UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA FT. MYERS DIVISION

Jennifer Goodall Plaintiff,))))))))
VS.)) CASE NO
Comprehensive Women's Health Center, Bayfront Medical Health Group; Bayfront Health Port Charlotte; Stephen B. Russell as the State Attorney for Florida's Twentieth Judicial Circuit; John Doe in his or her official capacity as Special Assistant State's Attorney; John and Jane Doe(s), physicians providing obstetric care at Bayfront Health Port Charlotte.)))))))))))))))
Defendants.)

DECLARATION OF DR. HYTHAM IMSEIS

- I, Dr. Hytham Imseis, declare and state as follows:
- 1. I am a Maternal-Fetal Medicine Specialist practicing in Charlotte, North Carolina with board certifications in Maternal-Fetal Medicine and Obstetrics and Gynecology. A maternal-fetal medicine specialist is an obstetrician/gynecologist who has completed 2-3 years of additional formal education and clinical experience within an American Board of Obstetrics and Gynecology (ABOG) approved Maternal-Fetal Medicine Fellowship Program and has special competence in: 1) the diagnosis and treatment of women with

complications of pregnancy; 2) pre-existing medical conditions which may be impacted by pregnancy; and 3) medical conditions which impact the pregnancy itself. A maternal-fetal medicine specialist requires advanced knowledge of the obstetrical, medical, genetic, and surgical complications of pregnancy and their effects on both the mother and fetus. Advanced knowledge of newborn adaptation is also necessary to ensure a continuum of excellence in care from the fetal to newborn periods.

- 2. I am licensed to practice medicine in Ohio and North Carolina. I participate in medical education programs for Obstetricians and Gynecologists across the United States. My research has been published in the *American Journal of Obstetrics and Gynecology* and in *Obstetrics and Gynecology* and I currently review manuscripts for publication in both the *American Journal of Obstetrics and Gynecology* and *Ultrasound in Obstetrics and Gynecology*.
- 3. I previously served as the Medical Director of the Mountain Area Perinatal Substance
 Abuse Program and the Mountain Area Health Education Teen Pregnancy Clinic. I
 currently serve on the Women's Executive Board and the Ethics Committee at the
 Novant Health Presbyterian Medical Center in Charlotte, North Carolina, and am on the
 board of National Advocates for Pregnant Women. My Curriculum Vitae is attached as
 Exhibit A.
- 4. After reviewing the letter sent to Jennifer Goodall from Cheryl Tibbett, Chief Financial Officer of Bayfront Health Port Charlotte, I find the letter to be misleading, threatening, and a deliberate effort to abandon the care of Ms. Goodall at 38 weeks' gestational age, the culmination of her pregnancy. Furthermore, the threats in the letter are a direct

- violation of ethical standards that have been set forth by the American College of Obstetricians and Gynecologists (ACOG). This is quite ironic since the letter refers to the physicians' ethical duty while completely violating several ethical standards, as well as the legal obligations of a health care provider as I understand them.
- 5. ACOG addresses trial of labor after one or more cesareans in its Practice Bulletin entitled *Vaginal Birth After Previous Cesarean Delivery*. Am. Coll. Obstetricians & Gynecologists, *Vaginal Birth After Previous Cesarean Delivery*, Practice Bulletin No. 115, Aug. 2010, *reaff'd* 2013. (Attached as Exhibit B). Practice Bulletins provide obstetricians and gynecologists with current information on established techniques and clinical management guidelines. They are guidelines for physicians' practice, not mandates on patient behavior. The Practice Bulletin does not require cesarean delivery for women with more than 2 previous cesarean deliveries. The document reports a potential for increased complications with vaginal birth in such patients but also states that data regarding the risk for women undergoing trial of labor after cesarean section with more than two previous cesarean deliveries are limited. While it is appropriate and within the standard of care to recommend cesarean delivery to a patient who has undergone three prior cesarean deliveries, such a history does not categorically preclude a trial of labor.
- 6. In her letter to Jennifer Goodall, Ms. Tibbett lists the potential risks of vaginal delivery after 3 cesarean sections: potential for uterine rupture, potential for massive bleeding, and maternal and/or fetal injury, up to and including fetal death. The letter implies that these risks are unique to vaginal delivery after three cesarean sections. They are

- not. These are simply the risks of vaginal delivery in any woman even one that has never undergone cesarean section. While the magnitude of these risks may be greater after three cesarean deliveries, it is only incrementally greater than that which exists in vaginal birth after two cesarean deliveries. Women with two prior cesarean deliveries are considered appropriate candidates for trial of labor by the ACOG.
- 7. In the letter Ms. Tibbett states "Our organization and physicians have an ethical and professional duty to do what is necessary to promote the best clinical outcomes for you and your unborn child." There is no professional duty to force patients to accede to medical recommendations.
- 8. According to Ms. Tibbett, the ethics committee for Bayfront Health endorsed the threats contained in her letter. These threats are blatantly unethical according to the ACOG Committee on Ethics. In its Committee Opinion entitled *Maternal Decision Making, Ethics, and the Law,* that Committee clearly states that "overriding a woman's autonomous choice, whatever its potential consequences, is neither ethically nor legally justified, given her fundamental rights to bodily integrity." .Comm. on Ethics, Am. Coll. Obstetricians & Gynecologists, *Maternal Decision Making, Ethics, and the Law,* Committee Opinion No. 321, Nov. 2005. (Attached as Exhibit C).
- 9. In her letter, Ms. Tibbett threatens to contact the Department of Children and Family services because Ms. Goodall has expressed a desire for vaginal birth and her physicians do not agree with this decision. She also threatens to seek judicial action in order to forcibly perform a cesarean delivery upon Ms. Goodall. Again, the ACOG Committee on Ethics unequivocally condemns such action:

Pregnant women's autonomous decisions should be respected. Concerns about the impact of maternal decisions on fetal well-being should be discussed in the context of medical evidence and understood within the context of each woman's broad social network, cultural beliefs, and values. In the absence of extraordinary circumstances, circumstances that, in fact, the Committee on Ethics cannot currently imagine, judicial authority should not be used to implement treatment regimens aimed at protecting the fetus, for such actions violate the pregnant woman's autonomy.

Id.

- 10. As Chief Financial Officer, Ms. Tibbett exerts her authority over Ms. Goodall by threatening that "a cesarean section will be performed with or without your consent." Based on the medical training I received, and the training provided to physicians and administrators in my practice, an Officer of a hospital should know that cesarean section performed without consent or legal authority would be considered an assault and battery, and a profound violation of bodily integrity. This threat is not medical advice but rather an admission of an intent to violate the law.
- 11. After making threats against Ms. Goodall if she seeks labor and delivery care at her institution, Ms. Tibbett concludes her letter by encouraging Ms. Goodall to find a physician who will agree to her demand for a vaginal delivery. The letter does not contain a referral. Because it is nearly impossible at such a late gestational age to find alternative care, and this would be known to medical professionals, the health care provider can only be understood to be abandoning this patient's care.
- 12. Where patients reject hospital recommendations the proper thing to do is to document the provision of advice and seek confirmation from the patient that it has been heard and rejected.

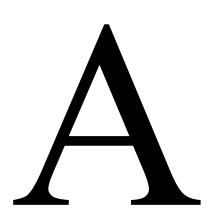
- 13. The type of threats contained in the letter could reasonably be expected to cause severe stress, anxiety, and fear in the recipient. Stress itself poses risk to pregnancy, and pregnant women are generally advised to avoid stress to the extent possible. It is deeply troubling, then, that a medical practice would send a communication so certain to cause enormous stress.
- 14. In conclusion, I find the letter sent to Ms. Goodall to be very threatening and coercive. I am deeply dismayed that a representative of a health care organization would formally threaten to perpetrate unethical behavior against a patient in order to coerce her to comply with a doctors recommendations or to frighten her into leaving the practice. This is simply unprofessional behavior which violates the very essence of health care.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Executed on July 17, 2014

Dr. Hytham Imseis

Exhibit



HYTHAM MANUEL IMSEIS, MD

Curriculum Vitae

OFFICE ADDRESS Presbyterian Maternal and Fetal Medicine Associates

1718 Éast 4th Street

Suite 404

Charlotte, North Carolina 28204-3193

Phone: (704) 384-5701 Fax: (704) 384-5642 Mobile: (704) 621-7601

E-mail: hmimseis@novanthealth.org

HOME ADDRESS 8416 Highgrove Street

Charlotte, North Carolina 28277-2801

Phone: (704) 752-3763 E-mail: imseis@gmail.com

DATE OF BIRTH August 9, 1967

CITIZENSHIP USA

MARITAL STATUS Married

June 3, 1995

SPOUSE Susan Elizabeth (Harrington) Imseis

CHILDREN Allison Brooke Imseis

August 9, 2005

Zachary Harrington Imseis

November 28, 2000

EMPLOYMENT Private Practice

Presbyterian Hospital

Presbyterian Novant Medical Group Maternal & Fetal Medicine Associates

Charlotte, North Carolina August 2007 – present

Maternal-Fetal Medicine Faculty

Mountain Area Health Education Center Department of Obstetrics & Gynecology

Asheville, North Carolina August 1997 – August 2007 Residency Director

Mountain Area Health Education Center Department of Obstetrics & Gynecology

Asheville, North Carolina July 2003 – August 2007

Director of Fetal Ultrasound

Regional OB/GYN Specialists, Mountain Area Health

Education Center and Mission Hospital

Asheville, North Carolina July 1998 – August 2007

APPOINTMENTS

Department of Obstetrics & Gynecology

Wake Forest University School of Medicine

Winston-Salem, North Carolina

Associate Professor June 2009 – present

Department of Obstetrics & Gynecology

University of North Carolina School of Medicine

Chapel Hill, North Carolina

Associate Professor July 1998 – August 2007

EDUCATION

Fellowship Ohio State University College of Medicine

Columbus, Ohio

Fellowship in Maternal-Fetal Medicine

July 1995 – June 1997

Residency Duke University Medical Center

Durham, North Carolina

Residency in Obstetrics and Gynecology

July 1991 – June 1995

Medical School Louisiana State University School of Medicine

New Orleans, Louisiana

Doctor of Medicine

August 1987 - May 1991

Undergraduate Tulane University

New Orleans, Louisiana

Bachelor of Science in Biology

Summa cum laude with Departmental Honors

August 1984 – May 1987

HONORS and AWARDS

Postgraduate

Outstanding Faculty Teaching Award — 2006
Department of Family Medicine

National Faculty Award for Excellence in Resident Education — 2005 Council on Resident Education in Obstetrics & Gynecology (CREOG)

APGO/Solvay Educational Scholar — 2003 American Professors of Gynecology & Obstetrics (APGO)

National Faculty Award for Excellence in Resident Education — 2002 Council on Resident Education in Obstetrics & Gynecology (CREOG)

ACOG District IV Special Projects Award — 2000
Grant for the prospective randomized study of pelvic muscle exercises following parturition utilizing neurophysiologic and kinesiologic evaluation (Co-investigator)

Outstanding Faculty Teaching Award — 1999
Department of Obstetrics & Gynecology

Outstanding Faculty Teaching Award — 1999
Department of Family Medicine

Excellence in Teaching Award — 1998
American Professors of Gynecology & Obstetrics (APGO)

Fellowship

Young Investigator Travel Award — 1996 International Society for the Study of Hypertension in Pregnancy

Bremer Foundation Grant — 1995 Grant for the study of the microbiologic effect of digital cervical examination (Primary investigator)

Residency Administrative Chief Resident
Residency Entertainment Director

Medical School Alpha Omega Alpha

Undergraduate Phi Beta Kappa

Deans' Honor Scholarship

COMMITTEES

Women's Executive Board Presbyterian Hospital Charlotte, North Carolina Member March 2010 – present

Ethics Committee
Presbyterian Hospital
Charlotte, North Carolina
Member
February 2010 – present

Committee for Obstetrical Care of the Underserved Population Presbyterian Hospital Charlotte, North Carolina Member August 2008 – present

North Carolina 17-P Advisory Board University of North Carolina Center for Maternal & Infant Health Member June 2006 – August 2007

Ethics Steering Committee Mission Health System Asheville, North Carolina Member January 2006 – August 2007

Ethics Committee
Mission Health System
Asheville, North Carolina
Member
December 2004 – August 2007

Fetal Alcohol Identification and Treatment Team
The Fullerton Genetics Center
Mission Health System
Asheville, North Carolina
Member
November 2004 – November 2005

Institutional Review Board Mission Health System Asheville, North Carolina Chairman April 2003 – August 2007

Institutional Review Board Mission Health System Asheville, North Carolina Member October 2000 – April 2003

Curriculum Committee
Mountain Area Health Education Center
Obstetrics & Gynecology Residency Program
Asheville, North Carolina
Member
July 1998 – August 2007

Resident Progress & Evaluation Committee Mountain Area Health Education Center Obstetrics & Gynecology Residency Program Asheville, North Carolina Member July 1998 – June 2003

Birth Spectrum of Care: Prematurity Prevention Program
Perinatal Management Committee
Mission St. Joseph's Health System
Asheville, North Carolina
Physician Co-Chair
January 1998 – December 2002

Antepartum Collaborative Practice Team Mission St. Joseph's Health System Asheville, North Carolina Member July 1997 – August 2007

PROFESSIONAL SERVICE

CREOG & APGO Annual Meeting Oral Abstract Judge March 2006

CREOG & APGO Annual Meeting Poster Judge March 2005

Centers for Disease Control and Prevention National Center for Chronic Disease Prevention & Health Promotion

Office of Extramural Research

Special Emphasis Panel for Program Announcement RFA DP05-010 Reproductive Health Research: Preterm Delivery

