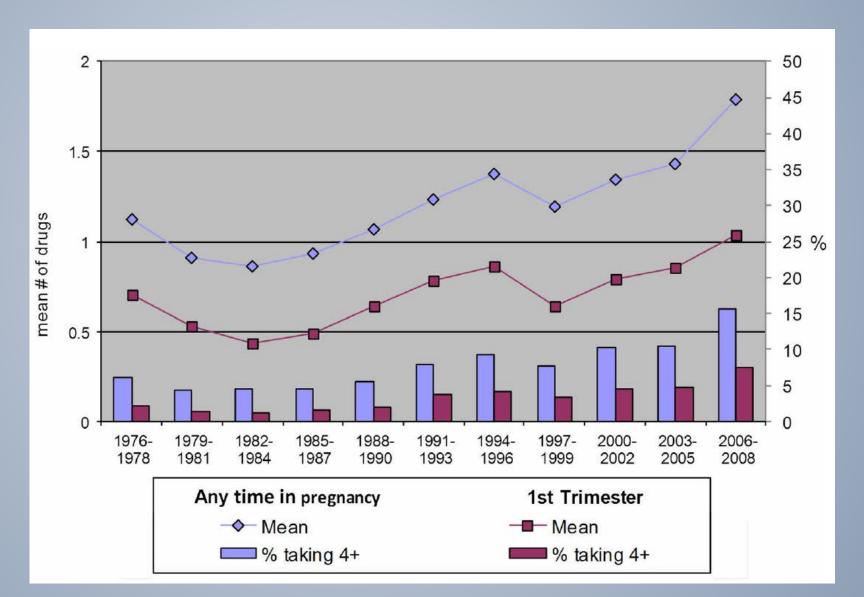
Michael F. Greene Disclosures

- > Associate Editor: New England Journal of Medicine
- > Section Editor: UpToDate
- > Editor: Creasy & Resnik's Maternal Fetal Medicine
- > Editor: deSwiet's Medical Disorders in Obstetric Practice



Medication Use in Pregnancy 1976-2008

Mitchell AJOG 2011;205:51





Prevalence of Drug Use in Pregnancy (World) Wyszynski Obstet Med 2016;9:21

Medication	Anytime	1 st Tri	2 nd Tri	3 rd Tri
Analgesics	56%	38%	44%	36%
Antacids	34%	21%	28%	28%
Nasal Med	16%	11%	13%	11%
Anti-microb	14%	9%	11%	10%
Laxatives	10%	7%	9%	8%





COMMITTEE OPINION SUMMARY

Number 646 • November 2015

(Replaces Committee Opinion No. 307, December 2004 and Committee Opinion No. 377, September 2007)

For a comprehensive overview of these recommendations, the full-text version of this Committee Opinion is available at http://dx.doi. org/10.1097/AOG.000000000001150.



Scan this QR code with your smart phone to view the full-text version of this Committee Opinon.

Committee on Ethics

The American Academy of Pediatrics, American Society for Reproductive Medicine, and Society for Maternal–Fetal Medicine endorse this document. This Committee Opinion was developed by the Committee on Ethics of the American College of Obstetricians and Gynecologists as a service to its members and other practicing clinicians. While this document reflects the current viewpoint of the College, it is not intended to dictate an exclusive course of action in all cases. This Committee Opinion was approved by the Committee on Ethics and the Executive Board of the American College of Obstetricians and Gynecologists.

Ethical Considerations for Including Women as Research Participants



ACOG November 2015

- Pregnant women in research trials should be defined as a "scientifically complex" rather than a "vulnerable" population.
- Maternal and fetal risks are deeply interconnected, and consideration of enrolling pregnant women in research requires balancing the risk of fetal harm with the potential for benefit and the importance of the information to be gained on the health of women and fetuses.



Guidelines for PERINATAL CARE Seventh Edition



Pre-Conception Care

- Family planning and pregnancy spacing
- Immunity and immunization status
- Risk factors for sexually transmitted infections (STIs)
- Substance use, including alcohol, tobacco, and recreational and illicit drugs
- Exposure to violence and intimate partner violence
- · Medical, surgical, and psychiatric histories
- Current medications (prescription and nonprescription)
 - Family history
 - Genetic history (both maternal and paternal)
 - Nutrition
 - Teratogens; environmental and occupational exposures
 - · Assessment of socioeconomic, educational, and cultural context



First trimester counseling (1)

- > Nutrition and weight gain
- > Avoidance of food borne infections; Listeria, Toxoplasmosis
- > Exercise
- > Dental care
- > Nausea & vomiting

Guidelines for Perinatal Care ACOG, AAP 7th Ed 2012



First trimester counseling (2)

- > Vitamin & mineral toxicity including Hg and fish intake
- > Avoidance of teratogens
- > Air travel
- > Prenatal diagnosis

Guidelines for Perinatal Care ACOG, AAP 7th Ed 2012



Conclusions (1)

> Obstetrical healthcare providers (MDs, CNMs, PAs, NPs, RNs) are under constant pressure to provide an increasingly wider array of healthcare services within the context of obstetrical care, while simultaneously holding the line on, or reducing, healthcare expenses.



Conclusions (2)

- Consequences of this expanded definition of routine obstetrical care include:
 - -Rapid expansion of the knowledge base needed to practice obstetrics
 - -Decreasing time available to address each of the elements of care



Conclusions (3)

- > Internet based resource
- > Publicly available
- > Reliable
- > Current
- > Evidence based