Panelist/Grant Reviewer Atlanta, Georgia January 2005

Diagnostic Medical Sonography Program
Asheville-Buncombe Technical Community College
Obstetrical Advisor
Asheville, North Carolina
September 2004 – August 2007

Pregnancy Exposure Riskline
North Carolina Teratogen Information Service
The Fullerton Genetics Center
Mission Health System
Medical Advisor
Asheville, North Carolina
August 2003 – August 2007

SEMINARS ORGANIZED

Risk Reduction and Patient Safety in Obstetrics
Course Director
Postgraduate Course
American College of Obstetricians and Gynecologists
57th Annual Clinical Meeting
May 2009

OB/GYN Update on Genetics Course Director Presbyterian Hospital March 2009

Risk Reduction in Obstetrics
Course Director
Presbyterian Hospital
November 2008

Risk Reduction in Obstetrics
Course Director
Postgraduate Course
American College of Obstetricians and Gynecologists
56th Annual Clinical Meeting
May 2008

Risk Reduction in Obstetrics
Course Director
Postgraduate Course
American College of Obstetricians and Gynecologists
55th Annual Clinical Meeting
May 2007

Methadone Trends and Treatment: Pregnancy and Newborns Course Director Mountain Area Health Education Center November 2006

Challenges in OB/GYN Ultrasound
Course Director
Mountain Area Health Education Center
November 2006

Monthly Multidisciplinary Fetal Board Conference Course Director Memorial Mission Hospital Ongoing

The 9th Annual Teaching Conference in Women's Health Issues
Course Co-Director
Mountain Area Health Education Center
April 2006

Challenges in OB/GYN Ultrasound
Course Director
Mountain Area Health Education Center
October 2002

Western North Carolina Clinical Research Symposium IRB 101: Protection of Human Subjects Course Director Mountain Area Health Education Center October 2001

Fetal Ultrasound Update
Course Director
Mountain Area Health Education Center
March 2001

Fetal Echocardiography and Fetal Anomalies Conference

Course Co-Director Mountain Area Health Education Center May 2000

EDITORIAL CONSULTATION

Editorial Board

Mecklenburg Medical Journal, 2009 – present

Manuscript Reviewer

American Journal of Obstetrics & Gynecology, 1996 – present Ultrasound in Obstetrics and Gynecology, 2008 – present

Abstract Reviewer

24th Annual Meeting of the Society for Maternal-Fetal Medicine — 2003 23rd Annual Meeting of the Society for Maternal-Fetal Medicine — 2002 22nd Annual Meeting of the Society for Maternal-Fetal Medicine — 2001

CERTIFICATION

Board Certified in Maternal-Fetal Medicine — April 12, 2000 Board Certified in Obstetrics and Gynecology — November 20, 1998 National Board of Medical Examiners — January 1992

LICENSURE

No. 97-00291 North Carolina License Issued March 22, 1997 Issued May 12, 1995 Ohio License No. 35-06-8446

PROFESSIONAL MEMBERSHIPS

Society for Maternal-Fetal Medicine, Member American College of Obstetricians and Gynecologists, Fellow International Society of Ultrasound in Obstetrics and Gynecology, Member American Institute of Ultrasound in Medicine, Member Society of Diagnostic Medical Sonography, Member F. Bayard Carter Society of Obstetricians and Gynecologists, Member North Carolina Obstetrical and Gynecological Society, Member Southern Obstetrical and Gynecologic Society, Member Mecklenburg County Medical Society, Member North Carolina Medical Society, Member American Medical Association, Member

PEER-REVIEWED PUBLICATIONS

Imseis H. Galvin S. Faculty and resident preference for two different forms of lecture evaluation American Journal of Obstetrics and Gynecology 2004, 191:1815-21.

Harkness C, Serfas D, Imseis H. L-transposition of the great arteries presenting as severe pre-eclampsia in a twin pregnancy. Obstetrics &

- Gynecology 1999, 94:851.
- **Imseis H**, Trout W, Gabbe S. The microbiologic effect of digital cervical examination. *American Journal of Obstetrics and Gynecology* 1999, 180:578-580.
- **Imseis H,** Murtha A, Alexander K, Barnett B. Spontaneous rupture of a primigravid uterus secondary to placenta percreta: A case report. *The Journal of Reproductive Medicine* 1998, 43:233-236.
- **Imseis H,** lams J. Identifying twin gestations at low risk for preterm birth with a transvaginal sonographic cervical measurement at 24-26 weeks gestation. *American Journal of Obstetrics and Gynecology* 1997, 177:1149-1155.
- **Imseis H,** Zimmerman P, Samuels P, Kniss D. Tumour necrosis factor- α induces cyclooxygenase-2 gene expression in first-trimester trophoblasts: Suppression by glucocorticoids and NSAIDs. *Placenta* 1997, 18:521-526.
- **Imseis H,** Greig P, Livengood C, Shunior E, Durda P, Erikson M. Characterization of the inflammatory cytokines in the vagina during pregnancy, labor, and with bacterial vaginosis. *Journal of the Society for Gynecologic Investigation* 1997, 4: 90-94.
- **Imseis H,** lams J. Glucocorticoid use in patients with preterm premature rupture of the fetal membranes. *Seminars in Perinatology* 1996, 20: 439-50.
- **Imseis H.** Oncogene analysis of the Lucké carcinoma and of early development in *Rana pipiens*. *An Honors Thesis*. Tulane University. May 1987. 71 pp.

ELECTRONIC PUBLICATIONS

- Imseis, H. Editor, *Normal Obstetrics: Preconceptional Care*. APGO Medical Student Educational Objectives, 7th Edition. Association of Professors of Gynecology and Obstetrics (APGO) Web site, http://www.apgo.org/members/index.cfm/cat/for%20educators.htm, May 2003.
- Imseis, H. Editor, *Normal Obstetrics: Antepartum Care*. APGO Medical Student Educational Objectives, 7th Edition. Association of Professors of Gynecology and Obstetrics (APGO) Web site, http://www.apgo.org/members/index.cfm/cat/for%20educators.htm, May 2003.

Jeanty P, **Imseis H**. A case of ultrasonographically detected fetal annular pancreas. <u>www.thefetus.net</u> July 9-23, 1999.

PUBLISHED ABSTRACTS

- Sutherland S, Moran C, Westling W, Gleim G, **Imseis H**, Brannan W. Preterm Prevention Program: Evaluation of a Community Effort Using Propensity Scores. *American Journal of Epidemiology* 2002, 155: S46.
- **Imseis H,** Trout W, Gabbe S. The microbiologic effect of digital cervical examination in patients with ruptured fetal membranes. *American Journal of Obstetrics and Gynecology* 1998, 178: S200.
- **Imseis H,** lams J. Identifying twin gestations at low risk for preterm delivery with a single transvaginal sonographic measurement. *American Journal of Obstetrics and Gynecology* 1997, 176: S6.
- **Imseis H,** Landon M, Smith K, Hissrich S, Gabbe S. The influence of insulin-dependent diabetes and the degree of glycemic control on second trimester triple screen markers. *American Journal of Obstetrics and Gynecology* 1997, 176: S178.
- Greig P, **Imseis H,** Livengood C. Characterization of IL-1 β , IL-6, and TNF- α in the vagina during pregnancy. *Cytokine* 1994, 6: 546.
- **Imseis H,** Mizell M, Ranier J, Hofmann L. 1987. Oncogene analysis of the Lucké carcinoma and of early embryonic development in *Rana pipiens*. *American Zoologist* 1987, 27: 144A.

ORAL PRESENTATIONS

- **Imseis H,** Coulson C, Galvin S. Defining professionalism: I know it when I see it. CREOG & APGO Annual Meeting, Salt Lake City, Utah, March 2007. *Received 2nd place award for best overall oral presentation.*
- Moore R, Imseis H, Galvin S. Data mining: Fishy research. North Carolina Obstetrical and Gynecological Society, Greensboro, North Carolina, May 2006. (Winner of Resident Research Award)
- Imseis H, Citron S, Galvin S. Resident acceptability of a newly implemented 360° peer evaluation process. CREOG & APGO Annual Meeting, Salt Lake City, Utah, March 2005.
- **Imseis H,** lams J. Identifying twin gestations at low risk for preterm delivery with a single transvaginal sonographic measurement. 17th Annual Meeting of the Society of Perinatal Obstetricians, Anaheim, California, January 1997.

- Imseis H, Zimmerman P, Samuels P, Kniss D. Dexamethasone inhibits tumor necrosis factor- α mediated induction of cyclooxygenase-2 in human first-trimester trophoblast cells. 10th World Congress of the International Society for the Study of Hypertension in Pregnancy, Seattle, Washington, August 1996.
- **Imseis H.** Characterization of the inflammatory cytokines in the vagina during pregnancy. North Carolina Obstetrical and Gynecologic Society, Asheville, North Carolina, May 1995.
- **Imseis H.** Oncogene analysis of the Lucké carcinoma and of early development in *Rana pipiens*. American Society of Zoologists, New Orleans, Louisiana, December 1987.

POSTER PRESENTATIONS

- Mitchell M, Galvin S, Major J, Furiguay P, Coulson C, Imseis H. Gastroschisis: A 15-year descriptive study. ACOG District IV Annual Meeting, Orlando, Florida, September 2008.
- Galvin S, Coulson C, **Imseis H.** "Effects of a targeted resident-created study guide on CREOG examination scores. CREOG & APGO Annual Meeting, Orlando, Florida, March 2008.
- Galvin S, Helms E, **Imseis H**, Coulson C. "Appropriate weight gain during pregnancy:" Progress across North Carolina perinatal regions. 7th Annual Women's Health Research Day, Center for Women's Health Research, University of North Carolina, Chapel Hill, April 2006.
- Imseis H, Galvin S, Lawrence H. How well do residency training experiences correlate with those of practicing OB/GYNs? CREOG & APGO Annual Meeting, Orlando, Florida, March 2006.
- **Imseis H**, Galvin S. Faculty and resident preference for two different forms of lecture evaluation. CREOG & APGO Annual Meeting, Lake Buena Vista, Florida, March 2004.
- Theofrastous J , Luck A, **Imseis H**, Coulson C, Galvin S. Randomized Trial of the Impact of Postpartum Biofeedback Therapy on Pelvic Floor Muscle Activity. Annual Meeting of the American Urogynecologic Society, Hollywood, Florida, September 2003.
- Sutherland S, Moran C, Westling W, Gleim G, **Imseis H**, Brannan W. Preterm Prevention Program: Evaluation of a Community Effort Using Propensity Scores. Society for Epidemiologic Research Meeting, Palm Desert, California, June 2002.

- Moran C, **Imseis H**, Brannan W. A community-wide prematurity prevention program. National Perinatal Association Annual Clinical Conference, Charlotte, North Carolina, November 2000.
- Galvin S, Sailer M, Forest A, **Imseis H**. Client improvement and birth outcomes in a perinatal substance abuse program. 11th Annual Meeting of the American Psychological Society, Washington, D. C., June 1999.
- **Imseis H,** Trout W, Gabbe S. The microbiologic effect of digital cervical examination in patients with ruptured fetal membranes. 18th Annual Meeting of the Society of Perinatal Obstetricians, Miami, Florida, February 1998.
- Imseis H, Zimmerman P, Kniss D. Constitutive activation of NF-κB in ED₂₇ trophoblast cells. 44th Annual Meeting of the Society of Gynecologic Investigation, San Diego, California, March 1997.
- **Imseis H,** Landon M, Smith K, Hissrich S, Gabbe S. The influence of insulin-dependent diabetes and the degree of glycemic control on second trimester triple screen markers. 17th Annual Meeting of the Society of Perinatal Obstetricians, Anaheim, California, January 1997.
- Greig P, **Imseis H**, Livengood C, Durda P. Interleukin-8 is present in the vagina during pregnancy with levels that correlate with vaginal neutrophil counts. 1995 Annual Meeting and Symposium of the Infectious Diseases Society for Obstetrics and Gynecology, Traverse City, Michigan, August 1995.
- Greig P, **Imseis H,** Livengood C. Characterization of IL-1 β , IL-6, and TNF- α in the vagina during pregnancy. 2nd International Cytokine Conference, Banff, Alberta, Canada, October 1994.

TEXTBOOK CONTRIBUTIONS

Contributed fetal ultrasound images to *Langman's Medical Embryology*, Ninth Edition. Ed. T. W. Sadler. Lippincott Williams & Wilkins, New York, 2003.

INVITED LECTURES

- Oh @#\$% she's pregnant! Inadvertent medical exposures in pregnancy. Internal Medicine Grand Rounds at Presbyterian Hospital, Charlotte, North Carolina, May 2009.
- Full day review of obstetrical and medical complications of pregnancy.

- ExamPro OB/GYN Board Review Course, Baltimore, Maryland, May 2009.
- The practice of obstetrics in a risk-averse culture. Postgraduate course entitled "Risk Reduction and Patient Safety in Obstetrics," American College of Obstetricians and Gynecologists Annual Clinical Meeting, Chicago, Illinois, May 2009.
- Shoulder dystocia. Postgraduate course entitled "Risk Reduction and Patient Safety in Obstetrics," American College of Obstetricians and Gynecologists Annual Clinical Meeting, Chicago, Illinois, May 2009.
- Operative vaginal delivery. Postgraduate course entitled "Risk Reduction and Patient Safety in Obstetrics," American College of Obstetricians and Gynecologists Annual Clinical Meeting, Chicago, Illinois, May 2009.
- A womb with a view! Let's look inside. Obstetrical ultrasound. Annual OB/GYN Update, Presbyterian Hospital, Charlotte, North Carolina, March 2009.
- The practice of obstetrics in a risk-averse culture. Annual OB/GYN Update, Presbyterian Hospital, Charlotte, North Carolina, March 2009.
- Opiate dependence and addiction in pregnancy. OB/GYN Grand Rounds at Presbyterian Hospital, Charlotte, North Carolina, February 2009.
- Psychiatric drugs in pregnancy: What do we do about SSRI's? 4th Annual Maternal-Neonatal Symposium. Annual OB/GYN Update. Charlotte Area Health Education Center, Charlotte, North Carolina, December 2008.
- *Diabetes in pregnancy.* America's OB/GYN Board Review Course, Charlotte, North Carolina, October 2008.
- *Preconceptional care.* America's OB/GYN Board Review Course, Charlotte, North Carolina, October 2008.
- The antenatal detection of Down syndrome. America's OB/GYN Board Review Course, Charlotte, North Carolina, October 2008.
- The antenatal detection of neural tube defects. America's OB/GYN Board Review Course, Charlotte, North Carolina, October 2008.
- Obstetrical ultrasound. America's OB/GYN Board Review Course, Charlotte, North Carolina, October 2008.
- Diseases, drugs and exposures in pregnancy. 17th Annual Review of Obstetrics and Gynecology, Orlando, Florida, October 2008.

- Cardiac disease in pregnancy. 17th Annual Review of Obstetrics and Gynecology, Orlando, Florida, October 2008.
- Operative vaginal delivery. 17th Annual Review of Obstetrics and Gynecology, Orlando, Florida, October 2008.
- Fetal monitoring: Intrapartum and antepartum fetal evaluation. 17th Annual Review of Obstetrics and Gynecology, Orlando, Florida, October 2008.
- Cardiac disease in pregnancy. Columbus Comprehensive Review, Columbus, Ohio, September 2008.
- Operative vaginal delivery. Columbus Comprehensive Review, Columbus, Ohio, September 2008.
- Shoulder dystocia. Columbus Comprehensive Review, Columbus, Ohio, September 2008.
- Diseases, drugs and exposures in pregnancy. Columbus Comprehensive Review, Columbus, Ohio, September 2008.
- Fetal monitoring: Intrapartum and antepartum fetal evaluation, Columbus Comprehensive Review, Columbus, Ohio, September 2008.
- Opiate dependence and addiction in pregnancy. OB/GYN Grand Rounds at Presbyterian Hospital, Charlotte, North Carolina, September 2008.
- Shoulder dystocia. Perinatal Conference. Health Management Associates Hospital System, Dallas, Texas. September 2008.
- Operative vaginal delivery. Perinatal Conference. Health Management Associates Hospital System, Dallas, Texas. September 2008.
- Is the Cesarean delivery rate excessive? Perinatal Conference. Health Management Associates Hospital System, Dallas, Texas. September 2008.
- Cervical ripening. Perinatal Conference. Health Management Associates Hospital System, Dallas, Texas. September 2008.
- Reducing the risk of intrapartum oxytocin use. Perinatal Conference. Health Management Associates Hospital System, Dallas, Texas. September 2008.
- The evolution of obstetrics in a risk-averse culture. Perinatal Conference. Health Management Associates Hospital System, Dallas, Texas. September 2008.

- Obstetrical emergencies. ExamPro OB/GYN Board Review Course, Baltimore, Maryland, September 2008.
- *Diabetes in pregnancy.* ExamPro OB/GYN Board Review Course, Baltimore, Maryland, September 2008.
- A practical approach to viral infections in pregnancy: CMV, Parvovirus, and Varicella. OB/GYN Grand Rounds at Presbyterian Hospital, Charlotte, North Carolina, September 2008.
- Medical futility in Maternal-Fetal Medicine. Multidisciplinary course entitled Medical Futility: A Kaleidoscope of Ethical Issues, Mountain Area Health Education Center, Asheville, North Carolina, September 2008.
- Maternal and fetal implications of viral infections in pregnancy: CMV, Parvovirus, and Varicella. Pediatric Grand Rounds at Presbyterian Hospital, Charlotte, North Carolina, June 2008.
- Comprehensive Review of Obstetrics. A 6 hour review course conducted at the Lincoln Medical Center Department of Obstetrics and Gynecology, Bronx, New York, June 2008.
- The practice of obstetrics in a risk-averse culture. Postgraduate course entitled "Risk Reduction in Obstetrics," American College of Obstetricians and Gynecologists Annual Clinical Meeting, New Orleans, Louisiana, May 2008.
- Shoulder dystocia. Postgraduate course entitled "Risk Reduction in Obstetrics," American College of Obstetricians and Gynecologists Annual Clinical Meeting, New Orleans, Louisiana, May 2008.
- Operative vaginal delivery. Postgraduate course entitled "Risk Reduction in Obstetrics," American College of Obstetricians and Gynecologists Annual Clinical Meeting, New Orleans, Louisiana, May 2008.
- Psychiatric drugs in pregnancy: What do we do about SSRI's? OB/GYN Grand Rounds at Presbyterian Hospital, Charlotte, North Carolina, February 2008.
- Pitocin Management in the Obstetrical Patient. Grand Rounds at Presbyterian Hospital, Charlotte, North Carolina, October 2007.
- Diseases, drugs and exposures in pregnancy. 16th Annual Review of Obstetrics and Gynecology, Orlando, Florida, October 2007.
- Operative vaginal delivery. 16th Annual Review of Obstetrics and Gynecology, Orlando, Florida, October 2007.

- Fetal monitoring: Intrapartum and antepartum fetal evaluation. 16th Annual Review of Obstetrics and Gynecology, Orlando, Florida, October 2007.
- Diseases, drugs and exposures in pregnancy. Columbus Comprehensive Review, Columbus, Ohio, September 2007.
- Operative vaginal delivery. Columbus Comprehensive Review, Columbus, Ohio, September 2007.
- Cardiac disease in pregnancy. Columbus Comprehensive Review, Columbus, Ohio, September 2007.
- Fetal monitoring: Intrapartum and antepartum fetal evaluation, Columbus Comprehensive Review, Columbus, Ohio, September 2007.
- The practice of obstetrics in a risk-averse culture. Postgraduate course entitled "Risk Reduction in Obstetrics," American College of Obstetricians and Gynecologists Annual Clinical Meeting, San Diego, California, May 2007.
- Shoulder dystocia. Postgraduate course entitled "Risk Reduction in Obstetrics," American College of Obstetricians and Gynecologists Annual Clinical Meeting, San Diego, California, May 2007.
- Operative vaginal delivery. Postgraduate course entitled "Risk Reduction in Obstetrics," American College of Obstetricians and Gynecologists Annual Clinical Meeting, San Diego, California, May 2007.
- A practical approach to viral infections in pregnancy: CMV, Parvovirus, and Varicella. Annual Meeting of the North Carolina Obstetrical and Gynecological Society, Asheville, North Carolina, April 2007.
- Methadone maintenance in pregnancy: The obstetrician's perspective. Course entitled "Methadone Trends and Treatment: Pregnancy and Newborn," Mountain Area Health Education Center, Asheville, North Carolina, November 2006.
- Shoulder dystocia. 15th Annual Review of Obstetrics and Gynecology, Orlando, Florida, October 2006.
- Operative vaginal delivery. 15th Annual Review of Obstetrics and Gynecology, Orlando, Florida, October 2006.
- Diseases, drugs and exposures in pregnancy. 15th Annual Review of Obstetrics and Gynecology, Orlando, Florida, October 2006.

- Opiate dependence and addiction in pregnancy. Annual NICU Clinical Update, Mission Hospitals, Asheville, North Carolina, January, April, July and October 2006.
- Psychiatric drugs in pregnancy: What do we do about SSRI's? Course entitled "Psychiatric Drugs in Pregnancy and Lactation," Pardee Hospital, Hendersonville, North Carolina, October 2006.
- *Diseases, drugs and exposures in pregnancy.* Columbus Comprehensive Review, Columbus, Ohio, October 2006.
- Cardiac disease in pregnancy. Columbus Comprehensive Review, Columbus, Ohio, October 2006.
- Fetal monitoring: Intrapartum and antepartum fetal evaluation. Columbus Comprehensive Review, Columbus, Ohio, October 2006.
- Ethical issues at the beginning of life. 11th Annual Ethics Conference: Applied Clinical Ethics, Mountain Area Health Education Center, Asheville, North Carolina, September 2006.
- The evolution of obstetrics in a risk-averse culture. 2006 Women's Health Symposium: Obstetric Update, Mountain Area Health Education Center, Asheville, North Carolina, March 2006.
- The evolution of obstetrics in a risk-averse culture. 9th Annual Teaching Conference in Women's health Issues, Asheville, North Carolina, March 2006.
- Methamphetamine use and other substance use in pregnancy. 23rd Annual Gravidas at Risk Conference, Wake Forest University School of Medicine, Hickory, North Carolina, November 2005.
- The evolution of obstetrics in a risk-averse culture. Grand Rounds at Transylvania Community Hospital, Brevard, North Carolina, October 2005.
- *Diseases, drugs and exposures in pregnancy.* Columbus Comprehensive Review. Columbus, Ohio, September 2005.
- Fetal monitoring: Intrapartum and antepartum fetal evaluation. Columbus Comprehensive Review, Columbus, Ohio, September 2005.
- The ultrasound diagnosis of structural fetal malformations. Annual Meeting of the North Carolina Birth Defects Monitoring Program, Asheville, North Carolina, August 2005.

- Transvaginal ultrasound of the cervix. 24th Annual Ultrasound Symposium of the North Carolina Ultrasound Society, Charlotte, North Carolina, March 2005.
- *IUGR and macrosomia.* 24th Annual Ultrasound Symposium of the North Carolina Ultrasound Society, Charlotte, North Carolina, March 2005.
- Methamphetamine use in pregnancy. Symposium entitled "Methamphetamines: What You Need to Know," Mountain Area Health Education Center, Asheville, North Carolina, March 2005.
- The prevention of preterm birth: Separating myths from reality. Grand Rounds at the Spruce Pine Community Hospital, Brevard, North Carolina, December 2004.
- *Diseases, drugs and exposures in pregnancy.* Columbus Comprehensive Review, Columbus, Ohio, October 2004.
- Fetal monitoring: Intrapartum and antepartum fetal evaluation. Columbus Comprehensive Review, Columbus, Ohio, October 2004.
- Transvaginal ultrasound of the cervix. Society of Diagnostic Medical Sonography Annual Conference. New Orleans, Louisiana, October 2004.
- IUGR and macrosomia. Society of Diagnostic Medical Sonography Annual Conference, New Orleans, Louisiana, October 2004.
- The clinical science of fetal alcohol spectrum disorders. Panelist at UNC Bowles Center for Alcohol Studies Second Annual Symposium: Fetal Alcohol Spectrum Disorders—Research to Practice, Chapel Hill, North Carolina, September 2004.
- The prevention of preterm birth: Separating myths from reality. Grand Rounds at the Transylvania Community Hospital, Brevard, North Carolina, June 2004.
- Caring for mothers (and fetuses) when a tragic fetal prognosis is identified on ultrasound regardless of whether the mother keeps or ends the pregnancy. Panelist at a program entitled "Perinatal Hospice," Mission St. Joseph's Health System, May 2004.
- The prevention of preterm birth: Separating myths from reality. Asheville Birth Conference, Asheville, North Carolina, April 2004.

- Personifying the fetus: Why fetal and maternal rights are now in conflict. Asheville Chapter of the National Organization for Women meeting, Asheville North Carolina, March 2004.
- Fetal complications in twin gestations. Course entitled "Year 2004 Obstetrics Update: Caring for Multiple Birth Families," Mountain Area Health Education Center, Asheville, North Carolina, March 2004.
- Ultrasound-guided invasive procedures: CVS, Amniocentesis and PUBS. Grand Rounds at Harris Regional Hospital, Sylva, North Carolina, October 2003.
- Drugs in pregnancy & lactation: Psychiatric medications and drugs of abuse. Two hour lecture track at the 16th Annual Addiction: Focus on Women Conference, Hendersonville, North Carolina, June 2002.
- The detection of Down syndrome with ultrasound. Symposium entitled "Birth Defects: The Western North Carolina Experience," Asheville, North Carolina, May 2002.
- The prenatal detection of cleft lip and palate. Symposium entitled "Birth Defects: The Western North Carolina Experience," Asheville, North Carolina, May 2002.
- A practical approach to viral infections in pregnancy: CMV, Parvovirus, and Varicella Piedmont OB/GYN Society, Hickory, North Carolina, April 2002.
- Drugs in pregnancy & lactation: Drugs of abuse & drugs for psychiatric diagnoses. Four hour lecture track at the North Carolina Winter School for Alcohol and Drug Studies, Montreat, North Carolina, February 2002.
 - Science and the art of childbirth Asheville Birth Conference, Asheville, North Carolina, January 2002.
- How medicine & medical care are co-opted by fetal rights. Lecturer and panelist at Maternal-State Conflicts: Claims of Fetal Rights & the Wellbeing of Women & Families, Mt. Sinai Hospital, New York, New York, January 2002.
- Maternal-fetal conflict: Ethical dilemmas in the care of pregnant women. Guest lecture in Medical Ethics course (Philosophy 309), University of North Carolina, Asheville, North Carolina, October 2001.
- Psychiatric drugs and abused drugs in pregnancy. Substance Abuse Professional Quarterly Meeting, Blue Ridge Mental Health Center, Asheville, North Carolina, October 2001.

- A practical approach to viral infections in pregnancy: CMV, Parvovirus, and Varicella. 5th Annual Meeting of the Lawrence Society of Obstetricians and Gynecologists, Asheville, North Carolina, September 2001.
- A practical approach to viral infections in pregnancy: CMV, Parvovirus, and Varicella. 50th Annual Meeting of the F. Bayard Carter Society of Obstetricians and Gynecologists, Durham, North Carolina, November 2000.
- IUGR: Are we overcalling the diagnosis? Luncheon conference at the 48th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, San Francisco, California, May 2000.
- Preterm labor: Prediction and prevention. Luncheon conference at the 48th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists, San Francisco, California, May 2000.
- Substance abuse and pregnancy Annual Meeting of the Western North Carolina Public Health Association, Asheville, North Carolina, May 2000.
- Depression and anxiety in pregnancy. Annual Meeting of the Western North Carolina Public Health Association, Asheville, North Carolina, May 2000.
- Ultrasound evaluation of fetal renal abnormalities. Course entitled "Fetal Echocardiography and Fetal Anomalies Conference," Mountain Area Health Education Center, Asheville, North Carolina, May 2000.
- Intrauterine growth restriction: Using the newest tools for fetal assessment. Course entitled "Fetal Echocardiography and Fetal Anomalies Conference," Mountain Area Health Education Center, Asheville, North Carolina, May 2000.
- Substance abuse and pregnancy. Three hour lecture track at the 13th Annual Addiction: Focus on Women Conference, Hendersonville, North Carolina, June 1999.
- Fetal fibronectin and salivary estriol. 1999 Annual Meeting of the North Carolina Obstetrical and Gynecologic Society, Asheville, North Carolina, May 1999.
- The clinical utility of transvaginal ultrasound of the cervix. 44th Annual Meeting of the Southern Obstetrical and Gynecological Society, Asheville, North Carolina, July 1998.
- Maternal cardiac disease in pregnancy. Course entitled "Care of the Critically III Obstetric Patient," Memorial Mission Hospital, Asheville, North

- Carolina, May 1998.
- The prevention of preterm premature rupture of membranes. Grand Rounds at Rutherford Hospital, Rutherfordton, North Carolina, November 1997.
- The role of the cervix in preterm delivery. MAHEC Department of Obstetrics and Gynecology First Annual Teaching Conference on Women's Health Issues, Cashiers, North Carolina, September 1997.
- Sonographic features of aneuploidy. Grand Rounds at Mount Carmel Medical Center, Department of Obstetrics and Gynecology, Columbus, Ohio, June 1997.
- The prevention of preterm premature rupture of membranes. Grand Rounds at Union Hospital, Terre Haute, Indiana, May 1997.
- Sexual activity during pregnancy. Grand Rounds at Ohio State University College of Medicine, Department of Obstetrics and Gynecology, Columbus, Ohio, April 1997.
- Glucocorticoid use in preterm premature rupture of the fetal membranes. Grand Rounds at Ohio State University College of Medicine, Department of Obstetrics and Gynecology, Columbus, Ohio, June 1996.
- Thromboembolic disease in pregnancy. Grand rounds at Duke University Medical Center, Department of Obstetrics and Gynecology, Durham, North Carolina, April 1995.

Exhibit

CLINICAL MANAGEMENT GUIDELINES FOR OBSTETRICIAN—GYNECOLOGISTS

Number 115, August 2010

(Replaces Practice Bulletin Number 54, July 2004 and Committee Opinion Number 342, August 2006) REAFFIRMED 2013

Vaginal Birth After Previous Cesarean Delivery

Trial of labor after previous cesarean delivery (TOLAC)* provides women who desire a vaginal delivery with the possibility of achieving that goal—a vaginal birth after cesarean delivery (VBAC)†. In addition to fulfilling a patient's preference for vaginal delivery, at an individual level VBAC is associated with decreased maternal morbidity and a decreased risk of complications in future pregnancies. At a population level, VBAC also is associated with a decrease in the overall cesarean delivery rate (1, 2). Although TOLAC is appropriate for many women with a history of a cesarean delivery, several factors increase the likelihood of a failed trial of labor, which compared with VBAC, is associated with increased maternal and perinatal morbidity (3–5). Assessment of individual risks and the likelihood of VBAC is, therefore, important in determining who are appropriate candidates for TOLAC. The purpose of this document is to review the risks and benefits of TOLAC in various clinical situations and provide practical guidelines for managing and counseling patients who will give birth after a previous cesarean delivery.

Background

Between 1970 and 2007, the cesarean delivery rate in the United States increased dramatically from 5% to more than 31% (6, 7). This increase was a result of several changes in the practice environment, including the introduction of electronic fetal monitoring and the decrease in use of vaginal breech deliveries and forceps deliveries (8–10). The increase in cesarean delivery rates was partly perpetuated by the dictum "once a cesarean always a cesarean" (11). In the 1970s, however, some began to reconsider this paradigm, and accumulated data have since supported TOLAC as a reasonable approach in selected pregnancies (4, 5, 12–14).

This change in approach and recommendations favoring TOLAC was reflected in increased VBAC rates (VBAC per 100 women with a prior cesarean delivery) from just more than 5% in 1985 to 28.3% by 1996. The overall cesarean delivery rate decreased to approximately 20% by 1996 (15). Yet, as the number of women pursuing TOLAC increased, so did the number of reports of uterine rupture and other complications during TOLAC (16–18). In part, these reports, and the professional liability pressures they engendered, have resulted in a reversal of VBAC and cesarean delivery trends. By 2006, the VBAC rate had decreased to 8.5% and the total cesarean delivery rate had increased to 31.1% (15, 19, 20). In some hospitals, TOLAC is no longer offered.

Committee on Practice Bulletins—Obstetrics. This Practice Bulletin was developed by the Committee on Practice Bulletins—Obstetrics with the assistance of William Grobman, MD, and Jeffrey Ecker, MD. The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

^{*}The term *trial of labor* refers to a trial of labor in women who have had a previous cesarean delivery, regardless of the outcome.

[†]The term *vaginal birth after cesarean delivery* is used to denote a vaginal delivery after a trial of labor.

In a 2010 consensus conference, the National Institutes of Health (NIH) examined the safety and outcome of TOLAC and VBAC and factors associated with decreasing rates. The NIH panel recognized that TOLAC was a reasonable option for many women with a prior cesarean delivery (21) and called on organizations to facilitate access to TOLAC. In addition, the panel recognized that "concerns over liability have a major impact on the willingness of physicians and healthcare institutions to offer TOL [TOLAC]" (21).

Evaluating the Evidence

Data detailing rates of VBAC after TOLAC and attendant maternal and neonatal outcomes associated with TOLAC versus planned repeat cesarean delivery can guide the health care provider and patient when deciding the approach to delivery in women with a prior cesarean delivery. There are currently no randomized trials comparing maternal or neonatal outcomes between women undertaking TOLAC and those undergoing a repeat cesarean delivery. Instead, recommendations regarding the approach to delivery are based on observational data that have reported the probability of VBAC once TOLAC is attempted, and compared the maternal and neonatal morbidities associated with TOLAC and repeat cesarean delivery (3–5, 12–14, 22–29). These data were summarized in the Evidence Report/ Technology Assessment that provided background for the 2010 NIH Consensus Conference (30).

Before considering the results of any analysis, it is important to note that the appropriate statistical comparison is by intention to deliver (TOLAC versus elective repeat cesarean delivery). Comparing outcomes from VBAC or repeat cesarean delivery after TOLAC with those from a planned repeat cesarean delivery is inappropriate because no one patient can be guaranteed VBAC, and the risks and benefits may be disproportionately associated with a failed TOLAC.

Clinical Considerations and Recommendations

What are the risks and benefits associated with a trial of labor after previous cesarean delivery?

Neither elective repeat cesarean delivery nor TOLAC are without maternal or neonatal risk (see Table 1 and Table 2). The risks of either approach include maternal hemorrhage, infection, operative injury, thromboembolism, hysterectomy, and death (4, 5, 13, 22, 31). Most maternal morbidity that occurs during TOLAC occurs when repeat cesarean delivery becomes necessary (3–5, 23).

Thus, VBAC is associated with fewer complications, and a failed TOLAC is associated with more complications, than elective repeat cesarean delivery (3–5, 22). Consequently, risk for maternal morbidity is integrally related to a woman's probability of achieving VBAC (32).

Uterine rupture or dehiscence* is the outcome associated with TOLAC that most significantly increases the chance of additional maternal and neonatal morbidity. The reported incidence of uterine rupture varies, in part because some studies have grouped true, catastrophic uterine rupture together with asymptomatic scar dehiscence. Additionally, early case series did not stratify rupture rates by the type of prior cesarean incision (ie, low transverse versus classical) (29).

One factor that markedly influences the chance of uterine rupture is the location of the prior incision on the uterus. Several large studies of women with a prior low

Table 1. Composite Maternal Risks from Elective Repeat Cesarean Delivery and Trial of Labor After Previous Cesarean Delivery

Maternal Risks	ERCD (%)	TOLAC (%)	
		One CD	Two or more CDs
Endometritis	1.5-2.1	2.9	3.1
Operative injury	0.426	0.4	0.4
Blood transfusion	1–1.4	0.7-1.7	3.2
Hysterectomy	0-0.4	0.2-0.5	0.6
Uterine rupture	0.4-0.5	0.7-0.9	0.9-1.8
Maternal death	0.02-0.04	0.02	0

Abbreviations: CD, cesarean delivery; ERCD, elective repeat cesarean delivery; TOLAC, trial of labor after cesarean delivery; VBAC, vaginal birth after cesarean.

Data from Landon MB, Hauth JC, Leveno KJ, Spong CY, Leindecker S, Varner MW, et al. Maternal and perinatal outcomes associated with a trial of labor after prior cesarean delivery. National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. N Engl J Med 2004;351:2581–9; Landon MB, Spong CY, Thom E, Hauth JC, Bloom SL, Varner MW, et al. Risk of uterine rupture with a trial of labor in women with multiple and single prior cesarean delivery. National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. Obstet Gynecol 2006;108:12-20; Macones GA, Peipert I, Nelson DB, Odibo A, Stevens EJ, Stamilio DM, et al. Maternal complications with vaginal birth after cesarean delivery: a multicenter study. Am J Obstet Gynecol 2005;193:1656-62; Hibbard JU, Ismail MA, Wang Y, Te C, Karrison T, Ismail MA. Failed vaginal birth after a cesarean section: how risky is it? I. Maternal morbidity. Am | Obstet Gynecol 2001;184:1365-71; and Rossi AC, D'Addario V. Maternal morbidity following a trial of labor after cesarean section vs elective repeat cesarean delivery: a systematic review with metaanalysis. Am | Obstet Gynecol 2008;199:224-31.

^{*}The terms uterine rupture and uterine dehiscence are not consistently defined in the literature so as to distinguish them from each other and are often, seemingly, used interchangeably. Although some connotations may suggest that dehiscence is less morbid than rupture, that convention is not used in this document. In this document these terms refer to symptomatic or clinically significant events unless otherwise noted.

transverse uterine incision reported a clinically determined uterine rupture rate of approximately 0.5–0.9% after TOLAC (4, 5, 12–14, 22). As discussed as follows, the risk of uterine rupture is higher in women with other types of hysterotomies.

In addition to providing an option for those who want the experience of a vaginal birth, VBAC has several potential health advantages for women. Women who achieve VBAC avoid major abdominal surgery, resulting in lower rates of hemorrhage, infection, and a shorter recovery period compared with elective repeat cesarean

Table 2. Composite Neonatal Morbidity from Elective Repeat Cesarean Delivery and Trial of Labor After Previous Cesarean Delivery

Neonatal Risks	ERCD (%)	TOLAC (%)	Comment
Antepartum stillbirth*1			
37–38 weeks	0.08	0.38	
39 weeks or greater	0.01	0.16	
HIE ¹	0-013	0.08	Secondary analysis (Spong, 2007 had three cases of HIE in cesarean delivery group)
Neonatal death ¹	0.05	0.08	Not significant
Perinatal death ²	0.01	0.13	Increase seen due to intrapartum hypoxia
Neonatal admission ³	6.0	6.6	Not significant
Respiratory morbidity ⁴	1–5	0.1–1.8	
Transient tachypnea ⁵	6.2	3.5	
Hyperbilirubinemia ⁵	5.8	2.2	

^{*}Excludes malformations

Abbreviations: ERCD, elective repeat cesarean delivery; HIE, hypoxic ischemic encephalopathy; TOLAC, trial of labor after previous cesarean delivery.

If uterine rupture, risk of HIE 6.2% (95% confidence interval, 1.8–10.6%), risk of neonatal death 1.8% (95% CI, 0–4.2%)

- Landon MB, Hauth JC, Leveno KJ, Spong CY, Leindecker S, Varner MW, et al. Maternal and perinatal outcomes associated with a trial of labor after prior cesarean delivery. National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. N Engl J Med 2004;351:2581–9.
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- Tan PC, Subramaniam RN, Omar SZ. Labour and perinatal outcome in women at term with one previous lower-segment Caesarean: a review of 1000 consecutive cases. Aust N Z J Obstet Gynaecol 2007;47:31–6.
- Signore C, Hemachandra A, Klebanoff M. Neonatal mortality and morbidity after elective cesarean delivery versus routine expectant management: a decision analysis. Semin Perinatol 2006;30:288–95.
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delivery (2, 6, 33). Additionally, for those considering larger families, VBAC may avoid potential future maternal consequences of multiple cesarean deliveries such as hysterectomy, bowel or bladder injury, transfusion, infection (34, 35), and abnormal placentation such as placenta previa and placenta accreta (35, 36).

► What is the vaginal delivery rate in women undergoing a trial of labor after previous cesarean delivery?

Most published series of women attempting TOLAC have demonstrated a probability of VBAC of 60-80% (4, 5, 12-14, 22, 23). However, the chance of VBAC for an individual varies based on demographic and obstetric characteristics (see box). For example, women whose first cesarean delivery was performed for an arrest of labor disorder are less likely than those whose first cesarean delivery was for a nonrecurring indication (eg, breech presentation) to succeed in their attempt at VBAC (37–43). Similarly, there is consistent evidence that women who undergo labor induction or augmentation are less likely to have VBAC when compared with those at the same gestational age with spontaneous labor without augmentation (44–47). Other factors that negatively influence the likelihood of VBAC include increasing maternal age, high body mass index, high birth weight, and advanced gestational age at delivery (44, 48-54). A shorter interdelivery interval and the presence of preeclampsia at the time of delivery also have been associated with a reduced chance of achieving VBAC (55, 56). Conversely, women who have had a prior vaginal delivery are more likely than those who have not to succeed in their TOLAC (44, 57).

Selected Clinical Factors Associated with Trial of Labor After Previous Cesarean Delivery Success

Increased Probability of Success (Strong predictors)

- · Prior vaginal birth
- Spontaneous labor

Decreased Probability of Success (Other predictors)

- Recurrent indication for initial cesarean delivery (labor dystocia)
- Increased maternal age
- Non-white ethnicity
- · Gestational age greater than 40 weeks
- · Maternal obesity
- Preeclampsia
- · Short interpregnancy interval
- · Increased neonatal birth weight

The probability that a woman attempting TOLAC will achieve VBAC depends on her individual combination of factors. Several investigators have attempted to create scoring systems to assist in the prediction of VBAC, but most have had limited success (46, 58–60). However, one model was developed specifically for women undergoing TOLAC at term with one prior low transverse cesarean delivery incision, singleton pregnancy, and cephalic fetal presentation (61). This model may have utility for patient education and counseling for those considering TOLAC at term (http://www.bsc.gwu.edu/mfmu/vagbirth.html).

Who are candidates for a trial of labor after previous cesarean delivery?

Good candidates for planned TOLAC are those women in whom the balance of risks (low as possible) and chances of success (as high as possible) are acceptable to the patient and health care provider. The balance of risks and benefits appropriate for one patient may seem unacceptable for another. Because delivery decisions made during the first pregnancy after a cesarean delivery will likely affect plans in future pregnancies, decisions regarding TOLAC should ideally consider the possibility of future pregnancies.

Although there is no universally agreed on discriminatory point, evidence suggests that women with at least a 60–70% chance of VBAC have equal or less maternal morbidity when they undergo TOLAC than women undergoing elective repeat cesarean delivery (62, 63). Conversely, women who have a lower than 60% probability of VBAC have a greater chance of morbidity than woman undergoing repeat cesarean delivery. Similarly, because neonatal morbidity is higher in the setting of a failed TOLAC than in VBAC, women with higher chances of achieving VBAC have lower risks of neonatal morbidity. One study demonstrated that composite neonatal morbidity is similar between TOLAC and elective repeat cesarean delivery for the women with the greatest probability of achieving VBAC (63).

The preponderance of evidence suggests that most women with one previous cesarean delivery with a low transverse incision are candidates for and should be counseled about VBAC and offered TOLAC. Conversely, those at high risk for complications (eg, those with previous classical or T-incision, prior uterine rupture, or extensive transfundal uterine surgery) and those in whom vaginal delivery is otherwise contraindicated are not generally candidates for planned TOLAC. Individual circumstances must be considered in all cases, and if, for example, a patient who may not otherwise be a candidate for TOLAC presents in advanced labor, the

patient and her health care providers may judge it best to proceed with TOLAC. Some common situations that may modify the balance of risks and benefits are considered as follows.

More Than One Previous Cesarean Delivery

Studies addressing the risks and benefits of TOLAC in women with more than one cesarean delivery have reported a risk of uterine rupture between 0.9% and 3.7%, but have not reached consistent conclusions regarding how this risk compares with women with only one prior uterine incision (64-68). Two large studies, with sufficient size to control for confounding variables, reported on the risks for women with two previous cesarean deliveries undergoing TOLAC (66, 67). One study found no increased risk of uterine rupture (0.9% versus 0.7%) in women with one versus multiple prior cesarean deliveries (66), whereas the other noted a risk of uterine rupture that increased from 0.9% to 1.8% in women with one versus two prior cesarean deliveries (67). Both studies reported some increased risk in morbidity among women with more than one prior cesarean delivery, although the absolute magnitude of the difference in these risks was relatively small (eg, 2.1% versus 3.2% composite major morbidity in one study) (67). Additionally, the chance of achieving VBAC appears to be similar for women with one or more than one cesarean delivery. Given the overall data, it is reasonable to consider women with two previous low transverse cesarean deliveries to be candidates for TOLAC, and to counsel them based on the combination of other factors that affect their probability of achieving a successful VBAC. Data regarding the risk for women undergoing TOLAC with more than two previous cesarean deliveries are limited (69).

Macrosomia

Women undergoing TOLAC with a macrosomic fetus (defined variously as birth weight greater than 4,000-4,500 g) have a lower likelihood of VBAC (50, 70–72) than women attempting TOLAC who have a nonmacrosomic fetus. Similarly, women with a history of past cesarean delivery performed for the indication of dystocia, have a lower likelihood of VBAC if the current birth weight is greater than that of the index pregnancy with dystocia (73). Some limited evidence also suggests that the uterine rupture rate is increased (relative risk 2.3, P<.001) for women undergoing TOLAC without a prior vaginal delivery and neonatal birth weights greater than 4,000 g (72). These studies used actual birth weight as opposed to estimated fetal weight thus limiting the applicability of these data when making decisions regarding mode of delivery antenatally (74). Despite

this limitation, it remains appropriate for health care providers and patients to consider past and predicted birth weights when making decisions regarding TOLAC, but suspected macrosomia alone should not preclude the possibility of TOLAC.

Gestation Beyond 40 Weeks

Studies evaluating the association of gestational age with VBAC outcomes have consistently demonstrated decreased VBAC rates in women who undertake TOLAC beyond 40 weeks of gestation (49, 75–77). Although one study has shown an increased risk of uterine rupture beyond 40 weeks of gestation (76), other studies, including the largest study that has evaluated this factor, have not found this association (77). Although chances of success may be lower in more advanced gestations, gestational age of greater than 40 weeks alone should not preclude TOLAC.

Previous Low Vertical Incision

The limited number of studies that have evaluated TOLAC in women with prior low vertical uterine incisions have reported similar rates of successful vaginal delivery compared with women with a previous low transverse uterine incision (78–81). In addition, there has not been consistent evidence of an increased risk of uterine rupture, or maternal or perinatal morbidity associated with TOLAC in the presence of a prior low vertical scar. Recognizing the limitations of available data, health care providers and patients may choose to proceed with TOLAC in the presence of a documented prior low vertical uterine incision.

Unknown Type of Previous Uterine Incision

The type of uterine incision performed at the time of a prior cesarean delivery cannot be confirmed in some patients. Although some have questioned the safety of offering VBAC under these circumstances, two case series, both from large tertiary care facilities, reported rates of VBAC success and uterine rupture similar to those from other contemporaneous studies of women with documented previous low transverse uterine incisions (82, 83). Additionally, in one study evaluating risk factors for uterine rupture, no significant association was found with the presence of an unknown scar (84). The absence of an association may result from the fact that most cesarean incisions are low transverse, and the uterine scar type can often be inferred based on the indication for the prior cesarean delivery. Therefore, TOLAC is not contraindicated for women with one previous cesarean delivery with an unknown uterine scar type unless there is a high clinical suspicion of a previous classical uterine incision.

Twin Gestation

The studies of women with twin gestations who attempt VBAC have consistently demonstrated that their outcomes are similar to those of women with singleton gestations who attempt VBAC (85–90). In two analyses of large populations, women with twin gestations had a similar chance of achieving VBAC as women with singleton gestations and did not incur any greater risk of uterine rupture or maternal or perinatal morbidity (89, 90). Women with one previous cesarean delivery with a low transverse incision, who are otherwise appropriate candidates for twin vaginal delivery, may be considered candidates for TOLAC.

▶ How does management of labor differ for patients undergoing vaginal birth after cesarean delivery?

Induction and Augmentation of Labor

Induction of labor for maternal or fetal indications remains an option for women undergoing TOLAC. However, the potential increased risk of uterine rupture associated with any induction, and the potential decreased possibility of achieving VBAC, should be discussed. Several studies have noted an increased risk of uterine rupture in the setting of induction of labor in women attempting TOLAC (4, 5, 81, 91–93). One study of 20,095 women who had undergone prior cesarean delivery (81) found a rate of uterine rupture of 0.52% for spontaneous labor, 0.77% for labor induced without prostaglandins, and 2.24% for prostaglandininduced labor. This study was limited by reliance on the International Classification of Diseases, 9th Revision coding for diagnosis of uterine rupture and the inability to determine whether prostaglandin use itself or the context of its use (eg, unfavorable cervix, need for multiple induction agents) was associated with uterine rupture.

In a multicenter study of 33,699 women undergoing TOLAC, augmentation or induction of labor also was associated with an increased risk of uterine rupture compared with spontaneous labor (0.4 % for spontaneous labor, 0.9% for augmented labor, 1.1% for oxytocin alone, and 1.4% for induction with prostaglandins with or without oxytocin) (4). A secondary analysis of 11,778 women from this study with one prior low transverse cesarean delivery showed an increase in uterine rupture only in women undergoing induction who had no prior vaginal delivery (1.5% versus 0.8%, P=.02). Additionally, uterine rupture was no more likely to occur when labor induction was initiated with an unfavorable cervix than with a favorable cervix (91). Another secondary analysis examined the association between maximum oxytocin dose and the risk of uterine rupture (94).

They noted a dose response effect with increasing risk of uterine rupture with higher maximum doses of oxytocin. Because studies have not identified a clear threshold for rupture, an upper limit for oxytocin dosing with TOLAC has not been established.

Studies of the effects of prostaglandins, grouped together as a class of agents, on uterine rupture in women with a prior cesarean delivery have demonstrated inconsistent results. Among three large studies investigating prostaglandins for induction of labor for women with a previous cesarean delivery, one found an increased risk of uterine rupture (81), a second reported no increased rupture risk (4), and a third found no increase risk of rupture when prostaglandins were used alone (with no subsequent oxytocin) (5). Studies of specific prostaglandins are limited in size, but indicate that rupture risk may vary among these agents. Evidence from small studies show that the use of misoprostol (prostaglandin E₁) in women who have had cesarean deliveries is associated with an increased risk of uterine rupture (95-98). Therefore, misoprostol should not be used for third trimester cervical ripening or labor induction in patients who have had a cesarean delivery or major uterine surgery (95–98).

Because data are limited, it is difficult to make definitive recommendations regarding the use of prostaglandin $\rm E_2$. One large study found an increase in uterine rupture only when oxytocin was used after cervical ripening with prostaglandins (5). Therefore, selecting women most likely to give birth vaginally while avoiding sequential use of prostaglandins and oxytocin appears to have the lowest risks of uterine rupture.

Induced labor is less likely to result in VBAC than spontaneous labor (44, 47, 92, 99). There is some evidence that this is the case regardless of whether the cervix is favorable or unfavorable, although an unfavorable cervix decreases the chance of success to the greatest extent (91, 100, 101). These factors may affect patient and health care provider decisions as they consider the risks and benefits of TOLAC associated with labor induction.

The use of oxytocin for augmentation of contractions, separate from induction of labor, during TOLAC has been examined in several studies. Some have found an association between oxytocin augmentation and uterine rupture (4, 93) whereas others have not (5, 102, 103). The varying outcomes of available studies and small absolute magnitude of the risk reported in those studies support that oxytocin augmentation may be used in patients undergoing TOLAC.

Studies on TOLAC outcomes after mechanical cervical ripening and labor induction with a transcervical catheter are retrospective and have relatively small sample sizes. Two studies showed no increase in the risk of uterine rupture (92, 104) whereas another reported an increase compared with women in spontaneous labor (105). Similar to other methods of cervical ripening and labor induction, it is unknown whether any increased risk is due to an unfavorable cervix or the method of ripening. Given the lack of compelling data suggesting increased risk with mechanical dilation and transcervical catheters, such interventions may be an option for TOLAC candidates with an unfavorable cervix.

External Cephalic Version

Limited data regarding external cephalic version for breech presentation in a woman with a prior uterine incision suggest that external cephalic version is not contraindicated if a woman is at low risk of adverse maternal or neonatal outcomes from external cephalic version and TOLAC (106–108). The chances of successful external version have been reported to be similar in women with and without a prior cesarean delivery.

Analgesia

Epidural analgesia for labor may be used as part of TOLAC, and adequate pain relief may encourage more women to choose TOLAC (109, 110). No high quality evidence suggests that epidural analgesia is a causal risk factor for an unsuccessful TOLAC (44, 110, 111). In addition, effective regional analgesia should not be expected to mask signs and symptoms of uterine rupture, particularly because the most common sign of rupture is fetal heart tracing abnormalities (24, 112).

Other Elements of Intrapartum Management

Once labor has begun, a patient with TOLAC should be evaluated by her obstetric provider. Most authorities recommend continuous electronic fetal monitoring. No data suggest that intrauterine pressure catheters or fetal scalp electrodes are superior to external forms of monitoring, and there is evidence that the use of intrauterine pressure catheters does not assist in the diagnosis of uterine rupture (113, 114).

Personnel familiar with the potential complications of TOLAC should be present to watch for fetal heart rate patterns that are associated with uterine rupture. Uterine rupture is often sudden and may be catastrophic, and accurate antenatal predictors of uterine rupture do not exist (115, 116). Acute signs and symptoms of uterine rupture are variable and may include fetal bradycardia, increased uterine contractions, vaginal bleeding, loss of fetal station, or new onset of intense uterine pain (25, 84, 112). However, the most common sign associated with uterine rupture is fetal heart rate abnormality, which has been associated with up to 70% of cases of uterine rup-

tures. This supports the recommendation of continuous fetal heart rate monitoring in labor (25, 29, 84).

Delivery

There is nothing unique about the delivery of the fetus or placenta during VBAC. Manual uterine exploration after VBAC and subsequent repair of asymptomatic scar dehiscence have not been shown to improve outcomes. Excessive vaginal bleeding or signs of hypovolemia are potential signs of uterine rupture and should prompt complete evaluation of the genital tract.

► How should future pregnancies be managed after uterine rupture?

If the site of the ruptured scar is confined to the lower segment of the uterus, the rate of repeat rupture or dehiscence in labor is 6% (117). If the scar includes the upper segment of the uterus, the repeat rupture rate has been reported to be as high as 32% (117, 118). Given both these rates, it is recommended that women who have had a previous uterine rupture should give birth by repeat cesarean delivery before the onset of labor. Because spontaneous labor is unpredictable and could occur before the recommended 39 weeks for an elective delivery, earlier delivery should be contemplated with consideration given to amniocentesis to document fetal lung maturity.

► How should second trimester delivery or delivery of an intrauterine fetal demise be accomplished in women with a previous cesarean delivery?

Some women with a history of a cesarean delivery will require delivery during the second trimester in a subsequent pregnancy. Although published series are relatively small, women with a prior cesarean delivery who undergo labor induction with prostaglandins (including misoprostol) have been shown to have outcomes that are similar to those women with an unscarred uterus (eg, length of time until delivery, failed labor induction, and complication rates) (119–124). The frequency of uterine rupture with labor induction in this setting in most series is less than 1% (125–127). For these women, dilation and evacuation as well as labor induction with prostaglandins are reasonable options (124, 125, 127–129).

In patients after 28 weeks of gestation with an intrauterine fetal demise and a prior cesarean scar, cervical ripening with a transcervical Foley catheter has been associated with uterine rupture rates comparable with spontaneous labor (105) and this may be a helpful

adjunct in patients with an unfavorable cervical examination. Because there are no fetal risks to TOLAC in these circumstances, TOLAC should be encouraged, and after the patient and the health care provider weigh the risks and benefits, TOLAC may even be judged appropriate for women at higher risk for cesarean scar complications (eg, prior classical uterine incision).

► How should women considering a trial of labor after previous cesarean delivery be counseled?

The interest in considering TOLAC varies greatly among women, and this variation is at least partly related to differences in the way individuals value the potential risks and benefits (1, 130–132). Accordingly, potential benefits and risks of both TOLAC and elective repeat cesarean delivery should be discussed and these discussions documented. Discussion should consider individual characteristics that affect the chances of complications associated with VBAC and TOLAC so that a patient can choose her intended route of delivery based on data that is most personally relevant.

A discussion of VBAC early in a woman's prenatal care course, if possible, will allow the most time for her to consider options for TOLAC or elective repeat cesarean delivery. Many of the factors that are related to the chance of VBAC or uterine rupture are known early in pregnancy (60, 61, 116). If the type of previous uterine incision is in doubt, reasonable attempts should be made to obtain the patient's medical records. As the pregnancy progresses, if other circumstances arise that may change the risks or benefits of TOLAC (eg, need for labor induction), these should be addressed. Counseling also may include consideration of intended family size and the risk of additional cesarean deliveries, with the recognition that the future reproductive plans may be uncertain or change.

Counseling should consider the resources available to support women electing TOLAC at their intended delivery site, and whether such resources match those recommended for caring for women electing TOLAC (discussed and detailed in the next section). Available data support that TOLAC may be safely undertaken in both university and community hospitals and facilities with and without residency programs (5, 23, 26, 27, 133).

After counseling, the ultimate decision to undergo TOLAC or a repeat cesarean delivery should be made by the patient in consultation with her health care provider. Global mandates for TOLAC are inappropriate because individual risk factors are not considered. Documentation of counseling and the management plan should be included in the medical record.

▶ What resources are recommended for health care providers and facilities offering a trial of labor after previous cesarean delivery?

Trial of labor after previous cesarean delivery should be undertaken at facilities capable of emergency deliveries. The American College of Obstetricians and Gynecologists (the College) and international guidelines have recommended that resources for emergency cesarean delivery should be "immediately available." Some have argued that this stipulation and the difficulty in providing required resources—especially in smaller centers with lower delivery volumes—limit women's access to TOLAC. This may be particularly true in rural areas where the option to travel to larger centers is difficult.

Restricting access was not the intention of the College's past recommendation. Much of the data concerning the safety of TOLAC was obtained from centers capable of performing immediate, emergency cesarean delivery. Although there is reason to think that more rapid availability of cesarean delivery may provide a small incremental benefit in safety, comparative data examining in detail the effect of alternate systems and response times are not available (134).

Because of the risks associated with TOLAC and that uterine rupture and other complications may be unpredictable, the College recommends that TOLAC be undertaken in facilities with staff immediately available to provide emergency care. When resources for immediate cesarean delivery are not available, the College recommends that health care providers and patients considering TOLAC discuss the hospital's resources and availability of obstetric, pediatric, anesthetic, and operating room staffs. These recommendations are concordant with those of other professional societies (135, 136). The decision to offer and pursue TOLAC in a setting in which the option of immediate cesarean delivery is more limited should be carefully considered by patients and their health care providers. In such situations the best alternative may be to refer patients to a facility with available resources. Another alternative is to create regional centers where patients interested in TOLAC can be readily referred and needed resources can be more efficiently and economically organized. Health care providers and insurance carriers should do all they can to facilitate transfer of care or comanagement in support of a desired TOLAC, and such plans should be initiated early in the course of antenatal care. However, in areas with fewer deliveries and greater distances between delivery sites, organizing transfers or accessing referral centers may be untenable. Respect for patient autonomy supports the concept that patients should be allowed to accept increased levels of risk, however, patients should be clearly informed of such potential increase in risk and management alternatives. Evaluation of a patient's individual chance of VBAC and risk for uterine rupture are central to these considerations. Such conversations and decisions should be documented, including reference to site-specific resources and anticipated risks. Referral also may be appropriate if, after discussion, health care providers find themselves uncomfortable with choices patients have made. Importantly, however, none of the principles, options, or processes outlined here should be used by centers, health care providers, or insurers to avoid appropriate efforts to provide the recommended resources to make TOLAC as safe as possible for those who choose this option. In settings where the staff needed for emergency delivery are not immediately available, the process for gathering needed staff when emergencies arise should be clear, and all centers should have a plan for managing uterine rupture. Drills or other simulation may be useful in preparing for these rare emergencies.

Respect for patient autonomy also argues that even if a center does not offer TOLAC, such a policy cannot be used to force women to have cesarean delivery or to deny care to women in labor who decline to have a repeat cesarean delivery. When conflicts arise between patient wishes and health care provider or facility policy or both, careful explanation and, if appropriate, transfer of care to facilities supporting TOLAC should be used rather than coercion. Because relocation after the onset of labor is generally not appropriate in patients with a prior uterine scar, who are thereby at risk for uterine rupture, transfer of care to facilitate TOLAC, as noted previously, is best effected during the course of antenatal care. This timing places a responsibility on patients and health care providers to begin relevant conversations early in the course of prenatal care.

Summary of Recommendations

The following recommendations are based on good and consistent scientific evidence (Level A):

- Most women with one previous cesarean delivery with a low-transverse incision are candidates for and should be counseled about VBAC and offered TOLAC.
- ▶ Epidural analgesia for labor may be used as part of TOLAC.
- Misoprostol should not be used for third trimester cervical ripening or labor induction in patients who have had a cesarean delivery or major uterine surgery.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- ▶ Women with two previous low transverse cesarean deliveries may be considered candidates for TOLAC.
- Women with one previous cesarean delivery with a low transverse incision, who are otherwise appropriate candidates for twin vaginal delivery, may be considered candidates for TOLAC.
- ▶ External cephalic version for breech presentation is not contraindicated in women with a prior low transverse uterine incision who are at low risk for adverse maternal or neonatal outcomes from external cephalic version and TOLAC.
- ▶ Those at high risk for complications (eg, those with previous classical or T-incision, prior uterine rupture, or extensive transfundal uterine surgery) and those in whom vaginal delivery is otherwise contraindicated (eg, those with placenta previa) are not generally candidates for planned TOLAC.
- ▶ Induction of labor for maternal or fetal indications remains an option in women undergoing TOLAC.
- ► TOLAC is not contraindicated for women with previous cesarean delivery with an unknown uterine scar type unless there is a high clinical suspicion of a previous classical uterine incision.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- A trial of labor after previous cesarean delivery should be undertaken at facilities capable of emergency deliveries. Because of the risks associated with TOLAC and that uterine rupture and other complications may be unpredictable, the College recommends that TOLAC be undertaken in facilities with staff immediately available to provide emergency care. When resources for immediate cesarean delivery are not available, the College recommends that health care providers and patients considering TOLAC discuss the hospital's resources and availability of obstetric, pediatric, anesthetic, and operating room staffs. Respect for patient autonomy supports that patients should be allowed to accept increased levels of risk, however, patients should be clearly informed of such potential increase in risk and management alternatives.
- ► After counseling, the ultimate decision to undergo TOLAC or a repeat cesarean delivery should be made by the patient in consultation with her health care provider. The potential risks and benefits of

both TOLAC and elective repeat cesarean delivery should be discussed. Documentation of counseling and the management plan should be included in the medical record.

Proposed Performance Measure

Percentage of women who are candidates for TOLAC with whom discussion of the risk and benefits of TOLAC compared with a repeat cesarean delivery has been documented in the medical record

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The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985-February 2010. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician-gynecologists were used.

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case—control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

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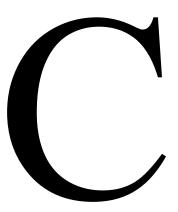
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ISSN 1099-3630

The American College of Obstetricians and Gynecologists 409 12th Street, SW, PO Box 96920, Washington, DC 20090-6920

Vaginal birth after previous cesarean delivery. Practice Bulletin No. 115. American College of Obstetricians and Gynecologists. Obstet Gynecol 2010;116:450–63.

Exhibit



ACOG

Committee on Ethics

Committee Opinion Opinion

Number 321, November 2005

Maternal Decision Making, Ethics, and the Law

ABSTRACT: Recent legal actions and policies aimed at protecting the fetus as an entity separate from the woman have challenged the rights of pregnant women to make decisions about medical interventions and have criminalized maternal behavior that is believed to be associated with fetal harm or adverse perinatal outcomes. This opinion summarizes recent, notable legal cases; reviews the underlying, established ethical principles relevant to the highlighted issues; and considers six objections to punitive and coercive legal approaches to maternal decision making. These approaches 1) fail to recognize that pregnant women are entitled to informed consent and bodily integrity, 2) fail to recognize that medical knowledge and predictions of outcomes in obstetrics have limitations, 3) treat addiction and psychiatric illness as if they were moral failings, 4) threaten to dissuade women from prenatal care, 5) unjustly single out the most vulnerable women, and 6) create the potential for criminalization of otherwise legal maternal behavior. Efforts to use the legal system to protect the fetus by constraining pregnant women's decision making or punishing them erode a woman's basic rights to privacy and bodily integrity and are not justified. Physicians and policy makers should promote the health of women and their fetuses through advocacy of healthy behavior; referral for substance abuse treatment and mental health services when indicated; and development of safe, available, and efficacious services for women and families.

Ethical issues that arise in the care of pregnant women are challenging to physicians, politicians, lawyers, and ethicists alike. One of the fundamental goals of medicine and society is to optimize the outcome of pregnancy. Recently, some apparent attempts to foster this goal have been characterized by legal action and policies aimed at specifically protecting the fetus as an entity separate from the woman. These actions and policies have challenged the rights of pregnant women to make decisions about medical interventions and have criminalized maternal behavior that is believed to be associated with fetal harm or adverse perinatal outcomes.

Practitioners who care for pregnant women face particularly difficult dilemmas when their patients reject medical recommendations, use illegal

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ISSN 1074-861X

The American College of Obstetricians and Gynecologists 409 12th Street, SW PO Box 96920 Washington, DC 20090-6920

12345/98765

Maternal decision making, ethics, and the law. ACOG Committee Opinion No. 321. American College of Obstetricians and Gynecologists. Obstet Gynecol 2005;106:1127–37. drugs, or engage in a range of other behaviors that have the potential to cause fetal harm. In such situations, physicians, hospital representatives, and others have at times resorted to legal actions to impose their views about what these pregnant patients ought to do or to effect particular interventions or outcomes. Appellate courts have held, however, that a pregnant woman's decisions regarding medical treatment should take precedence regardless of the presumed fetal consequences of those decisions. In one notable 1990 decision, a District of Columbia appellate court vacated a lower court's decision to compel cesarean delivery in a critically ill woman at 26 weeks of gestation against her wishes, stating in its opinion that "in virtually all cases the question of what is to be done is to be decided by the patient—the pregnant woman—on behalf of herself and the fetus" (1). Furthermore, the court stated that it could think of no "extremely rare and truly exceptional" case in which the state might have an interest sufficiently compelling to override a pregnant patient's wishes (2). Amid often vigorous debate, most ethicists also agree that a pregnant woman's informed refusal of medical intervention ought to prevail as long as she has the ability to make medical decisions (3, 4).

Recent legislation, criminal prosecutions, and legal cases much discussed in both courtrooms and newsrooms have challenged these precedents, raising the question of whether there are circumstances in which a woman who has become pregnant may have her rights to bodily integrity and informed consent overridden to protect her fetus. In Utah, a woman who had used cocaine was charged with homicide for refusing cesarean delivery of a fetus that was ultimately stillborn. In Pennsylvania, physicians obtained a court order for cesarean delivery in a patient with suspected fetal macrosomia. Across the country, pregnant women have been arrested and prosecuted for being pregnant and using drugs or alcohol. These cases and the publicity they have engendered suggest that it is time to revisit the ethical issues involved.

The ethics of caring for pregnant women and an approach to decision making in the context of the maternal–fetal relationship have been discussed in previous statements by the American College of Obstetricians and Gynecologists (ACOG) Committee on Ethics. After briefly reiterating those discussions, this opinion will summarize recent, notable cases; review the underlying, established ethical

principles relevant to the highlighted issues; consider objections to punitive and coercive legal approaches to maternal decision making; and summarize recommendations for attending to future ethical matters that may arise.

Recent Cases

In March 2004, a 28-year-old woman was charged with first-degree murder for refusing to undergo an immediate cesarean delivery because of concerns about fetal well-being and later giving birth to a girl who tested positive for cocaine and a stillborn boy. According to press reports, the woman was mentally ill and intermittently homeless and had been brought to Utah by a Florida adoption agency to give birth to the infants and give them up. She ultimately pled guilty to two counts of child endangerment.

In January 2004, a woman who previously had given birth vaginally to six infants, some of whom weighed close to 12 pounds, refused a cesarean delivery that was recommended because of presumed macrosomia. A Pennsylvania hospital obtained a court order to perform the cesarean delivery and gain custody of the fetus before and after delivery, but the woman and her husband fled to another hospital, where she reportedly had an uncomplicated vaginal delivery of a healthy 11-pound infant.

In September 2003, a 22-year-old woman was prosecuted after her son tested positive for alcohol when he was born in Glens Falls, New York. A few days after the birth, the woman was arrested and charged with two counts of child endangerment for "knowingly feeding her blood," containing alcohol, to her fetus via the umbilical cord. Several months later, her lawyers successfully appealed her conviction.

In May 1999, a 22-year-old woman who was homeless regularly used cocaine while pregnant and gave birth to a stillborn infant in South Carolina. She became the first woman in the United States to be tried and convicted of homicide by child abuse based on her behavior during pregnancy and was given a 12-year prison sentence. The conviction was upheld in the South Carolina Supreme Court, and the U.S. Supreme Court recently refused to hear her appeal. At a postconviction relief hearing, expert testimony supported arguments that the woman had had inadequate representation, but the court held that there was no ineffective assistance of counsel and that she is not entitled to a new trial. This decision is being appealed.

Ethical Considerations

Framing Ethics in Perinatal Medicine

It is likely that the interventions described in the preceding cases were motivated by a shared concept that a fetus can and should be treated as separable and legally, philosophically, and practically independent from the pregnant woman within whom it resides. This common method of framing ethical issues in perinatal medicine is not surprising given a number of developments in the past several decades. First, since the 1970s, the development of techniques for imaging, testing, and treating fetuses has led to the widespread endorsement of the notion that fetuses are independent patients, treatable apart from the pregnant women upon whom their existence depends (5). Similarly, some bioethical models now assert that physicians have moral obligations to fetal "patients" that are separate from their obligations to pregnant women (6). Finally, a number of civil laws, discussed later in this section, aim to create fetal rights separate from a pregnant woman's rights.

Although frameworks that treat the woman and fetus as separable and independent are meant to simplify and clarify complex issues that arise in obstetrics, many writers have noted that such frameworks tend to distort, rather than illuminate, ethical and policy debates (7). In particular, these approaches have been criticized for their tendency to emphasize the divergent rather than shared interests of the pregnant woman and fetus. This emphasis results in a view of the maternal–fetal relationship as paradigmatically adversarial, when in fact in the vast majority of cases, the interests of the pregnant woman and fetus actually converge.

In addition, these approaches tend to ignore the moral relevance of relationships, including the physically and emotionally intimate relationship between the woman and her fetus, as well as the relationships of the pregnant woman within her broader social and cultural networks. The cultural and policy context, for example, suggests a predominantly child-centered approach to maternal and child health, which has influenced current perspectives on the fetus. The prototype for the federal Maternal and Child Health Bureau dates back to 1912, when the first organization was called into existence by reformers such as Florence Kelley, who stated that "the U.S. should have a bureau to look after the child crop," and Julia Lathrop, who said that "the final

purpose of the Bureau is to serve all children, to try to work out standards of care and protection which shall give to every child his fair chance in the world." The current home page of the Maternal and Child Health Bureau web site cites as its "vision" an equally child-centered goal (8).

At times, in the current clinical and policy contexts, when the woman and fetus are treated as separate individuals, the woman and her medical interests, health needs, and rights as moral agent, patient, and research subject fade from view. Consider, first, women's medical interests as patients. Researchers performing "fetal surgery"—novel interventions to correct fetal anatomic abnormalities-have been criticized recently not only for their tendency to exaggerate claims of success with regard to fetal and neonatal health, but also for their failure to assess the impact of surgery on pregnant women, who also undertake the risks of the major surgical procedures (9). As a result, several centers performing these techniques now use the term "maternal-fetal surgery" to explicitly recognize the fact that a woman's bodily integrity and health are at stake whenever interventions directed at her fetus are performed. Furthermore, a study sponsored by the National Institute of Child Health and Human Development comparing maternal-fetal surgery with postnatal repair of myelomeningocele (the Management of Myelomeningocele Study) is now assessing maternal as well as fetal outcomes, including measurement of reproductive and health outcomes, depression testing, and economic and family health outcomes in women who participate in the clinical trial.

Similarly, new civil laws that aim to treat the fetus as separate and independent have been criticized for their failure both to address the health needs of the woman within whose body the fetus resides and to recognize the converging interests of the woman and fetus. In November 2002, a revision of the state child health insurance program (sCHIP) that expanded coverage to "individual(s) under the age of 19 including the period from conception until birth" was signed into law. The program does not cover pregnant women older than 18 years except when medical interventions could directly affect the well-being of their fetuses. For example, under sCHIP, intrapartum anesthesia is covered, according to the U.S. Department of Health and Human Services, only because "if a woman's pain during a labor and delivery is not reduced or properly

relieved, adverse and sometimes disastrous effects can occur for the unborn child" (10).

Furthermore, for beneficiaries of sCHIP, many significant women's health issues, even those that are precipitated by pregnancy (eg, molar gestation, postpartum depression, or traumatic injury from intimate partner violence not impacting the fetus), are not covered as a part of routine antenatal care (11). This approach has been criticized not only for its failure to address the health needs of women, but also for its failure to achieve the narrow goal of improving child health because it ignores the fact that maternal and neonatal interests converge. For instance, postpartum depression is associated with adverse effects in infants, including impaired maternal-infant interaction, delayed cognitive and emotional development, increased anxiety, and decreased self-esteem (12, 13). Thus, the law ignores the fact that a critical component of ensuring the health of newborns is the provision of comprehensive care for their mothers.

Likewise, in April 2004, the Unborn Victims of Violence Act was signed into law, creating a separate federal offense if, during the commission of certain federal crimes, an individual causes the death of, or bodily injury to, a fetus at any stage of pregnancy. The law, however, does not categorize the death of or injury to a pregnant woman as a separate federal offense, or create sentence enhancement for those who assault or murder a woman while pregnant. The statute's sponsors explicitly rejected proposals that had virtually identical criminal penalties but recognized the pregnant woman as the victim, despite the fact that murder is responsible for more pregnancyassociated deaths in the United States than any other cause, including hemorrhage and thromboembolic events (14, 15).

Beyond its impact on maternal and child health, a failure to recognize the interconnectedness of the pregnant woman and fetus has important ethical and legal implications. Because an intervention on a fetus must be performed through the body of a pregnant woman, an assertion of fetal rights must be reconciled with the ethical and legal obligations toward pregnant women *as women*, persons in their own right. Discussions about rights of the unborn often have failed to address these obligations. Regardless of what is believed about fetal personhood, claims about fetal rights require an assessment of the rights of pregnant women, whose personhood within the legal and moral community is indisputable.

Furthermore, many writers have noted a moral injury that arises from abstracting the fetus from the pregnant woman, in its failing to recognize the pregnant woman herself as a patient, person, and rights-bearer. This approach disregards a fundamental moral principle that persons never be treated solely as means to an end, but as ends in themselves. Within the rhetoric of conflict and fetal rights, the pregnant woman has at times been reduced to a vessel—even a "fortress" holding the fetus "prisoner" (16). As George Annas aptly described, "Before birth, we can obtain access to the fetus only through its mother, and in the absence of her informed consent, can do so only by treating her as a fetal container, a nonperson without rights to bodily integrity" (3).

Some writers have argued that at the heart of the distorting influence of the "two-patient" model of the maternal-fetal dyad is the fact that, according to traditional theories that undergird medical ethics, the very notion of a person or a patient is someone who is physically separate from others. Pregnancy, however, is marked by a "particular and particularly thoroughgoing kind of intertwinement" (17). Thus, the pregnant woman and fetus fit awkwardly at best into what the term "patient" is understood to mean. They are neither physically separate, as persons are understood to be, nor indistinguishably fused. A framework that instead defines the professional ethical obligations with a deep sensitivity to relationships of interdependency may help to avoid the distorting influence of the two-patient model as traditionally understood (18). Although this opinion does not specifically articulate a novel comprehensive conceptual model for perinatal ethics, in the discussion that follows, the Committee on Ethics takes as morally central the essential connection between the pregnant woman and fetus.

Ethics Committee Opinions and the Maternal-Fetal Relationship

In the context of a framework that recognizes the interconnectedness of the pregnant woman and fetus and emphasizes their shared interests, certain opinions previously published by the ACOG Committee on Ethics are particularly relevant. These include:

- "Informed Consent" (19)
- "Patient Choice in the Maternal–Fetal Relationship" (20)
- "At-Risk Drinking and Illicit Drug Use: Ethical Issues in Obstetric and Gynecologic Practice" (21)

One fundamental ethical obligation of health care professionals is to respect patients' autonomous decision making and to adhere to the requirement for informed consent for medical intervention. In January 2004, the Committee on Ethics published a revised edition of "Informed Consent" in which the following points are defended:

- "Requiring informed consent is an expression of respect for the patient as a person; it particularly respects a patient's moral right to bodily integrity, to self-determination regarding sexuality and reproductive capacities, and to the support of the patient's freedom within caring relationships."
- "The ethical requirement for informed consent need not conflict with physicians' overall ethical obligation to a principle of beneficence; that is, every effort should be made to incorporate a commitment to informed consent within a commitment to provide medical benefit to patients and thus respect them as whole and embodied persons."

Pregnancy does not obviate or limit the requirement to obtain informed consent. Intervention on behalf of the fetus must be undertaken through the body and within the context of the life of the pregnant woman, and therefore her consent for medical treatment is required, regardless of the treatment indication. However, pregnancy presents a special set of issues. The issues associated with informed refusal of care by pregnant women are addressed in the January 2004 opinion "Patient Choice in the Maternal-Fetal Relationship" (20). This opinion states that in cases of maternal refusal of treatment for the sake of the fetus, "court-ordered intervention against the wishes of a pregnant woman is rarely if ever acceptable." The document presents a review of general ethical considerations applicable to pregnant women who do not follow the advice of their physicians or do not seem to make decisions in the best interest of their fetuses. Although the possibility of a justifiable court-ordered intervention is not completely ruled out, the document presents several recommendations that strongly discourage coercive measures:

• "The obstetrician's response to a patient's unwillingness to cooperate with medical advice . . . should be to convey clearly the reasons for the recommendations to the pregnant woman,

- examine the barriers to change along with her, and encourage the development of health-promoting behavior."
- "[Even if] a woman's autonomous decision [seems] not to promote beneficence-based obligations (of the woman or the physician) to the fetus, . . . the obstetrician must respect the patient's autonomy, continue to care for the pregnant woman, and not intervene against the patient's wishes, regardless of the consequences."
- "The obstetrician must keep in mind that medical knowledge has limitations and medical judgment is fallible" and should therefore take great care "to present a balanced evaluation of expected outcomes for both [the woman and the fetus]."
- "Obstetricians should consider the social and cultural context in which these decisions are made and question whether their ethical judgments reinforce gender, class, or racial inequality."

In addition to revisiting questions of how practitioners should address refusal of treatment in the clinic and delivery room, the four cases outlined previously illustrate punitive and coercive policies aimed at pregnant women who engage in behaviors that may adversely affect fetal well-being. The 2004 opinion "At-Risk Drinking and Illicit Drug Use: Ethical Issues in Obstetric and Gynecologic Practice" (21) specifically addresses addiction and the prosecution of women who use drugs and alcohol during pregnancy and recommends strongly against punitive policies:

- "Addiction is not primarily a moral weakness, as it has been viewed in the past, but a 'brain disease' that should be included in a review of systems just like any other biologic disease process."
- "Recommended screening . . . connected with legally mandated testing or reporting . . . endanger[s] the relationship of trust between physician and patient, place[s] the obstetrician in an adversarial relationship with the patient, and possibly conflict[s] with the therapeutic obligation."
- Punitive policies "are unjust in that they indict the woman for failing to seek treatment that actually may not be available to her" and in that they "are not applied evenly across sex, race, and socioeconomic status."

 Physicians must make a substantial effort to "treat the patient with a substance abuse problem with dignity and respect in order to form a therapeutic alliance."

Finally, recent legal decisions affirm that physicians have neither an obligation nor a right to perform prenatal testing for alcohol or drug use without a pregnant woman's consent (22, 23). This includes consent to testing of the woman that could lead to any form of reporting, both to legal authorities for purposes of criminal prosecution and to civil child welfare authorities.

Against Coercive and Punitive Legal Approaches to the Maternal–Fetal Relationship

This section addresses specifically the ethical issues associated with the cases outlined previously and delineates six reasons why restricting patients' liberty and punishing pregnant women for their actions during pregnancy that may affect their fetuses is neither wise nor justifiable. Each raises important objections to punishing pregnant women for actions during pregnancy; together they provide an overwhelming rationale for avoiding such approaches.

1. Coercive and punitive legal approaches to pregnant women who refuse medical advice fail to recognize that all competent adults are entitled to informed consent and bodily integrity.

A fundamental tenet of contemporary medical ethics is the requirement for informed consent, including the right of competent adults to refuse medical intervention. The Committee on Ethics affirms that informed consent for medical treatment is an ethical requirement and is an expression of respect for the patient as a person with a moral right to bodily integrity (19).

The crucial difference between pregnant and nonpregnant individuals, though, is that a fetus is involved whose health interests could arguably be served by overriding the pregnant woman's wishes. However, in the United States, even in the case of two completely separate individuals, constitutional law and common law have historically recognized the rights of all adults, pregnant or not, to informed consent and bodily integrity, regardless of the impact of that person's decision on others. For instance, in 1978, a man suffering from aplastic anemia sought a court order to force his cousin, who was the only compatible donor available, to submit

to bone marrow harvest. The court declined, explaining in its opinion:

For our law to compel the Defendant to submit to an intrusion of his body would change every concept and principle upon which our society is founded. To do so would defeat the sanctity of the individual and would impose a rule which would know no limits. . . . For a society that respects the rights of one individual, to sink its teeth into the jugular vein or neck of its members and suck from it sustenance for another member, is revolting to our hard-wrought concepts of jurisprudence. Forcible extraction of living body tissues causes revulsion to the judicial mind. Such would raise the specter of the swastika and the Inquisition, reminiscent of the horrors this portends. (24)

Justice requires that a pregnant woman, like any other individual, retain the basic right to refuse medical intervention, even if the intervention is in the best interest of her fetus. This principle was challenged unsuccessfully in June 1987 with the case of a 27-year-old woman who was at 25 weeks of gestation when she became critically ill with cancer. Against the wishes of the woman, her family, and her physicians, the hospital obtained a court order for a cesarean delivery, claiming independent rights of the fetus. Both mother and infant died shortly after the cesarean delivery was performed. Three years later, the District of Columbia Court of Appeals vacated the court-ordered cesarean delivery and held that the woman had the right to make health care decisions for herself and her fetus, arguing that the lower court had "erred in subordinating her right to bodily integrity in favor of the state's interest in potential life" (1).

2. Court-ordered interventions in cases of informed refusal, as well as punishment of pregnant women for their behavior that may put a fetus at risk, neglect the fact that medical knowledge and predictions of outcomes in obstetrics have limitations.

Beyond its importance as a means to protect the right of individuals to bodily integrity, the doctrine of informed consent recognizes the right of individuals to weigh risks and benefits for themselves. Women almost always are best situated to understand the importance of risks and benefits in the context of their own values, circumstances, and concerns. Furthermore, medical judgment in obstetrics itself has limitations in its ability to predict outcomes. In this document, the Committee on Ethics has argued that overriding a woman's autonomous choice, whatever its potential consequences, is neither ethi-

cally nor legally justified, given her fundamental rights to bodily integrity. Even those who challenge these fundamental rights in favor of protecting the fetus, however, must recognize and communicate that medical judgments in obstetrics are fallible (25). And fallibility—present to various degrees in all medical encounters—is sufficiently high in obstetric decision making to warrant wariness in imposing legal coercion. Levels of certainty underlying medical recommendations to pregnant women are unlikely to be adequate to justify legal coercion and the tremendous impact on the lives and civil liberties of pregnant women that such intervention would entail (26). Some have argued that court-ordered intervention might plausibly be justified only when certainty is especially robust and the stakes are especially high. However, in many cases of courtordered obstetric intervention, the latter criterion has been met but not the former. Furthermore, evidencebased medicine has revealed limitations in the ability to concretely describe the relationship of maternal behavior to perinatal outcome. Criminalizing women in the face of such scientific and clinical uncertainty is morally dubious. Not only do these approaches fail to take into account the standards of evidence-based medical practice, but they are also unjust, and their application is likely to be informed by bias and opinion rather than objective assessment of risk.

Consider, first, the limitations of medical judgment in predicting birth outcomes based on mode of childbirth. A study of court-ordered obstetric interventions suggested that in almost one third of cases in which court orders were sought, the medical judgment was incorrect in retrospect (27). One clear example of the challenges of predicting outcome is in the management of risk associated with shoulder dystocia in the setting of fetal macrosomia-which is, and should be, of great concern for all practitioners. When making recommendations to patients, however, practitioners have an ethical obligation to recognize and communicate that accurate diagnosis of macrosomia is imprecise (20). Furthermore, although macrosomia increases the risk of shoulder dystocia, it is certainly not absolutely predictive; in fact, most cases of shoulder dystocia occur unpredictably among infants of normal birthweight. Given this uncertainty, ACOG makes recommendations about when cesarean delivery may be considered, not about when it is absolutely indicated. Because of the inability to determine with certainty when a situation is harmful to the fetus or pregnant woman and the inability to guarantee that the pregnant woman will not be harmed by the medical intervention, great care should be exercised to present a balanced evaluation of expected outcomes for both parties (20). The decision about weighing risks and benefits in the setting of uncertainty should remain the pregnant woman's to make in the setting of supportive, informative medical care.

Medical judgment also has limitations in that the relationship of maternal behavior to pregnancy outcome is poorly understood and may be exaggerated in realms often mistaken to be of moral rather than medical concern, such as drug use. For instance, recent child development research has not found the effects of prenatal cocaine exposure that earlier uncontrolled studies reported (28). It is now understood that poverty and its concomitants-poor nutrition and inadequate health care—can account for many of the effects popularly attributed to cocaine. Before these data emerged, the criminal justice approach to drug addiction during pregnancy was fueled to a great degree by what is now understood to be the distorting image of the "crack baby." Such an image served as a "convenient symbol for an aggressive war on drug users [that] makes it easier to advocate a simplistic punitive response than to address the complex causes of drug use" (29). The findings questioning the impact of cocaine on perinatal outcome are among many considerations that bring sharply into question any possible justification for a criminal justice approach, rather than a public health approach, to drug use during pregnancy. Given the incomplete understanding of factors underlying perinatal outcomes in general and the contribution of individual behavioral and socioeconomic factors in particular, to identify homeless and addicted women as personally, morally, and legally culpable for perinatal outcomes is inaccurate, misleading, and unjust.

3. Coercive and punitive policies treat medical problems such as addiction and psychiatric illness as if they were moral failings.

Regardless of the strength of the link between an individual's behaviors and pregnancy outcome, punitive policies directed at women who use drugs are not justified, because these policies are, in effect, punishing women for having a medical problem. Although once considered a sign of moral weakness, addiction is now, according to evidence-based medicine, considered a disease—a compulsive disorder

requiring medical attention (30). Pregnancy should not change how clinicians understand the medical nature of addictive behavior. In fact, studies overwhelmingly show that pregnant drug users are very concerned about the consequences of their drug use for their fetuses and are particularly eager to obtain treatment once they find out they are pregnant (31, 32). Despite evidence-based medical recommendations that support treatment approaches to drug use and addiction (21), appropriate treatment is particularly difficult to obtain for pregnant and parenting women and the incarcerated (29). Thus, a disease process exacerbated by social circumstance—not personal, legal, or moral culpability is at the heart of substance abuse and pregnancy. Punitive policies unfairly make pregnant women scapegoats for medical problems whose cause is often beyond their control.

In most states, governmental responses to pregnant women who use drugs have upheld medical characterizations of addiction. Consistent with longstanding U.S. Supreme Court decisions recognizing that addiction is an illness and that criminalizing it violates the Constitution's Eighth Amendment prohibitions against cruel and unusual punishment, no state has adopted a law that specifically creates unique criminal penalties for pregnant women who use drugs (33). However, in South Carolina, using drugs or being addicted to drugs was effectively criminalized when the state supreme court interpreted the word "child" in the state's criminal child endangerment statute to include viable fetuses, making the child endangerment statute applicable to pregnant women whose actions risk harm to a viable fetus (23). In all states, women retain their Fourth Amendment freedom from unreasonable searches, so that pregnant women may not be subject to nonconsensual drug testing for the purpose of criminal prosecution.

Partly on the basis of the understanding of addiction as a compulsive disorder requiring medical attention, medical professionals, U.S. state laws, and the vast majority of courts do not support unique criminal penalties for pregnant women who use drugs.

4. Coercive and punitive policies are potentially counterproductive in that they are likely to discourage prenatal care and successful treatment, adversely affect infant mortality rates, and undermine the physician–patient relationship.

Even if the aforementioned ethical concerns could be addressed, punitive policies would not be justifiable on utilitarian grounds, because they would likely result in more harm than good for maternal and child health, broadly construed. Various studies have suggested that attempts to criminalize pregnant women's behavior discourage women from seeking prenatal care (34, 35). Furthermore, an increased infant mortality rate was observed in South Carolina in the years following the Whitner v State decision (36), in which the state supreme court concluded that anything a pregnant woman does that might endanger a viable fetus (including, but not limited to, drug use) could result in either charges of child abuse and a jail sentence of up to 10 years or homicide and a 20-year sentence if a stillbirth coincides with a positive drug test (23). As documented previously (21), threats and incarceration have been ineffective in reducing the incidence of alcohol and drug abuse among pregnant women, and removing children from the home of an addicted mother may subject them to worse risks in the foster care system. In fact, women who have custody of their children complete substance abuse treatment at a higher rate (37-39).

These data suggest that punishment of pregnant women might not result in women receiving the desired message about the dangers of prenatal substance abuse; such measures might instead send an unintended message about the dangers of prenatal care. Ultimately, fear surrounding prenatal care would likely undermine, rather than enhance, maternal and child health. Likewise, court-ordered interventions and other coercive measures may result in fear about whether one's wishes in the delivery room will be respected and ultimately could discourage pregnant patients from seeking care. Encouraging prenatal care and treatment in a supportive environment will advance maternal and child health most effectively.

5. Coercive and punitive policies directed toward pregnant women unjustly single out the most vulnerable women.

Evidence suggests that punitive and coercive policies not only are ethically problematic in and of themselves, but also unfairly burden the most vulnerable women. In cases of court-ordered cesarean deliveries, for instance, the vast majority of court orders have been obtained against poor women of color (27, 40).

Similarly, decisions about detection and management of substance abuse in pregnancy are fraught

with bias, unfairly burdening the most vulnerable despite the fact that addiction occurs consistently across race and socioeconomic status (41). In the landmark case of Ferguson v City of Charleston, which involved selective screening and arrest of pregnant women who tested positive for drugs, 29 of 30 women arrested were African American. Studies suggest that affluent women are less likely to be tested for use of illicit drugs than poor women of color, perhaps because of stereotyped but demonstrably inaccurate assumptions about drug use. One study found that despite similar rates of substance abuse across racial and socioeconomic status, African – American women were 10 times more likely than white women to be reported to public health authorities for substance abuse during pregnancy (42). These data suggest that, as implemented, many punitive policies centered on maternal behaviors, including substance use, are deeply unjust in that they reinforce social and racial inequality.

6. Coercive and punitive policies create the potential for criminalization of many types of otherwise legal maternal behavior.

In addition to raising concerns about race and socioeconomic status, punitive and coercive policies may have even broader implications for justice for women. Because many maternal behaviors are associated with adverse pregnancy outcome, these policies could result in a society in which simply being a woman of reproductive potential could put an individual at risk for criminal prosecution. For instance, poorly controlled diabetes is associated with numerous congenital malformations and an excessive rate of fetal death. Periconceptional folic acid deficiency is associated with an increased risk of neural tube defects. Obesity has been associated in recent studies with adverse pregnancy outcomes, including preeclampsia, shoulder dystocia, and antepartum stillbirth (43, 44). Prenatal exposure to certain medications that may be essential to maintaining a pregnant woman's health status is associated with congenital abnormalities. If states were to consistently adopt policies of punishing women whose behavior (ranging from substance abuse to poor nutrition to informed decisions about prescription drugs) has the potential to lead to adverse perinatal outcomes, at what point would they draw the line? Punitive policies, therefore, threaten the privacy and autonomy not only of all pregnant women, but also of all women of reproductive potential.

Recommendations

In light of these six considerations, the Committee on Ethics strongly opposes the criminal prosecution of pregnant women whose activities may appear to cause harm to their fetuses. Efforts to use the legal system specifically to protect the fetus by constraining women's decision making or punishing them for their behavior erode a woman's basic rights to privacy and bodily integrity and are neither legally nor morally justified. The ACOG Committee on Ethics therefore makes the following recommendations:

- In caring for pregnant women, practitioners should recognize that in the majority of cases, the interests of the pregnant woman and her fetus converge rather than diverge. Promoting pregnant women's health through advocacy of healthy behavior, referral for substance abuse treatment and mental health services when necessary, and maintenance of a good physician—patient relationship is always in the best interest of both the woman and her fetus.
- Pregnant women's autonomous decisions should be respected. Concerns about the impact of maternal decisions on fetal well-being should be discussed in the context of medical evidence and understood within the context of each woman's broad social network, cultural beliefs, and values. In the absence of extraordinary circumstances, circumstances that, in fact, the Committee on Ethics cannot currently imagine, judicial authority should not be used to implement treatment regimens aimed at protecting the fetus, for such actions violate the pregnant woman's autonomy.
- Pregnant women should not be punished for adverse perinatal outcomes. The relationship between maternal behavior and perinatal outcome is not fully understood, and punitive approaches threaten to dissuade pregnant women from seeking health care and ultimately undermine the health of pregnant women and their fetuses.
- Policy makers, legislators, and physicians should work together to find constructive and evidence-based ways to address the needs of women with alcohol and other substance abuse problems. This should include the development of safe, available, and efficacious services for women and families.

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